



**A RANDOMIZED CONTROLLED TRIAL EXAMINING
THE EFFECTS OF A MUSIC AND BIOFEEDBACK
PROGRAM ON THAI CANCER PATIENTS RECEIVING
PALLIATIVE CARE**

BY

TIPSUDA SUMNEANGSANOR

**A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT
OF THE REQUIREMENTS FOR THE DEGREE OF
DOCTOR OF PHILOSOPHY (NURSING SCIENCE)**

**FACULTY OF NURSING
THAMMASAT UNIVERSITY**

ACADEMIC YEAR 2018

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DISSERTATION

BY

MRS. TIPSUDA SUMNEANGSANOR

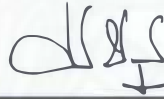
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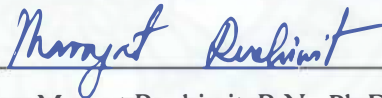
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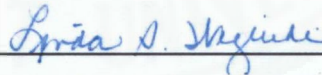
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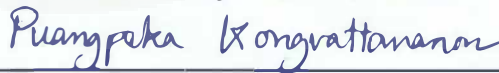
(Professor Manyat Ruchiwit, R.N., Ph.D.)

Member and Co-advisor



(Professor Linda S. Weglicki, R.N., Ph.D.)

Member



(Assistant Professor Puangpaka Kongvattananon, R.N., Ph.D.)

Member



(Assistant Professor Rangsiman Soonthornchaiya, R.N., Ph.D.)

Dean



(Associate Professor Teeranut Harnirattisai, R.N., Ph.D.)

Dissertation Title	A RANDOMIZED CONTROLLED TRIAL EXAMINING THE EFFECTS OF A MUSIC AND BIOFEEDBACK PROGRAM ON THAI CANCER PATIENTS RECEIVING PALLIATIVE CARE
Author	Tipsuda Sumneangsator
Degree	Doctor of Philosophy (Nursing Science)
Faculty/University	Faculty of Nursing Thammasat University
Dissertation Advisor	Professor Manyat Ruchiwit, R.N., Ph.D.
Dissertation Co-Advisor	Professor Linda S. Weglicki, R.N., Ph.D.
Academic Years	2018

ABSTRACT

Cancer can cause both physical and emotional symptoms, especially pain and stress. The relationship between stress and pain is complex. Stress can lead to physical effects which can increase pain. Intervention to decrease both physical and emotional symptoms is essential. The application of music together with biofeedback training for stress and pain in cancer patients is an interesting prospect. This research investigated the Effects of a Music and Biofeedback Program for Thai Cancer Patients within Palliative Care at Thammasat University Hospital. The sample size comprised 88 cancer patients by randomized controlled trial, divided into four groups with 22 cases in each group, and the total time period was 8 times. Experimental group 1 comprised cancer patients who were received music and received routine nursing care provided by Thammasat University Hospital (TUH). Experimental group 2 was a group of cancer patients who were received a biofeedback training program, and also received

routine nursing care provided by TUH, Experimental group 3 was a group of cancer patients who were received music together with a biofeedback training program, and also received routine nursing care provided by TUH, and the control group comprised cancer patients who were received routine only nursing care provided by TUH.

The instruments included: the Symptoms of Stress Inventory (SOSI), the pain score, biofeedback training, music relaxation, guidelines for stress and pain management, and a home music record. This study use advanced statistics, a repeated Measures between factors MANOVA, to determine whether there were statistically reliable mean differences among the groups. This research compared the average score of stress from the SOSI, pain score, VS, EEG, and EMG assessment of all groups.

The results of comparative analysis of stress in each time period between the three experimental groups found that the 3rd experimental group (music and biofeedback) had the highest mean during the time before the experiment. Means continuously decreased, with lowest mean in the 3rd stress. The 1st experimental group (music) and the 2nd experimental group (biofeedback) gave decreasing means, while the control group recorded higher stress means in all measurement periods. However, stress was highest in the 3rd experimental group. Moreover, The results of comparative analysis for each time period between experimental groups showed that SOSI, EEG, and EMG were significantly different in mean scores between time1 to time2, and time2 to time3 in groups 1, 2 and 3. Group 4 was not significantly different. The limitations of this study were patients with breast cancer, colorectal cancer, and cervical cancer and did not represent all types of cancer and the most participants have a very less pain or no pain (level 0-1 of pain scale) which was tolerable without medicine taken, so it

was not able to evaluate the changes of pain. Limitation of the experiment included practicing listening to music together with a biofeedback program. The researcher could not control the length of time for listening to the music and the patient's practice at home. Principles of practicing through a biofeedback program involved 8 times of correct practice with the researcher until the patients were able to self-control stress and implement the technique of relaxation by listening to the music for controlling and reducing stress effectively without using the tools. However, this study can help patients manage their stress more effectively. In addition to reducing mortality rate, lowering costs, and providing useful guidance for the prevention and treatment of cancer and the care of patients, it may also prove useful as information to support its implementation and application in nursing.

Key word: Music, Biofeedback Program, Cancer Patients, Palliative Care

ACKNOWLEDGEMENTS

This dissertation has been completely finished due to the kindness, help, and care of many people. I would like to express my sincere thanks to Prof. Dr. Manyat Ruchiwit (Major Advisor), Prof. Dr. Linda Weglicki (Co- Advisor), Prof. Dr. Sriprasit Boonvisut (Chairperson), Assist. Prof. Dr. Puangpaka Kongvattananon and Assist. Prof. Dr. Rangsiman Soonthornchaiya (Committee member) for their time, idea, and useful academic suggestions that could well facilitate this research to be successful.

Appreciation also goes to the Thammasat Radiation Oncology Center (TROC) at Thammasat University Hospital and all related staff and patients for their cooperation towards data collection.

Thank you The Royal Golden Jubilee Ph.D. Programme (RGJ) for the research funding support.

Thank you all professors of The Doctor of Philosophy Program in Nursing Science (International Program), Faculty of Nursing, Thammasat University for educating me the useful knowledge.

Thanks all obstacles for the lesson learned that make me stronger.

Finally, thank you my family members and friends for encouraging me whenever I was tired and for keep being together until today's success.

Tipsuda Sumneangsator

TABLE OF CONTENTS

	Page
ABSTRACT	(1)
ACKNOWLEDGEMENTS	(4)
LIST OF TABLES	(9)
LIST OF FIGURES	(10)
CHAPTER 1 INTRODUCTION	
1.1 Background and importance of the issue	1
1.2 Research Objectives	13
1.2.1 General purpose	13
1.2.2 Specific purpose	13
1.3 Research questions	14
1.4 The studied variables	15
1.4.1 Independent Variables	15
1.4.2 Dependent Variables	15
1.4.3 Control variables	15
1.4.4 The paired variables	16
1.5 Scope of study	16
1.6 Definition of research terms	17
1.7 Framework of the research	21
1.8 Research hypotheses	26
1.9 Expected benefits	26

CHAPTER 2 REVIEW OF LITERATURE	Page
2.1 Overview of cancer	30
2.1.1 Definition of cancer	30
2.1.2 Prevalence of Cancer: Worldwide, in Thailand, and countries leading cancer research	31
2.1.3 Cancer Risk factors	33
2.1.4 Cancer: Common signs and symptoms	38
2.1.5 Effective Cancer Interventions	40
2.2 Palliative care in cancer	42
2.2.1 Definition of palliative care	42
2.2.2 Palliative care from a worldwide perspective	43
2.2.3 Palliative care in Thailand and Palliative Care Continuum	44
2.3 Importance of stress as a risk factor in cancer patients	47
2.3.1 Definition of stress	47
2.3.2 Causes of stress in cancer patients	47
2.3.3 The stress response theory	49
2.3.4 Stress Assessment Measures	51
2.4 Importance of Pain as a major symptom in cancer patients	53
2.4.1 Definition of pain	53
2.4.2 Concept and principle of pain	54
2.4.3 Pain Assessment Measures	55
2.5 Effective and efficacious cancer-related interventions to mitigate stress and pain	58
2.5.1 Review of effective and efficacious cancer-related interventions	58
2.5.2 Music	60

	Page
CHAPTER 2 REVIEW OF LITERATURE (CONT.)	
2.5.2.1 Definition of music	60
2.5.2.2 Effects of music on the brain response and stress reduction	60
2.5.2.3 Effects of music on the brain response, pain pathways and pain reduction	61
2.5.2.4 Relaxation technique by music upon stress and pain in cancer patients	62
2.5.3 Biofeedback Training	63
2.5.3.1 Definition of biofeedback	63
2.5.3.2 Electroencephalograph (EEG) biofeedback training	64
2.5.3.3 Electromyography (EMG) biofeedback program	67
Summary and Importance of the proposed study	68
CHAPTER 3 RESEARCH METHODOLOGY	
3.1 Research Design	70
3.2 Population and sample	73
3.2.1 Population	73
3.2.2 Sample	73
3.2.3 Selection sample	74
3.2.4 Sample Size	74
3.2.5 Sampling method	74
3.3 The instruments, Questionnaires and Materials used in the research	77
3.4 Monitoring the quality of the tools	81

