



EFFECTIVENESS OF A PHONE-BASED SUPPORT PROGRAM ON SELF-CARE
CONFIDENCE, PSYCHOLOGICAL DISTRESS, AND QUALITY OF LIFE
AMONG WOMEN NEWLY DIAGNOSED WITH BREAST CANCER: A
RANDOMIZED CONTROLLED TRIAL

XI CHEN

A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF
THE REQUIREMENTS FOR DOCTOR DEGREE OF PHILOSOPHY
(INTERNATIONAL PROGRAM)

IN NURSING SCIENCE
FACULTY OF NURSING
BURAPHA UNIVERSITY

2024

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XI CHEN

คู่มือนี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปรัชญาดุษฎีบัณฑิต (หลักสูตรนานาชาติ)

สาขาวิชาพยาบาลศาสตร์

คณะพยาบาลศาสตร์ มหาวิทยาลัยบูรพา

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ลิขสิทธิ์เป็นของมหาวิทยาลัยบูรพา

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The Dissertation of Xi Chen has been approved by the examining committee to be partial fulfillment of the requirements for the Doctor Degree of Philosophy (International Program) in Nursing Science of Burapha University

Advisory Committee

Examining Committee

Principal advisor

.....
(Associate Professor Dr. Nujjaree Chaimongkol)

..... Principal examiner
(Professor Dr. Somchit Hanucharurnkul)

Co-advisor

.....
(Associate Professor Dr. Pornpat Hengudomsub)

..... Member
(Associate Professor Dr. Nujjaree Chaimongkol)

..... Member
(Associate Professor Dr. Pornpat Hengudomsub)

..... Member
(Assistant Professor Dr. Khemaradee Masingboon)

..... External Member
(Professor Dr. Ratsiri Thato)

..... Dean of the Faculty of Nursing
(Associate Professor Dr. Pornchai Jullamate)

This Dissertation has been approved by Graduate School Burapha University to be partial fulfillment of the requirements for the Doctor Degree of Philosophy (International Program) in Nursing Science of Burapha University

..... Dean of Graduate School
(Associate Professor Dr. Witawat Jangiam)

63810052: MAJOR: NURSING SCIENCE; Ph.D. (NURSING SCIENCE)

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The increasing number of breast cancer women undergoing chemotherapy may result in long-lasting, adverse physical side effects, and reduce quality of life are posing challenges to patients. This study aimed to determine the effectiveness of a Phone-Based Support Program (PBSP) for women newly diagnosed with breast cancer undergoing chemotherapy by comparing the patients' self-care confidence, psychological distress (including, symptom distress, anxiety and depression), and quality of life. A randomized controlled trial was designed, and a simple random sampling technique was used to recruit 94 patients aged 18-60 years who newly diagnosed with breast cancer undergoing chemotherapy. Data collection was carried out from April 22 to July 7, 2023, at the breast surgery and oncology department of Yancheng NO.1 People's Hospital, China. Research instruments consisted of five self-report questionnaires, including a demographic data, the Self-Care Self-Efficacy Scale, the M.D. Anderson Symptom Inventory, the Hospital Anxiety and Depression Scale, the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30. Their Cronbach's alphas coefficients ranged from 0.70 to 0.89. Descriptive statistics was used to describe the participants' characteristics and the study variables. The effect of PBSP on all outcomes was tested with MANOVA and two-way repeated measure ANOVA.

The results revealed that after completion of the intervention, participants in the intervention group had significantly higher self-care confidence, and quality of life, and lower psychological distress than that in the control group ($p < .05$).

These findings suggest that the PBSP is effective. It was found that

establishing Internet-based program is an effective way to promote health among breast patients. Nurses and related healthcare personnel should utilize this program to help patients with breast cancer.



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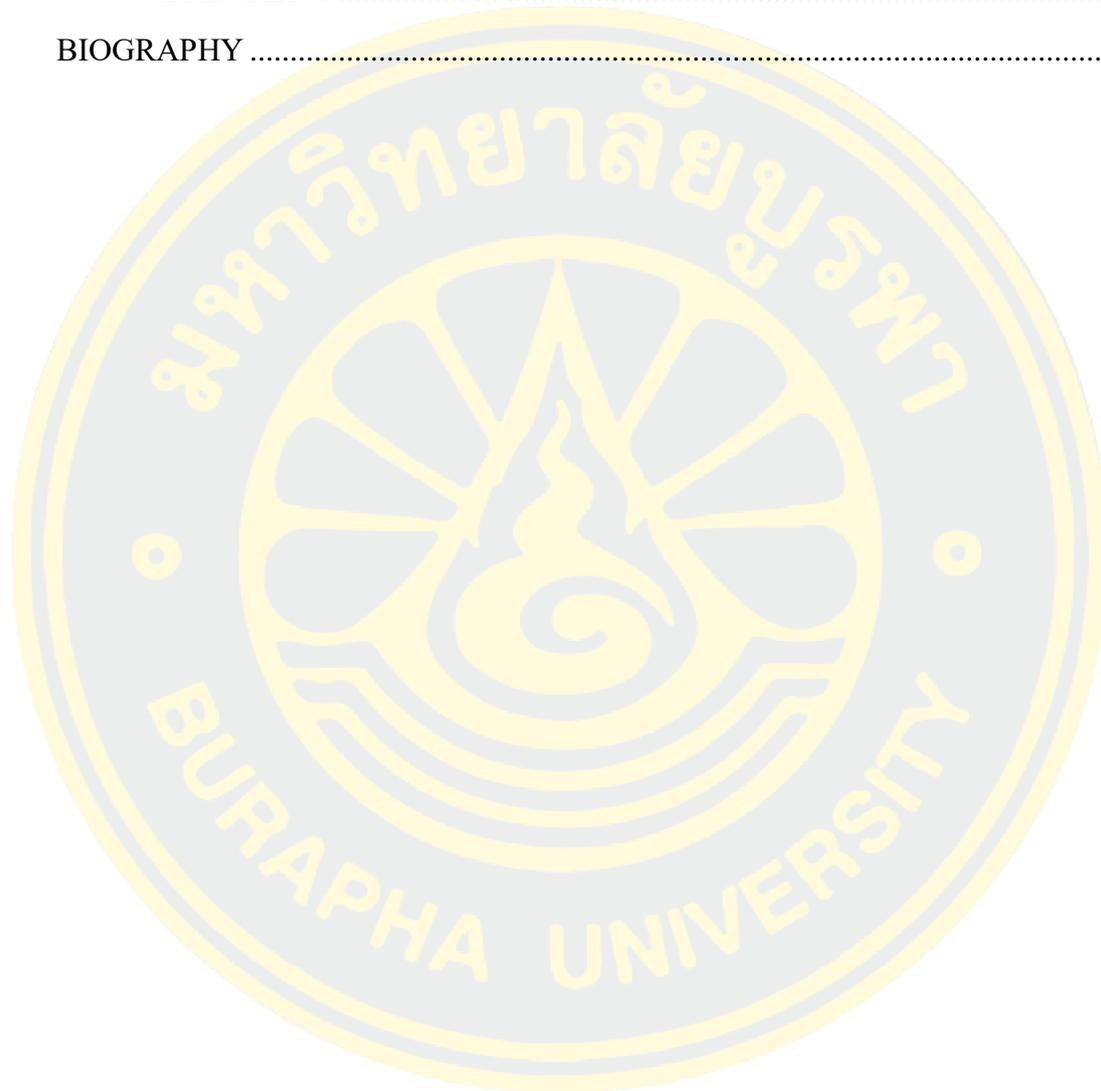
Xi Chen

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CHAPTER 1

INTRODUCTION

Statement and significance of the problem

According to the World Health Organization Global Cancer Observatory, the most frequent form of cancer among adult women is breast cancer. (Momenimovahed, 2019). In China, the incidence of breast cancer has increased significantly. Statistical data suggests an increase from around 60 occurrences per 100,000 women in 2008 to a forecasted rate of 100 per 100,000 women by 2021 (Han et al., 2021). Presently, breast cancer holds the distinction of being the most prevalent form of cancer among Chinese women and ranks as the sixth major cause of cancer-related mortality in this demographic (Cao, 2021). Approximately 80% of Chinese women diagnosed with invasive breast cancer receive chemotherapy as part of their treatment plan (Bao et al., 2018). In China, the median age range for breast cancer diagnosis is typically between 45 and 55 years. The mortality rate linked to breast cancer can be effectively lowered through strategies emphasizing early diagnosis and customized treatment methods. Breast cancer is mostly treated with surgery, radiation, chemotherapy, hormonal treatments, and others (Makhoul, et al., 2018).

The Tumor-Node-Metastasis (TNM) system is widely recognized as the most prevalent staging methodology for breast cancer, as highlighted in Sawaki (2019). Breast cancer represents a spectrum of different but heterogeneous diseases. Early breast cancer can often be completely surgically removed. However, the risk of recurrence after surgery has led to the development of adjuvant therapies. In the past, the combination of surgery followed by chemotherapy was considered the cornerstone of breast cancer treatment (Cornette et al., 2016). In China, chemotherapy is a frequently employed treatment modality for this disease. Chemotherapy is used by around 81.4% of patients with invasive breast cancer, with treatment lasting between eight months and a year on average (Wang et al., 2019).

The administration of chemotherapy leads to a spectrum of side effects that span both physiological and psychological domains. These include physical symptoms like pain, sleeplessness, nausea, reduced appetite, tiredness, and hair loss,

as identified by Ariza-Garcia et al. (2019). Additionally, it can result in psychological disturbances such as depression, anxiety, and worry (Wang et al., 2019). The severity of these side effects is often linked to the duration and timing of chemotherapy, the stage of the cancer, and the occurrence of relapses. Oh et al. (2020) discussed these factors collectively contribute to adverse effects on the psychological health of patients, and also impact their overall quality of life, as indicated by Chovanec et al. (2021).

The American Cancer Society categorizes cancer as a chronic condition, underscoring the U.S. healthcare system's emphasis on sustaining the welfare of individuals with chronic diseases (Anderson, 2019). Nurse researchers have traditionally concentrated on advancing optimal health and examining human behaviors, including self-care, amidst the dynamic spectrum of health (Wakefield, 2021). The American Nurses Association's incorporation of self-care into their social policy statement reflects a deep-seated commitment of the nursing profession to the exploration of human reactions in both wellness and sickness, laying the groundwork for additional research in this field (Meleis, 2011). Furthermore, the idea of self-efficacy, or people's belief in their ability to achieve desired results through their conduct, has been extensively researched, resulting in a substantial body of literature (Bandura, 1997). Self-efficacy is context-dependent and domain-specific. A person may have great self-efficacy in one area or sector of their life while having poor self-efficacy in others (Eller, 2019). Self-efficacy theory posits that an individual develops judgments about his or her ability to participate in self-care actions that yield desired outcomes. This judgment, known as self-efficacy, bridges the gap between knowledge and real self-care practices (Tsay, 2002). Self-care is a non-pharmacological approach that can assist manage common treatment side effects, such as chemotherapy, and reduce symptom discomfort (Wang et al., 2019).

This concept is particularly relevant in health contexts where patients are required to manage aspects of their self-care. (Orem, 2001). Self-care confidence is intrinsically linked to Bandura's self-efficacy theory, which posits that an individual's belief in their ability to execute actions required to manage prospective situations significantly influences their behavior (Bandura, 1997). Self-efficacy, as a broader

concept, is the foundation upon which self-care confidence is built, particularly in the context of health behavior and management.

Self-care confidence specifically refers to an individual's belief in their capability to effectively perform self-care activities. This belief is crucial for patients, especially those with chronic illnesses, as it directly impacts their ability to manage their condition, adhere to treatment regimens, and engage in health-promoting behaviors. The self-care confidence scale was originally a single-domain component of the Heart Failure Self-Care Index and was further developed into the more comprehensive Self-Care Self-Efficacy Scale (SCSES) (Riegel, et al., 2019a).

Although there has not found a study examined self-care confidence in patients with breast cancer. Researchers studying patients with chronic illnesses reported that patients' confidence, or self-efficacy, in their self-care behaviors is a mediating variable associated with positive health outcomes. Some studies have showed self-care self-efficacy has been associated with positive physical and mental health outcomes across patient populations. Self-care confidence affects one's performance of self-care behaviors, including the amount of energy one expends, how long one perseveres, how resilient one is, the amount of stress and anxiety that one experiences, and the decision-making processes involved in self-care (Buck, 2012). Higher self-care self-efficacy in chronically ill patients has been associated with lower depression, and greater physical function, social support, goal achievement, quality of life (QOL), and more positive health status. For patients with breast cancer, especially those who have newly diagnosed and undergoing chemotherapy, studies indicated that they might have low self-efficacy in doing things for themselves.

Several studies reported interventions that successfully increased self-care self-efficacy in diverse patient populations. Lii et al. (2007) used a group intervention for hemodialysis patients. The results showed that patients in the treatment group showed statistically significant improvements in self-care self-efficacy, depression and quality of life compared to patients in the comparison group. In addition, the study showed that the psychosocial group intervention significantly reduced depression and improved the self-care effectiveness and quality of life of hemodialysis patients. Robertson et al. (2013) indicated that building self-care self-efficacy lays the foundation for improvements in chronic disease self-care, higher

levels of self-efficacy are associated with greater mobility, engagement in activities of daily living and quality of life than lower levels among stroke survivors.

Psychological distress experienced by breast cancer patients is a multifaceted issue that encompasses various aspects of mental health, profoundly influenced by the physiological and psychological side effects of treatments like chemotherapy. Chemotherapy-induced symptom distress, including pain, insomnia, and nausea, significantly contributes to the overall psychological burden faced by these patients (Ariza-Garcia et al., 2019). This symptom distress is not merely a physical experience; it intertwines with and exacerbates psychological distress, leading to elevated levels of anxiety and depression (Wang et al., 2019). The prevalence and intensity of these psychological reactions are closely linked to the duration and intensity of chemotherapy, the occurrence of relapses, and the stage of cancer (Oh et al., 2020).

Further complicating the issue is the impact of these treatment-related side effects on quality of life, which encompasses both the negative aspects, such as psychological distress (e.g., depression and anxiety), and positive aspects, like life satisfaction and self-esteem (Chovanec et al., 2021; Marino et al., 2018). The intersection of physical symptom distress with psychological distress creates a complex clinical picture that necessitates a holistic approach in nursing care. Addressing both the physical and psychological needs of breast cancer patients is crucial for improving their overall well-being and quality of life.

Newly diagnosed patients face a variety of challenges, from the initial shock of a breast cancer diagnosis to the long-term management of the disease. Compared to people who have had breast cancer for longer, newly diagnosed patients often have more difficulty regulating their emotions, maintaining their quality of life, developing self-esteem, and developing effective coping strategies (Johnson & Smith, 2022). These challenges stem from a lack of familiarity with the disease trajectory and treatment processes, leading to heightened feelings of uncertainty and vulnerability. As a result, newly diagnosed patients may experience more profound emotional distress and a steeper decline in their quality of life (Williams et al., 2023). This phenomenon underscores the necessity for targeted support and interventions that address the unique needs of this patient population, facilitating a smoother transition into long-term disease management and adaptation (Davis & Lee, 2024).

Given the unique challenges faced by patients newly diagnosed with breast cancer, it is critical to implement strategies that increase confidence in self-care, which in turn can reduce psychological distress and improve quality of life. Studies have shown that self-care training and education significantly improve the effectiveness of self-care in managing symptoms and side effects of treatment, reducing the anxiety and depression that often accompany a new cancer diagnosis (Thompson & Lee, 2022).

Despite advances in cancer treatment which have increased breast cancer survival rates, the aggressiveness of the therapy increases the exposure of patients to treatment side-effects. Cancer and treatment-related symptoms are major stressors in patients with breast cancer undergoing treatment for the disease. Of all the symptoms, anxiety and depression are the most prevalent psychological symptoms perceived by breast cancer patients (Alagizy, 2020). Patients undergoing treatment for cancer face major physical and emotional challenges. Most breast cancer patients receiving chemotherapy experience psychological distress as a result of negative effects of chemotherapy agents, the uncertainty of post-treatment, and the occurrence of psychosocial problems. Anxiety is common at the initiation of treatment, worrying of the potential side effects of the agents and fear of recurrence after completion of treatment. The prevalence of depression varies between 8% and 36% depending on the site of breast cancer, diagnostic criteria, and prognosis (Mitchell et al., 2011; Saniah & Zainal, 2010; Zainal, et al., 2013).

During the past decades, QOL has become an important outcome in medical and psychological research. Increasingly there has been a growing recognition that maintaining or improving the QOL for cancer patients is an important treatment goal, since, it is well described previously that, clinical data only show small correlations with patients' judgments (Akin, 2019). It is a complex multi-dimensional assessment of the physical, psychological, and social well-being of individuals (Potter, 2012; Zitzmann, 2022). The adverse effects of different cancer- or treatment-related symptoms and types of treatment have been associated with QOL. Being diagnosed with breast cancer is a very stressful event and has tremendous consequences for most persons who experience it, affecting all aspects of life and the temporary side effects associated with the treatment may influence the patients' health related QOL during

treatment. In the case of breast cancer, the initial treatment usually consists of surgery, and after the operation many patients are recommended one or more additional treatments including radiotherapy, chemotherapy, and hormonal treatment. All these factors may, of course, impact the patients' QOL thus compromising the QOL (Adams et al., 2014; Bantam-Joppe et al., 2015; Hamer et al., 2017). Moreover, the incurable nature of breast cancer along with its reoccurrence causes psychological distress to clients than the diagnosis of primary breast cancer that in turn affects the QOL of these patients (Hassen et al., 2019; Meichenbaum, 2007; Ntiamoah, 2020).

To date, internet and mobile phone has been largely and easily accessed and used by most people. Research evidence revealed that internet-based management not only could enable health care professionals and patients to interact with each other via the internet to transmit health information and it can reach large groups of patients (Forkner-Dunn, 2003; Schickedanz et al., 2013). Some studies tested the effectiveness of mobile phone-based application for improving self-care behavior. Preliminary evidence suggests that a mobile phone-based application has had a positive impact in facilitating self-management symptom among women with breast cancer in Norway and the United States (Adriaans et al., 2021). In China, the study showed the role of applying a mobile application for self-efficacy and social support in reducing symptom distress among breast cancer patients (Zhu, 2018). A Comprehensive Health Enhancement Support System and the mobile phone-based symptom management program significantly enhanced participants' self-care behavior (Park et al., 2020). The evidence from the studies included is currently limited but suggests that mobile apps for women with breast cancer might be an acceptable information source and lead to improved patient well-being. They can also be used to report symptoms and adverse treatment-related effects and promote self-care.

In fact, in China, many hospitals set a day ward where patients and they could go home after chemotherapy, so they only have one day of face-to-face interaction with medical staff. Therefore, nurses have not enough time to look after these cancer patients and facilitate them to enhance and fulfil their self-care behavior. Evidence suggests that Chinese women with breast cancer received inadequate support from nurses and health care professionals (Zhang, 2018). With the increasing availability and access to online resources, women with breast cancer are more likely to search

the Internet for information (Bach, 2020). The limited available evidence suggested that phone-based application could be effective in enhancing self-care behavior (Kebede, 2019), psychosocial well-being and reducing symptom distress (Jongerius et al., 2019). The use of phone-based application as a medium for breast cancer chemotherapy patients' intervention research is still immature. Moreover, studies suggested that moderated phone-based interactive nursing have been shown to be promising interventions with consistent positive effects (Anand et al., 2021; Brinkel et al., 2017; Sarfo et al., 2021). In this study, therefore, the researcher would select the women with breast cancer who were at age 18-60 and after breast cancer surgery undergoing chemotherapy, to examine the effectiveness of a phone-based support program (PBSP) for women with the expectation that enhancing the patients' self-care confidence, and psychological distress in terms of symptom distress, anxiety, depression, and quality of life.

Research objectives

The purpose of this study was to determine the effectiveness of the Phone-Based Support Program (PBSP) for women newly diagnosed with breast cancer undergoing chemotherapy by comparing the self-care confidence, psychological distress (symptom distress, anxiety, and depression), and quality of life between participants in the intervention group and those in the control group, as well as within the intervention group for change over-time among 3-time repeated measured.

Research hypotheses

1. Participants in the intervention group have significantly higher self-care confidence than those in the control group at immediately post-intervention (T2), and follow-up period (T3), and within the intervention group, self-care confidence significantly increases from pre-intervention (T1) to post-intervention (T2), and follow-up period (T3).

2. Participants in the intervention group exhibit a greater reduction in psychological distress, including symptom distress, anxiety, and depression than those in the control group at immediately post-intervention (T2), and follow-up period (T3), and within the intervention group, the outcomes of psychological distress significantly

decrease from pre-intervention (T1) to post-intervention (T2), and follow-up period (T3).

3. Participants in the intervention group exhibit significant increase quality of life than those in the control group at immediately post-intervention (T2), and follow-up period (T3), and within the intervention group, and within the intervention group, the quality of life significantly increases over time from pre-intervention (T1) to post-intervention (T2), and follow-up period (T3).

Scope of study

The study was conducted at the Yancheng NO.1 People's Hospital in Jiangsu, China. Data collection was carried out from April 22 to July 7, 2023.

Conceptual framework

This study used Bandura's self-efficacy theory (Bandura, 1997) as its theoretical foundation. Individuals must feel that they can implement self-care activities in order to invest adequate effort and engage in self-care behavior. Self-efficacy is defined as a person's specific beliefs about their ability to execute actions in future situations. Four key sources impact the development of these beliefs: performance experience, vicarious experience, verbal persuasion, and emotional arousal, each of which contributes to the formation of self-efficacy and, as a result, influences behavior.

Performance accomplishments, also known as mastery experiences (Zamanzadeh et al.,2021), including one's own experiences or personal history of behavior, are identified as having the most significant impact on self-efficacy beliefs and future behavior. The second source is vicarious experience, which includes direct observations by a person. Learning via models is based on vicarious experiences, which entails observing others and applying those insights to one's own conduct. The effectiveness of the model learning is higher when the observed model is more similar to the observer. The third source, verbal persuasion, though weaker compared to the first two, involves feedback and instructions from others, texts, or self-instruction. Lastly, the least potent source, emotional arousal, influences self-efficacy expectations when these states are interpreted as indicators of one's ability or inability

to perform a behavior This interpretation influences perceptions of competence and controllability (Reeves & Chiang, 2019).

The Phone-Based Support Program (PBSP) is a comprehensive intervention employing a mobile application, specifically WeChat (Lankford, 2013), and it comprises several components: a Learning group, a Discussion group, an Ask-the-Expert group, and a Personal Stories group. This program integrates the four principal elements of self-efficacy theory as outlined by Burlington (2013): mastery experiences, vicarious experience, verbal persuasion, and emotional arousal.

In the context of this theory, mastery experiences are facilitated through the Learning group, where participants acquire knowledge about symptom management. Vicarious experiences are enabled via engaging with personal narratives in the Personal Stories group and through reciprocal sharing in the Discussion group. In the Discussion and Ask-the-Expert groups, peers and healthcare experts provide verbal comments and interactions to persuade participants. Lastly, the program's educational content and shared experiences are designed to influence patients' perceptions and expectations regarding their emotional arousal states in managing their condition.

Operational definition of variables

Self-care confidence refers to perception of women newly diagnosed with breast cancer undergoing chemotherapy on confidence of being able to perform and manage symptoms and daily activities by themselves, for example the patient who has the high level of self-care self-efficacy, he or she has confidence to learn active coping strategies, manage pain, increase the duration of night-time sleep and improve the level of physical activities, then getting good physical function, mental health, and quality of life. It will be measured by using the Self-Care Self-Efficacy Scale (Riegel et al., 2018b).

Symptom distress refers to the level of unease experienced due to various specific symptoms, including but not limited to fear, depression, sleep disturbances, worry, fatigue, nervousness, dietary issues, and apathy, particularly as reported by women who have recently been diagnosed with breast cancer and are undergoing chemotherapy. The measurement of this distress will be conducted utilizing the M.D. Anderson symptom Inventory (MDASI) (Cleeland, 2000).

Anxiety refers to the anxious anticipation of potential danger or adversity, accompanied by feelings of unease or physical symptoms of tension, particularly as experienced by women who have recently been diagnosed with breast cancer and are now undergoing chemotherapy. The assessment of anxiety levels in this context will be conducted through the use of the Hospital the Hospital anxiety and depression scale (So, 2010).

Depression refers to a perceived pathological emotional response for women newly diagnosed with breast cancer and undergoing chemotherapy. This response encompasses feelings of loss pertaining to normalcy and personal life, triggered by the cancer diagnosis, ongoing treatment, or potential complications. The quantification of depression in this patient group will be facilitated using the Hospital anxiety and depression scale (So, 2010).

Quality of life (QOL) refers to a measure of ability of women newly diagnosed with breast cancer undergoing chemotherapy to functional, symptomatic, and global quality of life aspects within his/her environment at a level consistent with his/her own expectations. It will be measured by using The Global Health Status scale from the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 (V3.0) was developed by Sprangers et al. (1996), and later translated into Chinese and validated by Wan (2008) and Zhao & Kanda (2000) to assess the quality of life in individuals diagnosed with cancer (Anderson, 1996).

A phone-based support program (PBSP) refers to a program of nursing intervention for female patients newly diagnosed with breast cancer and currently receiving chemotherapy developed by the researcher based on Bandura's self-efficacy theory. The program aims to enhance self-care confidence and quality of life as well as symptom distress, anxiety, and depression of the patients. This implementation contained 4 sessions for 3 weeks focusing on providing a new and available health education method for women with breast cancer through a phone-based application in addition to attend face-to-face support services.

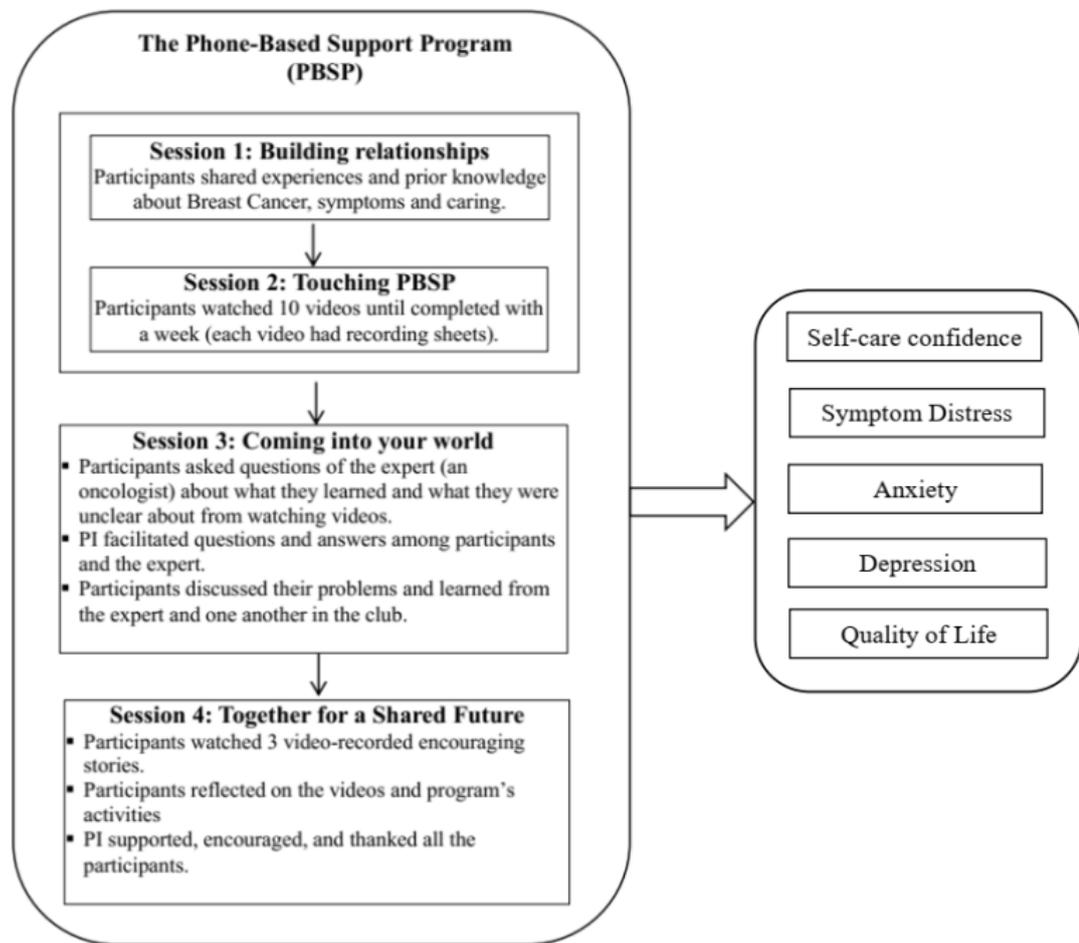


Figure 1 Conceptual framework of the study

CHAPTER 2

LITERATURE REVIEWS

This chapter provides a comprehensive review of pertinent literature, encompassing the following content areas:

1. The nature of breast cancer and treatment
2. The impact of breast cancer after surgery and undergoing chemotherapy
3. Essential self-care for reducing psychological distress and enhancing quality of life
4. Self-efficacy must be specific to self-care requirements to reduce psychological distress and improve QOL
5. Phone-/internet-/application-based Intervention for breast cancer women on related outcomes

1. The nature of breast cancer and treatment

The epidemiological characteristics of breast cancer:

Breast cancer continues to be a global health challenge: every year there are over one million new cases and 370,000 deaths worldwide. It is the most common cause of cancer death worldwide and affects both developed and developing countries. In China, the incidence of breast cancer has risen faster than the global average over the past two decades and is expected to reach 805,116 deaths per year by 2030 (Cardoso et al., 2018). The Global Cancer Observatory (GLOBCAN) indicates that breast cancer is the most common cancer among Chinese women, with an age-standardized rate (ASR) of 21.6 per 100,000 women (Ao et al., 2019; Jiang et al., 2020). Urban women in China face a higher risk, with the disease is most frequent in urban environments and fourth in rural places (Lei et al., 2021). The urban ASR is approximately double that of rural areas, with eastern coastal cities exhibiting the highest rates – Guangzhou's ASR being comparable to Japan's (S. Zhao et al., 2019). In less developed western or central areas of China, the ASR can be as low as 7.94 instances per 100,000 women (Zhou et al., 2020).