CHAPTER 3 RESEARCH METHODOLOGY(CONT.)	Page
3.4.1 Content validity	81
3.4.2 Reliability	82
3.4.3 Calibration of biofeedback instruments	82
3.5 Action research data collection	82
3.6 Protection of the rights of sample participants	85
3.7 Data Analysis	86
 CHAPTER 4 RESULTS	
Results	89
 CHAPTER 5 DISCUSSION AND RECOMMENDATIONS	104
Research results	106
Research limitations	112
Recommendations	112
Policy recommendations	112
Practical recommendations	113
Recommendations for further research	113
 REFERENCES	114
 APPENDICES	140
APPENDIX A The instruments	141
APPENDIX B Normal distribution testing	152
APPENDIX C The Institutional Review Board of the University	170
Ethics	
APPENDIX D Informed Consent Form, Participant Information	171
Sheet	
 BIOGRAPHY	181

LIST OF TABLES

Tables	Page
3.1 Research Design	71
4.1 Sociodemographic characteristics of the four treatment groups	92
4.2 Test of normal distribution	96
4.3 Analysis of variance homogeneity	97
4.4 Analysis of experimental group variable and 1 st stress interaction	98
4.5 Analysis of stress covariance and comparison of pair mean	98
4.6 Mauchly's test of sphericity	100
4.7 Descriptive statistics for all variables	101
4.8 Repeated measures MANOVA within-subjects and between-subjects	101
Appendix	
Age comparison between the four treatment groups	152
Summary of Skewness and Kurtosis for SOSI	155
Summary of Skewness and Kurtosis for EEG	159
Summary of Skewness and Kurtosis for EMG	163

LIST OF FIGURES

Figures	Page
1.1 Model of palliative cancer care by Von Roenn & Temel (2011)	13
1.2 The conceptual framework	25
3.1 Consort flow diagram	76
4.1 Consort flow diagram	90
Appendix	
QQ plot Analysis of stress at each time	153
Comparative analysis of stress in each time period among the four treatment groups	154
Q-Q Plot for the SOSI baseline (Time1) data	156
Q-Q Plot for the SOSI (Time2) data	157
Q-Q Plot for the SOSI (Time3) data	158
Q-Q Plot for the EEG baseline (Time1) data	160
Q-Q Plot for the EEG Time2 data	161
Q-Q Plot for the EEG Time3 data	162
Q-Q Plot for the EMG Time1 data	164
Q-Q Plot for the EMG Time2 data	165
Q-Q Plot for the EMG Time3 data	166
Estimated marginal means for SOSI	167
Estimated marginal means for EEG	168
Estimated marginal means for EMG	169

CHAPTER I

INTRODUCTION

1.1 Background and importance of the issue

In recent years, the need for palliative care has increased rapidly due to the global increase in the aging population. Palliative care began with a focus on care for the dying, particularly at the end of life stage when people are suffering from life-limiting diseases, such as cancer (Loscalzo, 2008). The World Health Organization (2014) stated that palliative care is a human right and “is a crucial part of integrated, people-centered health services” noting that “nothing is more people centered than relieving their suffering, be it physical, psychological, social, or spiritual”. As such, the WHO promotes resources to provide and develop palliative care throughout the world for both adults and children across a range of conditions. Palliative care has been recognized as an important component of the quality of life for cancer patients, as well as those with chronic conditions, and life-limiting and incurable illnesses (e.g., heart disease, organ failure, end-stage chronic illnesses, extreme frailty, etc.). The aim of palliative care concerns the prevention and relief of pain and suffering, as well as the promotion of comfort and improved well-being for patients and families (Zimmermann et al., 2014).

In recent years, the need for palliative care has increased rapidly. This is especially significant in relation to cancer, which grows and eventually spreads to vital organs. The aims of palliative care for cancer patients are to promote comfort and improve the well-being of patients and their families; this may be provided at all points along the cancer care continuum, from diagnosis to the end of life. (Krongyuth, Campbell &

Silpasuwan (2014); Khumtaveeporn, 2010). The proliferation of cancer forms has increased, while methods for improved treatment have remained limited, and the need for palliative care has escalated to become a major focus for patients and their families. As cancersymptoms worsen, more attention is needed to help control them (American Cancer Society, 2008).

Globally, based on the most current worldwide data available (WHO, 2012), cancer is one of the leading cause of death accounting for approximately 8.8 million deaths, 1 in every 6 deaths annually. Torre, Siegel, Ward and Jemal (2016) reported the number of new cancer cases at around 14 million per year; with new cases expected to increase to 35 million by 2035 (World Cancer Research Fund International, 2017). The most common forms of cancer related deaths worldwide include lung, liver, colorectal, stomach, and breast cancer (WHO, Updated February, 2017). Based on the same 2012 data, new cancer cases included lung (13%), breast (12%), colorectal (9.7%), prostate (7.9%), stomach (6.8%), and liver (5.6%) (World Cancer Research Fund International, 2017). The countries with the highest cancer rates include Denmark (for both men and women), France, Australia, Belgium, Norway, the United States, Ireland, South Korea, and the Netherlands—all with greater than 300+ people per 100,000 (age-standardized) (World Cancer Research Fund International, 2017). Just under three-quarters of cancer deaths occur in low- and middle-income countries (WHO, 2017), with higher income countries reporting lower death rates due to earlier diagnoses and access to advanced treatment options (Torre et al., 2016). Thailand, an upper-middle income country (Thailand Ministry of Health, 2012), is reported to be undergoing an epidemiological transition (Virani et al.,

2017), and is expected to see an increase in nearly all types of cancer diagnoses in the next decade; current overall rates are 140 people diagnosed per 100,000. While these increases are due to a number of factors, they are mostly influenced by the increased proportion of elderly in the Thai population (Virani et al., 2017).

In 2017, the World Health Organization defined the term cancer as “a generic term for a large group of diseases characterized by the growth of abnormal cells beyond their usual boundaries that can then invade adjoining parts of the body and/or spread to other organs.” Additionally, cancer occurs in equal proportions among men and women. The Department of Medical Services, Ministry of Public Health, Thailand, reported in 2017, 121 per 100,000 cancer rates among men and women; the most common cancers, regardless of gender, were colon or rectum cancer at 25.8% (males = 16.2%, females = 9.6%), lung at 22 % (males = 15.5%, females = 6.5%), liver at 18.9% (males = 15.3%, females = 3.6%), breast cancer in women at 37.5 %, and cervix cancer = 14.4%.

Cancer Risk Factors

There are a variety of risk factors associated with the more than 100 types of cancer. While it is generally not possible to know exactly why a person develops cancer, research has shown that certain risk factors increase a person’s chances of developing cancer- generally classified as those that can and those that cannot be controlled (National Cancer Institute, 2015). The most common controllable or behavioral risk factors include smoking, alcohol consumption, food consumption, or physical inactivity (WHO, 2017) while uncontrolled cancer risk factors include the environment, infection, or genetics

(Anand et al., 2008; Wanchai, 2016; Makboon, 2015; Wanchai, 2016; Yamashita & Wang, 2013).

Psychological factors have also been linked to cancer, particularly when associated with stress (Cormanique, Almeida, & Rech, 2015). A study conducted by the American Psychological Association (2016) illustrated that more than 50% of people identify stress as a source of personal health problems. Adults were reported to believe that stress can lead to the development of major diseases, such as heart disease, cancer, and mental disease. Stressors generally are associated with work, trauma, grief, and cancer-related malignancies (Denaro, Tomasello, & Russi, 2014). Stress, reported to be a complex and multi-factorial pathogenesis, similar to cancer, results in alterations in equilibrium within the sympathetic nervous system, hypothalamus, and immune and hormone systems, resulting in stress-induced diseases (ie., cancer) due to increased catecholamines, cortisol, neurotransmitters, hormones, and an impaired immune system (The American Cancer Society, 2017).

Cancer Symptoms

Common symptoms in cancer patients can be divided into: specific symptoms caused by cancerous organs, the most common cancer-related symptoms being pain (Prasongsook et al., 2017). The early stages may be painless but if cancer spreads to the bone or nerves it generates strong pain. Cancer is often found in patients with metastatic disease and between 50% and 90% of individuals with metastatic disease experience moderate to severe pain (Mercadante, & Cuomo, 2016; Prasongsook et al., 2017). For symptoms of side effects from treatment. One side effect is fever. Fever usually occurs when cancer has spread, especially for leukemia, and is the major cause of death for

patients with low white blood cells due to complications of chemotherapy (Cornely & Mellinshoff, 2017). Nausea, vomiting, and anorexia are common symptoms in 40-87% of advanced cancer patients that reduce the desire to receive chemotherapy (Wisuttikul, 2011). Insomnia is also found in 30-50% of cancer patients from pre-diagnosis to treatment (Tesviruch, 2015). Cancer causes difficulty in sleeping, waking up at night, difficulty in getting up early in the morning and drowsiness. These physical symptoms also affect the mental state of cancer patients; for example, patients receiving chemotherapy for at least three months were found to have high levels of stress. Moreover, more than 50% of patients experienced stress and anxiety that the symptoms would not improve with also fear of the side effects from treatment (Cameron & Waterworth, 2014; Opasrattanakorn, Detprapon & Sumdaengri, 2015) that affects the person's daily routine and quality of life (Waller, Williams, Groff, & Sandhu, 2013).