Breast cancer is a multi-factorial disease, influenced by genetics, environmental factors, and lifestyle behaviors. The average age of diagnosis in China is 45-55 years, younger than in Western countries (Cheng, et al., 2018). Data from Shanghai and Beijing show two age peaks in incidence, with a trend towards older age at diagnosis (Cheng et al., 2018). This tendency may be attributed to variations in reproductive habits and lifestyle factors, similar to trends in Taiwan and Hong Kong (Lin et al., 2019). Postmenopausal women face a 50% higher risk of breast cancer (Engmann et al., 2017). Blood type "A" and Rh-positive individuals are at a higher risk, suggesting the need for targeted screening (Meo et al., 2017).

Diet also plays a crucial role, higher intakes of fruits, vegetables, whole grains, and dietary fiber are related with decreased risk, and high consumption of red meat, animal fats, and refined carbohydrates linked to increased risk (Heath et al., 2020; Tan et al., 2017). As total dietary fat intake increases, the incidence of breast cancer increases (Shetty & Sreedharan, 2019). Western dietary patterns further elevate the risk (Xiao et al., 2019). Nutrients like folate, B vitamins, riboflavin, vitamin D, and calcium are inversely related to breast cancer risk (Houghton et al., 2019). Exposure to phthalates, used in various consumer products, is linked to an increase in estrogen receptor-positive breast cancer (Ahern et al., 2019; Meeker et al., 2009).

People taking hormone therapy are 3% more likely to develop breast cancer than those who have never taken such medication. In particular, the combination of estrogens and progestins increased the incidence of ER+ breast cancer, although this was not observed for ER- breast cancer in African American women. In addition, estrogen use alone was not associated with an increased risk of ER+ or ER- breast cancer (Rosenberg et al., 2023). According to findings from a cohort study conducted in the UK, the administration of insulin glargine in diabetes treatment is related with a 1.5 times higher risk of women with breast cancer compared to the use of NPH insulin (Lee & Chowdhury, 2020).

Both active and passive smoking are related with an increased risk of breast cancer, yet cessation of smoking in breast cancer patients can significantly reduce their mortality risk (Luo et al., 2019). Alcohol consumption increases the risk of breast cancer by approximately threefold compared to non-drinkers (Sinnadurai et al., 2020). Regular physical activity has been demonstrated to reduce the chance of

developing breast cancer, with higher intensity activity offering greater risk reduction (Tan et al., 2017). Disturbances in circadian rhythms are also associated with a higher risk of breast cancer. Early rising acts as a protective factor, whereas prolonged sleep duration increases risk, though the specific duration that elevates risk requires further study (Richmond et al., 2019).

The younger the age of menarche, the more likely it is to develop breast cancer. The age of menarche determines the risk of breast cancer in people who experience menarche before the age of 12. It is about twice as high as for people who are older than 12 (Thakur et al., 2017). Nulliparous women or those who are older than 30 years old for the first childbirth are more likely to develop breast cancer, and the age at first delivery is the strongest predictor of breast cancer risk. More than six times that of those aged 30 (Thakur et al., 2017). Women who have their first child beyond the age of 29 have a 3.53 times higher risk than those who give birth before the age of 20 (Sinnadurai et al., 2020). While delivery initially lowers the risk of breast cancer, the risk for multiparous women rises by 80% five years after childbirth and then falls by roughly 25% after 20 years (Nichols et al., 2019). Breastfeeding has a preventive impact against breast cancer, especially lowering the risk of ER- breast cancer but not ER+ breast cancer, as demonstrated by research such as Fortner et al. (2019). However, the association between parity and breast cancer risk is still debated (Nichols et al., 2019).

The role of surgery in breast cancer treatment:

A comprehensive, multicenter, nationwide study in China found that the distribution of breast cancer stages at diagnosis varied widely, with nearly half of patients being stage II. In contrast, in the United States, the majority of women, about 60%, were diagnosed with localized stage I or II breast cancer, 33% with regional stage III and a smaller proportion, about 5%, with stage IV (Si et al., 2015). Breast cancer clinical manifestations vary according to the type and stage of cancer, but the primary manifestation presents as painless lumps within the breast tissue. Other common clinical manifestations include nodes in the axilla, dimpling of the breast tissue, and bone pain which is a late symptom related to metastasis (Harbeck et al., 2019). Chest pain, dilated blood vessels, edema, hemorrhage, nipple

eczema/discharge, reddened skin, local tenderness, and warmth are also symptoms associated with breast cancer (Harbeck et al., 2019).

Over the years, remarkable progress has been made in the surgical treatment of breast cancer. Surgical interventions play an important role in the treatment of breast cancer. Their main goal is to remove the cancerous tissue and, in some cases, prevent the cancer from recurring. The choice of surgical technique depends largely on the stage, size, and preferences of the patient. Two main types of surgery are performed: Lumpectomy and mastectomy. In lumpectomy, also known as breast-conserving surgery, the tumor, and a small area of healthy tissue around the tumor are removed. This method is usually chosen when the cancer is detected at an early stage and is confined to a small area. A mastectomy, on the other hand, involves removing the entire breast. It is often recommended when the cancer is more extensive or there is a high risk of recurrence.

2. The impact of breast cancer after surgery and undergoing chemotherapy

Anatomic changes after surgical treatment:

Musculoskeletal changes after a mastectomy occur on both the affected and unaffected side. Mastectomy changes the tilt and position of the scapula at rest, leading to a number of changes in the shoulder joints, particularly on the left side. Shoulder strains and rotator cuff disorders are more common in women after mastectomy. Impairments in shoulder blade coordination and loss of strength have been documented up to six years after surgery (Lovelace et al., 2019a). Women who have had a unilateral mastectomy often have an asymmetrical gait that can be alleviated but not completely corrected with an external prosthesis. The damage is partly due to the direct effects of the surgical disruption of the tissue, which leads to fibrosis, inflammation and scarring as part of the healing process. Angiogenesis, the formation of new blood vessels during healing, is associated with inflammation and can cause local and regional pain syndromes (Kriek et al., 2018). Radiation therapy contributes to cell death and the release of inflammatory cytokines, causing tissue damage and fibrosis, thus significantly heightening the risk of long-term dysfunction and pain (Lovelace et al., 2019b; Sroussi et al., 2017). Sentinel lymph node biopsy is a common procedure in mastectomy or breast-conserving surgery. If the biopsy is

positive, particularly in advanced malignancy, dissection of the axillary lymph nodes may be necessary. The degree of lymphatic involvement correlates with the number of lymph nodes removed and is associated with a higher risk of shoulder and arm disability, lymphoedema and chronic pain syndromes (Cho et al., 2014).

Nerve injury, particularly to the intercostobrachial nerve and other brachial plexus nerves, can occur during surgery, particularly when axillary lymph node dissection is performed (Wang & Tepper, 2021). After therapy, strange feelings may occur in the chest wall, axilla, upper arm, and, on rare occasions, the upper back and side. Approximately 85% of women have hypoesthesia following treatment, and those with bigger regions of aberrant feeling are more likely to suffer from persistent pain (Lovelace et al., 2019b).

Functional changes post operation:

Compared to their counterparts, breast cancer survivors have a variety of long-term functional impairments, including decreased strength, aerobic capacity, and mobility. Aerobic ability declines once therapy ends, however other functional alterations may improve with time (Mak et al., 2017). More than half of these women had some degree of upper limb dysfunction, and 24% still had clinically significant dysfunction more than a year after treatment. A typical manifestation of shoulder dysfunction is problems with internal rotation and extension, which are essential for tasks such as tying bras (de Oliveira, et al., 2021). Furthermore, activities like dressing, bathing, hair care, and household chores involving mopping, sweeping, or reaching become arduous (Davies et al., 2018). These functional impairments can significantly impede the ability to perform daily activities and may even affect the capacity to work.

Chronic pain syndrome:

Chronic pain syndrome, especially neuropathic pain, is often cited as a major complication in breast cancer survivors. Various terms are used in the literature to describe this condition, including postmastectomy pain syndrome, chronic neuropathic pain after breast surgery and several others (Larsson et al., 2017; Piracha et al., 2017). The International Association for the Study of Pain defines postmastectomy pain syndrome as chronic, nonmalignant pain that appears soon after breast cancer surgery and affects locations such as the anterior thorax, axilla, and the

upper medial portion of the arm (Chappell et al., 2020). This syndrome affects the physical health of survivors and has a significant impact on their emotional and psychological state. Chronic pain can lead to limitations in daily activities, restrict mobility and often be a source of ongoing psychological distress, contributing to conditions such as depression and anxiety.

Axillary web syndrome:

Axillary web syndrome, often termed as axillary or lymphatic cording, is a condition identified by the presence of constrictive axillary tissue, limiting the range of motion in the arm or shoulder (Yeung et al., 2015). It manifests as two or three tight, non-erythematous cords under the skin, starting from the axilla, extending along the medial arm to the antecubital fossa, and terminating near the base of the thumb (Yeung et al., 2015). The incidence of this syndrome is reported to range from 10% to 85.4%, influenced by the criteria for diagnosis and the timing of its identification (Ryans et al., 2020). Factors such as younger age, lymph node involvement, post-surgical healing complications, extent of surgery performed, and lower BMI are associated with a higher risk of developing axillary web syndrome (Akezaki et al., 2021; Figueira et al., 2018). This syndrome could be just as common in women with a higher BMI, but less noticeable as there is more fatty tissue, which could also have a protective effect. Axillary reticular syndrome can have a significant impact on patients' recovery and quality of life after breast cancer surgery. It can limit the ability to perform activities of daily living, especially those that require arm mobility. Early recognition and intervention, including physiotherapy and exercise, are essential to managing this condition.

Lymphedema:

Lymphedema, characterized by regional swelling in one or both arms, results in pain, a sensation of heaviness, tightness, and reduced mobility (Lovelace et al., 2019b). The condition's prevalence, which can be as high as 94%, varies based on its definition, the timing of its diagnosis, and the methodology of the study (Armer & Stewart, 2010). Main risk factors contributing to the development of lymphedema include a high body mass index (BMI), undergoing a mastectomy, the extent of lymph node removal, and axillary lymph node dissection (Toyserkani et al., 2017; Ugur et al., 2013; Zou et al., 2018). This condition makes everyday activities difficult and can

increase pain, which has a negative impact on physical and mental health. In addition, lymphoedema affects quality of life and overall survival, which is a major burden for breast cancer survivors (Zou et al., 2018). In addition to these physical symptoms, lymphoedema can have serious psychosocial consequences. Due to the visible changes in appearance and functional limitations, this often leads to body image issues and social isolation. The treatment of lymphoedema requires a multi-faceted approach including physiotherapy, compression garments and in some cases surgery, emphasizing the need for comprehensive care for breast cancer survivors. The disease highlights the importance of early detection and intervention, as well as educating patients on preventative measures and self-management techniques to minimize the impact on survivors' daily lives and overall well-being.

Other pain syndromes:

Women receiving breast cancer therapy typically describe pain syndromes associated with musculoskeletal and neuromuscular conditions. These disorders include rotator cuff syndrome, arthralgias, adhesive capsulitis, cervical radiculopathy, and brachial plexopathy (Conejo et al., 2018; Glare et al., 2014; Lovelace et al., 2019b). Surgical procedures often lead to physical changes in the shoulder girdle that put breast cancer survivors at increased risk of developing these conditions, which can make them more difficult to treat and control. Physical changes to the shoulder girdle after surgery put breast cancer survivors at a higher risk than the general population, which can make these conditions more difficult to treat. Breast cancer survivors may have arthralgias (Fayed et al., 2013; Lovelace et al., 2019b; Yagata et al., 2016). These pain syndromes can significantly affect the survivors' mobility, dexterity, and quality of life. The management of these pain syndromes often requires a multidisciplinary approach, including pain management, physical therapy, and sometimes, surgical interventions.

The impact of breast cancer on psychological distress and quality of Life:

Women diagnosed with breast cancer often undergo a range of treatments. These treatments, both individually and collectively, are known to lead to numerous adverse side effects (Akram et al., 2017). It is common for cancer patients to experience various emotional and behavioral changes during the phases of diagnosis and treatment. These changes can range from psychiatric disorders to mild emotional

symptoms and behavioral alterations (Izci et al., 2016). Common psychiatric conditions observed include anxiety, depression, and adjustment disorders, potentially triggered by medications and the overall medical situation. Literature reviews suggest that the intensity of anxiety and depression increases during cancer treatment, subsequently impairing the quality of life (Reich et al., 2008).

Psychological distress in breast cancer patients encompasses a wide range of emotional and cognitive difficulties that can occur before, during and after the disease and treatment. The term usually refers to the anxiety, depression, fear, and stress that patients often experience. These emotional states can be triggered by a variety of factors, such as the shock of diagnosis, the uncertainty and side effects of treatments such as chemotherapy and radiotherapy, changes in body image after surgery and worries about cancer recurrence.

Chemotherapy, an adjuvant therapy, is widely administered to breast cancer patients, significantly enhancing survival rates (Asselain et al., 2018). Despite its effectiveness, chemotherapy is known to cause a plenty of physical symptoms alongside psychological distress including depression and anxiety (Oh & Cho, 2020). While these symptoms tend to diminish over time, they are linked to decreased quality of life and adherence to treatment (Donnelly et al., 2018; Polikandrioti et al., 2019). Particularly in breast cancer patients, cancer-related fatigue stands out as one of the most common symptoms post-treatments, significantly impacting health-related quality of life (HRQOL) (Bower, 2019; Saito et al., 2022).

Symptom distress:

Acute and chronic symptoms arising from a cancer diagnosis encompass both physical and psychological aspects, stemming from the disease itself and its treatment modalities. Symptom distress refers to the extent of suffering in response to these symptoms (Rhodes & Watson, 1987) and can manifest in various forms, including psychological, emotional, social, or spiritual, affecting patients' ability to manage their condition (Toledo, Ochoa, & Farias, 2021). Women diagnosed with breast cancer frequently report symptoms, starting from the time of diagnosis and, for some, persisting into survivorship (Gallagher et al., 2002; Schubart et al., 2014), and for some, distress persists into survivorship (Lam et al., 2012; Logan et al., 2019; Madison et al., 2021). Women diagnosed with breast cancer frequently report

symptoms, starting from the time of diagnosis and, for some, persisting into survivorship (Chandwani et al., 2012).

Postoperatively, the women suffered from surgical numbness and deformity, severe nausea and balding during chemotherapy and reported severe bone pain and peripheral neuropathy while taking paclitaxel. At the start of chemotherapy for breast cancer, a range of physical and psychological symptoms can occur that are influenced by co-existing health problems, previous cancer treatments and stress. In studies of women with breast cancer who have not yet undergone surgery or other treatment, patterns of severe stress and severe symptoms associated with mood and sleep disturbances, fatigue, pain, and cognitive impairment have been noted (Denieffe et al., 2014; Matthys et al., 2021). These symptoms not only persist post-surgery but can also contribute to distress during chemotherapy (So et al., 2021). A study found that symptom distress was greater linked to decreased ability to complete the prescribed chemotherapy regimen at baseline (Yee et al., 2017).

Insomnia is one of the most prevalent cancer-related symptoms (Schieber et al., 2019). According to Chen et al. (2018), the incidence of sleep problems among cancer patients is 50%, with a greater frequency in women and a larger occurrence among breast cancer patients compared to other malignancies. When a patient has terminal cancer, sleep difficulties and other symptoms grow significantly, especially in the terminal stage, substantially impacting quality of life (Itani, 2021). Insomnia in breast cancer patients can be triggered by a variety of circumstances, including psychological stress related to the diagnosis and the adverse effects of cancer drugs. Patients receiving adjuvant endocrine therapy are more likely to suffer from insomnia due to menopausal symptoms caused by the drugs. The link between these symptoms and insomnia is not surprising, as psychological symptoms and insomnia often co-occur and insomnia is a common symptom of both depression and generalized anxiety (Bao et al., 2016). These findings suggest that interventions focused on addressing depression and anxiety may also have a positive impact on improving sleep quality. Additionally, there is a notable association between drug use and insomnia (Matthews et al., 2014). A considerable majority of women (63%) reported suffering one or more forms of sleep disturbances, with 37% utilizing sleeping drugs during the previous 30 days (Carrasco-Garrido et al., 2018). Difficulties in falling asleep were shown to be

highly connected with increased discomfort and symptoms of depression, whereas issues related to getting up at midnight were significantly associated with higher levels of depression and lower levels of education (Stetler & Miller, 2005).

Anxiety and depression:

Breast cancer diagnosis and treatment may have a detrimental impact on women's physical and emotional well-being due to treatment side effects, dread of mortality, and feelings of social devaluation (Al Zahrani, et al., 2019; Suwankhong & Liamputtong, 2018). Furthermore, therapy for breast cancer may result in decreased functional ability, and changes in self-image, as well as anxiety, depression, and other psychological and emotional disturbances (Hung, Sanchez-Varela, & Bober, 2017). More than one-third of breast cancer patients suffer from mental illnesses, with anxiety and depression being the most common psychological symptoms (Brown et al., 2020).

Anxiety is defined as the fear of future danger or misfortune, accompanied by feelings of dysphoria or somatic symptoms of tension (Marques et al., 2009), whereas depression is defined as a pathological affective response to the loss of normalcy and one's personal world as a result of cancer diagnosis, treatment, or impending complications (Tel et al., 2011). If left untreated, anxiety and depression can have serious psychological, medical and health service utilization consequences. These include reduced likelihood of accepting, tolerating, and adhering to recommended treatments, and increased toxicities and severity of medical symptoms that, in turn, can increase healthcare costs and reduce quality of life (Beatty & Kissane, 2017).

Chemotherapy, which the patients are undergoing, entails extended durations of treatment, several hospitalizations, and side effects such as nausea, vomiting, and hair loss. Cancer diagnosis and treatment have been demonstrated to have major consequences on the psychological state of patients (Andersen et al., 2008; Fertig, 1997; Jacobsen et al., 2012). The immediate reaction to a cancer diagnosis ranges from shock and disbelief to symptoms such as dysphoria, irritability, loss of appetite and insomnia. Severe chemotherapy can increase psychological distress, and most of these patients have adjustment problems, including symptoms of anxiety and depression (Caruso et al., 2017; Chintamani et al., 2011). Thus, the morbidity associated with cancer and its treatment is not just physical.

Quality of life:

Patients with Breast cancer undergo kinds of treatment modalities. These treatments can variably influence the level of physical and psychological distress related to poorer body image and sexual problems experienced by breast cancer patients (Paterson, et al., 2016). In cases where the treatment includes mastectomy, the resultant surgical consequences can adversely affect both the physical and mental health of the patients. Such impacts are seen to detrimentally alter the quality of life (QOL) in individuals suffering from breast cancer (Duijts et al., 2011; Martino et al., 2020).

The concept of quality of life transcends the mere absence of illness or infirmity, encompassing a holistic state of physical, mental, and social well-being (Spitzer, 1987). It is also perceived as the individual's understanding of their life standing within the framework of the cultural and value systems they inhabit, and in alignment with their aspirations, expectations, norms, and concerns (Whoqol Group, 1995).

Studies in different demographic groups have shown that chemotherapy can worsen the quality of life of breast cancer patients. Chemotherapy also affects ovarian function, as alkylating agents have cytotoxic effects that reduce the number of primary follicles and lead to ovarian failure. This interruption in the production of sexual oestrogens leads to menopausal symptoms such as hot flushes, night sweats, irritability, sleep disorders, weight fluctuations and atrophy of the urogenital organs (Emri et al., 2018; Reichrath et al., 2020). The culmination of chemotherapy treatment often brings with it a range of toxic effects (Oun, Moussa, & Wheate, 2018). There are numerous studies in the literature that look at the quality of life of women being treated for breast cancer. However, there are few studies that specifically address the effects of chemotherapy on quality of life, and the studies that do exist show contradictory results. A German study has shown that adjuvant chemotherapy significantly impairs the quality of life of women undergoing such treatment, in contrast to women receiving radiotherapy and adjuvant hormone therapy (Galalae et al., 2005). Similarly, research from Sweden associated chemotherapy with a host of physical and emotional issues, including anxiety, pain, nausea/vomiting, body image

alterations, increased fatigue, among other side effects, leading to a reduced quality of life (Browall et al., 2008).

Professionals managing breast cancer treatment should be adept at recognizing and addressing the physical and psychosocial symptoms that can precipitate anxiety and depression. It is imperative to formulate patient-centric treatment and care protocols based on the levels of depression (Henry & Alias, 2018). It is also vital to address the quality of life of cancer patients and offer them with emotional and psychological support.

3. Essential self-care for reducing psychological distress and enhancing quality of life

Self-care is a critical practice in managing personal health, especially for individuals with chronic conditions like breast cancer. It involves activities aimed at maintaining health and well-being. Self-efficacy is the belief in one's capabilities to execute the courses of action required to manage prospective situations (Bandura, 1977). This concept plays a vital role in self-care, as a person's belief in their ability to perform self-care activities effectively is crucial for actual engagement in these practices. Self-care confidence, a derivative of self-efficacy, specifically refers to one's confidence in performing self-care activities. Research suggests a strong link between high levels of self-efficacy and self-care confidence, leading to better health management and outcomes (Smith, 2019).

Self-care has a role on reducing psychological distress such as symptom distress, anxiety, and depression in breast cancer patients involves exploring relevant research studies. For instance, a study by Jones et al. (2018) demonstrated that self-care practices like mindfulness meditation significantly reduced anxiety and depression in breast cancer patients. Regular physical activity as a form of self-care helped alleviate symptom distress and improve mood (Similarly, et al., 2020). These studies underscore the importance of integrating self-care routines in the management plan for breast cancer patients to enhance their psychological well-being.

The impact of self-care on improving quality of life (QOL) in breast cancer patients would involve reviewing relevant research. For example, a study by Brown and Jones (2019) showed that breast cancer patients who engaged in regular self-care

activities like balanced nutrition and stress management reported significant improvements in their overall quality of life. Another study by Lee et al. (2021) found that participation in self-care programs that included exercise and social support resulted in enhanced emotional well-being and life satisfaction among breast cancer survivors.

4. Self-efficacy must be specific to self-care requirements to reduce psychological distress and improve QOL

The theory of self-efficacy, as outlined by Bandura (1977), elucidates the development and modification of self-efficacy, and its profound impact on behavior change, performance achievements, and personal wellness. Bandura's model (1997) identifies four key sources influencing self-efficacy: performance accomplishments, vicarious experience, verbal persuasion, and emotional arousal (Bandura, 1997), all of which directly shape self-efficacy beliefs and subsequently, mediate behavior (Olivier & Shapiro, 1993). These elements are pivotal in interventions aimed at forging or modifying self-efficacy expectations, thereby empowering individuals to engage in behaviors to achieve their goals.

Self-efficacy expectations, synonymous with self-efficacy, refer to an individual's conviction in their capability to conduct specific behaviors (Eastman & Marzillier, 1984). This belief, coupled with the anticipation of certain outcomes (response-outcome expectations), plays a crucial role, especially when there is a strong conviction that the behavior will lead to desired outcomes. The belief in one's ability to initiate and sustain behaviors to achieve these outcomes is critical (Resnick, 2008).

Research in various health disciplines, including nursing, medicine, and psychosocial health, has focused on self-care self-efficacy. Nursing research typically defines self-care self-efficacy as a psychological construct derived from general self-efficacy, emphasizing an individual's confidence in their ability to execute self-care behaviors in specific contexts (Wu, Hsieh, Lin, & Tsai, 2016). This conceptualization differs by focusing solely on the self-care context rather than the broader scope of self-efficacy and self-management. Interdisciplinary research defines self-care self-

efficacy as the perceived capacity to execute self-care tasks (Al-Amer et al., 2016; Zhang et al., 2015).

Empirical evidence supports the link between self-efficacy and health outcomes in breast cancer patients, where a significant association has been found between symptom distress and self-efficacy levels (Baik et al., 2020). A positive self-belief in one's efficacy is indicative of an individual's commitment to promoting health behaviors and overall well-being (Liang et al., 2016). Research indicates that individuals with strong self-efficacy beliefs are more proactive in adopting strategies for symptom management (Liang et al., 2016). Patients with higher self-efficacy, particularly following chemotherapy, tend to be more motivated in managing symptoms (Geng et al., 2018). In addition, new breast cancer diagnoses often lead to significant declines in quality of life, with approximately one-third of patients experiencing psychological distress (Fradelos et al., 2017). Furthermore, studies have shown a significant inverse relationship between self-efficacy and psychological symptoms like anxiety and depression, suggesting that higher self-efficacy in cancer patients correlates with reduced emotional disorders, and vice versa (Mystakidou et al., 2013). Dalton et al. (2002) observed an increased risk of depression hospitalization up to ten years post breast cancer diagnosis. In diverse cancer patient groups, self-efficacy has been positively associated with mood (Lacour et al., 2020), psychological adjustment (Haugland, Wahl, Hofoss, & DeVon, 2016), emotional well-being, (Boehmer, Luszczynska, & Schwarzer, 2007), and overall physical health (Perry et al., 2015). Firouzbakht et al. (2020) explored the correlation between depression and self-efficacy in 93 chemotherapy breast cancer patients, finding a significant association between high depression levels and low self-efficacy, thus underlining the close relationship between self-efficacy and depression in breast cancer patients.

5. Phone-/internet-/application-based Intervention for breast cancer women on related outcomes

Research indicates that psychosocial interventions delivered in a clinical setting, incorporating elements like informational, emotional, social, and spiritual support, have been effective in enhancing pain relief, mood, life quality, and survival

rates at the 12-month mark in breast cancer patients (Fors et al., 2011; Mustafa et al., 2013). Nonetheless, the traditional face-to-face modality of these interventions often poses accessibility challenges for many cancer patients, given factors such as clinic location, travel time, and patient availability (Jones et al., 2007).

The rise of E-health and M-health technologies has opened new avenues for patient-healthcare professional interactions beyond the traditional clinic-based encounters (Lievevrouw & Van Hoyweghen, 2019). Internet or computer-based educational platforms have shown potential in enhancing breast cancer-related knowledge among women (Ryhanen et al., 2010). A systematic review examining the experiences of cancer survivors, which included 24 studies, identified early evidence supporting the efficacy of web-based support and resources, though these findings were not conclusive (Hong, Pena-Purcell, & Ory, 2012). Unlike web-based therapies, mobile applications (Apps) allow rapid and convenient access to information and social support without the need for a computer, making them more accessible (Zhang et al., 2016). In 2020, internet usage was reported at 70.6% in the Chinese population, with 63.4% accessing the internet via smartphones (Gao et al., 2020; Huang et al., 2020). underscoring the potential of Mobile Apps as a viable platform for psychosocial interventions due to their convenience and broader accessibility.

Emerging literature suggests the effectiveness of M-health interventions in areas such as weight management and depression screening among breast cancer patients (Kim et al., 2016; Quintiliani et al., 2016). Despite a considerable surge in the availability of apps targeting breast cancer, a study concentrating on M-health for breast illness identified a major gap in the evidence basis and medical professional engagement in the creation of these applications (Jongerijs et al., 2019). The development of such apps necessitates full authorship disclosure and robust clinical trials to foster their widespread implementation and effectiveness in the field of M-health (Jongerijs et al., 2019).

Self-efficacy/ Self-confidence:

Namkoong et al. (2010) initiated a study using an eHealth program, developed by a multidisciplinary team, to facilitate the exchange of treatment information among 177 breast cancer patients over four months. This Internet-based system offered various services, tailored to the patients and their caregivers. This study underscored

the importance of health self-efficacy in determining the emotional well-being outcomes of such informational exchanges, revealing a positive effect for patients with high self-efficacy and a negative impact for those with lower self-efficacy.

Anxiety and Depression:

Green and his colleagues (2004) conducted a randomized controlled trial (RCT) in the United States with 211 women having a history of breast cancer. They were divided into groups receiving different combinations of an interactive multimedia CD-ROM program and oral counseling. The study found that counseling reduced mean state anxiety scores, which were within normal ranges at baseline and post-intervention across all groups, regardless of risk status.

An RCT using an Interactive Digital Education Aid for 133 breast cancer patients to facilitate decision-making. The study found no significant differences in anxiety levels between the experimental group, which received the digital aid plus standard education, and the control group, which only received standard education. However, the study group reported higher satisfaction with the method of information delivery (Heller, Parker, Youssef, & Miller, 2008).

Kim et al. (2016) conducted a 48-week study in Korea with 78 breast cancer patients to assess the potential of a mobile mental-health tracker that uses three daily mental-health ratings as indicators of depression. The app collected daily mental-health assessments for sleep satisfaction, mood, and anxiety, and performed similarly to the Patient Health Questionnaire-9 (PHQ-9) tests in depression screening. Adherence to self-reporting was connected to higher accuracy in depression.

A clinical trial (CT) was done in White, African American, and Hispanic American women with breast cancer ($n = 180$) (Fogel et al 2003). The intervention strategy involved widespread usage of the Internet. The experimental minority group ($n = 37$)/white group ($n = 66$) used the Internet for breast cancer concerns, but the control minority group ($n = 10$)/white group ($n = 77$) did not. Minorities who used the internet reported higher levels of overall, assessment, and tangible social support ($p < 0.05$), but not belonging or self-esteem social support, compared to whites. There were no changes seen in stress, depressive symptoms, loneliness, or coping.

Quality of life:

Gustafson et al. (2001) used randomized controlled trials to implement Internet-based programs (Comprehensive Health Enhancement Support System, CHESS) that used a home computer with a modem connection to a central server for communication. The applications offered four fundamental sorts of services: information services, communication services with two conceptually distinct subcategories (discussion group and ask an expert service), and interactive services. The control group (n = 125) only read books about breast cancer. At the two-month follow-up, the CHESS group was considerably more skilled in accessing information, more comfortable engaging in treatment, and more confident in their doctor(s). At the 5-month follow-up, the CHESS group had considerably more social support and information competency, although. At the 5-month follow-up, the CHESS group had considerably higher levels of social support and information competence, but there was no significant difference in quality of life between the groups.

Owen et al (2005) set up a self-directed web-based education group to educate 53 US women with stage I or II breast cancer about symptom management. The control group (n = 27) received no education and was on a waiting list. The experimental group (n = 26) received a self-directed web-based coping skills training program, a series of websites with a bulletin board for asynchronous group discussions, a glossary of medical terminology, a database of breast cancer resources and websites, information, and tips on coping with common physical symptoms, a forum for sharing artwork and poetry, and six structured symptom management exercises. No significant effects on health-related quality of life, distress or physical well-being were found at pre- and 12-week follow-up. However, there was a significant interaction between the self-reported health status at the beginning of the study and the therapy.

In a randomized controlled trial, Yanez et al. (2018) assessed a smartphone application designed to enhance health-related quality of life (HR QoL) and alleviate cancer-specific distress among Hispanic breast cancer survivors in America. The app, grounded in eHealth intervention models for stress and coping and literature on breast cancer's psychosocial adaptation, featured six modules: nutrition, healthy eating, diabetes and heart disease prevention, exercise, lifestyle, and medical guidance. This

mobile intervention, accessible anytime and anywhere, aimed to reach underserved populations. Participants were randomized to either the intervention app, My Guide (offering psychoeducation and self-management), or a control app, My Health (providing health education), for six weeks, supplemented with weekly tele-coaching to promote adherence. The primary outcomes, overall and disease-specific HR QoL and cancer-specific distress, were evaluated at baseline, post-intervention, and eight weeks post-initial use. My Guide showed potential in improving HR QoL and addressing the gap in supportive care access for Hispanic women post-breast cancer treatment.

Summary

This literature review revealed a growing need to improve the self-care confidence, symptom distress, anxiety, depression, and quality of life for women newly diagnosed with breast cancer undergoing chemotherapy. The gap in health disparities is widening and it is imperative that nurses deliver sustainable and high-quality care to the patients. The use of smartphone APP is an effective way to allow breast cancer women to enhance self-care confidence, and decrease symptom distress, anxiety and depression, and quality of life, in a controlled and safe environment. This study will develop a phone-based support program (PBSP) for the women under the guidance of the incorporation of Bandura's self-efficacy theory. The PBSP theoretical framework has been demonstrated to be useful in the design of a psychoeducational program to optimize patients' health outcomes.

CHAPTER 3

RESEARCH METHODS

This chapter presents the research design, population and sample, sampling, instruments, protection of human rights, data collection procedures, the result of pilot study, and data analyses.

Research Design

A single-blinded randomized controlled trial (RCT) and repeated measures design technique was used to examine the effectiveness of the phone-based support program (PBSP) among women newly diagnosed with breast cancer undergoing chemotherapy. This study registered to the Thai Clinical Trial Registry (TCTR) number TCTR20230321010.

Population and participants

Target population

All breast cancer women newly diagnosed patients in China were the study population. The accessible population was the breast cancer women newly diagnosed undergoing chemotherapy receiving treatment at the Yancheng NO.1 People's Hospital in Jiangsu, China.

Participants

The participants were recruited through the accessible population.

The inclusion criteria were: (1) age between 18-60 years, (2) non-metastatic, or stage II or lower diagnosed in the past 3-8 weeks, (3) received chemotherapy following their surgical treatment, (4) had the ability to access the Internet via a mobile device, (5) contactable via the mobile phone for follow up, and (6) able to communicate with Mandarin.

The exclusion criteria were: (1) had a concurrent major physical illness, such as any physical surgery except for the surgery treatment for breast cancer, conditions or afflictions leading to potential lifelong disability, severe chronic diseases, deep coma, irreversible paralysis, or critical brain injuries, (2) had a chronic mental health

problem as diagnosed by a psychiatrist, and (3) unable to complete all session of the implementation.

The discontinuation criteria were: (1) serious diseases emerged during an implementation session, and (2) self-withdrawal or disappeared from the study.

Sample size

G* power 3.1.9.2 (Faul, Erdfelder, Lang, & Buchner, 2007) was used to calculate the sample size. An earlier study focusing on women diagnosed with breast cancer, which assessed quality of life, social support, and so on, revealed a moderate effect size of 0.46 (Gustafson et al., 2008). The effect size pertaining to self-care self-efficacy was not specified in this context. Conversely, parallel studies focusing on psychoeducation aimed at boosting self-efficacy in Chinese colorectal cancer patients reported a moderate effect size, specifically 0.60, for self-efficacy. (Zhang et al., 2014). The researcher used an effect size of 0.35 for the calculation. To attain a statistical power of 0.80 with a significance threshold set at 0.05, the calculated number of total samples was 72. Subsequently, the researcher added 30% of this number to compensate as an attrition rate from prior study (Sun et al., 2016). A total of 94 women, 47 participants in each group were required for this study.

Sampling

To ensure adequate blindness in the assessments, the participant recruitment was performed by a research assistant (RA-XW) who is a clinical nurse in the hospital setting. The group allocation was randomly assigned by using random number table method. The simple random sampling was used to random group by random number table 1-100 generated from Excel. The calculated sample size in this study was 94 cases, the numbers were already scrambled by Excel, the rule was the 1 to the 47 number were the intervention group, and the 48 to the 94 number were the control group.

The RA (XW) also made labels with numbers from 1 to 94 and put them in envelopes, the number labels were randomly drawn by the patient in the order in which they were enrolled. The patient was arranged into the corresponding group according to the results of the random number table group method. For example, an eligible patient was admitted to the hospital for chemotherapy. The RA (XW) evaluated whether the patient met the admission qualities. The Research Assistant

(XW) briefed the participants on various aspects of the study, including its objectives, data collection methods, and participant involvement. Additionally, they discussed the potential risks, the benefits of participation, and the participants' rights to withdraw from the study at any time. After the patient agreed to participate in the study, obtain their consent forms, the RA (XW) arranged for the patient to draw number label and checks the patient's group based on the number was divided group by the random number table.

One hundred and thirty patients were the accessible population. The count of patients admitted to the hospital on a given day did not meet the intended total sample size for the study. Therefore, they were recruited in four batches. For the first batch, 28 patients who were hospitalized for breast cancer chemotherapy that day, after inclusion and exclusion criteria, only 17 patients met the requirements, according to the result of random number table grouping and patient's sortation. The intervention group comprised 9 patients, while the control group consisted of 8 participants. The remaining three batches all used the same procedure until 94 samples were reached and accurate enrollment. Ultimately, the study obtained 47 participants in each of the two groups: the intervention group and the control group.

Setting of the study

This study was held in a super-tertiary hospital of Yancheng affiliated with a University School of Medicine, Nanjing, China. The hospital has 34 clinical departments, 23 medical and technical departments, 116 nursing units, 4,500 beds, also has a city-wide emergency center, all kinds of clinical centers, and included clinical teaching and research departments for medical and nursing students as well as other health sciences students.

The hospital has 7 general surgery departments and 5 oncology departments. All of which can treat breast cancer chemotherapy patients. Over 50 breast cancer related surgeries are performed every month, and the oncology department treats 60 patients for breast cancer chemotherapy every month. After the breast cancer surgery, chemotherapy is frequently administered to prevent recurring and metastasizing. The exact time of chemotherapy is about 3 weeks after the surgery varying from person to person, depending on the patient's physical recovery. The minimum standard treatment typically involves four cycles of chemotherapy, each spanning three weeks.

During each chemotherapy cycle, women with breast cancer typically have a day hospitalization stay lasting 1-2 days.

Research assistants

The researcher asked two clinical nurses to help as research assistants (RAs: XW and DY) during their duty off for participants' recruitment and data collection. One RA (XW) met interested women when they discharge after surgery in general surgery or after hospitalization in oncology department. Then she (XW) confirmed their eligibility, made appointment with them when they came to the hospital for chemotherapy first day, and obtained their consent forms. Then the other RA (DY) collected baseline data. After that the RA (XW) allocated women to intervention group (the PBSP plus routine care) or control group (only the routine care) and provided 30 min of the program protocol (content includes a description of the project, as well as the study members, and sign informed consent form) for participants in the intervention group before their first cycle of chemotherapy. The RA (DY) did not know the participants' grouping when collecting data. She (DY) collected data all participants (both groups) at baseline (week 0, T1) on the day that women with breast cancer were hospitalized for first cycle chemotherapy treatment) of pre-implementation PBSP, week 3 (T2) on the day that women with breast cancer are hospitalized for second cycle chemotherapy treatment) of post-intervention PBSP, and at week 7 (T3) on the day that women with breast cancer are hospitalized for third cycle chemotherapy treatment of follow-up in the clinics. Upon returning their third-round questionnaires, each participant received a token of appreciation in the form of a small gift (toothpaste).

Research instruments

The research instruments included the intervention for implementation and the data collecting instruments, which were as follows:

The intervention for implementation - The Phone-Based Support program (PBSP)

Guided by Bandura's self-efficacy theory (A. Bandura, 1997) and adapted from the Breast Cancer e-Support program (Zhu et al., 2018), the researcher developed the Phone-Based Support Program (PBSP). The program was executed using the 'WeChat' platform, a service provided by Tencent Corporation, located in

Guangzhou, Guangdong Province, China. The PBSP was designed to provide support to women from the start of their first chemotherapy cycle until the commencement of the third cycle, spanning a total of 7 weeks. The research assistant (XW) assisted the intervention group participants in joining the relevant WeChat groups. This arrangement enabled participants to access the PBSP at their convenience, from any time.

The PBSP is a multi-component intervention in a mobile application (Lankford et al., 2013): WeChat. The PBSP included 4 components: (1) a Learning group; (2) a Discussion group; (3) an Ask-the-Expert group; and (4) a Personal Stories group. Drawing from Bandura's self-efficacy theory, which includes elements such as direct mastery experiences, vicarious experiences, verbal persuasion, and arousal states, the Learning group in the program provided comprehensive information about breast cancer and strategies for symptom management. This approach aimed to enhance the participants' direct mastery experiences. The educational content was evidence-based and corroborated by a team of multidisciplinary oncology experts from China. In parallel, the Discussion group and the Ask-the-Expert group created platforms for interaction with peers and healthcare professionals, facilitating verbal persuasion and aiding in altering the participants' perceptions of their arousal states. Additionally, the Personal Stories group featured three video-recorded motivational stories, specifically designed to bolster the participants' vicarious experiences and arousal states.

The Learning group, formed as part of the PBSP, was directed and coordinated by the lead researcher, tailored to address the specific questions and concerns brought up within the program. In order to protect women's privacy, patients were encouraged to send questions to experts privately in the Ask-Expert Group, and general questions were discussed in the Discussion group. A breast oncologist in the hospital was invited to participate in the PBSP. Doctor was on duty every Tuesday to answer patients' questions. The PBSP intervention consists of 4 sessions (week 1-3). Summary of the PBSP presented in **Table 1**.

Week 1:

Session #1: The aim was to build trusting relationships between the researcher and participants. The researcher met them one by one on site. Activities in this session include discussing current state of physical and psychological, attitude of life of participants, attitude of life of participants, and strengthening the confidence of participants in privately.

Session #2: It was to understand the reality of PBSP. Activities included exploring cognitive about PBSP among participants and encouraging participants to practice PBSP by themselves. Participants saved 10 videos and learned them.

Week 2:

Session #3: The aim was to help patients as much as possible and answer questions. The participant may ask questions what they record it during watching videos in the Ask-the-expert group; the participants can discuss all problems in the Discuss group.

Week 3:

Session #4: This session aim was to reflect and evaluate the whole process on site one by one. Activities include watching 3 video-recorded encouraging stories, commending participants' intention to apply PBSP, answering all questions from the beginning until the participants were satisfied and clearly understand, and thanking peer participants.

Routine care

Routine care encompasses expert advice from hospital medical staff during the two-day hospital stay for each chemotherapy cycle. Prior to commencing treatment, nurses deliver guidance on chemotherapy protocols and potential side effects, and distribute a paper breast cancer health education manual, which includes diet, functional exercise of the affected limb, follow-up requirements. Participants in the control group had unrestricted access to the Internet to gather information regarding breast cancer and was followed up by telephone and recorded by the responsible nurse one week after discharge. However, after completing the study data collection, the researcher provided them with access to PBSP-related materials. Participants in both intervention and control group received routine care.

Table 1 Summary of the Phone-based Support Program

Procedure	Time	Activities
Preparation	Week 0 After obtaining IRB Approval	Meeting discharged women for eligibility confirmation and appointment scheduling for each session. Obtained inform consents and measured pre-intervention (T1).
Session1: Building relationships (60 mins)	Week 1 (On site)	-The research met them one by one on site. -Discussion the current state of physical and psychological, attitude of life of participants, attitude of life of participants, and strengthening the confidence of participants in privately.
Session2: Touching PBSP (20 mins)	Week 1 (Online: WeChat platform)	Learning group: - Participants shared experiences and prior knowledge about Breast Cancer, symptoms and caring. - Participants saved 10 videos (one video took about 5-7 minutes). They asked to watch all videos until completed with a week (each video had recording sheets) prior to meet for the next session. 10 videos were watched repeatedly in Breast Cancer Specialist WeChat official account, and a booklet on functional exercise of the affected limb was given 3 months after the operation.
Session 3: Coming into your world (30 mins)	Week 2 (online: WeChat platform)	Ask-the-expert group & Discussion group: - Participants asked questions to the expert (an oncologist) what they have learned and were unclear from watching videos. - The PI facilitated questions and answers among participants and the expert. - The participants discussed their problems and learned from the expert.
Session 4: Together for a Shared Future (40 mins)	Week 3 (On site)	Personal story group & Discussion group: - Participants watched 3 inspiring video-recorded encouraging stories to enhance the women's vicarious experience. - Participants had reflected the videos and whole activities - The PI supported, encouraged, and thank all participants.

Instruments for data collection

They contained 5 questionnaires:

1. A demographic questionnaire was developed by the researcher to gather participants' characteristics. It included their age, marital status, education level, employment status, monthly family income, breast cancer stage, TNM, surgery style, and chemotherapy scheme.

2. The self-care self-efficacy Scale (SCSES) was developed by Riegel et al. (2018a) as a self-report to measure self-care self-efficacy of chronic illness patients. The SCSES developed from the previous single-domain Self-Care Confidence Scale incorporated inside the Self-Care of Heart Failure Index. (Riegel, Jaarsma, Lee, & Strömberg, 2019a). It is already translated and used with Chinese women (Yu et al., 2021). The researcher already was granted by its original creator to use the Chinese version of SCSES. This 10-item instrument is offered as a single-domain scale to measure self-efficacy in self-care maintenance (action to maintain physiologic stability; 4 items), self-care monitoring (actions to observe behavior and detect changes in signs and symptoms; 3 items), and self-care management (actions recognizing health changes and managing illness exacerbation; 3 items). The items are scored on a scale from 1 to 5, with higher scores indicating greater self-care self-efficacy. In the Chinese version, the translated content's validity received endorsement from a panel of experts in the field, achieving a content validity index of 0.91. The Cronbach's alpha coefficients of the single factor were reported at 0.89 (Yu et al., 2021). In the present study, the Cronbach's alpha for the Chinese version was also recorded as 0.89.

3. The M.D. Anderson Symptom Inventory (MDASI), developed by Cleeland et al. (2000) to measure symptom distress. A total of thirteen common (core) cancer-related symptoms included in the MDASI: pain, fatigue, nausea, sleep disturbance, distress, shortness of breath, memory difficulties, appetite loss, drowsiness, dry mouth, sadness, vomiting, and numbness or tingling. The MDASI is composed of a 13-item symptom scale and a 6-item interference scale. Both rated using a 0-to-10 numerical system (Cleeland et al., 2000). Each symptom is graded on an 11-point scale (0-10) to reflect the existence and severity of the condition, with 0 indicating "not present" and 10 representing "maximum severity". A total score runs from 0 to 130, with higher

scores indicating that patients were more distressed by their symptoms. The overall score ranges from 0 to 130, with higher levels indicating more symptom discomfort. The MDASI has been translated into Chinese for use with cancer patients, with Cronbach's alpha reliability values of 0.74 and 0.88 for the symptom and interference subscales, respectively (Zhang et al., 2021). The MDASI in its Chinese version was approved for use in this study, and the Cronbach's alpha reliability of the Chinese version was determined to be 0.85.

4. The Hospital Anxiety and Depression Scale (HADS) was originally in English developed by Zigmond and Snaith (1983), and later translated into the Cantonese/Chinese version and developed by Lam et al. (1995). This scale is extensively utilized among the Chinese population for assessing various health conditions (Alexander et al., 2010). For this research, permission was granted to use the scale. HADS comprises 14 items, designed to evaluate anxiety and depression in medical contexts. It includes two subscales: a 7-item anxiety scale and a 7-item depression scale. Each item is rated on a 4-point Likert scale ranging from 0 to 3, with scores for anxiety and depression each potentially ranging from 0 to 21. Higher scores indicate more severe anxiety or depression (Leung, Wing, Kwong, Lo, & Shum, 1999). The original HADS has demonstrated strong reliability and validity in breast cancer survivors. The Chinese version of HADS reported Cronbach's alpha coefficients of 0.81 for the anxiety scale and 0.72 for the depression scale (So et al., 2010). In the current study, the Chinese version of HADS showed a Cronbach's alpha reliability of 0.70.

5. The Global Health Status scale from the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 (V3.0), initially developed by Sprangers et al. (1996), was later translated into Chinese with validations conducted by Wan (2008) and Zhao & Kanda (2000) for assessing the quality of life in individuals with cancer. Authorization to utilize the Chinese version of the QLQ-C30 (V3.0) was obtained for this study. This scale is a 30-item, cancer-specific questionnaire that encompasses various aspects of quality of life, divided into three subscales: a) Functional subscale 15 items including physical functioning (items 1-5), role functioning (items 6-7), emotional functioning (items 21-24), cognitive functioning (items 20-25), and social functioning (items 26-27); b) Symptom subscale

13 items including fatigue (items 10, 12, 18), pain (items 9, 19), and nausea/vomiting (items 14, 15), dyspnea (item 8), appetite loss (item 13), sleep disturbance (item 11), constipation (item 16), diarrhea (item 17), and financial impact (item 28); and c) Global QOL subscale 2 items including global quality of life (items 29-30). Items are scored on a 4-point Likert scale, except for the global quality of life items which use a 7-point scale (Fayers et al., 2020). Scores are transformed to a 0-100 scale, with higher scores indicating better quality of life. Wan et al. (2008) confirmed that the simplified Chinese version of EORTC QLQ-C30 had good construct validity. An earlier study affirmed the validity of this Chinese version for assessing quality of life in Chinese cancer patients (Zhao & Kanda, 2000).

For the QLQ-C30, this scale has a total of 30 items, of which 28 items reflect the specific situations in the lives of cancer patients, and the item remaining NO.29 and 30 present the global quality of life of cancer patients (Giesinger et al., 2016). So, the researchers conducted data analysis on the scores of 28 items. They hope to have a more detailed understanding of the patients' quality of life. In this study, the researcher conducted data analysis based on the scores of 28 items to have a more detailed understanding of the patients' quality of life. In present study, its Chinese version had Cronbach's alpha reliability of 0.80.

Protection of human subjects

The research received approval from the Institutional Review Board of Burapha University in Thailand (IRB: G-HS103/2565) and in the hospital setting, China (IRB: 2022-K-103). The specifics of the study were clearly communicated to research participants. The informed consent letter in Chinese which approved by Burapha University's and Yancheng City No.1 People's Hospital's Institutional Review Board (IRB). The participants were asked to sign the consent forms before they participate in the study. Participation was voluntary, and confidentiality was maintained.

1. Contact the hospital and department before the implementation of this study, obtain their consent to enter the relevant department, establish a trusting relationship with the participants, regularly summarize the data collection and progress, and make timely adjustments and modifications.

2. The survey data was collected by research assistants who were uniformly trained. The research assistants need to be familiar with the content of the questionnaire and clear research objectives and can guide patients with breast cancer to fill it out individually.

3. There are two forms of questionnaire completion. Each participant was guided to scan the QR code to complete the online questionnaire or fill out the paper-copy version with a pen, which took approximately 25 mins to complete. It is possible to ask for assistance at any time if they are unclear or need assistance with reading the questionnaires.

4. When the participant completed all questionnaires, the research assistants checked the completeness of the questionnaire and thank the participant for their participation. Participants may ask any questions about the study to the research assistants.

5. Before data analysis, all questionnaires were coded, two-person data entry was used, and data analysis was completed by professionals to ensure the authenticity as well as the objectivity of the data.

Psychometric properties of research instruments for data collection

For the intervention, its contents and protocol were approved by three experts including one is breast surgery specialists in China, one professor is from advanced practical nurses, one professor is from Thailand. They considered and validated the intervention programs. One of the breast cancer specialists suggested that Tumor stage I patients should also be included in the study. Then, the pilot research was carried out to assess the feasibility of the PBSP, and reliability of the research instruments.

For instrument for data collection, the SCSES, the MDASI, the HADS, and the (EORTC) QLQ-C30 are already in Chinese version.

Validity

The SCSES-Chinese version, the MDASI-Chinese version, the HADS-Chinese version, and the (EORTC) QLQ-C30-Chinese version have been validated and utilized in other previous studies and evaluated within a Chinese sample, these

instruments have demonstrated robust content and construct validity. Consequently, in the current study, reassessing their content validity was not required to examine again.

Reliability

The internal consistency reliability of all instruments used in the study was assessed through Cronbach's alpha. A Cronbach's alpha value of 0.70 is considered to reflect acceptable reliability, while a value of 0.80 or higher is indicative of good reliability (Hair, 2009). The reliability values of the SCSES, the MDASI, the HADS, and the (EORTC) QLQ-C30 were 0.89, 0.85, 0.70, 0.80 separately in this study.

A pilot test for the feasibility of the intervention

To develop and assess the feasibility and preliminary effects of the Phone-based Support Program (PBSP) for women with breast cancer undergoing chemotherapy in self-care self-efficacy, symptom distress and quality of life. 20 women with breast cancer receiving chemotherapy treatment, who were recruited through target sampling technique (then were not in the main study again). The one-group participants were measured their self-care self-efficacy, symptom distress, and quality of life at 3 times: before the intervention (T1, week 1), after completed the intervention week 3 (T2), and at follow-up (T3, week 7). The PBSP showed feasibility and effectiveness in improving SCSE, reducing symptom distress, and enhancing quality of life. The recruitment procedures were completed with 20 participants voluntarily participating in the program. The completion of all onsite and online questionnaires, participation with no attrition, and follow-up measures suggest that the participants well-accepted and satisfied with the PBSP. The reliability of SCSES, the MDASI, and the (EORTC) QLQ-C30 were 0.72, 0.74, 0.71 separately, they were all acceptable. The PBSP was feasible, and they could improve SCSE, decrease symptom distress, and promote quality of life.

Data collection procedures

The data collection was started after the approval of the research proposal by the Institutional Review Board for Graduate Studies, Burapha University, and the informed consent letter which approved by Yancheng City No.1 People's Hospital's. The researcher, along with the research assistants, conveyed the details of participation in the study. The researcher outlined the measures taken to maintain

confidentiality throughout the research process. Prior to their involvement, all participants were required to sign a consent form.

The researcher trained both RAs to assist in the procedures. One RA (XW) was trained how to recruit the participants, research ethics, and the sampling method while the other (DY) was trained about the process of data collection for using the questionnaires. The RA (DY) met the participants each group in a private room in the ward and asked them to answer the questionnaires at pre-test (T1, week 0), post-test (T2, week 3), and follow up (T3, week 7).

The researcher announced and posted the study objectives and criteria to all eligible participants who were interested in participating the program at the department (general surgery) where performs breast surgery and the oncology department focuses on treating breast cancer patients who are admitted for chemotherapy for the first time. After posting recruitment notices through posting posters, Memos, and official accounts. The RA (XW) met interested women (some patients contacted the researcher directly, some patients were notified by the office nurse when they were hospitalized), confirmed their eligibility, and made appointment with them, when they come to the hospital for chemotherapy first day. After the patient understands PBSP, signed an informed consent form that were then be obtained for voluntarily participation.

The researcher implemented the PBSP. During week 1-3, participants in the intervention group received the PBSP and routine care of the hospital. At the end of week 3 and completed session 4 of the intervention (the first day of admission for the second chemotherapy session), they were asked to complete the questionnaires again (except for the demographic questionnaire) for the measure of post-intervention (T2). Participants in the control group were received routine care only, they were also asked to complete the questionnaire for the second time (T2). The researcher made appointment with them for the follow-up at week 7. The follow-up measure (T3, week 7) was at the day that participants in the intervention and control group come to the hospital for treatment follow-up at the hospital (the first day of admission for the third chemotherapy session). **Figure 2** shows procedures of data collection.

Data analysis

Data analyses were performed by using the SPSS statistical software program and the statistical significance level was set at $p < 0.05$.

1. Descriptive statistics were used to describe the participants' characteristics and outcome variables.

2. MANOVA and two-way repeated measure ANOVA were used to examine the differences of outcome variables among three time-measures.

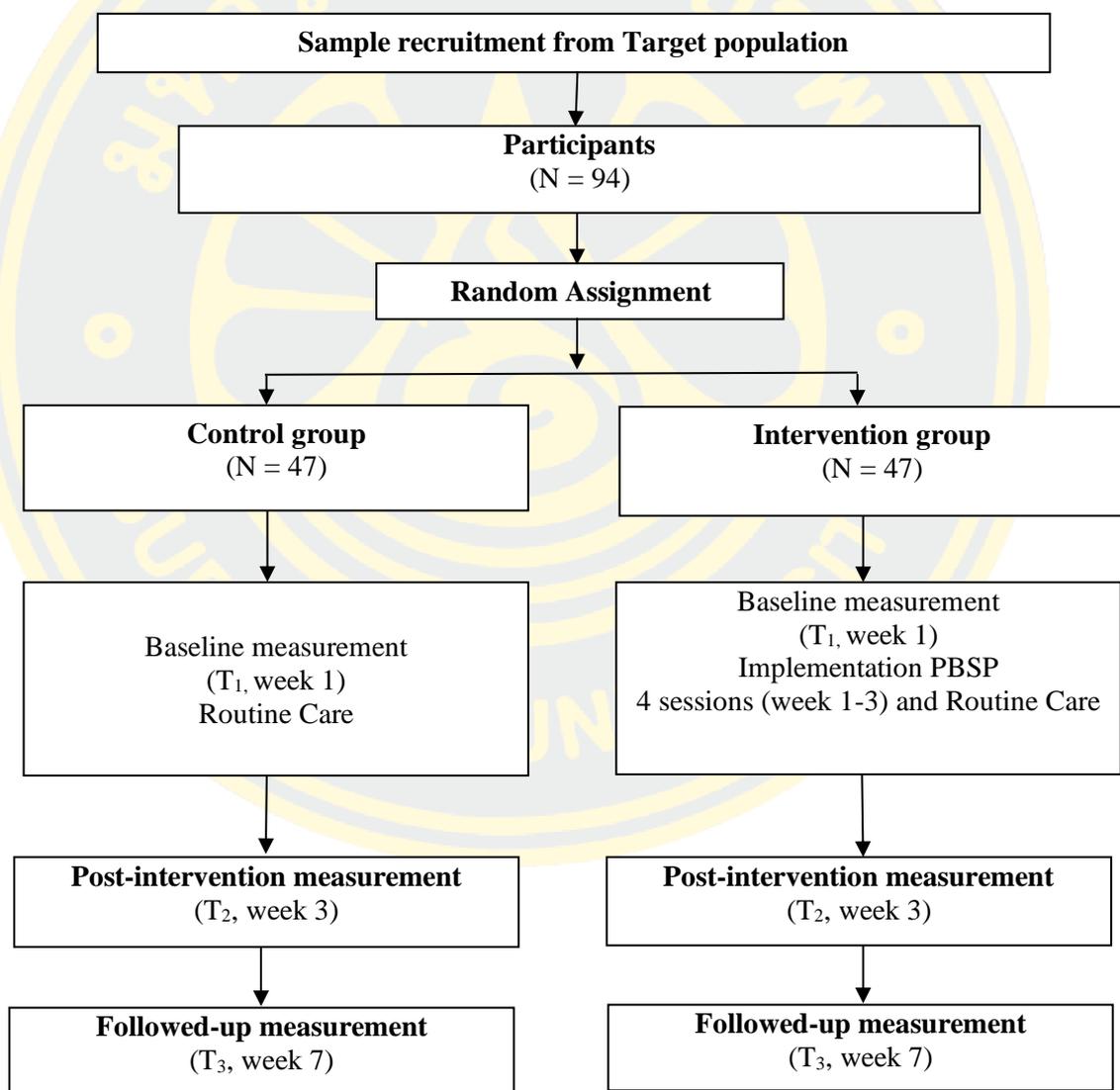


Figure 2 Process of data collection

CHAPTER 4

RESULTS

This chapter presented results of the study in seven parts. The first part revealed the CONSORT Flow Diagram. The second part described the demographic characteristics of the participants. The third part reported the evaluation of statistical assumptions for the dependent variables. The fourth part reported descriptive statistics of the outcome variables. The fifth part reported the comparisons of pre-intervention scores of outcome variables. The sixth part presented the study hypotheses testing. The final part reported summary of the findings.