Cancer Interventions

There are many types of cancer treatment available depending on the type of cancer and how advanced it is. Some cancer patients will receive only one type of treatment, such as pharmacological, surgery, chemotherapy or radiation. However, most patients receive a combination of treatments (Thailand Cancer Rehabilitation Club, 2017).

Pharmacological treatment is mainly used in cancer patients to manage symptoms and treat side effects and commonly includes medication such as, opioids and NSAIDs for alleviating pain (Prommer, 2015). Surgery, can completely cure the disease and relieve temporary symptoms. The only cancer mass may be removed or picked away from the nearby lymph nodes and good tissue (Chaithongsakul, 2015), and chemotherapy

may be given for additional treatment. The goal is to increase the chances of a complete cure compared to using only one specific treatment (Laoitthi & Parinyanitikul, 2016), and radiation therapy uses high energy radiation to kill or stop the growth of cancer cells. It is commonly used after surgery (Demaria, Golden & Formenti, 2015). It is also well-established that many cancer treatments, particularly chemotherapy and radiation therapy, result in unfavorable side effects and suffering. For example, Mols, Beijers, Vreugdenhil, & Galantis (2014) conducted a systematic review of 25 published studies of chemotherapy-induced peripheral neuropathy and its association with the quality of life of cancer patients. The methodological quality of each of the selected articles was evaluated with a 13-item standardized checklist by two reviewers. The result showed that of the 25 included studies, 11 studied (in 25 studies) the association of chemotherapy on the quality of life in cancer patients, while the others concluded that more chemotherapy was associated with a lower quality of life in cancer patients.

There are many ways in which non-pharmacologic cancer treatments that are available can deal with symptoms in cancer patients (e.g., fear of diagnosis, treatment options and side effects, and consequences of their diagnosis on the family, etc.) (Cormanique et al., 2015) and symptoms (e.g., pain, fatigue, nausea, vomiting, diarrhea, edema, loss of appetite, and weight loss) (Greenberg et al., 2015; Martin and Lizzy, 2015; Toccafondi et al., 2017).

The most common effective non-pharmacologic interventions include: mindfulness meditation (Lengacher et al., 2012), cognitive behavioral therapy (Hofmann,

Asnaani, Vonk Sawyer, & Fang, 2012), music (Gallagher et al., 2017), and biofeedback (Alvarez, Meyer, Granoff & Lundy, 2013).

Mindfulness is a practice of meditation that mainly focuses on inward and outward breathing of one's own with the aims to develop awareness of the present moment, promote relaxation, and reduce stress and anxiety (Matchim, Armer, & Stewart, 2011). Mindfulness can be used to develop the presence of mind and reduce stress in patients with various diseases, especially cancer. Lengacher, Reich, Post-White et al (2012), who conducted a study titled "Mindfulness Based Stress Reduction in Post-Treatment Breast Cancer Patients: An Examination of Symptoms and Symptom clusters, indicated that mindfulness-based stress reduction can decrease symptoms such as fatigue, sleep disorder, stress, and anxiety and contribute to a better quality of life in cancer patients. However, Hilton et al. (2016) conducted a systematic review with meta-analyses using the Hartung-Knapp-Sidik-Jonkman method. Quality of evidence was assessed using the GRADE to examine the evidence on the efficacy and safety of mindfulness meditation interventions for the treatment of chronic pain in adults; the findings revealed low-quality evidence for mindfulness meditation in decreasing pain. While, Cherkin et al. (2016) conducted a study of 342 adults that were experiencing lower back pain and results showed both mindfulness-based stress reduction (MBSR) and cognitive behavioral therapy (CBT) have greater improvement in back pain alleviation at 26 and 52 weeks compared to regular care. There were no significant differences in outcomes between MBSR and CBT.

Music Therapy as an Effective Intervention in Pain and Stress

Music, used as an effective non-pharmacologic tool for relaxation and reducing pain in cancer patients, has been recognized for several decades (Pichler & Pichler, 2014), through which healthcare professionals encourage patients to improve their health through the rhythm and melody of music, with both psychological and physiological benefits. Music interventions have been broadly used in various health conditions. Music helps the brain to release endorphins, thereby reducing the awareness of pain and stress through the components of the gate control theory of pain (Kaliyaperumal & Subash, 2010). Presently, music continues to be used to improve the health and well-being of cancer patients (Chanda & Levitin, 2013). The influence of music as an effective tool for relaxation and reducing pain in cancer patients has been recognized for several decades (Pichler & Pichler, 2014). A number of studies support the idea of the beneficial effects of music in decreasing stress, depression, and the perception of pain in cancer patients as part of palliative care (Gallagher et al., 2017; Toccafondi et al., 2017; Warth et al., 2014). For example, Karagozoglu, Tekyasar and Yilmaz (2013) found that music therapy had positive effects on chemotherapy-induced stress, anxiety, and nausea. Warth et al. (2014) showed that music is an effective treatment for the promotion of relaxation and well-being in cancer patients. Stanczyk (2011) found that the effect of music therapy application in cancer care can be used to reduce stress, pain, and anxiety level. Music therapy is an effective form of support for patients with cancer during their treatment. The use of music therapy as a type of intervention may have value within the Thai cancer population.

Biofeedback Therapy as an Effective Intervention for Pain and Stress

Biofeedback has also been shown to be an effective approach to treating stress and reducing pain in cancer patients (Greenberg et al., 2015; Shockey et al., 2013; Wang et al., 2015). Biofeedback is a tool that patients use to develop their own stress management capabilities and has been shown to affect blood pressure, muscle tension, and chronic pain (Kaushik, 2016; Shockey et al., 2013). In cases where stress comprises a major element of the disease symptoms, patients are able to benefit from biofeedback based upon the learning model of psychophysiological psychotherapy (Ruchiwi, 2014). Patients learn to control their stress by developing awareness of stress or their physiological reactions. Through reinforced biofeedback training, the patient learns to control their emotions by themselves, eventually without the need of a biofeedback instrument (Frank, Khorshid, Kiffer, Moravec & McKee, 2010; Lemaire et al., 2011; Tsai, 2007).

Previous research conducted in Thailand, with respect to music therapy and/or biofeedback training, has been limited. Various researchers in Thailand, have studied biofeedback (Del Pozo, Gevirtz, Scher & Guarneri, 2004; Janmanee, 2013; Ruchiwit, 2012; Thongkhum, 2015) and relaxation techniques such as deep breathing and visualization (Janmanee, 2013; Ruchiwit, 2012) with children, in chronic diseases, and within chronic conditions such as heart disease; however, research is lacking regarding combined use of music and biofeedback training to reduce both the pain and stress of Thai cancer patients within palliative care. This such combination, therefore, was examined in this dissertation.

Theoretical/Conceptual Frameworks

There are a number of theoretical and conceptual frameworks used to guide research focused on palliative cancer care and that address symptoms (pain will be addressed in this study using principles from Gate Control Theory) and stress management (Selye's Stress Response Theory). All three theories/conceptual models were used to guide this dissertation.

Stress Response Theory (Selye, 2013)

For this study, the stress response theory (Selye, 2013) was used to explain the stress response and response to stressors. Stress response theory, later called the general response syndrome (GRS), leads to a three-stage stress response – Alarm reaction, resistance, and exhaustion. In the first stage of GRS, when one has stress, one's body will experience changes in the autonomic nervous system (ANS). The ANS has an effect on the epinephrine controlled by hypothalamus, which produces and increases cardiac output, blood pressure, and dilates the pulmonary airways to increase oxygen intake, thereby increasing respiratory rate and muscle tension (Kondur, 2012). In the second stage, the stage of resistance, the body tries to recover. In this stage, the body reverts to a state of physiological calmness, or homeostasis, by resisting the alarm response. If this adaptation phase continues for a prolonged period of time without relaxation to balance the stress response, patients become prone to fatigue as the effort to sustain arousal results in a negative stress. In the last stage, the stage of exhaustion, one or more target organs show

signs of dysfunction. If the stress continues beyond the body's capacity, the organism exhausts resources and becomes vulnerable to disease such as cancer (Selye, 2013).