CONSORT Flow Diagram

The participants who newly diagnosed with breast cancer undergoing chemotherapy received treatment at the breast surgery and oncology department of Yancheng NO.1 People's Hospital. One hundred and thirty accessible populations were assessed for eligibility criteria and invited to participate in the research project, and 36 patients were excluded. Those of the exclusion included their age were more than 60 years old (12), not in Stage II or lower (10), received radiotherapy (8), had other serious diseases (2), unable to use WeChat (4). Eventually, 94 participants were remaining and willing to participate. They were randomly assigned equally to the intervention and the control groups (47 cases per group).

For the intervention group, at baseline (pre-test, week 0, T1), a day before the implementation of the intervention, a research assistant asked the participants to fill out 5 questionnaires (a demographic information, the SCSE, the MDASI, the HADS, the QLQ-C30). Then, they received the PBSP plus routine care. The intervention was consecutively implemented for 3 weeks. At post-intervention (week 3, T2) and follow-up (week 7, T3) measures, they were asked to fill out the SCSE, the MDASI, the HADS, and the QLQ-C30 again. There was no participant drop-out during the implementation and follow-up period. For the control group, they received the routine care. The research assistant also asked them to fill out all questionnaires at week 0 (T1), week 3 (T2), and week 7 (T3) the same as in the intervention group.

After testing all assumptions for subsequent statistical analyses, three outliers were removed. There were one (case # 19) in the intervention group and two outliers (cases # 56 and # 73) in the control group. Finally, the total participants in the intervention group were 46, and 45 in the control group. Details were shown in **Figure 3**.

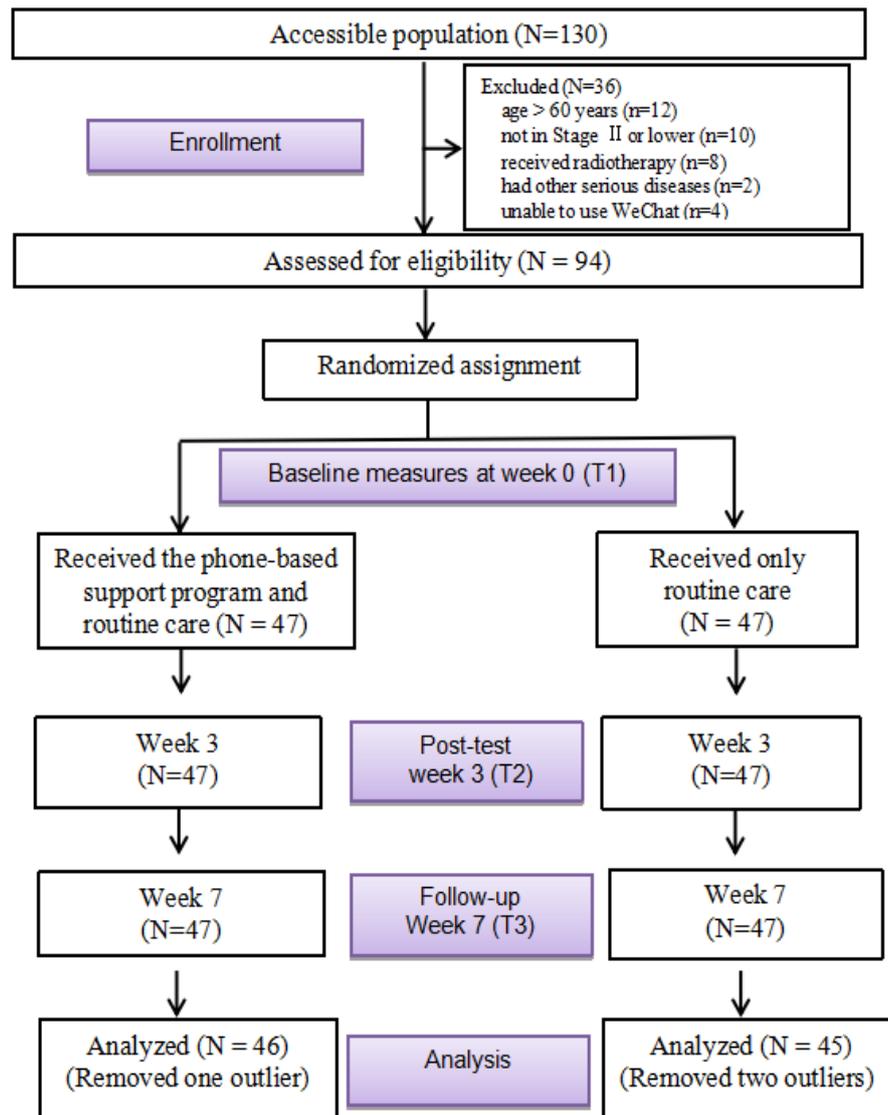


Figure 3 CONSORT flow diagram

The demographic characteristics of the participants

The demographic data of the participants consisted of two parts: participants' general and clinical characteristics. Part 1 described the participants' general information, such as age, marital status, education level, employment status, and monthly family income (in USD). Part 2 described the health information of the participants, including breast cancer stage, the current stage of TNM, surgery style, and chemotherapy scheme. These demographic characteristics were analyzed using descriptive statistics including frequency, percentage, mean, and standard deviations. The differences in demographic characteristics between the intervention and control group were compared by using chi-square test and independent t-test as shown in **Table 2** and **Table 3**.

Table 2 describes the general information of participants in the intervention (46 cases) and the control groups (45 cases). For the intervention group, participants were all females. Their mean age was 48.09 years (SD = 8.25, range 29-50). Almost 80% were living together with spouse. Most of them had education less than high school (52.17%). More than half of them were unemployed (56.52%) while 43.48% were employed. Regarding family income, about one half had their family incomes less than 500 USD per month (52.17%). For the control group, there were 45 participants with average age of 50.59 years (SD = 6.1, range = 33-60). All of them were females. Almost one half had education less than high school (48.89%). More than two thirds of them were employed (62.22%). Regarding family income, 60% of them had the incomes less than 500 USD per month.

Table 3 describes the clinical characteristics of participants in the intervention (46 cases) and the control groups (45 cases). For the intervention group, about ninety percent of the participant had breast cancer stage II. About one half of them (52.17%) were in the T2N1M0. Most of them were received modified radical mastectomy surgery style (82.61%) and AC-T chemotherapy scheme (73.91%). For the control group, the proportion of categories were similar to that of the intervention group. Most of them had breast cancer stage II (84.44%), T2N1M0 (57.78%), modified radical mastectomy (93.33%), and AC-T scheme (77.78%).

Subsequently, characteristics of participants between the intervention and the control groups were compared to determine the differences by using independent t-

test for continuous data and chi-square for categorical data. The results showed no significant differences ($p > .05$). Details were presented in **Table 2** and **Table 3**.

Table 2 Descriptive statistics of participants' general characteristics

Characteristic	Intervention group (N=46)		Control group (N=45)		t	χ^2	p value
	n	%	n	%			
Age (years)							
Average (SD)	48.09 (± 8.25)		50.59 (± 6.10)		-1.64		0.11
Range	29-59		33-60				
Marital status							
Living together with spouse (married)	35	76.08	39	86.67		1.68	0.19
Non-spouse living (Single, divorced or widowed)	11	23.92	6	13.33			
Education level							
Less than HS	24	52.17	22	48.89		0.12	0.94
High school or diploma	10	21.74	10	22.22			
Some college or higher education	12	26.09	13	28.89			
Employment status							
Employed	20	43.48	28	62.22		3.21	0.07
Unemployed	26	56.52	17	37.78			
Monthly family income (in USD)							
Less than 500	24	52.17	27	60.00		0.57	0.45
500 or more	22	47.83	18	40.00			

Table 3 Clinical characteristics of participants

Characteristic	Intervention group (N=46)		Control group (N=45)		χ^2	p-value
	n	%	n	%		
Breast cancer stage						
I	5	10.87	7	15.56	0.44	0.51
II	41	89.13	38	84.44		
TNM						
T1N1M0	4	8.70	6	13.33	5.12	0.08
T2N1M0	24	52.17	26	57.78		
T2N0M0	18	39.13	13	28.89		
Surgery style						
Modified radical mastectomy	38	82.61	42	93.33	2.46	0.12
Laparoscopic unilateral radical mastectomy	8	17.39	3	6.67		
Chemotherapy scheme						
AC-T	34	73.91	35	77.78	1.74	0.42
TAC	4	8.70	6	13.33		
TC	8	17.39	4	8.89		

Abbreviations: The TNM system for cancer staging involving the tumor (T), node (N), and metastases (M):

T1: The tumor is 20 millimeters (2 centimeters) in diameter or less.

T2: The tumor is larger than 20 mm but not larger than 50 mm.

N0: No cancer was found in the lymph nodes/Only areas of cancer smaller than 0.2 mm are in the lymph nodes.

N1: The cancer has spread to 1 to 3 axillary lymph nodes and/or the internal mammary lymph nodes. If the cancer in the lymph node is larger than 0.2 mm but 2 mm or smaller.

M0: There is no evidence of distant metastases.

TC: docetaxel + cyclophosphamide, 4 cycles.

AC-T: doxorubicin + cyclophosphamide, 4 cycles, then docetaxel 4 cycles.

TAC: docetaxel + adriamycin + cyclophosphamide, 6 cycles.

Evaluations of statistical assumptions for the dependent variables

The total scores of the DVs (SCSE, the MDASI, the HADS, and the QOL) of both the intervention and the control groups, and among 3 time-measures were examined. Multivariate techniques and their univariate counterparts were based on a fundamental set of assumptions representing the requirements of the underlying statistical theory. Assumption testing for MANOVA comprised 1) Outliers, 2) Normality, 3) Sphericity, 4) Homogeneity of variances and co-variances, 5) Intercorrelation, 6) Multicollinearity, and 7) Independence. In addition, the assumptions for 2-way repeated measures ANOVA were the same as in the MANOVA

1. Test for outliers

The univariate outliers of the variables were tested using a box plot, which revealed that the intervention group had one case outlier (Case No. 19 for SCSE data at Time1 and Time3). The control group had two cases outliers (Case No. 56 for SCSE data at Time1 and Case No. 63 for QOL data at Time 2). The multivariate outliers of variables were tested by Mahala Nobis distance with chi-square. There was no multivariate outlier in terms of probability of values (Mahala Nobis values $<.001$). Thus, the total sample size was 46 cases for the intervention group and 45 cases for the control group.

2. Normality testing

The scores of the DVs were tested for univariate normality, Kolmogorov-Smirnov ($p > 0.05$), and by visual inspection of the participants' histograms and normal Q-Q plots. These results indicated that the SCSE, the MDASI, the HADS, the QOL were within the normal distribution for both the intervention and the control groups. A z-value of skewness and kurtosis was calculated by dividing the skewness or kurtosis value by their standard error. Values were between ± 1.96 , which corresponds to a 0.05 error level. These results indicated that the SCSE, the MDASI, the HADS, and the QOL were within the normal distribution for both the intervention and the control groups.

3. Mauchly's test of sphericity (within-subject)

Mauchly's test of sphericity was used to test the assumption of sphericity. The total score of results showed no significant ($p > 0.05$) indicated that the homogeneity of variance-covariance matrices was equal, and the sphericity assumptions were met.

The sphericity of the SCSE, the MDASI, the HAD and the QLQ ($p < 0.05$). According to the p-value, therefore, the study selected Greenhouse-Geisser or Huynh-Feldt to corrected estimates of sphericity to report the results of repeated measure MANOVA.

4. Homogeneity of variances and co-variances

Box's M is similar to Levene's test for the ANOVA case. The result of Box's M was not significant. It means the assumption of MANOVA was met. Levene's statistics was used to test the assumption of homogeneity of variance for the between-subject design. The test of homogeneity of variances for the between-subject comparison showed no significance ($p > 0.05$). This indicated that the variance of the dependent variables between groups was equal. Then the homogeneity of variance assumption was met. All of the error variance of the subscale was equal across groups.

5. Intercorrelation

Intercorrelation among the DVs (Bartlett's test of sphericity) were sufficient correlation among DVs to proceed with analysis ($p < .001$).

6. Multicollinearity

Pearson correlation coefficients between DVs were all below 0.60 which means there were no multicollinearity. It was strong power of the analysis.

7. Independence

Intraclasscorrelation (ICC) was significant ($p > .001$), there was independent in the data.

Descriptive statistics of the outcome variables

In this study, outcome variables included the total score self-care self-efficacy, symptom distress, hospital anxiety and depression and the quality of life. They were measured at pre-intervention (week 0, T1), post-intervention (week 3, T2), and follow-up (week 7, T3) as illustrated from **Table 4** to **Table 7**.

Table 4 Means and standard deviations of the scores of self-care self-efficacy of participants in the intervention and the control groups among 3 time-measures

Self-care self-efficacy (SCSE)	Week	Intervention group (N=46)		Control group (N=45)	
		M	SD	M	SD
Total score	0	23.07	2.82	22.07	3.32
	3	34.07	2.82	22.58	2.07
	7	45.46	2.61	23.13	3.16
Subscale score					
Self-care maintenance	0	9.22	2.06	6.42	1.73
	3	13.67	2.26	6.87	1.91
	7	18.09	1.33	7.40	2.23
Self-care monitoring	0	7.07	1.54	6.98	1.91
	3	10.41	2.09	7.02	1.97
	7	13.72	0.91	6.82	2.37
Self-care management	0	6.78	1.95	6.87	1.91
	3	9.96	1.71	7.40	2.23
	7	13.65	1.08	6.98	1.91

Table 5 Means and standard deviations of the scores of symptom distress of participants in the intervention and the control groups among 3 time-measures

Symptom distress (MDASI)	Week	Intervention group (N=46)		Control group (N=45)	
		M	SD	M	SD
Total score	0	94.35	17.53	96.98	11.77
	3	67.63	9.61	94.31	11.15
	7	38.91	7.06	93.67	13.75
Subscale score					
Cancer-related symptoms	0	65.91	15.47	65.47	11.84
	3	48.37	7.92	64.16	8.99
	7	27.15	5.96	63.87	12.08
Symptoms interfered with life	0	28.43	5.43	31.51	5.89
	3	19.26	5.01	30.16	5.12
	7	11.76	3.50	29.80	5.15

Table 6 Descriptive statistics of the score of anxiety and depression of participants in the intervention and the control groups among 3 time-measures

Hospital Anxiety and Depression (HAD)	Week	Intervention group (N=46)		Control group (N=45)	
		M	SD	M	SD
Total score of Hospital Anxiety	0	11.24	2.66	10.89	1.92
	3	7.59	2.69	10.11	1.94
	7	4.89	1.64	10.00	2.52
Total score of Hospital Depression	0	11.33	1.83	11.27	2.16
	3	7.50	2.54	11.11	2.54
	7	3.65	1.57	10.36	2.30

Table 7 Descriptive statistics of the score of quality of life of participants in the intervention and the control groups among 3 time-measures

Quality of Life (QOL)	Week	Intervention group (N=46)		Control group (N=45)	
		M	SD	M	SD
Total score (28 items)	0	68.89	5.39	68.96	5.54
	3	79.15	5.45	70.97	7.35
	7	88.94	4.40	71.75	5.43
Functional subscales (15 items)	0	65.69	6.01	64.60	8.33
	3	77.57	6.23	66.11	8.90
	7	89.67	4.52	67.30	8.08
Physical Functioning (5 items)	0	65.00	8.56	63.17	12.82
	3	75.87	9.09	65.33	12.40
	7	88.04	7.49	65.78	11.48
Role Functioning (2 items)	0	61.14	14.00	61.67	14.69
	3	76.09	15.99	68.89	16.13
	7	90.76	10.01	70.56	17.10
Emotional Functioning (4 items)	0	67.66	10.06	68.19	13.96
	3	73.23	10.51	69.86	12.73
	7	90.90	9.10	69.59	10.34
Cognitive Functioning (2 items)	0	70.38	17.75	61.94	15.30
	3	82.34	14.33	59.72	15.97
	7	92.39	7.21	63.06	19.58
Social Functioning (2 items)	0	63.32	16.96	66.39	15.50
	3	87.23	12.77	64.17	20.75
	7	87.50	10.54	67.50	21.55
Symptom subscales (13 items)	0	72.58	8.22	73.97	5.23
	3	80.98	6.62	76.58	8.54
	7	88.09	5.86	76.88	6.22
Total score of global quality of life (2 items)	0	58.70	15.57	59.21	14.50
	3	69.26	11.36	64.13	18.18
	7	78.57	9.99	68.73	11.32

Comparisons of pre-intervention scores of outcome variables

The scores of all outcome variables were compared between the intervention and the control groups for each time-point measure (Time 1, Time 2 and Time 3) by using MANOVA. The results showed no significant differences ($p > .05$) in mean scores of self-care self-efficacy, symptom distress, hospital anxiety and depression and the QOL between the intervention and the control groups at pre-intervention (Time 1) However, there were significant difference between Time 2 and Time 3 for each outcome. (Table 8).

Table 8 Comparative analysis of group effects of variables by using MANOVA

Outcome	Time	SS	df	MS	F	p	η^2p
Self-care confidence	T1	22.68	1	22.68	2.40	0.13	0.03
Symptom distress	T1	157.34	1	157.34	0.70	0.40	0.01
Anxiety	T1	2.79	1	2.79	0.52	0.47	0.01
Depression	T1	10.15	1	10.15	2.42	0.12	0.03
Quality of life	T1	0.13	1	0.13	0.00	0.95	0.00
Self-care confidence	T2	3001.76	1	3001.76	489.49	< 0.001	0.85
Symptom distress	T2	16192.83	1	16192.83	149.65	< 0.001	0.63
Anxiety	T2	144.93	1	144.93	26.24	< 0.001	0.23
Depression	T2	296.63	1	296.63	46.00	< 0.001	0.34
Quality of life	T2	1522.63	1	1522.63	36.45	< 0.001	0.29
Self-care confidence	T3	11335.52	1	11335.52	1354.88	< 0.001	0.94
Symptom distress	T3	68195.34	1	68195.34	574.55	< 0.001	0.87
Anxiety	T3	593.68	1	593.68	131.94	< 0.001	0.60
Depression	T3	1022.16	1	1022.16	265.42	< 0.001	0.75
Quality of life	T3	6720.72	1	6720.72	275.52	< 0.001	0.76

Testing of research hypotheses

This study aimed to examine the effectiveness of PBSP among women newly diagnosed with breast cancer undergoing chemotherapy. Research hypotheses were to compare the study outcomes of the self-care confidence, symptom distress, anxiety and depression and the quality of life of the participants between the intervention and the control group, and among three-time measures.

1. Comparisons of self-care self-efficacy (SCSE) scores between the intervention and the control groups, and among three-time measures within the intervention group.

Two-way repeated measures ANOVA (one between-one within) was used to determine a mean difference in total scores of SCSE between the intervention and the control groups at pre-intervention (week 0), post-intervention (week 3), and follow-up (week 7), and within a group among the 3-time measures. The results showed a significant interaction effect of Group *Time ($F(1.09, 47.67) = 387.53, p < .001, \text{Partial } \eta^2 = 0.90$). Moreover, the results also revealed significant main effects of Group (between-subjects) ($F(1, 44) = 606.08, p < .001, \text{Partial } \eta^2 = 0.93$) and Time (within-subjects) ($F(1.26, 55.36) = 740.06, p < .001, \text{Partial } \eta^2 = 0.94$) (Table 9).

Table 9 Repeated measure ANOVA of the total scores of self-care self-efficacy

Source variation	SS	df	MS	F ^a	p-value	η^2p
Between Subjects						
Group	9140.89	1	9140.89	606.08	< .001	0.93
Error	663.61	44	15.08			
Within subjects						
Time	6172.36	1.26	4906.16	740.06	< .001	0.94
Error	366.98	55.36	6.63			
Group*Time	5099.05	1.08	4707.22	387.53	< .001	0.90
Error	578.95	47.66	12.15			

^a = Greenhouse-Geisser was used to adjust the degree of freedom, η^2p = Partial Eta Squared

Because the interaction (Group*Time) effect supersedes to the main effects. Subsequently, simple main effects of Group and Time were then run after the finding of a significant interaction effect to examine the differences between the two groups at each point of times, and the differences of change in SCSE over time within each group.

For the simple main effect of Group, Bonferroni-corrected pairwise t-tests were used to compare differences in total scores of self-care self-efficacy between the intervention and the control groups at each pair of time points. The results showed that at baseline, pre-intervention (Week 0, T1), SCSE score was not different between the two groups ($p > 0.05$). At post-intervention (Week 3, T2), and at follow-up (Week 7, T3), scores of SCSE in the intervention group were significantly higher than that in the control group ($F(1,44) = 430.92, p < 0.001, \text{Partial } \eta^2 = 0.91$, and $F(1,44) = 1253.27, p < .001, \text{Partial } \eta^2 = 0.97$, respectively) (Table 10 and Figure 4). These findings indicated that after receiving the PBSP, participants in the intervention group had better self-care confidence than the control group and could maintain this effect to the follow-up period.

Table 10 Simple main effect of Group on SCSE scores at each time points

Source variation	SS	df	MS	F	p-value	η^2p
Baseline (Week 0, T1)						
Between subjects	24.54	1	24.54	1.98	0.165	0.05
Error	542.96	44	12.34			
Post-intervention (Week 3, T2)						
Between subjects	2992.90	1	2992.90	430.92	< 0.001	0.91
Error	305.60	44	6.95			
Follow-up (T3)						
Between subjects	11222.50	1	11222.50	1253.27	< 0.001	0.97
Error	394.00	44	8.96			

η^2p = Partial Eta Squared

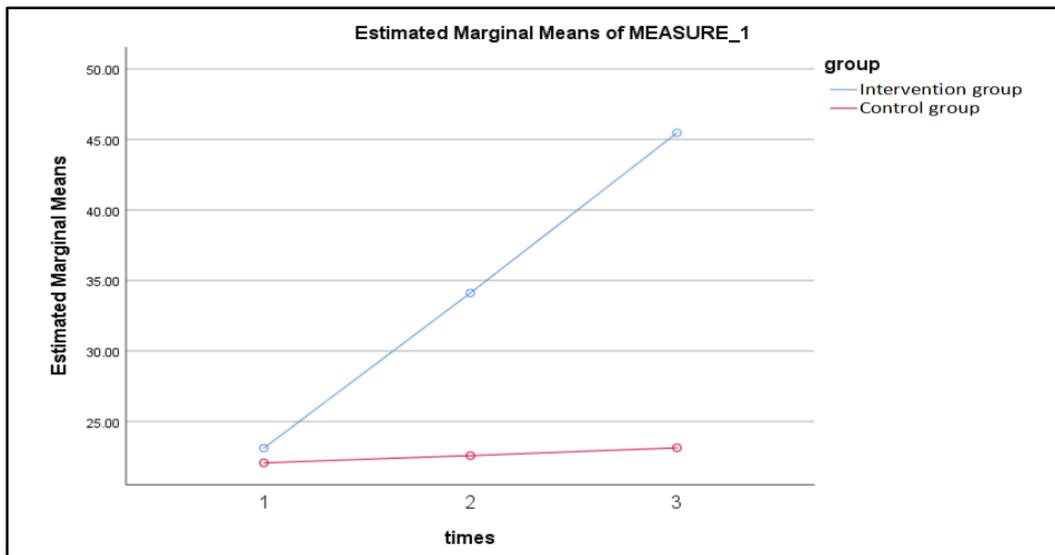


Figure 4 Comparisons of means of total SCSE scores between the intervention and the control groups, and among 3-time measures

For the simple main effect of Time, within the intervention group, there was statically significant difference of SCSE scores among the three times points ($F_{2, 90} = 1278.35, p < .001, \eta^2p = 0.97$), indicating that there was different of SCSE scores at least one pair of times. However, there was not different of SCSE in the control group (Table 11).

Table 11 Simple main effect of Time on SCSE scores in the intervention and the control groups

Source variation	SS	df	MS	F	p-value	η^2p
Intervention group						
Time	11532.70	2	5766.35	1278.35	< .001	0.97
Error	405.97	90	4.51			
Control group						
Time	25.62	2	12.81	2.08	0.13	0.05
Error	541.72	88	6.16			

η^2p = Partial Eta Squared

Table 12 Pairwise comparisons using Bonferroni of the difference in SCSE scores between each pair of time in the intervention and the control groups

Source variation	M_{diff}	SE	p-value	95% CI for difference ^b	
				Lower Bound	Upper Bound
Intervention group					
Week 0 vs Week 3	-11.00	0.00	<.001	-11.00	-11.00
Week 3 vs Week 7	-11.39	0.54	<.001	-12.74	-10.04
Week 0 vs Week 7	-22.39	0.54	<.001	-23.74	-21.04
Control group					
Week 0 vs Week 3	-0.51	0.37	0.51	-1.43	0.40
Week 3 vs Week 7	-0.56	0.38	0.46	-1.51	0.40
Week 0 vs Week 7	-1.07	0.74	0.46	-2.90	0.76

b. Adjustment for multiple comparisons: Bonferroni

Next, pairwise comparisons using Bonferroni-corrected paired t-test were run to examine the difference between each pair of time-measures. For the intervention group, the SCSE scores at post-intervention (Week3, T2) and follow-up (Week 7, T3) were significantly higher than that at baseline (Week 0, T1) ($M_{diff} = 11.00$ and $M_{diff} = 22.39$, $p < .001$, respectively), and the scores at follow-up (Week 7, T3) was significantly higher than that at post-intervention (Week 3, T2) ($M_{diff} = 11.39$, $p < .001$). The participants who received the PBSP had better SCSE over time. There was no pair of time difference in the control group ($p > 0.05$). Details were in **Table 12** and **Figure 4**.

The line graph (**Figure 4**) presented that the SCSE scores in the intervention group were higher than in the control group at T2 and T3 whereas the line connecting each time point (Week 0, Week 3, and Week 7) in the intervention group increased over time. This confirmed the statistical findings.

2. Comparisons of symptom distress (MDASI) scores between the intervention and the control groups, and among three-time measures within the intervention group.

Two-way Repeated measures ANOVA (one between-one within) was used to determine a mean difference in total scores of symptom distress between the intervention and the control groups at pre-intervention (week 0), post-intervention (week 3), and follow-up (week 7), and within a group among the 3-time measures. The results showed a significant interaction effect of Group *Time ($F(1.71, 75.37) = 109.78, p < .001, \text{Partial } \eta^2 = 0.71$). Moreover, the results also revealed significant main effects of Group (between-subjects) ($F(1, 44) = 249.23, p < .001, \text{Partial } \eta^2 = 0.85$), and Time (within-subjects) ($F(2, 88) = 160.74, p < .001, \text{Partial } \eta^2 = 0.79$) (**Table 13**).

Table 13 Repeated measure ANOVA of the total symptom distress (MDASI) scores

Source variation	SS	df	MS	F ^c	p-value	η^2p
Between subjects						
Group	52780.09	1	52780.09	249.23	<.001	0.85
Error	9318.07	44	211.77			
Within subjects						
Time	39223.70	2	19611.85	160.74	<.001	0.79
Error	10736.97	88	122.01			
Time*Group	30951.79	1.71	18068.53	109.78	<.001	0.71
Error	12405.55	75.37	164.59			

c= Huynh-Feldt was used to adjust the degree of freedom, η^2p = Partial Eta Squared

Because the interaction (Group*Time) effect supersedes to the main effects. Subsequently, simple main effects of Group and Time were then run after the finding of a significant interaction effect to examine the differences of symptom distress between the two groups at each point of times, and the differences of change in symptom distress over time within each group.