Gate Control Theory (Melzack and Wall, 1967)

The way individuals experience pain is very complex and pain is influenced by a number of factors, such as stress and tension, psychological mood, prior experience with pain, and the underlying conditions causing the pain (Bishop, 1980). Gate-control theory (Melzack & Wall, 1967) suggests that sensory signals encounter "nerve gates" at the level of the spinal cord preventing the transmission of pain signals. Gate control theory consists of 4 major components: 1. the spinal gate mechanism; 2. the central control system; 3. the central biasing system; and 4. the action system. Each system works collaboratively to reduce pain (Melzack & Wall, 1967; Juangpanich, Onbunreang, Khansorn, Khansorn & Vatanasapt, 2012; Srisaeng & Supornpun, 2015; Lohitthai, Chemama & Siriphan, 2017). Most of the pain experienced in cancer patients is chronic pain caused by tumor compression and cancer metastasis (Juangpanich, Onbunreang, Khansorn, Khansorn & Vatanasapt, 2012). Compression results in induced nociceptors sending nerve impulses through the nerve fibers and spinal cord to the reticular formation in the brainstem, along with processing in the limbic system that induces emotional responses to pain, lowered endorphin levels, and causes anxiety and more pain to patients in a continuous cycle (Juangpanich, Onbunreang, Khansorn, Khansorn & Vatanasapt, 2012).

Model of palliative cancer care (Von Roenn and Temel, 2011)

In recent years, the need for palliative care has increased rapidly due to the growth of global aging population. The aims of palliative care are to prevent and relieve pain and suffering, as well as to promote comfort and improve well-being of patients and families (Zimmermann et al., 2014). The World Health Organization (2018) defined palliative care as, “an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual”, such as cancer. Palliative care is currently recognized as an important part of cancer care at all stages. Palliative care may be provided at all points along the cancer care palliative care continuum, from diagnosis to the end of life. The need for palliative care among those diagnosed with cancer has become a major focus for patients and their families (American Cancer Society, 2018). When a patient receives palliative care, they may continue to receive cancer treatment that results in stress, fatigue, sleep disturbance, and symptoms associated with side effects of treatment (National Cancer Institute, 2017). Therefore, prevention, relieve suffering, as well as the promotion of comfort in patients and families is important. The application of music therapy coupled with biofeedback training for stress and pain relief in cancer patients is an interesting prospect.

Model of palliative cancer care

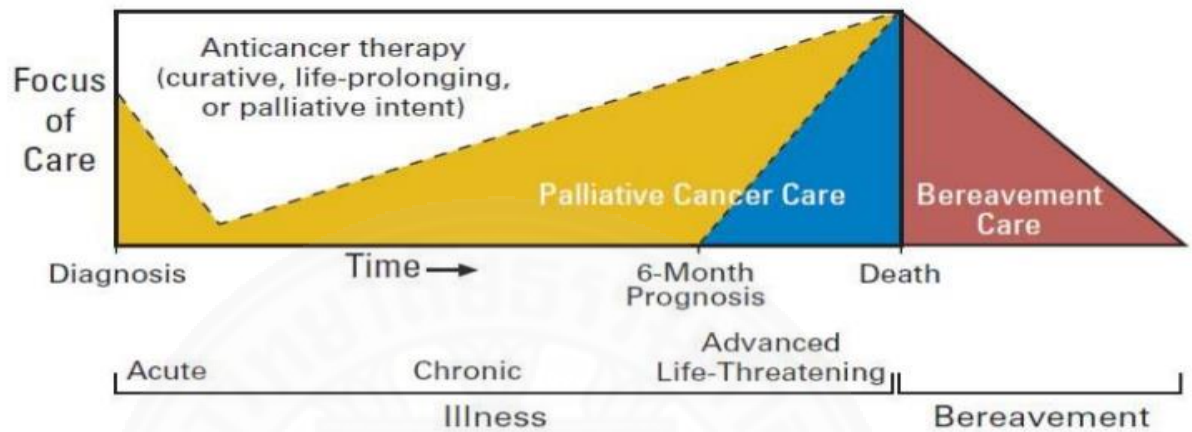


Figure 1.1. Model of palliative cancer care by Von Roenn & Temel (2011)

1.2 Research Objectives

1.2.1 General purpose

To conduct a randomized control trial examining the effects of music and a biofeedback program on Thai cancer patients receiving palliative care.

1.2.2 Specified aims

1.2.2.1 To compare the mean scores for pain and stress levels in Thai cancer patients receiving palliative care before and after listening to music therapy

1.2.2.2 To compare the mean scores for pain and stress levels in Thai cancer patients receiving palliative care before and after participating in the biofeedback program

1.2.2.3 To compare the mean scores for pain and stress levels in Thai cancer patients receiving palliative care before and after listening to music therapy combined with a biofeedback program

1.2.2.4 To compare the mean scores for pain and stress levels in Thai cancer patients receiving palliative care among the patients that are listening to music, listening music together with the biofeedback program and, and routine nursing care only

1.3 Research question

1.3.1 What are the differences in the stress and pain for Thai cancer patients who received palliative care and participated in music compared to those who received routine nursing care only?

1.3.2 What are the differences in the stress and pain for Thai cancer patients who received palliative care and that participated in the biofeedback program compared to those who received routine nursing care only?

1.3.3 What are differences in the stress and pain for Thai cancer patients who received palliative care and participated in music therapy together with the biofeedback program compared to those who received routine nursing care only?

1.4 Study variables

1.4.1 Independent variables

Independent variables consist of 4 variables, including Experimental Group 1 comprising Thai cancer patients who will be undergoing music therapy and receiving routine nursing care provided by Thammasat Radiation Oncology Center (TROC) at Thammasat University Hospital; Experimental Group 2 comprising Thai cancer patients who will be participating in the biofeedback program and also receiving routine nursing care provided by Thammasat Radiation Oncology Center (TROC) at Thammasat University Hospital; Experimental Group 3 comprising Thai cancer patients who will be undergoing music therapy together with participating in the biofeedback program, and also receiving routine nursing care provided by Thammasat Radiation Oncology Center (TROC) at Thammasat University Hospital; and a Control Group comprising Thai cancer patients who will be receiving routine nursing care only provided by Thammasat Radiation Oncology Center (TROC) at Thammasat University Hospital.

1.4.2 Dependent variables

The dependent variables are:

1.4.2.1 Stress, measured using stress cortisol levels, vital signs including pulse, blood pressure, Alpha brain waves using EEG, and muscle tension using EMG.

1.4.2.2 Pain, measured by pain score from TUH, and patient-reported pain frequency and pain relief.

1.4.3 The control variables include stages II b and III of cancer, a moderate level of stress, as well as a mild to moderate pain score.

1.4.4 The paired variables include type of cancer such as colorectal cancer, cancer of the liver, breast cancer, lung cancer or cancer of the cervical/ovarian, and treatment such as during of radiation or chemotherapy.

1.5 Scope of the Study

This randomized control pretest-posttest study examined the effects of music singularly and also when combined with biofeedback program on the reduction in reported pain and stress in Thai adult cancer patients, those diagnosed with colorectal cancer, cancer of the liver, breast cancer, lung cancer or cancer of the cervical/ovarian, obtained from Thammasat University Hospital (TUH). The sample was comprised of 92 cancer patients, randomly assigned, by use of a table of random numbers, to four equal groups (23 per group), including a control group (who received routine nursing care provided by Thammasat Radiation Oncology Center (TROC) at Thammasat University Hospital). The study was conducted over 8 weeks. Experimental group 1 was comprised of Thai adult cancer patients that receiving music and routine nursing care provided by Thammasat Radiation Oncology Center (TROC) at Thammasat University Hospital.

Experimental group 2 was comprised of Thai adult cancer patients receiving biofeedback program and routine nursing care provided by Thammasat Radiation Oncology Center (TROC) at Thammasat University Hospital.

Experimental group 3 was comprised of Thai adult cancer patients receiving music together with biofeedback program and routine nursing care provided by Thammasat Radiation Oncology Center (TROC) at Thammasat University Hospital; and

Control group, was comprised of Thai adult cancer patients, receiving routine nursing care only. The study was conducted from May to October 2018.

1.6 Definition of research terms

(1) Music was defined as vocal or instrumental sounds (or both) combined in such a way as to produce beauty of form, harmony, and expression of emotion (Oxford Dictionary, 2017). For this study music involved listening to patient self-selected classical, jazz, royal, and natural sound music. Thai instrumental music, which was self-selected based upon each person's favorite type of music. All music options had similar rhythms of roughly 60 to 66 beats per minute in common patterns (Levitin, Grahn & London, 2017) as this patterning has been shown to increase the generation of alpha waves in the brain resulting in subsequent increase in the feeling of relaxation in cancer patients (Ruchiwit, 2012). The participants in the music intervention group (Group 1) listened to their personal choice of music using headphones connected to an MP3 player, twice a day (for 15-30 minutes per session); ideally, once in early morning (5 a.m.–11 a.m.) and once in the evening (6 p.m.–11 p.m.) over the 8-week intervention period.

(2) Biofeedback program is a self-regulatory stress management tool where patients are trained in how to regulate bodily processes (e.g., heart rate, blood pressure, and muscle tension) that usually occur involuntarily (Frank, Khorshid, Kiffer, Moravec & McKee, 2010), including (Ratanasiripong, Kaewboonchoo, Ratanasiripong, Hanklang & Chumchai, 2015; Ruchiwi, 2014; Wang et al., 2015). It is aimed to control stress by developing awareness of their physiological reactions. Through reinforced biofeedback

training, patients learned how to control their emotions and eventually, they no longer needed a biofeedback instrument (Frank, Khorshid, Kiffer, Moravec, & McKee, 2010; Lemaire et al., 2011; Wang et al., 2015). In order to monitor the effects of biofeedback, brain waves were monitored using EEG and muscle tension was measured using EMG biofeedback. EEG is a method for detecting the electrical activity of the brain in the form of brainwaves, which can be represented as waveforms of various amplitudes and frequencies. In this study, EEG biofeedback is used to measure the electrical activity of the temporal lobe, which is the main part of the brain responsible for auditory perception (Ruchiwit, 2014). The results of the measurements are desynchronized patterns generated during the time in which patient have feelings of stress and excitement, which are responsible for the occurrences of beta frequencies in the brain (Jena, 2015). In this study, alpha waves having the frequencies ranging between 8 and 12 hertz will be monitored and recorded. Muscle tension, especially in the trapezius muscle, demonstrates tension. The participants can observe the amplitude of the muscle from the EMG signal, which is usually when the muscles relax. The amplitude is between 3 and 5 microvolts. During EEG and EMG biofeedback training, the participants were able to visualize graphical diagrams corresponding to their brain waves and muscle tension on Procom Infiniti (Ruchiwit, 2014).

(3) Stress is a response to a stressor that disturbs our physical, mental or emotional state (Konduru, 2012). Stress has been shown to lead to the development of major diseases such as heart disease, cancer, and mental disease (Konduru, 2012; Ruchiwit, 2014). This study will use the symptoms of stress inventory (*SOSI*), which can be used as

a scale to measure the responses of the body, mind, and behaviors towards stress during the previous month (Ruchiwi, Rugwongprayoon, Vuthiarpa, & Liagchawengwong, 2012; Thongkhum, 2015). In this study, the focus was cancer patients with moderate levels of stress defined as a score from 44-137 on the SOSI. Additionally, physiological changes to stress were measured using EEG and EMG biofeedback, and vital signs.

(4) Pain, defined for this study as increased muscle tension around an area and is related to stress (Martin & Lizzy, 2015) and was measured using frequency of use of pain relief medication and a numerical rating scale (scores ranging from 0-10; where 0 equals no pain and 10 means very severe pain), used at Thammasat University Hospital (Pothamuang, 2012). For this study, cancer patients with a mild to moderate pain score of ≤ 6 were the population of interest

(5) Palliative care is “an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual” (WHO, 2018, from: <https://www.who.int/news-room/facts-in-pictures/detail/palliative-care>). Palliative care may be provided at any point along the cancer care continuum, from diagnosis to the end of life. When a patients receive palliative care, they may continue to receive cancer treatment (National cancer institute. (2017). For this study focus on caring for cancer patients with stage IIB and III. These stage focus to treatment in cancer patients such as radiation, chemotherapy or surgery

(6) Cancer patients are patients with Stage IIB or III cancer. Stage IIB and III means that the tumors greater than 2 cm but less 5 cm and lymph nodes involved. Both stage IIB and stage III, indicate that larger cancers or tumors may have spread into the lymph nodes or nearby tissues, but not to other parts of the body. These stages emphasize the need for treatment which has both physical and psychological side effects. Therefore, prevention and relief of suffering is essential in this stage (Vineis & Wild, 2014).

(7) Routine nursing care for this study is defined as the nursing care received by Thammasat Radiation Oncology Center (TROC) at Thammasat University Hospital for cancer-related care and this may include health education, individual counseling, cancer treatment without receiving either music therapy or participating in the biofeedback training program. In this study, all groups received nursing care from the same nurse and had the same treatment.

(8) Cancer treatment is treatment provided by medical doctor at Thammasat University Hospital such as radiation therapy, chemotherapy include health education, individual counseling.

(9) Pain relief medication is medication taken by study participants in order to control or relieves pain, including: 1) non-opioids such as non-steroidal anti-inflammatory NSAIDs; and 2) opioids such as codeine and Tramadol (Umar, Steele, Menter, & Hawk, 2016).

1.7 Framework of the Research

There are a number of theoretical and conceptual frameworks used to guide research focused on palliative cancer care and that address symptoms (pain will be addressed in this study using principles from gate control theory) and stress management (Selye's Stress Response Theory). All three theories/conceptual models were used to guide this dissertation.

Palliative care has been recognized as an important component of the quality of life of cancer patients at any point along the cancer care continuum, from diagnosis to the end of life. When a patient receives palliative care, they may continue to receive cancer treatment which has side effects both physically and psychologically (National Cancer Institute, 2017)

Intervention to decrease both physical and emotional symptoms is essential, especially pain and stress. Hans Selye proposed the stress response theory. He stated that numerous physiological adaptations happen as a result of repeated exposures to stress and these have pathological impacts. Selye defined these aggregate changes as the general response syndrome (GRS), a procedure in which the body tries to control stress by adjusting to it. When a person is stressed, changes occur, especially in the autonomic nervous system (ANS). Responses of the sympathetic nervous system to stress are related to biochemical exchanges in various parts of the body. The hypothalamus is a structure in the brain that functions as the control center of the sympathetic nervous system and the hypothalamus-pituitary-adrenal (HPA) axis. When the hypothalamus identifies extra energy needed to fight a stressor, it releases endorphins and cortisol. These hormones are

released in response to stress and are related to vital signs exchange, such as an increase in cardiac output and blood pressure (Kondur, 2012) and are related to beta frequencies in the brain (brain waves). It is associated with feelings of relaxation and calmness (Jena, 2015).

Stress causes physical effects that can increase pain levels through the nociceptors are simulated and send the nerve impulse along to the nerve fiber, spinal cord and reticular formation in the brainstem which work with limbic system (followed by the gate control theory of pain). The pain will be activated and endorphins (produced by hypothalamus) will be reduced leading to higher degrees of pain (Juangpanich, Onbunreang, Khansorn, Khansorn, & Vatanasapt, 2012; Mercadante, & Cuomo, 2016; Prasongsook et al., 2017). Moreover, stress also produces changes in the body's hormonal systems. These changes are believed to affect the pain system, making it more sensitive (Martin & Lizzy, 2015). Thus, stress and pain are major symptoms that severely impact cancer patients undergoing palliative care and should be targeted for prevention. If stress continues beyond the body's capacity, the organism exhausts its resources and becomes vulnerable to disease from oncoming cancer, which can eventually lead to death (Selye, 2013). Stress management techniques are important for health professionals to master and should be taught to patients and made available not only to people whose symptoms are obvious (Liza, 2011). Therefore, identifying stress management techniques is of the utmost importance since it is the key first step to preventing problems in Thai cancer patients experiencing palliative care.

Music and biofeedback programs can be effective for many symptoms, such as stress, chronic pain, and muscle tension (Kaushik, 2016). Both music and biofeedback use

a psychophysiological psychotherapy model of learning, which helps to make patients aware of their thoughts, feelings, and behaviors related to their physiology. Music helps the brain to release endorphins, thereby reducing the awareness of pain and stress through the components of the gate control theory of pain (Kaliyaperumal & Subash, 2010). Pain messages pass through to the brain, and if the gates are more open, then people are likely to experience a high level of pain. However, if the gates are more closed, then people are likely to experience less pain. One factor that closes the gates is relaxation, produced from listening to music (Juangpanich, Onbunreang, Khansorn, Khansorn, & Vatanasapt, 2012).

Biofeedback is an important instrument for stress management (Kaushik, 2016). In cases where stress comprises a major element of the disease symptoms, patients can benefit from biofeedback based upon the learning model of psychophysiological psychotherapy. This form of biofeedback helps patients learn how to control their stress through building a greater awareness of how their emotions and feelings are linked to physiological factors. Over time, the patients learn to control their emotions by themselves without the need of a biofeedback instrument (Frank, Khorshid, Kiffer, Moravec, & McKee, 2010).

In Summary:

The purpose of this study, guided by an integrated framework using Gate Control Theory, Stress Response and the Continuum of Palliative Care, was to examine the effects of using novel treatment approaches that included music therapy and biofeedback to reduce stress and pain for Thai adult cancer patients diagnosed with Stage IIB and III cancers of all types who were receiving palliative care at Thammasat University

Hospital. The long-term goal of this study is to provide a program for reducing stress and pain among Thai adult cancer patients receiving palliative care, regardless of their cancer diagnosis. (See Figure 1.2.)