For the simple main effect of Group, Bonferroni-corrected pairwise t-tests were used to compare differences in total scores of symptom distress between the intervention and the control groups at each pair of time points. The results showed that at baseline, pre-intervention (Week 0, T1), symptom distress score was not different between the two groups ($p > 0.05$). At post-intervention (Week 3, T2), and at follow-up (Week 7, T3), scores of symptom distress in the intervention group were significantly lower than that in the control group ($F(1,44) = 131.30, p < 0.001, \text{Partial } \eta^2 = 0.75$, and $F(1,44) = 632.84, p < .001, \text{Partial } \eta^2 = 0.94$; respectively) (Table 14 and Figure 5). These findings indicated that after receiving the PBSP, participants in the intervention group had less symptom distress than the control group and could maintain this effect to the follow-up period.

Table 14 Simple main effect of Group on MDASI scores at each point of times

Source variation	SS	df	MS	F	p-value	η^2p
Baseline (T1)						
Between subjects	115.60	1	115.60	0.44	0.51	0.01
Error	11575.40	44	263.08			
Post-intervention (T2)						
Between subjects	16321.60	1	16321.60	131.30	< 0.001	0.75
Error	5469.40	44	124.31			
Follow-up (T3)						
Between subjects	67294.68	1	67294.68	632.84	< 0.001	0.94
Error	4678.82	44	106.34			

η^2p = Partial Eta Squared

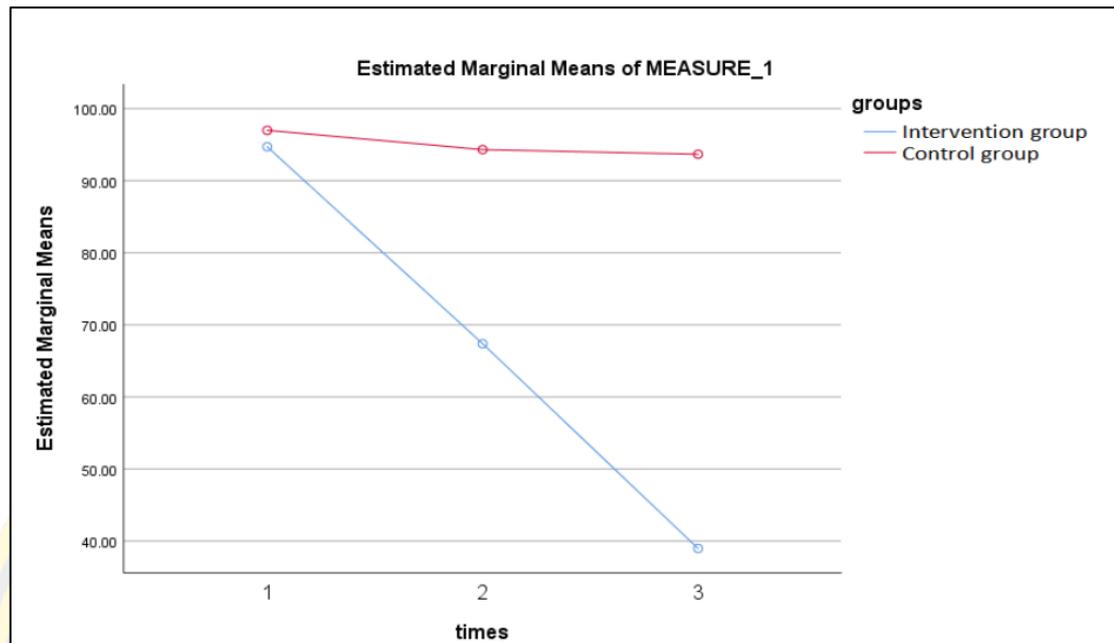


Figure 5 Comparisons of means MDASI scores between the intervention and the control groups, and among 3-time measures

For the simple main effect of Time, in the intervention group, there was statically significant difference of MDASI scores among the three times points ($F_{2, 90} = 231.84$, $p < .001$, $\eta^2 p = 0.84$), indicating that there was different of MDASI scores at least one pair of times. However, there was not different of MDASI in the control group (**Table 15**).

Table 15 Simple main effect of Time on MDASI scores in the intervention and control group

Source variation	<i>SS</i>	<i>df</i>	<i>MS</i>	<i>F</i>	<i>p-value</i>	$\eta^2 p$
Intervention group						
Time	70710.01	2	35355.01	231.84	< .001	0.84
Error	13724.65	90	152.50			
Control group						
Time	277.35	2	138.67	1.24	0.29	0.03
Error	9810.65	88	111.49			

$\eta^2 p$ = Partial Eta Squared

Next, pairwise comparisons using Bonferroni-corrected paired t-test were run to examine the difference of symptom distress between each pair of time-measures. For the intervention group, the MDASI scores at post-intervention (Week 3, T2) and follow-up (Week 7, T3) were significantly lower than that at baseline (Week 0, T1) ($M_{diff}=26.72$ and $M_{diff}= 55.43$, $p <.001$, respectively), and the scores at follow-up (Week 7, T3) was significantly lower than that at post-intervention (Week 3, T2) ($M_{diff}= 28.72$, $p<.001$). The participants who received the PBSP had lower symptom distress over time. Details were in **Table 16** and **Figure 5**.

The line graph (**Figure 5**) presented that the MDASI scores in the intervention group were lower than in the control group at T2 and T3 whereas the line connecting each time point (Week 0, Week 3, and Week 7) in the intervention group had decreased over time. This confirmed the statistical findings.

Table 16 Pairwise comparisons using Bonferroni of the difference in MDASI scores between each pair of time in the intervention and control group

Source variation	M_{diff}	SE	p-value	95% CI for difference ^b	
				Lower Bound	Upper Bound
Intervention group					
Week 0 vs Week 3	26.72	3.02	< .001	19.22	34.22
Week 3 vs Week 7	28.72	1.68	< .001	24.55	32.89
Week 0 vs Week 7	55.43	2.83	< .001	48.41	62.46
Control group					
Week 0 vs Week 3	2.67	2.47	0.86	-3.49	8.83
Week 3 vs Week 7	0.64	2.63	1.00	-5.91	7.19
Week 0 vs Week 7	3.31	1.35	0.05	-0.05	6.67

b =Adjustment for multiple comparisons: Bonferroni.

3. Comparisons of Hospital Anxiety (HA) scores between the intervention and the control groups, and among three-time measures within the intervention group.

Two-way repeated measures ANOVA (one between-one within) was used to determine a mean difference in total scores of HA between the intervention and the control groups at pre-intervention (week 0), post-intervention (week 3), and follow-up (week 7), and within a group among the 3-time measures. The results showed a significant interaction effect of Group *Time ($F(2, 88) = 35.72, p < .001, \text{Partial } \eta^2 = 0.45$). Moreover, the results also revealed significant main effects of Group (between-subjects) ($F(1, 44) = 75.39, p < .001, \text{Partial } \eta^2 = 0.63$) and Time (within-subjects) ($F(1.60, 70.40) = 70.94, p < .001, \text{Partial } \eta^2 = 0.62$) (**Table 17**).

Table 17 Repeated measure ANOVA of the total scores of hospital anxiety

Source variation	SS	df	MS	F ^c	p-value	$\eta^2 p$
Between Subjects						
Group	393.62	1	393.62	75.39	<.001	0.63
Error	229.72	44	5.22			
Within subjects						
Time	602.36	1.60	376.49	70.94	<.001	0.62
Error	373.64	70.40	5.31			
Group*Time	339.03	2	169.52	35.72	<.001	0.45
Error	417.64	88	4.75			

c= Huynh-Feldt was used to adjust the degree of freedom, $\eta^2 p$ = Partial Eta Squared

Because the interaction (Group*Time) effect supersedes to the main effects. Subsequently, simple main effects of Group and Time were then run after the finding of a significant interaction effect to examine the differences between the two groups at each point of times, and the differences of change in hospital anxiety over time within each group.

For the simple main effect of Group, Bonferroni-corrected pairwise t-tests were used to compare differences in total scores of hospital anxiety between the intervention group and the control group at each pair of time points. The results showed that at baseline, pre-intervention (Week 0, T1), hospital anxiety score was not different between the two groups ($p > 0.05$). At post-intervention (Week 3, T2), and at

follow-up (Week 7, T3), scores of hospital anxiety in the intervention group were significantly lower than that in the control group ($F(1,44) = 20.52, p < 0.001$, Partial $\eta^2 p = 0.32$, and $F(1,44) = 193.82, p < .001$, Partial $\eta^2 p = 0.82$, respectively) (**Table 18** and **Figure 6**). These findings indicated that after receiving the PBSP, participants in the intervention group had lower hospital anxiety than the control group and could maintain this effect to the follow-up period.

Table 18 Simple main effect of Group on hospital anxiety scores at each time points

Source variation	SS	df	MS	F	p-value	$\eta^2 p$
Baseline (Week 0, T1)						
Between subjects	2.84	1	2.84	0.57	0.45	0.01
Error	219.16	44	4.98			
Post-intervention (Week 3, T2)						
Between subjects	136.90	1	136.90	20.52	< .001	0.32
Error	293.60	44	6.67			
Follow-up (Week 7, T3)						
Between subjects	592.90	1	592.90	193.82	< .001	0.82
Error	134.60	44	3.06			

$\eta^2 p$ = Partial Eta Squared

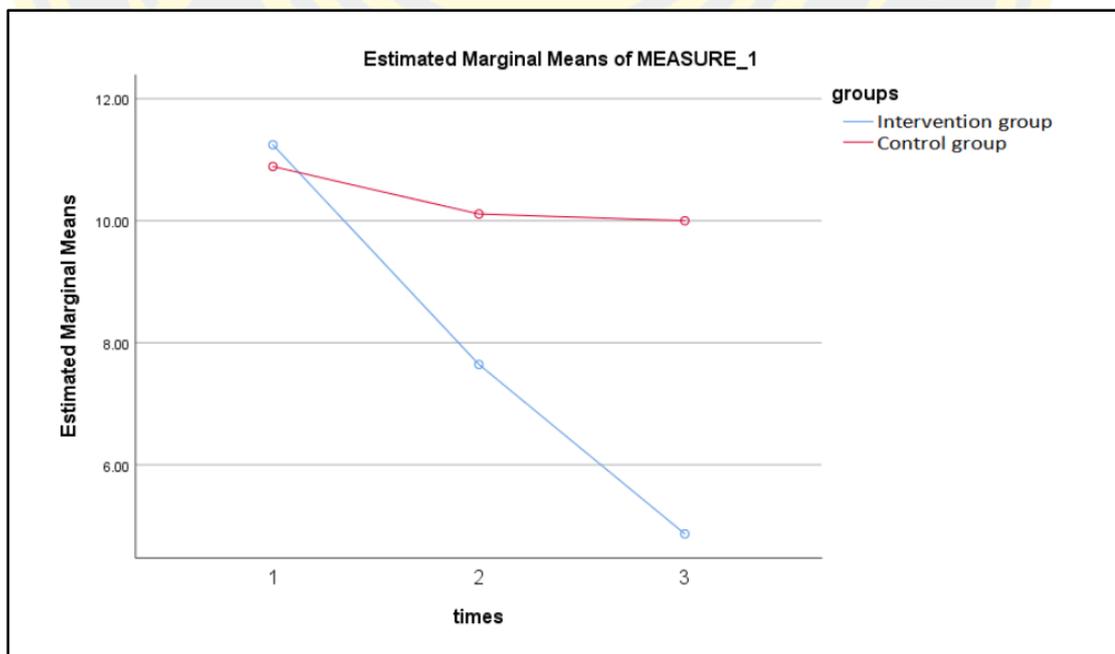


Figure 6 Comparisons of means hospital anxiety scores between the intervention and the control groups, and among 3-time measures

For the simple main effect of Time in the intervention group, there was statically significant difference of hospital anxiety scores among the three times points ($F_{2, 90} = 96.48, p < .001, \text{Partial } \eta^2 = 0.68$). This indicated that there was different of hospital anxiety scores at least one pair of times. However, there was not different of hospital anxiety in the control group (**Table 19**).

Table 19 Simple main effect of Time on hospital anxiety scores in the intervention and control group

Source variation	SS	df	MS	F	p-value	η^2p
Intervention group						
Time	933.80	2	466.90	96.48	<.001	0.68
Error	435.54	90	4.84			
Control group						
Time	21.11	2	10.56	2.56	0.08	0.06
Error	362.89	88	4.12			

η^2p = Partial Eta Squared

Next, pairwise comparisons using Bonferroni-corrected paired t-test were run to examine the different of hospital anxiety between each pair of time-measures. For the intervention group, the hospital anxiety scores at post-intervention (Week 3, T2) and follow-up (Week 7, T3) were significantly lower than that at baseline (Week 0, T1) ($M_{diff} = 3.65$ and $M_{diff} = 6.35, p < .001$, respectively), and the scores at follow-up (Week 7, T3) was significantly lower than that at post-intervention (Week 3, T2) ($M_{diff} = 2.70, p < .001$). The participants who received the PBSP had lower hospital anxiety over time. Details were in **Table 20** and **Figure 6**.

The line graph (**Figure 6**) presented that the hospital anxiety scores in the intervention group were lower than in the control group at T2 and T3 whereas the line connecting each time point (Week 0, week 3, week 7) in the intervention group had decreased over time. This confirmed the statistical findings.

Table 20 Pairwise comparisons using Bonferroni of the difference in hospital anxiety scores between each pair of time in the intervention and the control groups

Source variation	M_{diff}	SE	p-value	95% CI for difference ^b	
				Lower Bound	Upper Bound
Intervention group					
Week 0 vs Week 3	3.65	0.53	<.001	2.34	4.97
Week 3 vs Week 7	2.70	0.46	<.001	1.56	3.83
Week 0 vs Week 7	6.35	0.38	<.001	5.40	7.29
Control group					
Week 0 vs Week 3	0.78	0.36	0.11	-0.12	1.68
Week 3 vs Week 7	0.11	0.49	1.00	-1.12	1.34
Week 0 vs Week 7	0.89	0.42	0.12	-0.16	1.93

b=Adjustment for multiple comparisons: Bonferroni.

4. Comparisons of Hospital Depression scores between the intervention and the control groups, and among three-time measures within the intervention group.

Two-way repeated measures ANOVA (one between-one within) was used to determine a mean difference in total scores of hospital depression between the intervention and the control groups at pre-intervention (week 0), post-intervention (week 3), and follow-up (week 7), and within a group among the 3-time measures. The results showed a significant interaction effect of Group*Time ($F(2, 88) = 64.94$, $p < .001$, Partial $\eta^2 = 0.60$). Moreover, the results also revealed significant main effects of Group (between-subjects) ($F(1, 44) = 173.47$, $p < .001$, Partial $\eta^2 = 0.80$) and Time (within-subjects) ($F(2, 88) = 146.98$, $p < .001$, Partial $\eta^2 = 0.77$) (**Table 21**).

Table 21 Two-way repeated measure ANOVA of the total scores of hospital depression

Source variation	SS	df	MS	F	p-value	η^2p
Between Subjects						
Group	713.78	1	713.78	173.47	<.001	0.80
Error	181.05	44	4.12			
Within subjects						
Time	943.03	2	471.52	146.98	<.001	0.77
Error	282.30	88	3.21			
Group*Time	610.81	2	305.40	64.94	<.001	0.60
Error	413.86	88	4.70			

η^2p = Partial Eta Squared

Because the interaction (Group*Time) effect supersedes to the main effects. Subsequently, simple main effects of Group and Time were then run after the finding of a significant interaction effect to examine the differences of hospital depression between the two groups at each point of times, and the differences of change in hospital depression over time within each group.

For the simple main effect of Group, Bonferroni-corrected pairwise t-tests were used to compare differences in total scores of hospital depression between the intervention and the control groups at each pair of time points. The results showed that at baseline, pre-intervention (Week 0, T1), hospital depression score was not different between the two groups ($p > 0.05$). At post-intervention (Week 3, T2), and at follow-up (Week 7, T3), scores of hospital depression in the intervention group were significantly lower than that in the control group ($F(1,44) = 49.48, p < 0.001, \text{Partial } \eta^2 = 0.53$, and $F(1, 44) = 253.89, p < .001, \text{Partial } \eta^2 = 0.85$, respectively) (**Table 22** and **Figure 7**). These findings indicated that after receiving the PBSP, participants in the intervention group had lower hospital depression than the control group and could maintain this effect to the follow-up period.

Table 22 Simple main effect of Group on hospital depression scores at each time points

Source variation	SS	df	MS	F	p-value	η^2p
Baseline (Week 0, T1)						
Between subjects	8.71	1	8.71	2.55	0.12	0.06
Error	150.29	44	3.42			
Post-intervention (Week 3, T2)						
Between subjects	302.50	1	302.50	49.48	0.00	0.53
Error	269.00	44	6.11			
Follow-up (T3)						
Between subjects	1013.38	1	1013.38	253.89	0.00	0.85
Error	175.62	44	3.99			

η^2p = Partial Eta Squared

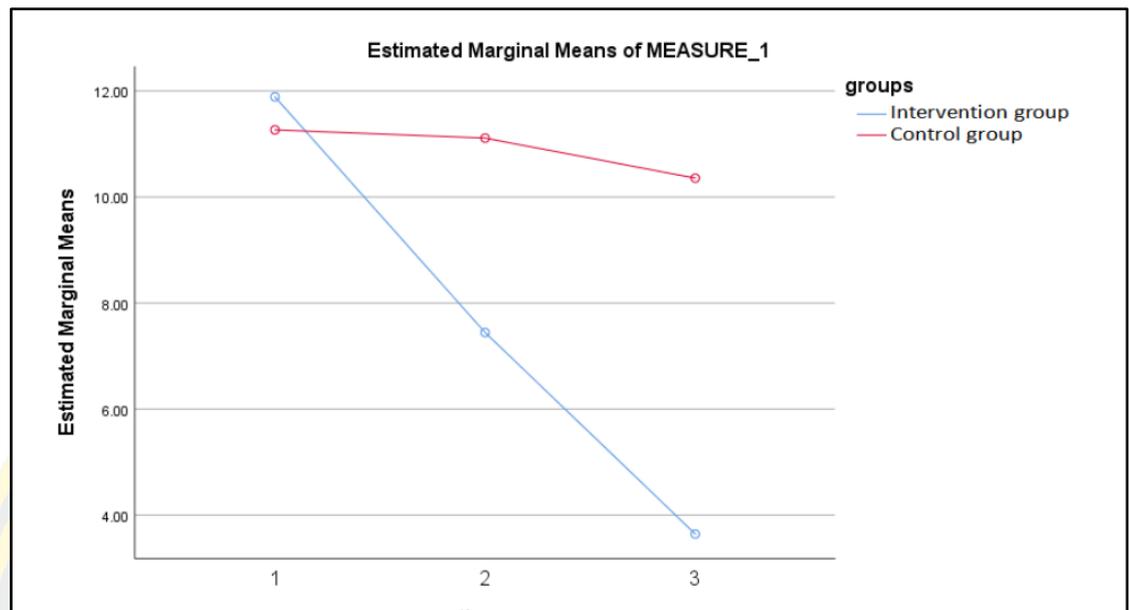


Figure 7 Comparisons of means hospital depression scores between the intervention and the control groups, and among 3-time measures

For the simple main effect of Time, in the intervention group, there was statically significant difference of hospital depression scores among the three times points ($F_{2, 90} = 194.22, p < .001, \eta^2 p = 0.81$), indicating that there was different of hospital depression scores at least one pair of times. However, there was not significant difference in the control group (**Table 23**).

Table 23 Simple main effect of Time on hospital depression scores in the intervention and the control groups

Source variation	<i>SS</i>	<i>df</i>	<i>MS</i>	<i>F^C</i>	<i>p-value</i>	$\eta^2 p$
Intervention group						
Time	1580.48	2	790.24	194.22	0.00	0.81
Error	366.19	90	4.07			
Control group						
Time	21.38	1.71	12.48	2.83	0.07	0.06
Error	332.62	75.36	4.41			

c= Huynh-Feldt was used to adjust the degree of freedom, $\eta^2 p$ = Partial Eta Squared

Next, pairwise comparisons using Bonferroni-corrected paired t-test were run to examine the different between each pair of time-measures. For the intervention group, the hospital depression scores at post-intervention (Week 3, T2) and follow-up (Week 7, T3) were significantly lower than that at baseline (Week 0, T1) ($M_{diff}=4.44$ and $M_{diff}=8.28$, $p<.001$, respectively), and the scores at follow-up (Week 7, T3) was significantly lower than that at post-intervention (Week 3, T2) ($M_{diff}= 3.85$, $p<.001$). The participants who received the PBSP had lower hospital depression over time. Details were in **Table 24** and **Figure 7**.

The line graph (**Figure 7**) presented that the hospital depression scores in the intervention group were lower than in the control group at T2 and T3 whereas the line connecting each time point (Week 0, Week 3, and Week 7) in the intervention group had decreased over time. This confirmed the statistical findings.

Table 24 Pairwise comparisons using Bonferroni of the difference in hospital depression score between each pair of time in the intervention and the control groups

Source variation	M_{diff}	SE	p-value	95% CI for Difference	
				Lower Bound	Upper Bound
Intervention group					
Week 0 vs Week 3	4.44	0.45	<.001	3.33	5.54
Week 3 vs Week 7	3.85	0.45	<.001	2.73	4.97
Week 0 vs Week 7	8.28	0.36	<.001	7.39	9.18
Control group					
Week 0 vs Week 3	0.16	0.31	1.00	-0.60	0.91
Week 3 vs Week 7	0.76	0.47	0.34	-0.41	1.92
Week 0 vs Week 7	0.91	0.44	0.13	-0.18	2.00

5. Comparisons of quality of life (QOL) scores between the intervention and the control groups, and among three-time measures within the intervention group.

Two-way repeated measures ANOVA (one between-one within) was used to determine a mean difference in total scores of QOL between the intervention and the control groups at pre-intervention (week 0), post-intervention (week 3), and follow-up (week 7), and within a group among the 3-time measures. The results showed a significant interaction effect of Group *Time ($F(1.73, 75.96) = 61.63, p < .001, \text{Partial } \eta^2 = 0.58$). Moreover, the results also revealed significant main effects of Group (between-subjects) ($F(1, 44) = 159.50, p < .001, \text{Partial } \eta^2 = 0.78$) and Time (within-subjects) ($F(2, 88) = 119.18, p < .001, \text{Partial } \eta^2 = 0.73$) (**Table 25**).

Table 25 Repeated measure ANOVA of the total scores of QOL

Source variation	SS	df	MS	F ^a	p-value	$\eta^2 p$
Between Subjects						
Group	4689.66	1	4689.66	159.50	<.001	0.78
Error	1293.71	44	29.40			
Within subjects						
Time	5873.26	2	2936.63	119.18	<.001	0.73
Error	2168.44	88	24.64			
Time*Group	3350.68	1.73	1940.91	61.63	<.001	0.58
Error	2392.32	75.96	31.50			

^a = Greenhouse-Geisser was used to adjust the degree of freedom, $\eta^2 p$ = Partial Eta Squared

Because the interaction (Group*Time) effect supersedes to the main effects. Subsequently, simple main effects of Group and Time were then run after the finding of a significant interaction effect to examine the differences of quality of life between the two groups at each point of times, and the differences of change in quality of life over time within each group.

For the simple main effect of Group, Bonferroni-corrected pairwise t-tests were used to compare differences in total scores of QOL between the intervention and the control groups at each pair of time points. The results showed that at baseline, pre-intervention (Week 0, T1), QOL score was not different between the two groups

($p > 0.05$). At post-intervention (Week 3, T2), and at follow-up (Week 7, T3), scores of QOL in the intervention group were significantly higher than that in the control group ($F(1,44) = 41.20$, $p < 0.001$, $\text{Partial } \eta^2 = 0.48$, and $F(1,44) = 332.86$, $p < .001$, $\text{Partial } \eta^2 = 0.88$, respectively) (**Table 26** and **Figure 8**). These findings indicated that after receiving the PBSP, participants in the intervention group had better QOL than the control group and could maintain this effect to the follow-up period.

Table 26 Simple main effect of Group on QOL scores at each time points

Source variation	SS	df	MS	F	p-value	η^2p
Baseline (Week 0, T1)						
Between subjects	0.66	1	0.66	0.02	0.88	0.01
Error	1243.42	44	28.26			
Post-intervention (Week 3, T2)						
Between subjects	1474.49	1	1474.49	41.20	< .001	0.48
Error	1574.78	44	35.79			
Follow-up (T3)						
Between subjects	6565.19	1.00	6565.19	332.86	< .001	0.88
Error	867.84	44.00	19.72			

η^2p = Partial Eta Squared

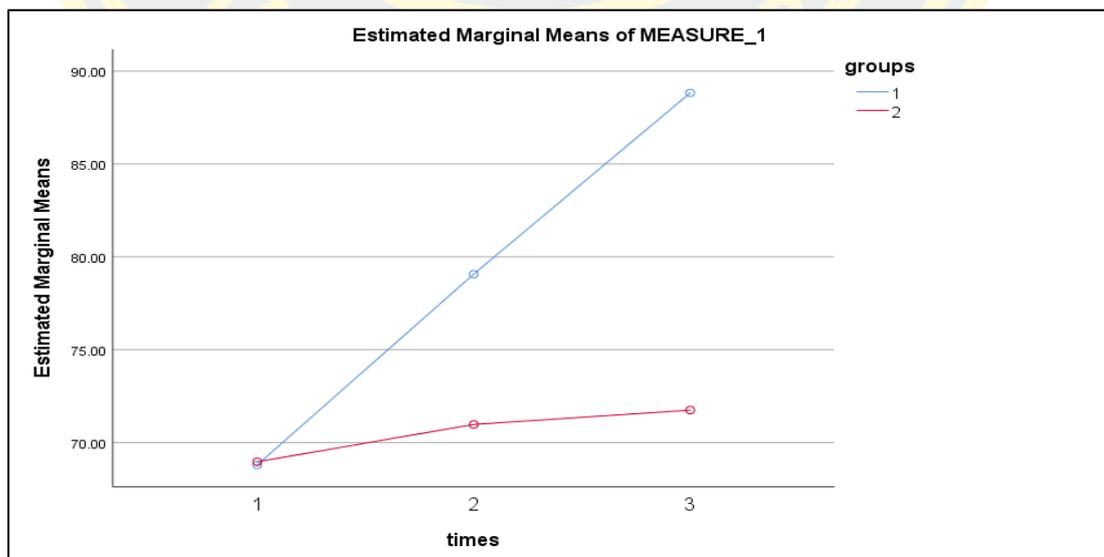


Figure 8 Comparisons of means QOL scores between the intervention and the control groups, and among 3-time measures

For the simple main effect of Time, in the intervention group, there was statically significant difference of QOL scores among the three times points ($F_{2, 90} = 226.10, p < 0.001, \eta^2_p = 0.84$), indicating that there was different of QOL scores at least one pair of times. However, there was not different of QOL in the control group (**Table 27**).

Table 27 Simple main effect of Time on QOL scores in the intervention and the control groups

Source variation	SS	df	MS	F	p-value	η^2_p
Intervention group						
Time	9248.29	2	4624.15	226.10	<0.001	0.83
Error	1840.67	90	20.45			
Control group						
Time	186.19	2	93.09	3.01	0.05	0.06
Error	2720.53	88	30.92			

Next, pairwise comparisons using Bonferroni-corrected paired t-test were run to examine the difference of quality of life between each pair of time-measures. For the intervention group, the QOL scores at post-intervention (Week 3, T2) and follow-up (Week 7, T3) were significantly higher than that at baseline (Week 0, T1) ($M_{diff} = -10.37$ and $M_{diff} = -20.05, p < .001$, respectively), and the scores at follow-up (Week 7, T3) was significantly higher than that at post-intervention (Week 3, T2) ($M_{diff} = -9.78, p < .001$). The participants who received the PBSP had better QOL over time. Details were in **Table 28** and **Figure 8**.

The line graph (**Figure 8**) presented that the QOL scores in the intervention group were higher than in the control group at T2 and T3 whereas the line connecting each time point (Week 0, Week 3, and Week 7) in the intervention group increased over time. This confirmed the statistical findings.

Table 28 Pairwise comparisons using Bonferroni of the mean Difference in QOL scores between each pair of time differences in the intervention and the control groups

Source variation	M_{diff}	SE	p-value	95% CI for difference ^b	
				Lower Bound	Upper Bound
Intervention group					
Week 0 vs Week 3	-10.27	0.93	<.001	-12.59	-7.95
Week 3 vs Week 7	-9.78	0.84	<.001	-11.87	-7.70
Week 0 vs Week 7	-20.05	1.05	<.001	-22.65	-17.45
Control group					
Week 0 vs Week 3	-2.01	1.34	0.43	-5.36	1.34
Week 3 vs Week 7	-0.78	1.01	1.00	-3.29	1.74
Week 0 vs Week 7	-2.79	1.14	0.06	-5.62	0.05

b. Adjustment for multiple comparisons: Bonferroni.

Summary of the findings

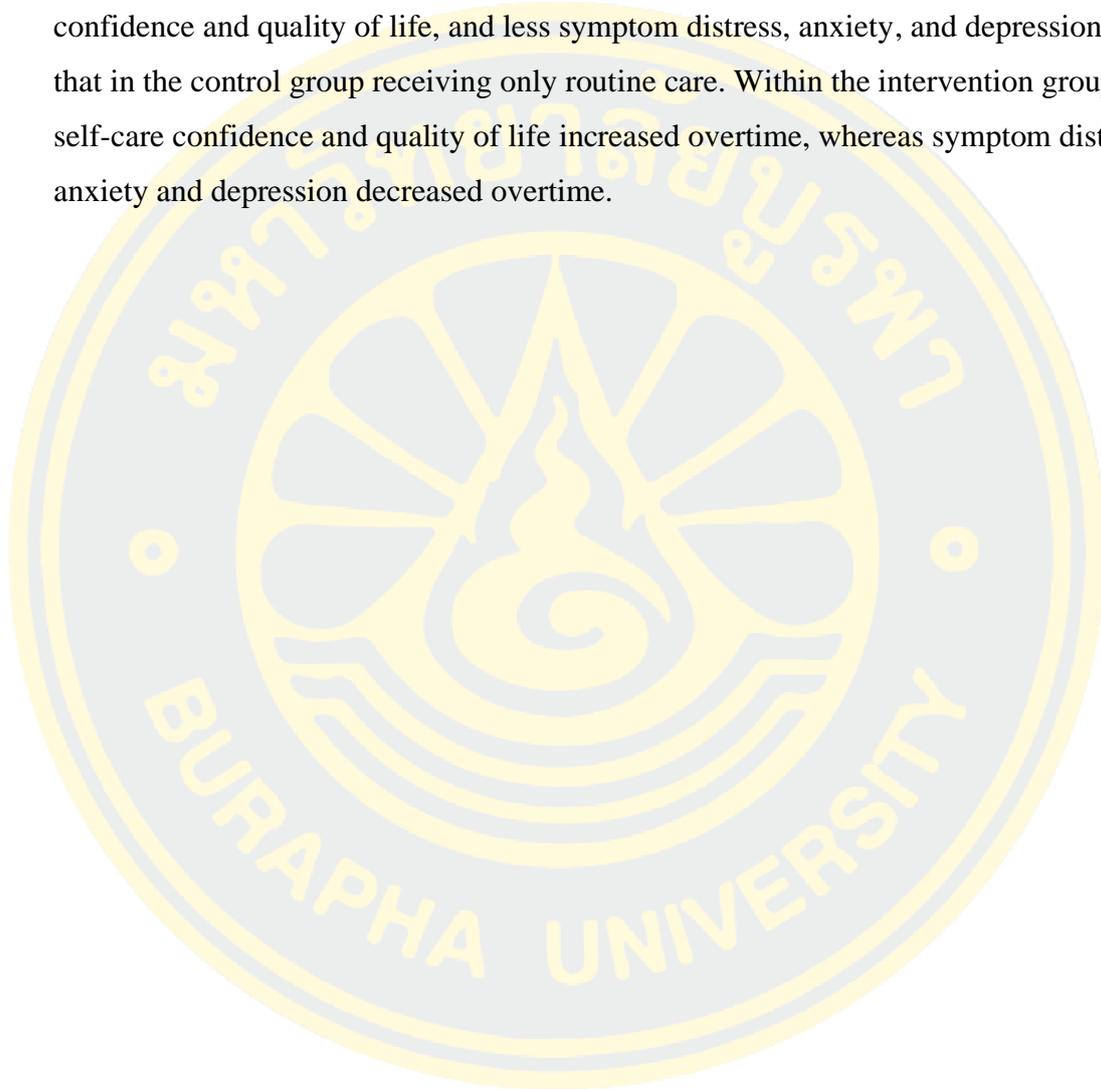
Self-care confidence, symptom distress, hospital anxiety and depression and the quality-of-life outcomes determined the effectiveness of this PBSP in the intervention group as comparing to the control group at three-time measurements.

At baseline, before implementing the PBSP, the mean scores of SCSES (Self-care self-efficacy), MDASI (symptom distress), HADS (hospital anxiety and depression), and QOL (quality of life) between the intervention and the control groups were found no difference.

Two-way repeated measure ANOVA were performed to determine the differences of the scores of each outcome between the intervention and the control groups, and within-group (3-time-measurements). The results revealed that the mean scores of the SCSES and the QOL of participants in the intervention group were higher than those in the control group at post-intervention (Week 3, T2) and follow-up (Week 7, T3). Within the intervention group, the SCSE and the QOL at follow-up and post-intervention were higher than at baseline. In the meantime, the mean scores of the MDASI and the HADS of participants in the intervention group were lower than those in the control group at post-intervention (Week 3, T2) and follow-up (Week 7,

T3). Within the intervention group, the MDASI and the HAD at follow-up and post-intervention were higher than at baseline.

These findings suggest the PBSP was effective in that participants in the intervention group receiving the PBSP plus routine care had better Self-care confidence and quality of life, and less symptom distress, anxiety, and depression than that in the control group receiving only routine care. Within the intervention group, self-care confidence and quality of life increased overtime, whereas symptom distress, anxiety and depression decreased overtime.



CHAPTER 5

CONCLUSION AND DISCUSSION

This chapter presents the summary and discussions. Conclusions, strengths and limitations, suggestions, and recommendations are also presented.

Summary of the study

This study aimed to evaluate the effectiveness of the PBSP for the participants who newly diagnosed with breast cancer undergoing chemotherapy. A single-blind, randomized control trial was designed. Ninety-four participants were recruited at the breast surgery and oncology department of Yancheng NO.1 People's Hospital, Jiangsu Province, China, from April 22 to July 7, 2023. Participants were equally and randomly allocated into the intervention and control groups, with each group comprising 47 individuals. Assessments of self-care confidence, symptom distress, hospital anxiety and depression, and quality of life were conducted at three time points: baseline (Week 0, T1), after the intervention (Week 3, T2), and at a follow-up (Week 7, T3). For these assessments, the Chinese versions of the SCSE, MDASI, HAD, and QLQ were used, which demonstrated Cronbach's alphas of 0.89, 0.85, 0.70, and 0.80, respectively. Throughout the course of the intervention, there were no dropouts among participants. Additionally, one outlier in the intervention group and two outliers in the control group were identified and excluded from the analysis. Therefore, the data of 46 participants in the intervention and 45 participants in the control group were analyzed by descriptive statistics, MANOVA, and two-way repeated measure ANOVA.

After the intervention, the scores of SCSE and QOL were higher, and the scores of MDASI and HAD in the intervention group were lower than those in the control group at post-intervention and follow-up. Moreover, within the intervention group, the score of SCSE, MDASI, HAD, and QOL after completion of the implementation and at follow-up were better than those of pre-intervention, and increased overtime.

Discussions of the findings

The discussions are following the research hypotheses:

Hypothesis 1: Participants in the intervention group have significantly higher self-care confidence than those in the control group at immediately post-intervention (T2), and follow-up period (T3), and within the intervention group, self-care confidence significantly increases from pre-intervention (T1) to post-intervention (T2), and follow-up period (T3).

According to the introduction of the above content, researchers assess patients' self-confidence by measuring in self-care self-efficacy (SCSE). The results showed an increase in the self-care self-efficacy of participants who newly diagnosed with breast cancer undergoing chemotherapy in the intervention group from pre-intervention (Week 0, T1) to post-intervention (Week 3, T2), and follow-up (Week 7, T3). There were statistically significant differences compared with those in the control group ($F_{1,44} = 606.08$, $p < .001$, Partial $\eta^2 = 0.93$). In addition, and also the self-care self-efficacy at post-intervention was higher than that at baseline ($M_{diff} = 11.00$, $p < .001$). The results have confirmed that the PBSP is effective in that it could improve self-care confidence in the patients with breast cancer. This hypothesis was supported.

Evidence suggests that breast cancer is taking the form of a chronic illness (Loh & Yip, 2006). As the course of the disease prolongs, the patient's self-care ability continues to decline. Self-care Self-efficacy is defined as confidence in one's ability to conduct self-management chores necessary to effectively manage chronic illness (Tsay & Healstead, 2002). Based on the most updated version of the Middle Range Theory of Self-care of Chronic Illness (Riegel, Jaarsma, Lee, & Strömberg, 2019b), the SCSES was proposed as a single-domain scale to measure self-efficacy in self-care maintenance (action to maintain physiologic stability), self-care monitoring (actions to track behavior, detect and interpret changes in signs and symptoms), and self-care management. Tsay et al. (2002) revealed that developing self-care Self-efficacy is the cornerstone for better illness self-care. Therefore, the PBSP which stabilizes the inner confidence strength the patients' abilities to perform self-management tasks required to effectively cope breast cancer. This finding is consistent with the effectiveness of educational mobile application that improved self-

care, self-efficacy and knowledge among adult patients with hypertension (Dwairej & Ahmad, 2022).

Therefore, the PBSP could enhance the self-care confidence for patients with breast cancer. At present, there are several research on linking self-care self-efficacy with mobile application program. However, most of studies addressed on self-efficacy. Zhu et al. (2018) found that an application program (App) that provides patients with individually tailored information and a support group of peers and health care professionals could promote women's self-efficacy, social support and symptom management, thus improving their quality of life and psychological well-being. Also, the findings of a systematic review and meta-analysis, it supported e-health-based program demonstrated a statistically significant on self-efficacy. Social Support have the relationship with self-care self-efficacy. Qian & Yuan (2012) showed that social support has a substantial correlation with self-care self-efficacy. After being diagnosed with cancer, some patients become socially isolated and are afraid to share the illness or participate in social activities. This circumstance may impede the patients' information searching. The PBSP is a major source of practical and emotional support that put together individuals with the same illness. Through the group, patients could interact with one another to encourage each other and offer emotional support. It is precisely because of this interaction, a part of PSBP, that the patient's self-care confidence is improved.

Hypothesis 2: Participants in the intervention group have significantly lower mean scores on symptom distress than that of the control group at immediately post-intervention (T2), and follow-up period (T3). Within the intervention group, mean scores on symptom distress are significantly decreased from pre-intervention (T1) to post-intervention (T2), and follow-up period (T3).

The results showed a decrease in symptom distress of participants who newly diagnosed with breast cancer undergoing chemotherapy in the intervention group from pre-intervention (Week 0, T1) to post-intervention (Week 3, T2) and follow-up (Week 7, T3), and there were statistically significant differences compared with those in the control group ($F_{1,44} = 249.23$, $p < .001$, Partial $\eta^2 = 0.85$). In addition, the symptom distress of participants in the intervention group at the follow-up was lower

than those at baseline and post-intervention ($M_{diff} = -55.43$ and $M_{diff} = -28.72$, $p < .001$, respectively), and also the symptom distress at post-intervention was lower than that at baseline ($M_{diff} = -26.72$, $p < .001$). The results have confirmed that the PBSP is effective in that it helps alleviate symptom distress in the patients with breast cancer. This hypothesis was supported.

Patients are often affected by a variety of uncomfortable symptoms after a cancer diagnosis, some from the disease itself and some from the side effects of chemotherapy. Chemotherapy is a routine treatment option for breast cancer patients after surgery. As a result, patients are often affected by a variety of uncomfortable symptoms during the treatment process. Self-efficacy is key concepts that affect symptom distress outcomes for patient with breast cancer in all stages of treatment. Self-efficacy is a person's ability to implement behavior for a desired outcome (Albert Bandura, 2000). Patients should have self-manage their symptoms to reduce symptoms of distress but may have not enough self-efficacy to do so. The PBSP used the WeChat, an application for online social connection using widely and commonly in China, to improve cancer patients' self-efficacy and that improved patients' symptom management capabilities to reduce the impact of cancer-related symptoms on their lives. In usual daily life, breast cancer patients are primarily responsible for managing their own health, and they must be able to implement specific behaviors for symptom management tasks, such as symptom recognition, prevention, and actions to reduce or alleviate symptom intensity, duration, and frequency (White et al., 2017). In the learning group of PBSP, the researcher and breast-related medical experts developed a video push on the theme of common symptoms. The main purpose was to teach patients to monitor their own symptoms and deal with the basic symptoms that appear at that time, so as to avoid unnecessary panic. At the same time, they could communicate with the attending doctor at any time. The PBSP has increased patient's knowledge awakens and subconscious mind in fighting the disease, and at the same time created a platform for patients to socialize, thereby decreasing the patient's symptom distress.

Evidence from this study of 2-arm RCT for multiple patients by Berry et al. (2014). They investigated the impact of a self-report evaluation and an educational Internet intervention on symptom distress after cancer treatment. Patients were asked

to report the intensity of common symptoms and therapeutic side effects at any time, and they were given individualized self-care training that included on-screen, tailored coaching, as well as encouragement to characterize the severity, pattern, and alleviating/aggravating variables associated with their symptoms. The results showed that the intervention group experienced much less symptom discomfort during therapy, particularly among participants under the age of 50.

Hypothesis 3: Participants in the intervention group have significantly lower mean scores on hospital anxiety and depression than that of the control group at immediately post-intervention (T2), and follow-up period (T3). Within the intervention group, mean scores on hospital anxiety and depression is significantly decreased from pre-intervention (T1) to post-intervention (T2), and follow-up period (T3).

The results showed a decrease in the hospital anxiety and depression of participants who newly diagnosed with breast cancer undergoing chemotherapy in the intervention group from pre-intervention (Week 0, T1) to post-intervention (Week 3, T2) and follow-up (Week 7, T3), and there were statistically significant differences compared with those in the control group ($F_{1,44} = 75.39, p < .001, \eta^2 p = 0.63$; $F_{1,44} = 173.47, p < .001, \eta^2 p = 0.80$). For hospital anxiety, the participants in the intervention group at the follow-up was lower than those at baseline and post-intervention ($M_{diff} = -6.35$ and $M_{diff} = -2.70, p < .001$, respectively), and also the hospital anxiety at post-intervention was lower than that at baseline ($M_{diff} = -3.65, p < .001$). For hospital depression, the participants in the intervention group at the follow-up was lower than those at baseline and post-intervention ($M_{diff} = -8.28$ and $M_{diff} = -3.85, p < .001$, respectively), and also the hospital depression at post-intervention was lower than that at baseline ($M_{diff} = -4.44, p < .001$). The results have confirmed that the PBSP is effective in that it helps alleviate hospital anxiety and depression in the patients with breast cancer. This hypothesis was supported.

Evidence suggests that clinically based psychosocial therapies involving information, emotional, social, and spiritual supports may alleviate pain and reduce anxiety and depression in women with breast cancer (Fors et al., 2011; Mustafa et al., 2013). However, typical face-to-face therapies may not be suitable for many cancer

patients due to accessibility difficulties such as clinic location, travel duration, and inter-changeability.

The PBSP provided a place for breast cancer patients to express their emotions via the WeChat online platform and peer groups. After getting along in the online social group, they become like relatives. They not only communicated in the WeChat group, but also communicate face to face in the ward when they were admitted to the hospital at the same time. In addition, breast medical specialists join the PBSP in every week, which is very beneficial for patients to relieve anxiety and depression. Several previous studies have found similar to these findings. Urech et al. (2018) investigated the effects of Internet-based educational interventions on depression, statistical results showed significant in distress. Børøsdund et al. (2014) designed 3-arm RCT on symptom distress, anxiety, depression, and self-efficacy for 167 breast cancer patients in Norway. They reported that after 6 months of follow-up participants in the arm 1 [(an Internet-based patient-provider communication service (IPPC))] significantly reduced depression compared with the usual care group (arm 3). The multi-component intervention WebChoice (arm 2) had additional positive effects on reductions in symptom distress, anxiety, and depression compared with the usual care group (arm 3). Moreover, Lee et al. (2014) found a single-session psycho-education intervention among several types of cancer on distress management for a tablet PC Duration (N=19). The intervention included 3 weeks of 20 min per day for psycho-education material components: (1) distress education; (2) cancer survivor interview; (3) coping strategies and stress management; (4) psychosocial services. Only a sham-control VDO clip for the control group (N=16). The comparison of result showed significant in depression and QOL ($p < 0.05$). This evidence appropriate to utilize e-technology in empowering patients to manage their cancer treatment-related symptoms. These prior findings were consistent with the results of this study.

Hypotheses 4: Participants in the intervention group have significantly higher mean scores on quality of life than that of the control group at immediately post-intervention (T2), and follow-up period (T3). Within the intervention group, mean scores on quality of life are significantly increased from pre-intervention (T1) to post-intervention (T2), and follow-up period (T3).

The results showed an increase in the quality of life of participants who newly diagnosed with breast cancer undergoing chemotherapy in the intervention group from pre-intervention (Week 0, T1) to post-intervention (Week 3, T2) and follow-up (Week 7, T3), and there were statistically significant differences compared with those in the control group ($F_{1,44} = 159.50$, $p < .001$, $\eta^2 p = 0.78$). In addition, for the intervention group, the QOL scores at post-intervention (Week 3, T2) and follow-up (Week 7, T3) were significantly higher than that at baseline (Week 0, T1) ($M_{diff} = 20.05$ and $M_{diff} = 10.27$, $p < .001$, respectively), and the scores at follow-up (Week 7, T3) was significantly higher than that at post-intervention (Week 3, T2) ($M_{diff} = 9.78$, $p < .001$). The results have confirmed that the PBSP is effective in that it helps improve quality of life in the patients with breast cancer. This hypothesis was supported.

The global quality of life score reflected patients' perceptions of general health and quality of life in the preceding week, but it was insufficiently sensitive to detect particular variations over time. The summary score was generated using 28 out of 30 of the EORTC QLO-C30 scale, and the findings revealed statistically significant changes between groups in summary scores after the intervention and during the follow-up.

Breast cancer is a common disease among women, and the main treatment method is surgery. Although surgery improves the patient's survival, subsequent chemotherapy causes a series of symptoms that affect the patient's quality of life. Lev et al. (2001) examined the effect of an intervention among 56 women who were in stage I-III breast cancer. They found that the intervention could help increase the patients' quality of life. At present, smartphones have become popular, so how to use local materials and reduce investment while providing full life cycle care for cancer patients is crucial. The traditional nursing mode can only play its role in the postoperative hospitalization fragmented health promotion, and a simple follow-up after discharge, it cannot give the continuing care guidance for patients, especially when they suffer from some side action of chemotherapy. WeChat, the platform with the most instant messaging users, has the advantages of instantiation, convenient information exchange and dissemination, multi-mode visualization, and the ability to open a convenient channel for communication between medical staff, patients, and their families.

The PBSP used the WeChat as a mean to deliver a whole caring for patients. It is a bridge between home and hospital. Using the WeChat platform to provide prolonged care for breast cancer patients following surgery might assist doctors and nurses in managing patients' post-discharge situations. Sending PBSP videos over WeChat might assist patients better comprehend the relevant medical information, improve their recognition and attention to nursing, and boost patients' confidence in their ability to fight the condition. Furthermore, the WeChat platform has a call video capability, which allows for more immediate contact between physicians and patients in the Ask-Expert group. Moreover, it promoted physical recovery by advising patients to adjust sleep, exercise, diet, medication, and other aspects, so as to help them establish a positive attitude to face the disease. Therefore, the PBSP supply the new thoughts for clinical nurse to carry out full-process and systematic care. The PBSP presents an independence that can enrich life and improve the quality of life for patients. The Chinese participants enjoyed applying it, and they can enter the groups related their needs. The PBSP assisted the participants as an interventional tool for the self-management of symptoms. They also can catch the most suitable information medical-related guidance automatically for self-care. This enhanced patient operative competence and self-efficacy, resulting in a higher quality of life, according to Bandura's self-efficacy hypothesis.

Conclusion

In this study, the based theory is self-efficacy theory, and the researcher designed the PSBP through a mobile app (WeChat). The PSBP is effective on improving self-care confidence and quality of life, and reducing psychological distress in patients with newly diagnosed breast cancer who were receiving chemotherapy comparing between the intervention and the control groups. Moreover, within the intervention group, the changes were improved overtime. Then provide the rationale that can achieve this effectiveness, as participants engaged more with the PSBP and experienced its benefits, their self-efficacy and subsequent self-care behaviors improved. The continuous interaction with the app likely provided ongoing mastery experiences, vicarious learning, verbal persuasion, and emotional arousal, enhancing their confidence and ability to manage their health. The increase in self-efficacy leads

to better self-care confidence. By showing that enhanced self-efficacy leads to better self-care confidence. This confidence is crucial for patients to engage in consistent self-care behaviors such as maintenance (keeping up with treatment and health routines), monitoring (being aware of changes in their condition), and management (actively addressing health issues). These behaviors are essential for managing a chronic and challenging condition like breast cancer. By empowering patients through improved self-care confidence, the PSBP helps in reducing symptoms of distress, anxiety, and depression. As patients feel more capable of managing their health, their overall quality of life improves.

Strength and limitations

Three key elements should be acknowledged as the strengths of this study:

First, to evaluate the effectiveness of the PBSP, this study used a randomized control trial (RCT) design. This was the strongest intervention study design for determining cause-and-effect relationships. The three essential elements of a true experiment were used in this study including an intervention or treatment, a comparison or control group for the prevention of maturation threat, and random assignment of participants to an intervention or control group for the prevention of history and selection threat (Gray et al., 2017). In this study, the research assistant who collected the data and participants was blind in this study. To minimize bias, the allocation was kept hidden from the enrolled research assistant and participants. The study group was masked from the research assistant and had non-access to the data or information regarding group assignment.

Second, this study is a comprehensive program in collaboration with medical workers and patients to promote the self-care confidence, psychological distress, and quality of life during hospitalization and home. The researcher provided nurse with a manual and guideline to enhance the patients' self-care confidence, psychological distress, and quality of life.

At last, since at this era most people easily access to the internet. The PBSP is Internet-based nursing service. The implementation integrated using online platform (WeChat) via a mobile phone which is convenient, and the participants can have access anywhere and anytime. They can also repeatedly watch provided clip VDOs as

much as they wanted whenever they would like to. This delivery method is modern and user friendly.

Limitations:

The threat of data contamination may occur due to some cases of participants in both groups living in the same department at the same time. Although the researchers used the PBSP to isolate the participants of the intervention groups in separate rooms. Communication between the two groups was possible. In addition, this study was conducted only in one setting in China; therefore, it has limitation on generalizability in other settings with different contexts. This study did not consider about the participants' underlying medical conditions, which may limit the general applicability and depth of analysis of the research findings.

Suggestions and recommendations

The study's findings offered evidence for healthcare practitioners to increase self-care confidence, psychological distress, and quality of life in newly diagnosed breast cancer patients. Furthermore, this intervention broadens the field of practice for health professionals and nurses, who may utilize the data to support the notion of self-efficacy. The integration of mobile phone technology with breast cancer patient care is consistent with the China Health 2030 Plan and essential in COVID-19 pandemic situation. It allows patients to receive continuing and equal care and stay safe from COVID-19. The identified gaps in this study are the introduction of health policies and organizational supports for Internet-based nursing service implementation in breast cancer patients. The findings may reflect the necessary development of a comprehensive service model that utilizes Internet-based nursing service for self-care of breast cancer patients. Internet-based nursing service may be a useful adjunct to usual care with multidisciplinary approach. The widespread use of WeChat in China has greatly reduced the difficulty for patients, especially elderly patients, to operate other software. This research project is established on the WeChat platform, which provides an information method for the development of mobile nursing service projects. Therefore, it is important to allow patients to participate in breast cancer care program. Nurses should use easy-to-understand words to teach patients relevant self-care professional knowledge.

Future research should focus on combining other platform technologies, such as Internet plus nursing services, public accounts, video accounts, live broadcast rooms, etc., to facilitate more intuitive face-to-face video communication with patients, help patients solve practical problems, and improve breast cancer patients' quality of care.

Implications

The findings of this study provided evidence to guide nurses to enhance self-care confidence, psychological distress, and quality of life for breast cancer patients. It was found that establishing Internet based program is an effective way to promote health among breast patients.

For nursing practice:

The PBSP, which should be utilized by healthcare personnel, especially nurse, can development self-efficacy to enhance health, while its effects can be maintained until the whole disease cycle. Nurses can manage and provide the PBSP for their patients, which will benefit confidence. The PBSP had four sessions in, and was started on the day before though chemotherapy firstly. Nurses working with women with breast cancer could utilize the PBSP to provide continuity of care for the patients in different settings. The women with breast cancer undergoing chemotherapy could consult with nurses to enhance self-care confidence, and psychological distress easily when they meet diseases related problems.

For nursing education:

The findings of this study might be applied to nursing education by educating advanced nurse practitioners. Nurse instructors should apply the PBSP practice instructions to promote self-care confidence, psychological distress, and quality of life when teaching both theory and practice so that nursing students can gain a more insightful understanding of this issue. The curriculum should include the process self-efficacy theory, which promotes systems thinking and behavioral change; it may also be included into particular nursing courses in pediatric critical care or childcare.

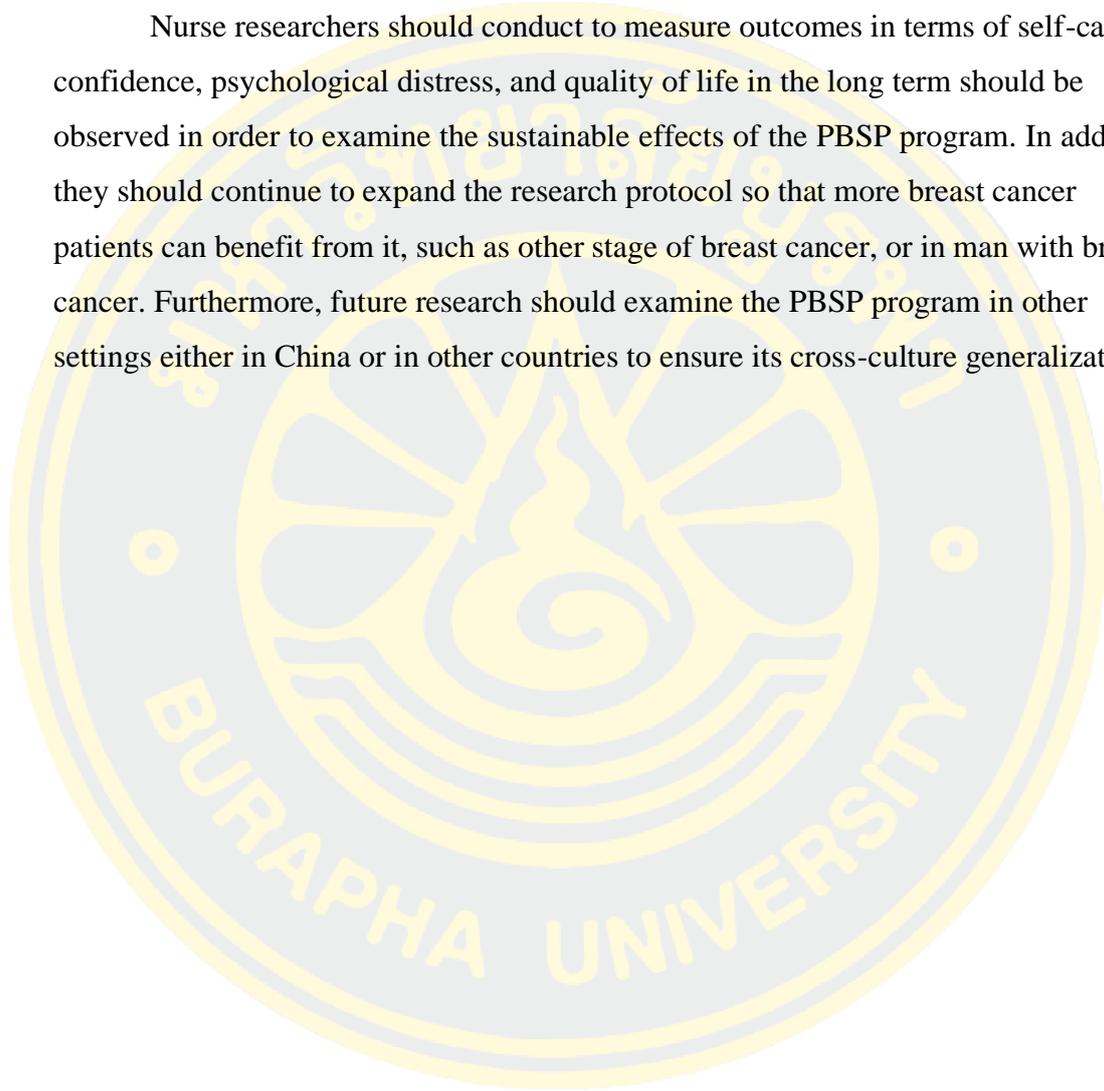
For health policy:

Nurse administrators could obtain, support, and administer the PBSP for nurses who working with breast cancer women undergoing chemotherapy integrated

with the hospital' routine care. Competent authorities should provide other remuneration and related incentive systems to relevant nursing staff participating in the Internet based nursing.

For future research:

Nurse researchers should conduct to measure outcomes in terms of self-care confidence, psychological distress, and quality of life in the long term should be observed in order to examine the sustainable effects of the PBSP program. In addition, they should continue to expand the research protocol so that more breast cancer patients can benefit from it, such as other stage of breast cancer, or in man with breast cancer. Furthermore, future research should examine the PBSP program in other settings either in China or in other countries to ensure its cross-culture generalization.