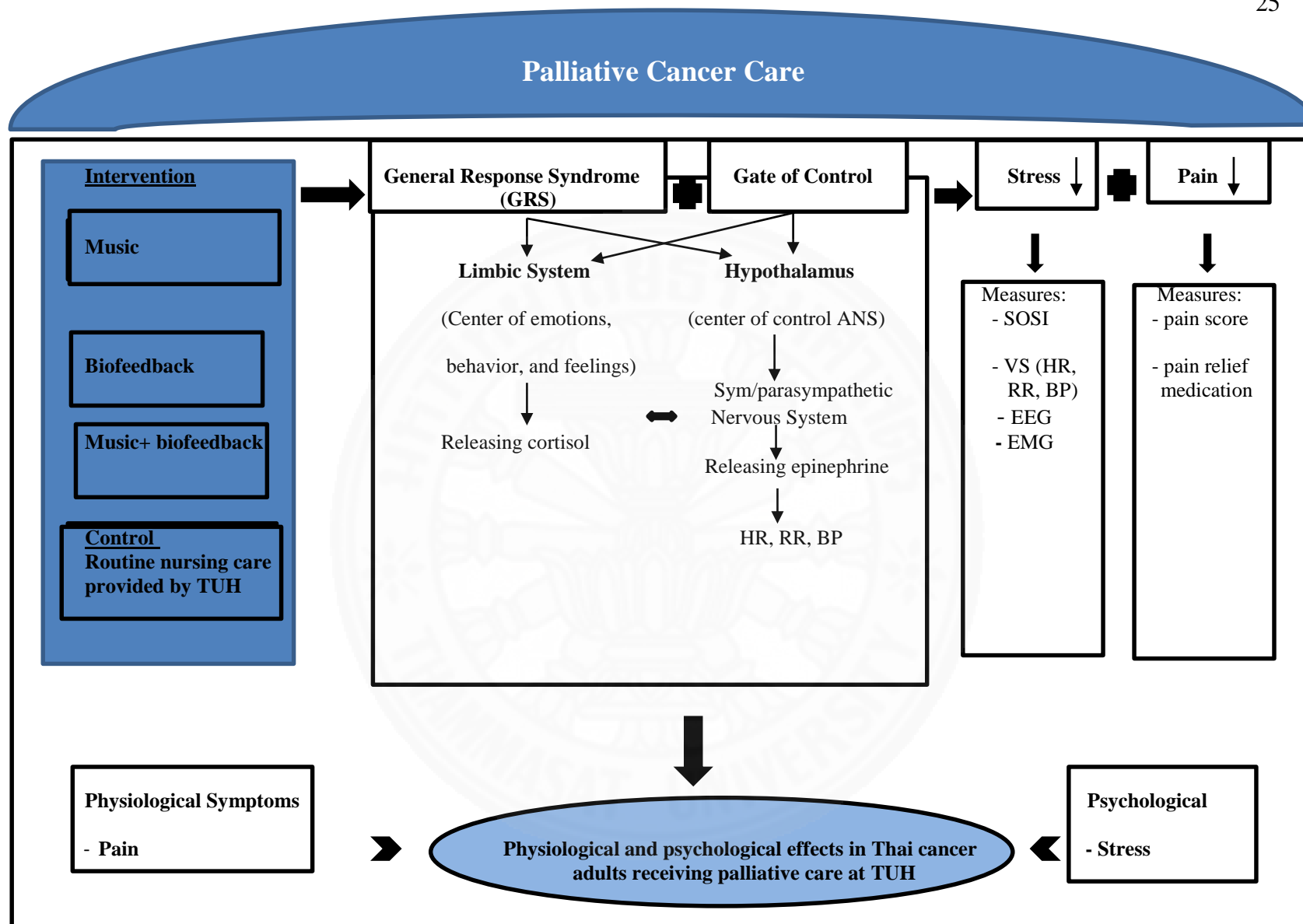


Figure 1.2: The conceptual framework of “A randomized controlled trial examining the effects of a music and biofeedback program on Thai cancer patients receiving palliative care.”

1.8 Research hypotheses

Hypothesis 1: Patients that receive music and biofeedback program have a greater significant decrease in pain compared to those receiving music only, biofeedback program only, or those in routine care control groups.

Hypothesis 2: Patients that receive music and biofeedback program have a greater significant decrease in stress compared to those receiving music only, biofeedback program only, or those in routine care control groups.

Hypothesis 3: Patients that receive music and biofeedback program have a greater significant decrease in the construct of healthy functioning as measured by a linear combination of SOSI, pain score, EEG, EMG, and vital signs compared to those receiving music therapy only, biofeedback only, or those in routine care control groups.

1.9 Expected benefits

The results of this study will be useful for implementation and application in nursing. Specifically, the findings can also help patients manage their stress appropriately by applying music together with biofeedback training programs in the clinical setting and it is expected that patients will be able to manage their pain and stress at home without the biofeedback instrument in the long run. In addition, this intervention can reduce mortality rates, lower costs, and provide useful guidance for the prevention and treatment of cancer and the care of cancer patients.

Nursing practices

This intervention is an alternative nursing therapeutic technique of stress management for cancer patients with pain and stress. Nurses can easily use this intervention in patients with stress because it is available daily without the need for

tools, and can help reduce stress levels and prevent complications in patients that have stress and pain.

Nursing

Thai nurses providing direct patient and family care during palliative care for those diagnosed with cancer would benefit from focused training and certification in the use of music therapy and biofeedback, either singularly or when combined, to assist in reducing pain and stress across their cancer illness trajectory. Specifically in palliative care units, because these interventions can help patients manage their stress, reduce their mortality rates, lower costs, and provide useful guidance for the prevention and treatment of cancer and care of patients. The results of the study may also prove useful as information to support the implementation and application of relaxation techniques in nursing.

Research study

This research study will serve as a foundation for further nursing research on music therapy together with biofeedback training for application in other contexts, such as for patients with other diseases and health conditions, or in other settings.

CHAPTER II

LITERATURE REVIEW

This study aims to study the effects of music and biofeedback programs on the pain and stress experienced by cancer patients when receiving palliative care. This chapter will present an overview of the therapies and the literature describing the concepts of interest, which will be described as follows:

2.1 Overview of cancer:

2.1.1 Definition of cancer

2.1.2 Prevalence of Cancer: Worldwide, in Thailand, and Countries leading cancer research

2.1.3 Cancer Risk factors

2.1.4 Cancer: Common signs and symptoms

2.1.5 Effective Cancer Interventions

2.2 Palliative care in cancer

2.2.1 Definition of palliative care

2.2.2 Palliative care from a worldwide perspective

2.2.3 Palliative care in Thailand and Palliative Care Continuum

2.3 Importance of stress as a risk factor in cancer patients

2.3.1 Definition of stress

2.3.2 Causes of stress in cancer patients

2.3.3 The stress response theory

2.3.4 Stress Assessment Measures

2.4 Importance of Pain as a major symptom in cancer patients

2.4.1 Definition of pain

2.4.2 Concept and principle of pain

2.4.3 Pain Assessment Measures

2.5 Effective and efficacious cancer-related interventions to mitigate stress and pain

2.5.1 Review of effective and efficacious cancer-related interventions

2.5.2 Music

2.5.2.1 Effects of music on the brain response and stress reduction

2.5.2.2 Effects of music on the brain response and stress reduction

2.5.2.3 Effects of music on the brain response, pain pathways and pain reduction

2.5.2.4 Relaxation technique by music upon stress and pain in cancer patients

2.5.3 Biofeedback Training

2.5.3.1 Definition of biofeedback

2.5.3.2 Electroencephalograph (EEG) biofeedback training

2.5.3.2 Electromyography (EMG) biofeedback program

Summary and Importance of the proposed study

2.1 Overview of cancer

2.1.1 Definition of cancer

To identify what cancer disease is, general and specific definitions from dictionaries and literatures were explored. Such as meaning of “cancer” in the English Dictionary: “A disease caused by an uncontrolled division of abnormal cells in a part of the body”. The World Health Organization (WHO, 2017), identifies cancer as “a generic term for a large group of diseases characterized by the growth of abnormal cells beyond their usual boundaries that can then invade adjoining parts of the body and/or spread to other organs”. This is consistent with the United States, National Cancer Institute (2017), a world leader in cancer research, definition, “the name given to a collection of related diseases, in which abnormal cells divide without control and can invade nearby tissues and can spread to other parts of the body through the blood and lymph systems”. In all types of cancer, some of the body’s cells begin to divide without stopping and spread into surrounding tissues”. It is well-established that normal cells may become cancer cells. Before cancer cells form in tissues of the body, the cells go through abnormal changes called hyperplasia, dysplasia, and then may change further into cancer cells. In hyperplasia, there is an increase in the number of cells in an organ or tissue that appear normal under a microscope. In dysplasia, the cells look abnormal under a microscope but are not cancer. Hyperplasia and dysplasia may or may not become cancer. There are five general categories of cancers, they are: 1) Carcinomas, begin in the skin or tissues that line the internal organs, 2) Sarcomas, develop in the bone, cartilage, fat, muscle or other connective tissues, 3) Leukemia, begins in the blood and bone marrow, 4) Lymphomas, start in the immune system, and 5) Central nervous

system cancers, develop in the brain and spinal cord (Cancer Center Treatments of America, 2017).

This study supports these overall definitions in that cancer refers to a group of diseases that growth of abnormal cells rapidly without stopping and spread into surrounding tissues.

2.1.2 Prevalence of cancer: Worldwide, in Thailand, and in Countries Leading Cancer Research

2.1.2.1 Increasing number of cancer survivors

The American Cancer Society and the National Cancer Institute collaborate to estimate the number of current and future cancer survivors, more than 15 million Americans with a history of cancer. The most type of cancer are prostate (3,306,700), colon and rectum (724,700), and melanoma (614,470) among males and breast (3,560,580), uterine corpus (757,200), and colon and rectum (727,350) among females. More than one-half (56%) of survivors were diagnosed within the past 10 years, and almost one-half (47%) are aged 70 years or older (Miller, Siegel, Lin et al., 2016). The number of cancer survivors is expected to grow by one third from 15.5 million in 2016 to 20.3 million by 2026 (American Society of Clinical Oncology, 2017). The number of cancer survivors to growth because of changing demographically (increase in the aging population), and living longer from early detection and treatment (Miller et al., 2016).

2.1.2.2 Prevalence of Cancer Worldwide

Globally, cancer is a leading cause of death. According to Torre, Siegel, Ward & Jemal (2016), new cancer cases number around 14 million annually and cancer patients' deaths at about 600,000 per year in the United States. The number of cancer patients is forecast to increase by 50% to 15 million new cases annually by 2020 (World Health Organization, 2007). Countries with the highest cancer rates include Denmark (for both men and women), France, Australia, Belgium, Norway, United States, Ireland, South Korea, and the Netherlands – all with greater than 300+ people per 100,000 (age-standardized) (World Cancer Research Fund International, 2017). Just under three-quarters of cancer deaths occur in low and middle-income countries (World Health Organization, 2017) with higher income country reporting lower death rates due to earlier diagnoses and access to advanced treatment options (Torre, Siegel, Ward & Jemal, 2016). Thailand, an upper-middle income country (Thailand Ministry of Health, 2012), is reported to be undergoing an epidemiological transition (Virani et al., 2017), is expected to see an increase in nearly all types of cancer diagnoses in the next decade; current overall rates are 140 people diagnosed per 100,000. In less developed countries are estimated to contribute for 58% and 68% of the world cancer burden, while new cases of cancer are expected to increase to 63% in less developed countries (Lalitwongsa, Pongnikorn, Daoprasert, Sriplung & Bilheem, 2015).

2.1.2.3 Prevalence of Cancer in Thailand

In Thailand, cancer is one of the leading causes of suffering leading to death. Furthermore, the rate of hospital admissions for cancer patients is around 78 people per 100,000, and almost 90% of diagnosed cancer patients ultimately die from

cancer (Doorenbos et al., 2013). Moreover, cancer registrations rates are 143 per 100,000 people for males and 132 per 100,000 people for females. In 2012, there were 112,392 estimated new cases of cancer patients in Thailand (Wilailak & Lertchaipattanakul, 2016). The Department of Medical Services, Ministry of Public Health Thailand in 2017 reported and 121 per 100,000 people for males and females found as a cancer patients. Most common cancers, regardless of gender are colon or rectum = 25.8% (male = 16.25, female = 9.6%), lung = 22% (male = 15.5%, female = 6.5%), liver = 18.9% (male = 15.3%, female = 3.6%), breast in women = 37.5% and cervix = 14.4%. The reported is expected to see an increase in nearly all types of cancer diagnoses in the next decade (Virani et al., 2017).

From all of report showed that the mortality rate from cancer is expected to rise both in Thailand and globally.

2.1.3 Cancer Risk Factors

Cancer risk factors are generally classified as those that can and those that cannot be controlled. The most common controllable or behavioral risk factors include tobacco use, alcohol use, unhealthy diet, and physical inactivity (WHO, 2017) while uncontrolled cancer risk factors include environmental (external), aging, and genetics. Uncontrolled risk factors are described first, followed by those that can be controlled by behavior.

2.1.3.1 Uncontrollable Risk Factors – Internal and Environmental factors

2.1.3.1.1 Genetic Factors. Cancer is known to be caused by changes to genes that control the way our cells function, especially how they grow and divide (WHO, 2017). Cancer-causing genetic changes occur as cells divide or following

exposure to carcinogenic substances that damage DNA. These include certain chemicals in carbon-producing substances (exhaust fumes) and ultraviolet radiation from the sun. Genetic changes that occur after conception are called somatic (or acquired) changes and often result in impairment of the immune system which transmits some genes to the next generation as a cancer family history. Oliveira, Pinheiro, Figueiredo, Seruca & Carneiro (2015) proposed that gastric cancer can be genetically passed onto the next generation. Thai women also exhibit family history of breast or cervical cancer development (Rakkapao, Promthet, Moore, Solikhah & Hurst, 2017).

2.1.3.1.2 Environmental factors: Environmental carcinogens include vehicle exhaust fumes, discharge gases from industrial plants and carcinogenic substances found in foods and beverages such as aflatoxins in dry peanuts or in food stored for a long time. Volatile organic compounds (VOCs) such as benzene and 1,3-butadiene that spread and accumulate in air cause both physical and biological damage to human health by activating cancer formation, especially skin cancer and lung cancer (Anand et al., 2008). Meat cooked at high temperature forms mutagenic heterocyclic amines and polycyclic aromatic hydrocarbons which develop into carcinogens (Anand et al., 2008; Wanchai, 2016), while high-fat food consumption increases levels of cytotoxic free fatty acids and bile acids in the intestine which induce colorectal cancer (Bisen, 2016).

2.1.3.1.3 Infection is a potential cause of cancer by reducing T cells which balance pathogen levels and tumor control in the body (Speiser et al., 2014). Hepatitis B and C are major causes of liver cancer resulting from cirrhosis. In Thailand, infection by the liver fluke from eating undercooked freshwater fish such as Koi-pla is known to cause cancer in the bile duct. Other carcinogenic pathogens include human

papilloma virus (HPV) that causes genital warts and activates cervical cancer. In addition, HIV causes immune deficiency syndromes. Consequently, humans are vulnerable to various types of carcinogenesis including lymphoma, vascular and rectal cancers (Gillison et al., 2014; Khumtaveeporn, 2010; Oh & Weiderpass, 2014; Vineis & Wild, 2014).

2.1.3.2 controllable Risk Factors

2.1.3.2.1 Smoking is the single most modifiable risk factor for developing cancer. Tobacco smoke contains more than 4,000 chemicals and over 70 of these are carcinogenic. One smoking by-product as tar is a viscous cancer-causing substance which sticks on the lungs. When smokers breathe, tar in the lungs combines with inhaled dust and accumulates in the alveoli causing coughing, sputum, lung cancer and emphysema. In addition, smoke from cigarettes floating in the air is diluted in the air and due to ambient lower temperature make it cool down quickly. The dust of smoke is smaller, and while the smoke is floating in the air, it will have more oxygen result in reaction of some substance becomes more toxic substance such as nitrogen oxides. And when the environment has more oxygen, it will combines with oxygen and becomes Nitrogen Dioxide which more toxic to body (Makboon, 2015; Wanchai, 2016). In Thailand, the smoking population aged 15-79 is 21.3%. Men are 27 times more likely to smoke than women for all age groups. Overall, male smokers number 42.3% with women at 1.6%. The smoking population aged 25-55 is higher than all other age groups (Bureau of Non Communicable Disease, 2015). Smoking or living in smoking areas results in cancer, respiratory ailments and other fatal diseases. The Bureau of Non Communicable Disease Thailand (2015) reports that 20% of lung cancers are associated with smoking. Probability of lung cancer involves type, quantity and duration of

smoking. It is reported that the risk of developing lung cancer in those inhaling cigarette smoke in smoking areas will increase more than 20% compared to smokers himself. (Kim et al., 2014). Malhotra et al. (2017) found that smokers were exposed to a higher risk of lung and esophageal cancer compared with nonsmokers, while Li, Cheung, Chan & Lam (2017) found that 80% of cancer patients caused by smoking are male 72.9% of all cancer patients. Those who smoked average 13 times a day for more than 42 years and led to the death of cancer within 8-10 years later. Moreover, smoking also increased the risk of breast cancer.

2.1.3.2.2 Alcohol ingestion has also been identified as a causative factor in the development of liver and colon cancer (Torre, Siegel, Ward & Jemal, 2016; Yamashita & Wang, 2013). Alcohol, also known as ethanol or ethyl alcohol, is a chemical substance found in beer, wine, and liquor as well as in some medicines, mouthwashes, household products, and essential oils (scented liquids taken from plants). Alcohol is produced by the fermentation of sugars and starches by yeast. Cancer develops either due to 1) DNA damage, 2) impairment in the body's ability to break down and absorb a variety of nutrients that may be associated with cancer risk including vitamin A, nutrients in the vitamin B complex such as folate, vitamin C, vitamin D, vitamin E, and carotenoids, and/or 3) generation of reactive oxygen species (chemically reactive molecules that contain oxygen) which can damage DNA, proteins, and lipids (fats) through oxidation (National Cancer Institute, 2015). Strong scientific consensus based on extensive research evidence suggests that the more alcohol a person drinks regularly over a period of time, the higher his or her risk of developing an alcohol-associated cancer.