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<https://doi.org/10.1007/s12282-018-0830-3>





APPENDICES



APPENDIX A
Intervention Plan

The Phone-Based Support Program (PBSP)

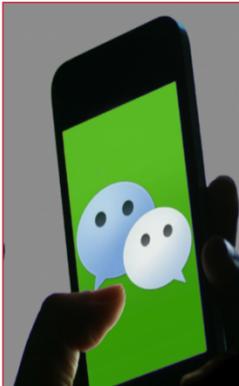
Times	Objectives	Intervention Group		
		Relevant to the theoretical based	Contents	Activities
After obtaining Approval	To make appointment with participants	After obtaining Approval from to the Institutional Review Board (IRB) Burapha University in Thailand and in China. RA (XW) met interested women when they discharge after surgery.		
Confirming participants	To assignment participants	1. RAs confirm eligibility, and make appointment with them face to face, when they come to the hospital for chemotherapy first day in Breast Surgery and oncology department, obtain their consent forms. 2. 47 participants will be in intervention group. RA(DY) measures them by using SCSES, MDASI, HADS, (EORTC) QLQ-C30.		
Session1: Building relationships (Week 1)	-To strengthen the confidence of participants. - To discuss current state of physical and psychological, attitude of life of participants -To introduce the PBSP	Bandura's SE theory described four different influence procedures or sources of SE: own experiences, vicarious experience, verbal persuasion, and emotional arousal.	1. The researcher say hello and introduce herself to the participants 2. The researcher describes the research objectives and program details. 3. The researcher encouraged participant to express their feelings. 4. RA (XW) inform and introduce PBSP in wards (breast cancer surgery and oncology department) at the Yancheng NO.1 People's Hospital in Jiangsu, China. 5. RA meet one by one on site.	Every participant talks about experiences and prior knowledge before gaining knowledge about Breast Cancer.
Session2: Touching PBSP (Week 1)	-To join in Learning group	Regarding the self-efficacy theory, own experiences have been found to have the highest impact on SE	Learning group, provides 10 topics about breast cancer postoperative and chemotherapy, including two parts:	1. Every participant should watch 10 videos during the week 1.

<p>Session 3: Coming into your world (Week 2)</p>	<p>- To join in Ask-the-expert & discuss group</p>	<p>beliefs and thereby on future behavior. In PBSP, Own experiences include the provision of symptom management knowledge in the Learning group.</p>	<p>1. Breast cancer postoperative Education: 1) exercise and recovery. 2) how to deal with upper limb lymphoedema. 3) follow-up notice. 2. breast cancer chemotherapy: 4)making healthier food choices. 5) how to manage mental health. 6) sleep management. 7) alopecia management. 8) vomiting management. 9) constipation management. 10) oral mucositis management.</p>	<p>2.Each video can be watched repeatedly, but at least once in its entirety. 3.Each video has a recording sheet, is used to record what the participant gets from videos.</p>
<p>Session 3: Coming into your world (Week 2)</p>	<p>- To join in Ask-the-expert & discuss group</p>	<p>Regarding the self-efficacy theory, vicarious experience is the second source and includes all experiences observed by the individual him/herself. Model learning builds on vicarious experiences by observing others and drawing conclusions for one's own behavior and its predictors. In PBSP, verbal persuasion comes from feedback and verbal cues</p>	<p>1. A oncologist will attend the ask-the-expert group, Dr. Lei-Lei Tao, PhD, oncologist. His research area is chemotherapy for breast tumors. This group opening time is 9:00-12:00 am on Tuesday. 2.Discuss group opening time is 12:00-13:00 pm on Tuesday. 3. PI can receive all questions from participants in anytime, encountering private issues, ask doctor alone.</p>	<p>Ask-the-expert group: The participant may ask questions what they record it during watching videos. Discuss group: The group is presiding by the researcher, and the participants can discuss all problems in the group.</p>

<p>Session 4: Together for a Shared Future (Week 3)</p>	<p>- To join in Personal stories group</p>	<p>from peers and health care professionals in the Discussion group and Ask-the-Expert group.</p> <p>In PBSP, vicarious experiences involve reading others' personal stories in the Personal Stories group, and the learning materials and sharing of experiences may modify patient's perceptions of their expected arousal states.</p>	<p>Personal Stories group: recorded interviews with three women. The criteria of three women: three women who completed chemotherapy after breast cancer diagnosis and surgery will be available, have strong language skills, and can be able to convey positive energy.</p>	<p>1.The researcher will invite participants watch a video, named 'Live with the disease and be a normal person' . 2.The participant should prepare the reflection of the whole activities, before the PI meets every participant person onsite.</p>
<p>Week 3: Stage feedback</p>	<p>To obtain post-test data</p>	<p>RA(DY) measure by using SCSES, MDASI, HADS, (EORTC) QLQ-C30.</p>		
<p>Week 7: The extension of AI(Love)</p>	<p>To obtain the follow up data</p>	<p>RA(DY) measure by using SCSES, MDASI, HADS, (EORTC) QLQ-C30 during the follow up time.</p>		

The phone-based Support Program (PBSP)

Register for PBSP



Install WeChat App
on mobile phone



Scanning code



Add each other as
friends



Enter different
groups separately

Four components of the PBSP based on Bandura's self-efficacy theory



Learning Group



Discussion &
Ask-the-Expert group



Personal Stories group

Work interface display for PBSP



PI push relevant videos as scheduled in Learning Group



All videos are uploaded to the public account



Interaction between doctor and patient in Discussion & Ask-the-Expert group



Communicate after watching other patients' self-report videos in the personal stories group

Health education on 10 common issues related to breast cancer in Learning Group

乳腺癌患者术后患肢功能锻炼
Breast Cancer Surgery
— Functional exercise for the affected limb

乳腺癌患者术后随访
Breast Cancer Surgery
— Follow Up

乳腺癌术后预防患肢淋巴水肿
Breast Cancer Surgery
— how to deal with upper limb lymphoedema

乳腺癌患者心理健康管理
Breast Cancer Patients
— Mental health management

乳腺癌患者的饮食
Breast Cancer Patients
— Food choices and questions

如何处理化疗引起的呕吐?
Breast Cancer
— how to deal with vomiting caused by chemotherapy drugs

如何处理化疗引起的口腔炎?
Oral mucositis caused by chemotherapy

乳腺癌患者的睡眠管理
Breast Cancer
— Sleep Management

如何预防化疗引起的便秘?
Constipation prevention after chemotherapy

如何应对化疗引起的脱发?
Breast Cancer
— how to deal with hair loss caused by chemotherapy drugs

Chinese and English version of the booklet on functional exercises for breast cancer after surgery three months in Learning Group

Rehabilitation exercises for affected limbs after breast surgery
(For three months after surgery)

乳腺术后患肢功能康复操

(适用于术后3个月患者)
制作者: 盐城市第一人民医院乳腺外科护理组
演 示: 徐媛媛

盐城市第一人民医院
YANCHENG NO.1 PEOPLE'S HOSPITAL

Chinese version of the booklet on functional exercises for breast cancer after surgery three months in Learning Group

乳腺术后患肢功能康复操

(适用于术后3个月患者)
盐城市第一人民医院甲乳外科

盐城市第一人民医院
YANCHENG NO.1 PEOPLE'S HOSPITAL

Videos of three patients talk about their illness experiences in Personal stories Group



Video Comments

Your Name: _____

Video Number	Watching Date	Video name	Do you think what you get from video?
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			



APPENDIX B

Ethical document

สำเนา

ที่ IRB3-018/2566



เอกสารรับรองผลการพิจารณาจริยธรรมการวิจัยในมนุษย์
มหาวิทยาลัยบูรพา

คณะกรรมการพิจารณาจริยธรรมการวิจัยในมนุษย์ มหาวิทยาลัยบูรพา ได้พิจารณาโครงการวิจัย

รหัสโครงการวิจัย : G-HS103/2565

โครงการวิจัยเรื่อง : Effectiveness of a phone-based support program on self-care self-efficacy, psychological well-being, and quality of life among women newly diagnosed with breast cancer undergoing chemotherapy: a randomized controlled trial

หัวหน้าโครงการวิจัย : MRS.XI CHEN

หน่วยงานที่สังกัด : คณะพยาบาลศาสตร์

BUU Ethics Committee for Human Research has considered the following research protocol according to the ethical principles of human research in which the researchers respect human's right and honor, do not violate right and safety, and do no harms to the research participants.

Therefore, the research protocol is approved (See attached)

1. Form of Human Research Protocol Submission Version 2: 17 February 2023
2. Research Protocol Version 1: 19 January 2023
3. Participant Information Sheet Version 2: 17 February 2023
4. Informed Consent Form Version 1: 19 January 2023
5. Research Instruments Version 1: 19 January 2023
6. Others (if any) Version 1: -

วันที่รับรอง : วันที่ 14 เดือน มีนาคม พ.ศ. 2566

วันที่หมดอายุ : วันที่ 14 เดือน มีนาคม พ.ศ. 2567

ลงนาม *Assistant. Professor Ramorn Yampratoom*

(*Assistant. Professor Ramorn Yampratoom*)

Chair of The Burapha University Institutional Review Board

Panel 3 (Clinic / Health Science / Science and Technology)



盐城市第一人民医院伦理委员会

科研项目伦理审查批准件

伦审号【2022】-（K-103）

项目名称	基于电话的支持项目在首发乳腺癌化疗患者中的应用		
申请人	陈曦	申请专业	护理学
审查人所在单位	盐城市第一人民医院		
审查材料	试验方案	有 <input checked="" type="checkbox"/> 无 <input type="checkbox"/>	审查途径 会议审查 <input type="checkbox"/> 快速审查 <input checked="" type="checkbox"/>
	知情同意书	有 <input checked="" type="checkbox"/> 无 <input type="checkbox"/>	
	申报书	有 <input type="checkbox"/> 无 <input checked="" type="checkbox"/>	

伦理委员会审评意见

项目符合伦理学基本原则，同意。

主任委员签名:



日期:

2022.12.6



APPENDIX C

List of experts



บันทึกข้อความ

ส่วนงาน บัณฑิตวิทยาลัย มหาวิทยาลัยบูรพา โทร. ๒๗๐๐ ต่อ ๗๐๗, ๗๐๕, ๗๐๑
 ที่ อว ๘๑๓๗/๓๙๐๒ วันที่ ๒๖ ตุลาคม พ.ศ. ๒๕๖๕
 เรื่อง ขอเรียนเชิญเป็นผู้ทรงคุณวุฒิตรวจสอบความตรงของเครื่องมือวิจัย

เรียน ผู้ช่วยศาสตราจารย์ ดร.เขมรดี มาสิงบุญ (คณะพยาบาลศาสตร์)

ด้วย Mrs. XI CHEN รหัสประจำตัวนิสิต ๖๓๘๑๐๐๕๒ นิสิตหลักสูตรปรัชญาดุษฎีบัณฑิต สาขาวิชา
 พยาบาลศาสตร์ (หลักสูตรนานาชาติ) คณะพยาบาลศาสตร์ ได้รับอนุมัติเค้าโครงดุษฎีนิพนธ์เรื่อง “Effectiveness of
 a Phone-based Support Program on Self-care Self-efficacy, Psychological Well-being, and Quality of
 Life Among Women Newly Diagnosed with Breast Cancer Undergoing Chemotherapy: A Randomized
 Controlled Trial” โดยมี รองศาสตราจารย์ ดร.นุจรี ไชยมงคล เป็นประธานกรรมการควบคุมดุษฎีนิพนธ์ และเสนอท่าน
 เป็นผู้ทรงคุณวุฒิตรวจสอบความตรงของเครื่องมือวิจัยนั้น

ในการนี้ บัณฑิตวิทยาลัย มหาวิทยาลัยบูรพา จึงขอเรียนเชิญท่านซึ่งเป็นผู้ที่มีความรู้ ความสามารถ
 และประสบการณ์สูง เป็นผู้ทรงคุณวุฒิตรวจสอบความตรงของเครื่องมือวิจัย โดยนิตได้ส่งเค้าโครงเล่มดุษฎีนิพนธ์
 (ฉบับย่อ) และเครื่องมือวิจัยไปให้ท่านเรียบร้อยแล้ว ทั้งนี้ สามารถติดต่อนิตตั้งรายนามข้างต้นได้ที่หมายเลขโทรศัพท์
 +๘๖-๑๕๙๔-๙๑๔๒-๑๑๓ หรือที่ E-mail: 124512121@qq.com

จึงเรียนมาเพื่อทราบและโปรดพิจารณา

(รองศาสตราจารย์ ดร.นุจรี ไชยมงคล)
 คณบดีบัณฑิตวิทยาลัย



MHESI 8137/1504

Graduate School, Burapha University
169 Longhad Bangsaen Road,
Saensuk, Muang, Chonburi
Thailand, 20131

October 26th, 2022

Dr. Lei-Lei Tao
Oncologist, Department of Medical Oncology,
Yancheng No.1 People's Hospital,
No.66, Renmin South Road, Yancheng City,
Jiangsu Province, China

Subject: Invitation to be an expert content to validate research instruments

Dear Dr. Lei-Lei Tao

Enclosure: 1. Thesis proposal
2. Research instruments

Mrs. Xi Chen, student ID 63810052, a graduate student of the Doctor of Philosophy in Nursing Science (International Program), Faculty of Nursing, Burapha University, Thailand, was approved her dissertation proposal entitled: "Effectiveness of a phone-based support program on self-care self-efficacy, psychological well-being, and quality of life among women newly diagnosed with breast cancer undergoing chemotherapy: a randomized controlled trial" under supervision of Assoc. Prof. Dr. Nujjaree Chaimongkol, the principle advisor and offer you to be an expert content.

On behalf of the Graduate School, Burapha University, therefore, I would like to invite you who are highly knowledgeable, capable and experienced being a qualified person to validate the research instruments (as attached). You can contact Mrs. Xi Chen via mobile phone +86-1594-9142-113 or E-mail: 124512121@qq.com

Please kindly consider.

Sincerely yours,

(Assoc. Prof. Dr. Nujjaree Chaimongkol)
Dean of Graduate School, Burapha University

Graduate School Office
Tel: +66 3810 2700 ext. 701, 705, 707
E-mail: grd.buu@go.buu.ac.th
http://grd.buu.ac.th





MHESI 8137/1503

Graduate School, Burapha University
169 Longhad Bangsaen Road,
Saensuk, Muang, Chonburi
Thailand, 20131

October 26th, 2022

Xiaomei Xu
Oncology Nurse, Department of Medical Oncology,
Yancheng No.1 People's Hospital,
No.66, Renmin South Road, Yancheng City,
Jiangsu Province, China

Subject: Invitation to be an expert content to validate research instruments

Dear Xiaomei Xu

Enclosure: 1. Thesis proposal
2. Research instruments

Mrs. Xi Chen, student ID 63810052, a graduate student of the Doctor of Philosophy in Nursing Science (International Program), Faculty of Nursing, Burapha University, Thailand, was approved her dissertation proposal entitled: "Effectiveness of a phone-based support program on self-care self-efficacy, psychological well-being, and quality of life among women newly diagnosed with breast cancer undergoing chemotherapy: a randomized controlled trial" under supervision of Assoc. Prof. Dr. Nujaree Chaimongkol, the principle advisor and offer you to be an expert content.

On behalf of the Graduate School, Burapha University, therefore, I would like to invite you who are highly knowledgeable, capable and experienced being a qualified person to validate the research instruments (as attached). You can contact Mrs. Xi Chen via mobile phone +86-1594-9142-113 or E-mail: 124512121@qq.com

Please kindly consider.

Sincerely yours,

(Assoc. Prof. Dr. Nujaree Chaimongkol)
Dean of Graduate School, Burapha University

Graduate School Office
Tel: +66 3810 2700 ext. 701, 705, 707
E-mail: grd.buu@go.buu.ac.th
<http://grd.buu.ac.th>

เอกสารนี้ลงนามด้วยลายเซ็นอิเล็กทรอนิกส์ ตรวจสอบได้ที่ (<https://e-sign.buu.ac.th/verify>)





APPENDIX D

Permission to use the instruments

Instrument Use Agreement

I, Ms. Chen Xi, am requesting to use the The Self-Care Self-Efficacy Scale - Chinese Version instrument in My doctoral dissertation entitle "Effectiveness of a phone-based support program on self-care self-efficacy, psychological well-being, and quality of life among women newly diagnosed with breast cancer undergoing chemotherapy: A randomized controlled trial"

I agree to these Terms and Conditions:

- Not to change the self-care instrument in anyway without explicit permission of the instrument author.
- To calculate scores in the manner prescribed (see website and publications).
- To properly cite the instrument in all publications using it, referring to the original publication.
- Not to include the instrument itself in any publication because that transfers the copyright to the journal publisher.

Note that we encourage all users of our self-care instruments to always measure confidence because confidence has been shown repeatedly to be associated with success in performing self-care. If the instrument you have chosen does not include items addressing confidence (usually the last section of the instrument), please request permission to use the Self care Self efficacy scale (available on the website).

The instrument authors agree to these Terms and Conditions:

- You have permission to use this instrument in your research now and in perpetuity, if the terms and conditions of this agreement continue to be met.

Signature of User: Chen Xi Date: 8th, July, 2022

Signature of Instrument Author: Barbara Riegel Date: July 8, 2022

DocuSign Envelope ID: 8CB6ADD9-4C66-4B7E-AAD6-613BF820502A

SYMPTOM ASSESSMENT TOOL LICENSE AGREEMENT

This Symptom Assessment Tool License Agreement (the "Agreement," including both Part I License Information and Part II Terms & Conditions) is entered into as of the Effective Date by and between The University of Texas M. D. Anderson Cancer Center ("MD Anderson") and the Licensee identified below. MD Anderson and Licensee may each hereinafter be individually referred to as a "Party" and collectively as the "Parties."

Under certain license agreements with Symptom Assessment Systems, LLC, MD Anderson has obtained the exclusive right to grant a license to use, reproduce, and/or distribute copies of, the Symptom Assessment Tool. Licensee desires to obtain the right to use, reproduce, and/or distribute copies of, the Symptom Assessment Tool for the Permitted Use described herein.

NOW, THEREFORE, in consideration of the promises, conditions, covenants and warranties herein contained, the Parties agree as follows:

PART I LICENSE INFORMATION

1.	Licensee	Name: Burapha University	
		ATTN: Chen Xi	
		Address Line 1: 169 Longhard Bangsaen Road	
		Address Line 2: Chon Buri, Chon Buri 20131	
		Address Line 3: Thailand	
		Address Line 4: N/A	
		Email Address: 124512121@qq.com	
2.	Permitted Use	Student research (thesis, dissertation)	
3.	Symptom Assessment Tool	MDASI-CORE Chinese-Simplified, Chinese-Traditional	
4.	License Fee:	\$100.00	

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Agreement.

Licensee (see Item 1, above)

Signed: Chen Xi
(signature of representative)

Name: Chen Xi
(printed name of representative)

Title: PhD candidate
(position within Licensee organization)

Date: 6th. August, 2022
(date signed by representative)

The University of Texas M.D. Anderson Cancer Center

Signed: Andrew Dennis
(signature of representative)

Name: Andrew Dennis
(printed name of representative)

Title: Managing Director
(position within MD Anderson)

Date: 8/16/2022 | 11:22 AM CDT
(date signed by representative)

Part II Terms & Conditions are available at the following URL:
<https://www.mdanderson.org/content/dam/mdanderson/documents/about-md-anderson/about-us/Office-of-Technology-Commercialization/Terms-Conditions-BPI,MDASI,v11,NMD951.pdf>

HADS Work Order

Work order No. 2211143
Under Master User License Agreement

This Work Order is issued under the Master User License Agreement by and between Mapi Research Trust ("MRT") and Chen Xi (Burapha University) ("User"). Upon execution by both Parties, together with the Master User License Agreement dated ("MULA"), this Work Order identifies and governs the licensing by MRT of the COA referenced herein ("COA"), and is made a part of and is subject to the MULA.

This Work Order ("WO") is in addition to any and all previous Work Orders under the MULA.

This WO includes the terms and conditions of the MULA, which are hereby incorporated by this reference as though the same was set forth in its entirety and shall be effective as of the WO Effective Date set forth herein.

All capitalized terms which are not defined herein shall have the same meanings as set forth in the MULA.

This WO, including all attachments and the MULA contain the entire understanding of the Parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. If the terms and conditions of this WO or any attachment conflict with the terms and conditions of the MULA, the terms and conditions of the MULA will control, unless this WO specifically acknowledges the conflict and expressly states that the conflicting term or provision found in this WO controls for this WO only. This WO may be modified only by written agreement signed by the Parties.

1. User information

MULA Reference	Burapha University_TH_435502_MULA_20220822
User name	Chen Xi
Category of User	Student
User address	Long Had Bangsaen Road, Saen Suk, Chon Buri Distict, Chon Buri 2013, chon buri, 20260, Thailand
User VAT number	
User email	124512121@qq.com
User phone	
Billing information (if different from the above)	Legal form: Address: Country: VAT number (if applicable): Addressee: PO number of internal reference (if applicable):

2. WO information

WO Number	2211143
-----------	---------

HADS Work Order

WO Effective Date	Last date of signature of this WO by the Parties
WO Expiration Date ("Term")	<ul style="list-style-type: none"> Fixed-term license: upon completion of the Stated Purpose, as defined in 4.1
Name of User's contact in charge of the WO	Chen Xi

3. Identification of the COA

Name of the COA	HADS - Hospital Anxiety and Depression Scale
Author	Snaith RP; Zigmond AS;
Copyright Holder	GL Assessment Ltd
Copyright notice	HADS copyright © R.P. Snaith and A.S. Zigmond, 1983, 1992, 1994. Record form items originally published in Acta Psychiatrica Scandinavica 67, 361-70, copyright © Munksgaard International Publishers Ltd, Copenhagen, 1983. Published by GL Assessment Limited, 1st Floor Vantage London, Great West Road, London TW8 9AG, UK. All rights reserved. GL Assessment is part of the GL Education Group.
Bibliographic reference	Snaith RP. The Hospital Anxiety And Depression Scale. Health and Quality of Life Outcomes. 2003 Aug; 1:29 (Full text article) White D, Leach C, Sims R, Atkinson M, Cottrell D. Validation of the Hospital Anxiety and Depression Scale for use with adolescents. Br J Psychiatry. 1999 Nov;175:452-4 Herrmann C. International experiences with the Hospital Anxiety and Depression Scale - a review of validation data and clinical results. Journal of Psychosomatic Research 1997;42(1):17-41 Zigmond AS, Snaith RP. The Hospital Anxiety and Depression Scale. Acta Psychiatr Scand 1983;67:361-370
Module(s)/version(s) needed	

4. Context of use of the COA

The User undertakes to use the COA solely in the context of the Stated Purpose as defined hereafter.

4.1 Stated Purpose

Other project

Title	EFFECTIVENESS OF A PHONE-BASED SUPPORT PROGRAM ON SELF-CARE SELF-EFFICACY, PSYCHOLOGICAL WELL-BEING, AND QUALITY OF LIFE AMONG WOMEN NEWLY DIAGNOSED WITH BREAST CANCER UNDERGOING CHEMOTHERAPY: A RANDOMIZED CONTROLLED TRIAL
-------	--

HADS Work Order

Disease or condition	
Planned Term*	Start: 09/2022 End: 04/2024
Description (including format or media)	

4.2 Language Versions

4.2.1 Country and languages

MRT grants the License to use the COA on the following countries and in the languages indicated in the table below:

Language	For use in the following country	Availability
Chinese	China (Simplified)	Available

5. Price and payment terms

In consideration for the License granted under this WO, the User agrees to pay the following amount:

MRT Fees	Royalty fees	Total
0 euros	0 euros	0 euros

For the review and approval of the Screenshots of the original version of the COA, the User shall sign a Proposal for Screenshots review with MRT and pay the associated fees.

HADS Work Order

6. Specific requirements for the COA

- The Copyright Holder of the COA has granted ICON LS exclusive rights to translate the COA in the context of commercial studies or any project funded by for-profit entities. ICON LS is the only organization authorized to perform linguistic validation/translation work on the COA.
- In case the User wants to use an e-Version of the COA, the User shall send the Screenshots of the original version of the COA to MRT or ICON LS for review and approval. The Screenshots review may incur additional fees.
- In case the User wants to use an e-Version of the COA, ICON LS shall update (if needed) and populate the COA translations into the User's or IT Company's system and the User shall send the Screenshots of the translations of the COA to ICON LS for approval. The update (if needed), population of translations and the Screenshots review may incur additional fees.
- The User shall ensure that all persons administering the COA are qualified personnel or are working under the supervision of one or more appropriately qualified persons.
- Please include cost of the HADS Manual at €62.95 per copy (plus shipping) in any quote: Yes No
- Quantity required:0.....
- TOTAL MANUAL/S COSTS: € [.....0.....]
- MRT's processing fees: € [.....0.....]
- TOTAL SHIPPING COSTS: € [.....0.....]
- TOTAL COST: € [.....0.....]
- Ship to (name, address, phone, email required):
- Please note that neither GL Assessment (GLA) nor the Mapi Research Trust (MRT) hold the rights to the following translated HADS questionnaires:
- GERMAN language translation of the HADS. If you require the German translation of the HADS, please contact Sylvia.Schlutius@hogrefe.ch at Hogrefe AG, Bern, Switzerland.
- Please do not include any number of administrations that are intended for the German HADS translation usage on this form as you may be charged twice.
- Permission to use the HADS from a user based in the United Kingdom/ Republic of Ireland/ Channel Islands are managed by GL Assessment. For other countries, permissions are managed by Mapi Research Trust.

EXECUTED, as of the WO Effective Date, by the duly authorized representatives as set forth below.

MAPI RESEARCH TRUST

Signature: Michel Michel, Director PCS

Name: Michel Michel, Director PCS

Chen XI (BURAPHA UNIVERSITY)

Signature: Chen Xi

Name:



HADS Work Order

Title: _____

Title:

Date: 17 Oct 2022 16:59:15 UTC (Z)

Date: 18 Oct. 2022

Your request for an EORTC-questionnaire Request ID : 97024 ☆**NO** no-reply 发给 124512121 邮件可翻译为中文 [立即翻译](#)

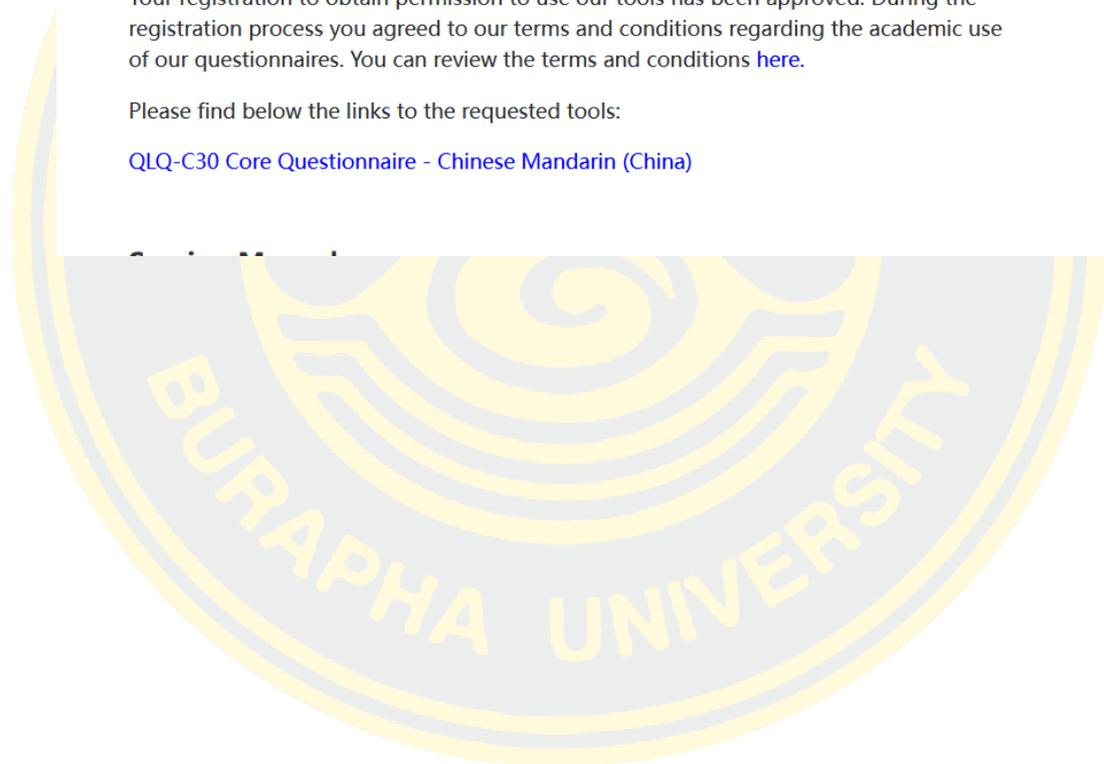
Dear Xi Chen,

Thank you for registering on the EORTC Quality of Life Group website.

Your registration to obtain permission to use our tools has been approved. During the registration process you agreed to our terms and conditions regarding the academic use of our questionnaires. You can review the terms and conditions [here](#).

Please find below the links to the requested tools:

[QLQ-C30 Core Questionnaire - Chinese Mandarin \(China\)](#)





APPENDIX E

Informed consent form



Participant Information Sheet

Research protocol code: G-HS103/2565

(A research code will be assigned by the Burapha University Institutional Review Board Office upon completing the submission)

Research Title: Effectiveness of a phone-based support program on self-care self-efficacy, psychological well-being, and quality of life among women newly diagnosed with breast cancer undergoing chemotherapy: a randomized controlled trial

Dear (address the participants)

I am Mrs. Chen Xi, a doctoral nursing student at Faculty of Nursing, Burapha University, would like to invite you to participate in a reach project, entitled 'Effectiveness of a phone-based support program (PBSP) on self-care self-efficacy, psychological well-being, and quality of life among women newly diagnosed with breast cancer undergoing chemotherapy: a randomized controlled trial', Before agreeing to participate in this project, the details of the projects are as follows:

I invite you to participate in a research study. The objective of this study is: To determine the effectiveness of phone-based support program for women newly diagnosed with breast cancer undergoing chemotherapy by comparing patients' self-care self-efficacy, psychological well-being, and quality of life.

This is a program of nursing intervention for women with breast cancer who are undergoing chemotherapy developed by the researcher based on Bandura's self-efficacy theory. The program aims to enhance self-care self-efficacy, and decrease symptom distress, anxiety and depression of the patients. This intervention focuses on providing a new and available health education method for women with breast cancer through a phone-based application in addition to attend face-to-face support services, the duration takes 3 weeks.

Separately, if you decide to volunteer for the research study, you will also complete pretest, posttest and follow-up measures, a multiple-choice questionnaire on your level during undergoing chemotherapy, and a demographic questionnaire. Volunteers will be randomly assigned to either a control group or an intervention group.

The control group will receive the routine care involves professional guide from doctors and nurses of the hospital during the two-day hospitalization for each cycle of chemotherapy. and complete the pretest, posttest, and follow-up measures. Before treatment commences, nurse will provide information on chemotherapy and possible side effects. The control group may freely use the internet to search for information about breast cancer. However, after completion of the study data collection, the researcher will provide them to access the PBSP app by their own. The participants both the experiment and control groups will receive routine care.

The intervention group will receive phone-based support program and routine care. The PBSP is a multi-component intervention that based on a mobile application: WeChat, and includes a Learning group, a Discussion group, an Ask-the-Expert group, and a Personal Stories group. Four factors from the self-efficacy theory, including mastery experiences (performance outcomes), vicarious experience, verbal persuasion, and emotional arousal are incorporated into the PBSP. Regarding the self-efficacy theory, own experiences include the provision of symptom management knowledge in the Learning group; vicarious experiences involve reading others' personal stories in the Personal Stories group and sharing experiences in the Discussion group; verbal persuasion comes from feedback and verbal cues from peers and health care professionals in the Discussion group and Ask-the-Expert group; and the learning materials and sharing of experiences may modify patient's perceptions of their expected arousal states.

The scores of anxiety and depression will be as an individual in a pool of the sample, and that will not be able to indicate which score belong to whom. At the beginning of the study, the researcher applies good communication skills to gain the first trust and establish a good nurse-patient relationship. When the researcher talks to the patient for the first time, she should pay attention to creating a relaxed conversation atmosphere. During the study, if a participant shows a sign of anxiety or depression, such as difficulty sleeping, reluctant to talk, loss of appetite and so on, the researcher can notice these. When talking, the researcher pay attention to the speed of speech, can give the appropriate name according to the patient's status, position, cultural level, occupation, age, during the communication process, be good at listening, listening reflects the respect and understanding of the patient, do not easily interrupt the patient, do not give an evaluation of the patient's views, but guide the patient to evaluate from an objective perspective themselves, provide the patient with some coping strategies, such as optimistic response, try to think of the good The patient should try to maintain a normal life without being bothered by the disease. However, if a participant shows a heaving sign of anxiety or depression, the researcher will refer that participant to consult a psychologist at the site hospital, and do the combined multidisciplinary treatment.

It is not known if you will personally benefit from participating in this research study. However, what we learn from this study regarding the benefits of using PBSP to enhance self-care self-efficacy, and psychological well-being.

There are minimal risks involved in participating in this study. For some participants, answering questions about one's level of fear thing may be uncomfortable. Please note that if you do experience any discomfort while completing this study, you may discontinue at any time. All participants will be provided with a small gift (approximately RMB ¥50) when they returned their questionnaires.

I will not ask you for your name or any other identifying information. The questionnaire will remain anonymous and will not be linked with this consent document. Data will be stored on the principal investigators password-protected computer and only this investigator will have access to it.

Any information obtained about you as a result of your participation in this research will be kept as confidential as legally possible. Specifically, the materials will be kept in a locked file and locked room of Nursing Documents, and the data will be stored on a secure, password-protected computer. Consent documents will be kept separate from the data, and there will be no identifying information on the data. Only participant numbers will be used in the main database, which will be assigned at the time of recruitment; these numbers will in no way be linked with any names or identifying information. Data and materials will be kept for seven years after completion of the study, at which time all paper copies will be shredded and electronic records will be permanently destroyed.

If you would like to know the overall findings of this study, you may contact Chenxi at 124512121@qq.com; otherwise, you will not be informed of the results. Your participation in this study is completely voluntary. You are free to withdraw your consent and remove yourself from participation in this study at any time, without penalty, and this will not affect your grade for this course. If you decide not to participate in this study, it will in no way affect your grade in this course. It will not cost you to participate in this study, and you will not be compensated for your participation.

The research will be conducted by Mrs. Chen Xi under the supervision of my principal advisor, Assistant Professor Dr. Nujjaree Chaimongkol. If you have any questions, please contact me at mobile number: +8615949142113 or by email 124512121@qq.com and/or my advisor's e-mail address pornchai@buu.ac.th. Or you may contact Burapha University Institutional Review Board (BUU-IRB) telephone number: **+66 38102620**. Your cooperation is greatly appreciated. You will be given a copy of this consent form to keep. Including the researcher's contact information, affiliation, phone number, or email address for the participants/ subjects in case they have any questions.

Include the following statement "If the researchers do not follow the research protocol as stated in in the Participant Information Sheet, please contact Burapha

University Institutional Review Board Office, Burapha University (Division of Research and Innovation), Tel. 038-102620 at the end of the information sheet.

Mrs. Chen Xi





Consent Form

研究编号: 2022-K-103

题目: 基于电话的支持计划对新诊断为乳腺癌并正在接受化疗的妇女的自我护理自我效能、心理健康和生活质量的有效性: 一项随机对照试验

----年----月----日

在签名之前, 研究人员陈曦女士已经向我详细介绍了参与本研究的目的、方法、程序、益处和可能的风险, 我也理解所有的解释。我自愿同意参与本研究。我明白, 我有权在任何时候退出研究, 而不会受到任何惩罚, 也不会影响任何课程的成绩。

研究员陈曦女士已向我解释, 参与者的所有数据和信息都将被保密, 并只用于本研究。我已经清楚地阅读并理解了与参与本研究有关的信息, 并在此同意书上签字。

参与者签名.....

(.....)

研究者签名

(.....)

知情同意书

尊敬的患者：

我们将邀请您参加一项基于电话的支持项目在首发乳腺癌化疗患者中的应用研究, 在您决定是否参加该项目之前, 请尽可能仔细阅读以下内容, 它可以帮助您了解该项项目以及为何要进行该项目, 项目的程序和期限, 参加后可能给您带来的益处、风险和不适。如果您愿意, 您也可以和您的亲属、朋友一起讨论, 或者请您的医生给予解释, 帮助您做出决定是否参加此项目。如有任何疑问请您向负责该项新技术新项目的医生或研究者提出。

一、项目介绍

该项目目前在国外尚处于领先水平, 目前我市尚无医院开展。国外对乳腺癌患者的疾病管理的模式多有报道。但国内却还不成熟。随着乳腺癌的发病率不断增加, 以手术联合放化疗综合治疗的开展, 使得乳腺癌患者的生存率有了很大的提升, 但也会带来一系列的并发症, 如身体、心理上不同程度的影响。该项目是以智能电话为基础制定的支持方案, 该方案简便易行, 可操作性强, 可以避免患者来回奔波, 适合患者自我管理, 提高患者的生活质量; 其次, 可为临床实践提供参考价值, 为本区域乳腺癌患者的管理提供依据。

二、项目研究资料

该项目主要操作规范: 参与该项目的患者常规接受乳腺癌术后护理、书面康复宣教单与康复运动指导, 另增加为期3周的以智能电话为基础的支持护理, 该方案形成的主要理论依据是自我效能理论, 班杜拉通过大量研究发现, 自我效能感的形成与变化受直接经验、间接经验、言语劝说、内在动力这四个因素的影响。本研究将自我效能理论运用到乳腺癌术后化疗患者的管理中, 借助微信平台实施干预。该方案共有3个阶段。首先建立以自我效能理论基础的疾病管理平台包含4个版块: 学习、专家咨询、讨论、个人故事; 其次依据这四

个版块制定相应的运行管理机制；最终对参与该方案的患者的自我护理自我效能、心理健康和生活质量方面进行评价。

该项目将在盐城市第一人民医院甲乳外科进行，预计有94名受试者自愿参加。如果在实施过程中出现任何不适，或病情发生新的变化或任何意外情况，不管是否与医疗新技术研究有关，均应及时通知您的医生，他将对此做出判断和医疗处理。该项目期间不产生任何费用。您的医疗记录(病理、理化检验报告等)将完整的保存在医院，医生(研究者)，专业学术委员会、伦理委员会和卫生监督管理部门将被允许查阅您的医疗记录，任何有关本项研究及结果的公开报告将不会披露您的个人身份。我们将在法律允许的范围内尽一切努力保护您个人医疗资料的隐私。

您可以选择不参加本项研究，或者在任何时候通知研究者后退出而不会招到歧视或报复，您的任何医疗待遇与权益不会因此而受到影响。如果您需要其他治疗，或者您没有遵守研究计划，或者发生了与研究相关的损伤或者有任何其他原因，可以不得到您的同意而被要求退出本项目研究。

您参加本项目研究是自愿的。您可随时了解与本研究有关的信息资料，如果您有与本研究有关的问题，或您发生了与研究相关的损伤，或有关于本项研究参加者权益方面的问题您可以通过(15949142113)与(研究者：陈曦)联系。

三、患者同意声明

我已经阅读了上述有关本研究的介绍，而且有机会就此项研究与医生讨论并提出问题。我提出的所有问题都得到了满意的答复。我知道参加本研究可能产生的风险和受益。我知晓参加研究是自愿的。我确认已有充足时间对此进行考虑，而且明白：我可以随时向医生咨询更多信息。我可以随时退出本研究，不会受到歧视或报复，医疗待遇与受益不会受到影响。我同样清楚，如果中途退出研究，特别是由于治疗的原因是我退出研究时，我若将病情变化告诉医生，完成相应的体格检查和理化检查，

这将对我本人和整个研究十分有利。如果因病情变化我需要采取任何其他的药物治疗,

我会事先征求医生的意见或在事后如实告诉医生。我同意卫生管理监督部门、伦理委员会或专业学术委员会查阅我的研究资料。我同意口或拒绝口除本研究以为的其他研究利用我的医疗记录和病理检查标本。

我将获得一份经过签名并注明日期的知情同意书副本。最后,我决定同意参加本项研究,并尽量遵从医嘱。

患者(受试者)签名_____

签字日期: _____年_____月_____日

联系电话:_____ 手机:_____

四、研究者声明

我确认已向患者解释了该项目的详细情况,包括其权力以及可能的受益和风险,并给其一份签署过的知情同意书副本。

研究者签名_____

签字日期: _____年_____月_____日

联系电话:_____ 手机:_____



APPENDIX F

Questionnaire (English version)

Instructions

You are being asked to complete the included surveys as part of a research project that is examining the phone-based support program among women newly diagnosed with breast cancer undergoing chemotherapy. Your participation is completely voluntary, and your completion of the surveys will serve as your consent to participate. You may choose not to answer any of the questions. Please complete the following demographic sheet and the survey. Please mark all responses clearly. If you change your response, please make sure that you clearly negate the unwanted response and that you clearly indicate the desired response. There are no right or wrong answers to any of the questions- just answer the questions truthfully. Please review each question on the demographic sheet and the survey to confirm that you answered all questions that you intended to answer. Thank you for your participation.

Section A: Demographic Form

Date: _____

Sign number: _____

Please answer the following questions. Please indicate which statement is true for you by ticking the appropriate response or writing in the space provided. Thank you!

Age:

Marital status:

- Single
- Married
- Divorced
- Widowed

Highest education level:

- Less than HS diploma
- High school
- Some college bachelor's degree
- Graduate degree Higher education

Employment status:

- Student
- Unemployed (looking for a job)
- Unemployed (not Self-employed looking for a job)
- Full-time employment
- Part-time employment

Monthly family income:

- Lower than 4000RMB
- 4000-6000RMB
- 6000-8000RMB
- More than 4000RMB

Breast cancer stage:

- 1
- 2
- 3
- 4
- unknown

TNM:**Cycle of treatment (chemotherapy):****Chemotherapy regimens:****Surgery style:**

- Mastectomy
- Lumpectomy

Section B: The Self-Care Self-Efficacy Scale

In general, how confident are you that you can: (Circle one number for each statement)

	Not Confident		Somewhat Confident		Extremely Confident
1. Keep yourself stable and free of symptoms?	1	2	3	4	5
2. Follow the treatment plan you have been given?	1	2	3	4	5
3. Persist in following the treatment plan even when difficult?	1	2	3	4	5
4. Monitor your condition routinely?	1	2	3	4	5
5. Persist in routinely monitoring your condition even when difficult?	1	2	3	4	5
6. Recognize changes in your health if they occur?	1	2	3	4	5
7. Evaluate the importance of your symptoms?	1	2	3	4	5
8. Do something to relieve your symptoms?	1	2	3	4	5
9. Persist in finding a remedy for your symptoms even when difficult?	1	2	3	4	5
10. Evaluate how well a remedy works?	1	2	3	4	5

Section D: The Hospital Anxiety and Depression Scale (HADS)

Tick the box beside the reply that is closest to how you have been feeling in the past week. Don't take too long over you replies: your immediate is best.

D	A		D	A	
		I feel tense or 'wound up':			I feel as if I am slowed down:
	3	Most of the time	3		Nearly all the time
	2	A lot of the time	2		Very often
	1	From time to time, occasionally	1		Sometimes
	0	Not at all	0		Not at all
		I still enjoy the things I used to enjoy:			I get a sort of frightened feeling like 'butterflies' in the stomach:
0		Definitely as much		0	Not at all
1		Not quite so much		1	Occasionally
2		Only a little		2	Quite Often
3		Hardly at all		3	Very Often
		I get a sort of frightened feeling as if something awful is about to happen:			I have lost interest in my appearance:
	3	Very definitely and quite badly	3		Definitely
	2	Yes, but not too badly	2		I don't take as much care as I should
	1	A little, but it doesn't worry me	1		I may not take quite as much care
	0	Not at all	0		I take just as much care as ever
		I can laugh and see the funny side of things:			I feel restless as I have to be on the move:
0		As much as I always could		3	Very much indeed
1		Not quite so much now		2	Quite a lot
2		Definitely not so much now		1	Not very much
3		Not at all		0	Not at all
		Worrying thoughts go through my mind:			I look forward with enjoyment to things:
	3	A great deal of the time	0		As much as I ever did
	2	A lot of the time	1		Rather less than I used to
	1	From time to time, but not too often	2		Definitely less than I used to
	0	Only occasionally	3		Hardly at all
		I feel cheerful:			I get sudden feelings of panic:
3		Not at all		3	Very often indeed
2		Not often		2	Quite often
1		Sometimes		1	Not very often
0		Most of the time		0	Not at all
		I can sit at ease and feel relaxed:			I can enjoy a good book or radio or TV program:
	0	Definitely	0		Often
	1	Usually	1		Sometimes
	2	Not Often	2		Not often
	3	Not at all	3		Very seldom

Section E: The Global Health Status scale from the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 (V3.0)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

	Not at All	A Little	Quite a Bit	Very Much
1. Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2. Do you have any trouble taking a long walk?	1	2	3	4
3. Do you have any trouble taking a short walk outside of the house?	1	2	3	4
4. Do you need to stay in bed or a chair during the day?	1	2	3	4
5. Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4
6. Were you limited in doing either your work or other daily activities?	1	2	3	4
7. Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8. Were you short of breath?	1	2	3	4
9. Have you had pain?	1	2	3	4
10. Did you need to rest?	1	2	3	4
11. Have you had trouble sleeping?	1	2	3	4
12. Have you felt weak?	1	2	3	4
13. Have you lacked appetite?	1	2	3	4
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4
26. Has your physical condition or medical treatment interfered with your family life?	1	2	3	4
27. Has your physical condition or medical treatment interfered with your social activities?	1	2	3	4
28. Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall health during the past week?

1 2 3 4 5 6 7

Very poor

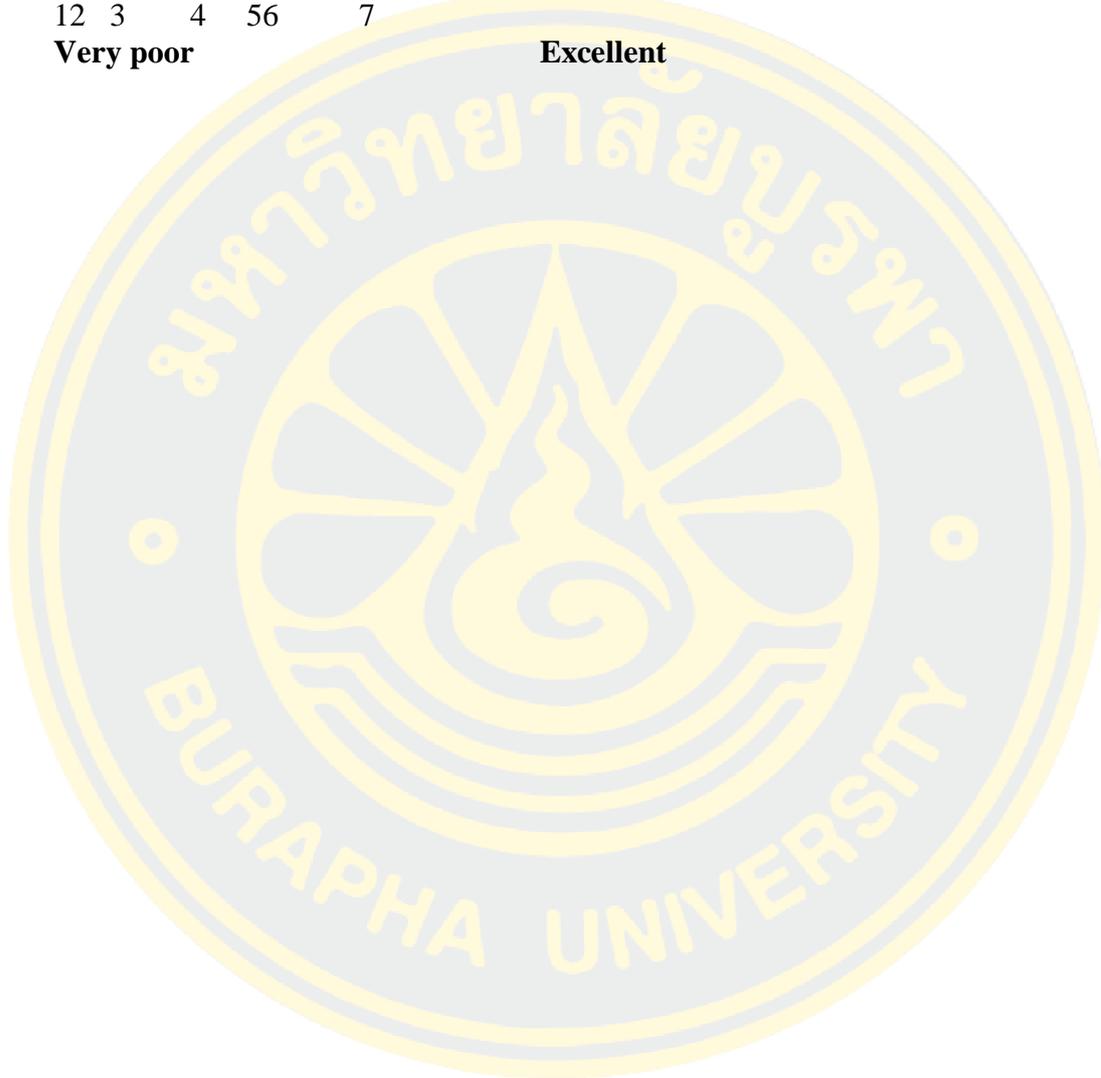
Excellent

30. How would you rate your overall quality of life during the past week?

1 2 3 4 5 6 7

Very poor

Excellent





APPENDIX G

Questionnaire (Chinese version)

第一部分：一般资料

日期： 抽签号：

请回答下列问题。请在适当的答案上打勾或在所提供的空间内书写，以表明哪项陈述对你来说是真实的。

1. 年龄： _____

2. 婚姻状况：

- 单身
- 已婚
- 离异
- 寡居

3. 学历：

- 低于高中毕业
- 高中
- 学士学位
- 研究生学位

4. 就业状况：

- 学生
- 未就业（正在找工作）
- 失业（非自营职业者在找工作）
- 全职工作
- 兼职工作

5. 家庭月收入：

- 低于 4000 元
- 4000-6000 元
- 6000-8000 元
- 超过 4000 元

6. 乳腺癌疾病分期：

- 1
- 2
- 3
- 4
- 未知

7. TNM 分期： _____

8. 治疗周期（化疗）： _____

9. 化疗方案： _____

10. 外科手术方式： _____

第二部分：自我照护自我效能问卷

在过去的一个月，请回想你如何注意自己的身体情况，以完成这份问卷。
一般来说，你有多大信心可以：（请圈出一个最合适的数字）

	没有信心		有点信心		非常有信心
1. 保持稳定的身体状况，避免出现其他的症状？	1	2	3	4	5
2. 遵循医护人员叮嘱的治疗计划？	1	2	3	4	5
3. 即使有所困难，仍继续坚持遵循治疗计划？	1	2	3	4	5
4. 惯常监测自己的状况？	1	2	3	4	5
5. 即使有所困难，仍能继续坚持监测自己的状况？	1	2	3	4	5
6. 如果你的健康出现变化，你能察觉吗？	1	2	3	4	5
7. 评估自己的症状的重要性？	1	2	3	4	5
8. 采取一些行动去减轻自己的症状？	1	2	3	4	5
9. 即使有所困难仍继续坚持去寻找控制症状的方法？	1	2	3	4	5
10. 评估治疗方法的成效？	1	2	3	4	5

第三部分：The M.D. Anderson 症状调查主要项目

第 1 部分： 您的症状有多严重？我们想知道您在**过去的 24 小时中**，下列症状的严重程度。请将下列每一项从 0（无症状）至 10（能想象的最严重程度）之间圈一数字以表示症状的严重程度。

	无症状											能想象的最严重程度										
	0	1	2	3	4	5	6	7	8	9	10	0	1	2	3	4	5	6	7	8	9	10
1.您疼痛最严重的程度为?																						
2.您疲劳(乏力)最严重的程度为?																						
3.您恶心最严重的程度为?																						
4.您睡眠不安最严重的程度为?																						
5.您苦恼(心烦)最严重的程度为?																						
6.您气短最严重的程度为?																						
7.您健忘最严重的程度为?																						
8.您胃口最差的程度为?																						
9.您瞌睡(昏昏欲睡)最严重的程度为?																						
10.您口干最严重的程度为?																						
11.您悲伤感最严重的程度为?																						
12.您呕吐最严重的程度为?																						
13.您疼痛麻木感最严重的程度为?																						

第 2 部分：您的症状干扰您生活的程度？

各种症状经常干扰我们的感觉和活动。**在过去的 24 小时中**，您的症状对以下各个项目的干扰程度如何？请选择 0（症状未带来干扰）到 10（症状带来严重干扰）表示每个项目受症状干扰的程度。

	无干扰											完全受干扰										
	0	1	2	3	4	5	6	7	8	9	10	0	1	2	3	4	5	6	7	8	9	10
14.一般活动?																						
15.情绪?																						
16.工作(包括家务劳动)?																						
17.与他人的关系?																						
18.走路?																						
19.享受生活?																						

第四部分：医院焦虑和抑郁量表 (HADS)

本调查表用以帮助医生了解您的情绪。请仔细阅读调查表的每一项目，在最接近您过去七天的心情的那一项目下划横线，不必管表格两边的数字。对您的选项不必过多考虑，您对每一项目的第一反应可能比长时间思考的结果更正确。

焦虑	抑郁			焦虑	抑郁
		我觉得紧张或感觉神经紧绷	我觉得自己好像慢吞吞的		
3		几乎总是如此	几乎总是如此		3
2		经常如此	经常如此		2
1		有时如此	有时如此		1
0		从未如此	从未如此		0
		我仍然喜欢我过去所喜欢的事物	我有些害怕，觉得心里“七上八下”的		
	0	和过去一样喜欢	从未如此	0	
	1	不像过去那么喜欢	有时如此	1	
	2	只有一点喜欢	经常如此	2	
	3	几乎都不喜欢	几乎总是如此	3	
		我有些害怕，感觉要发生什么可怕的事情	我对自己的外表不关心		
3		这感觉很确定且强烈	的确如此		3
2		有感觉，但不是很强烈	本该多留意却没有做到		2
1		有一点，但不令我担心	我可能不会那么在意		1
0		一点也没有	同以前一样在意		0
		我能够笑出来并且能够领会到事情有趣的一面	我感到坐立不安，好像控制不住地要动起来		
	0	如同过去一样	几乎总是如此	3	
	1	现在不太多了	经常如此	2	
	2	现在的确不多了	有时如此	1	
	3	根本做不到	从未如此	0	
		心里有焦虑的想法	我能够充满快乐地期待事物		
3		几乎总是如此	同以前一样		0
2		经常如此	比以前相对少		1
1		有时如此	的确大不如以前了		2
0		几乎从未如此	几乎无期待		3
		我觉得开心愉快	我会突然感到惊恐		
	3	从未如此	几乎总是如此	3	
	2	很少如此	经常如此	2	
	1	有时如此	很少如此	1	
	0	几乎总是如此	从未如此	0	
		我能够安稳地坐着并且感觉放松	我能够欣赏好书、好的广播或电视节目		
0		总是如此	经常如此		0
1		经常如此	有时如此		1
2		很少如此	不常如此		2
3		从未如此	极少如此		3

第五部分：EORTC 生命质量测定量表 QLQ-C30 (V3.0)

我们想了解有关您和您的健康的一些情况，请您亲自回答下面所有问题，这里的答案并无“对”与“不对”之分，只要求在最能反映您情况的那个数字上画圈。您所提供的资料我们将会严格保密。

	没有	有点	很多	非常多
1. 您从事一些费力的活动有困难吗，比如说提很重的购物袋或手提箱？	1	2	3	4
2. 长距离行走对您来说有困难吗？	1	2	3	4
3. 户外短距离行走对您来说有困难吗？	1	2	3	4
4. 您白天需要呆在床上或椅子上吗？	1	2	3	4
5. 您在吃饭、穿衣、洗澡或上厕所时需要他人帮忙吗？	1	2	3	4
在过去的一星期内：	1	2	3	4
6. 在工作和日常活动中是否受到限制？	1	2	3	4
7. 您在从事您的爱好或休闲活动时是否受到限制？	1	2	3	4
8. 您有气促吗？	1	2	3	4
9. 您有疼痛吗？	1	2	3	4
10. 您需要休息吗？	1	2	3	4
11. 您睡眠有困难吗？	1	2	3	4
12. 您觉得虚弱吗？	1	2	3	4
13. 您食欲不振（没有胃口）吗？	1	2	3	4
14. 您觉得恶心吗？	1	2	3	4
15. 您有呕吐吗？	1	2	3	4
16. 您有便秘吗？	1	2	3	4
17. 您有腹泻吗？	1	2	3	4
18. 您觉得累吗？	1	2	3	4
19. 疼痛影响您的日常活动吗？	1	2	3	4
20. 您集中精力做事有困难吗，如读报纸或看电视？	1	2	3	4
21. 您觉得紧张吗？	1	2	3	4
22. 您觉得忧虑吗？	1	2	3	4
23. 您觉得脾气急躁吗？	1	2	3	4
24. 您觉得压抑（情绪低落）吗？	1	2	3	4
25. 您感到记忆困难吗？	1	2	3	4
26. 您的身体状况或治疗影响您的家庭生活吗？	1	2	3	4
27. 您的身体状况或治疗影响您的社交活动吗？	1	2	3	4
28. 您的身体状况或治疗使您陷入经济困难吗？	1	2	3	4

对下列问题，请在 1-7 之间选出一个最适合您的数字并画圈。

29. 您如何评价在过去一星期内您总的健康情况?

1 2 3 4 5 6 7

非常差

非常好

30. 您如何评价在过去一星期内您总的生命质量?

1 2 3 4 5 6 7

非常差

非常好



BIOGRAPHY

NAME Xi CHEN

DATE OF BIRTH 23 September 1988

PLACE OF BIRTH Yancheng City, Jiangsu Province, China

PRESENT ADDRESS Room 2204, Building 5, No.22 Yanhe West Road, Tinghu District, Yancheng City, Jiangsu Province, China

POSITION HELD 2012-2016 Primary nurse (RN), Yancheng city No.1 People's Hospital
2017-present Supervisor nurse (RN), Yancheng city No.1 People's Hospital

EDUCATION 2010-2012 (Bachelor of Nursing) School of Nursing, Nanjing Medical University, Jiangsu Province, China
2013-2016 (Master of Nursing) School of Medical, Yangzhou University, Jiangsu Province, China
2019-present (Doctor of Philosophy in Nursing Science International Program) Faculty of Nursing, Burapha University, Thailand

AWARDS OR GRANTS 2016 Excellent Graduate Scholarship second, Yangzhou University, Jiangsu Province, China