In Thailand, the number of cancer patients caused by alcoholic drinks increased to be 770,000 people worldwide (5.5% of all cancer patients). The deaths from cancers related to alcohol consumption increased approximately 480,000 patients (5.8% of the total who died of cancer). In both groups, 360,000 men and 120,000 women were epidemically found in Asia and Southeast Asia. The WHO (2014) and others (Praud et al., 2016). In Thailand, it is estimated that drinking spirits or alcoholic drinks in the past one year is about 17.7 million (32.3%). Men drink approximately 4 times greater than women. In the working age Thai population, those 25-59 years of age, the percentage of alcoholic drinking is higher than the other groups (38.2% in 100%) (Bureau of Non Communicable Disease, 2015). Consumption of alcoholic drinks is a major risk factor for liver cancer and can also cause several other types of cancer including head and neck cancers, particularly oral cavity and larynx cancers and even breast cancer. Women drinking more than 45 grams of alcohol per day (three glasses of wine) increased their risk of breast cancer by about 50% (National Center Institute, 2017).

2.1.3.2.3 Food consumption. Some foods may cause cancer. Over-grilled meat contains carcinogenic substances which induce stomach cancer. Eating habits are associated with cancer development. Low whole grain foods and high-fat foods are key factors in the development of breast, colon, uterus and prostate cancers (Bisen, 2016). Pacheco et al. (2016) showed that men who ate high-fat foods and drank coffee or alcoholic drinks were at higher risk of developing cancer.

2.1.4 Cancer Signs and Symptoms

Common symptoms in cancer patients can be divided into:

2.1.4.1 Specific symptoms caused by cancerous organs. There is no obvious symptom in the first stages of cancer; however, when cancer progresses, tumor masses are formed which then invade and compress surrounding organs and produce a host of symptoms. The most common cancer-related symptom is pain (Johannsen, Farver, Beck & Zachariae, 2013; Mercadante & Cuomo, 2016). The early stages may be painless but if cancer spreads to the bone or nerves it generates strong pain. Cancer is often found in patients with metastatic disease and between 50% and 90% of individuals with metastatic disease experience moderate to severe pain (Mercadante, & Cuomo, 2016; Prasongsook et al., 2017). This severe pain occurs due to compression of nearby body tissues as the cancer tumor spreads and stimulation of nociceptors (pain receptors) which in turn send nerve impulses that pass through the spinal cord to the brain and reticular formation of the brain stem for pain perception. The limbic system stimulates the body's emotional response to pain and decreases endorphins, resulting in more pain in patients as a continuous cycle (Juangpanich, Onbunreang, Khansorn, Khansorn & Vatanasapt, 2012). Other common-related symptoms from the early to aggressive stage include fatigue as the most undesirable side effect of cancer in both adults and children. According to a study by Barsevick et al. (2013), 75-99% of patients with advanced cancer experienced fatigue as the greatest impact on their daily lives (LaVoy, Fagundes & Dantzer, 2016).

2.1.4.2 Symptoms of side effects from treatment. Each patient experiences different symptoms of side effects from treatments depending on their immunity and treatment method. One side effect is fever. Most patients with cancer experience fever

which causes immunity changes or reactions to treatment (Borisutbuathi & Kongpanvijit, 2014). Fever usually occurs when cancer has spread, especially for leukemia, and is the major cause of death for patients with low white blood cells due to complications of chemotherapy (Cornely & Mellingshoff, 2017). In the United States, death rates from fever with low white blood cells in cancer patients are approximately 9-11%. Studies in Thailand found the death rate of patients from fever with low white blood cells at 24% (Borisutbuathip & Kongpanvijit, 2014). Nausea, vomiting, and anorexia are common symptoms in 40-87% of advanced cancer patients that reduce the desire to receive chemotherapy (Wisuttikul, 2011). Nausea and vomiting may occur after 2-3 hours or more than 24 hours after chemotherapy treatment and symptoms can be continuous for 2-3 days (Janelsins et al., 2013). Individual symptoms depend on the type of chemotherapy, amount of medication and type of cancer (Thai Society of Clinical Oncology, 2017). Insomnia is also found in 30-50% of cancer patients from pre-diagnosis to treatment (Tesviruch, 2015). According to Sakon, KataWang & Neyomka (2016), 44-95% of children with cancer experience sleep problems. Cancer causes difficulty in sleeping, waking up at night, difficulty in getting up early in the morning and drowsiness. These physical symptoms also affect the mental state of cancer patients. Opasrattanakorn, Detprapon & Sumdaengri (2015) found that patients receiving chemotherapy for at least three months had high levels of stress. Studies in cancer patients treated with chemotherapy at the Chonburi Cancer Center found that those receiving chemotherapy had common psychological symptoms such as stress and fear of treatment (Thamnipa, Konsue & Therasakvichya, 2014). Cameron & Waterworth (2014) studied life experiences of intestinal cancer patients during chemotherapy. Results showed that more than 50% of patients experienced stress and

anxiety that the symptoms would not improve with also fear of side effects from treatment.

2.1.5 Effective Cancer Interventions

There are many forms of intervention for cancer including operation, chemotherapy, radiation therapy, and non-pharmacological methods.

An operation can completely cure the disease and relieve temporary symptoms. The cancer mass may be removed from nearby lymph nodes and good tissue (Chaithongsakul, 2015). This is often done in cancer patients at the initial position (Stage 1) or, in some cases, cancer spreads to neighboring tissues or through hollow organs (Stage 2) (Thailand Cancer Rehabilitation Club, 2017).

Chemotherapy may be given as additional treatment after an operation to increase the chances of complete recovery (Laoitthi & Parinyanitikul, 2016). Chemotherapy in this case is intended to eliminate cancerous cells remaining from surgical treatment that cannot be seen or detected by x-ray. Doctors may choose chemotherapy before the operation to help reduce the size of the tumor and make surgery easier (Fehringer et al., 2017). For patients with a high prevalence of cancer, chemotherapy may be needed to control the spread without hope of entirely curing the disease. The patient lives longer with reduced symptoms and a better quality of life (Thai Society of Clinical Oncology, 2017; Thanipa, 2015). Chemotherapy side effects impact in patients as fatigue (LaVoy, Fagundes & Dantzer, 2016), muscle pain (Prasongsook et al., 2017), and difficult eating (Janelsins et al., 2013).

Radiation therapy uses high energy radiation to kill or stop the growth of cancer cells. Generally, irradiation is performed five days a week for about 5-6 weeks and commonly used after surgery (Demaria, Golden & Formenti, 2015). Radiation

therapy is considered to be the most effective treatment currently available (Pongthavornkamol, Lekdamrongkul, Wanawarodom & Ratchawong, 2014) that can entirely cure the disease or offer temporary relief. Most Thai cancer patients, approximately 60-80%, are treated with radiation therapy (Katanyoo, Boonchoo, Jongthanakorn & Rongsriyam, 2013).

Many cancer treatments result in unfavorable side effects and suffering. Fehringer et al. (2017) showed that 30% to 60% of patients treated with chemotherapy had reduced quality of life. Darby et al. (2013) found that radiation therapy increased the risk of heart disease among breast cancer patients (800 cases) within the first five years after treatment.

Non-pharmacological interventions for cancer patients: A wide range of non-pharmacological approaches are available to handle symptoms in cancer patients. Music therapy is one non-pharmacological approach that can reduce stress and pain through melody and rhythm. Music enhances the secretion of endorphins in the brain which affects the levels of stress and pain in the body (Kaliyaperumal & Subash, 2010; Warth et al., 2014). Music has been used to reduce stress and anxiety, pain, and promote quality of life in cancer patients and their families (Chanda & Levitin, 2013). Biofeedback is a tool that patients can use to develop their own stress management capabilities for various diseases such as high blood pressure, muscle tension, and chronic pain (Kaushik, 2016). Patients learn how to control and develop stress awareness through physical reactions associated with the stress. In this way, patients can control stress on their own without having to use biofeedback (Lemaire et al., 2011). Mindfulness is a practice of meditation that mainly focuses on inward and outward breaths, with the aim to develop awareness of the present moment, promote relaxation

and reduce stress and anxiety (Matchim, Armer & Stewart, 2011). Mindfulness is used to develop the mind and reduce stress in patients with various diseases, especially cancer. Lengacher et al. (2012) conducted a study entitled “Mindfulness-based Stress Reduction in Post-Treatment Breast Cancer Patients: An Examination of Symptoms and Symptom Clusters” which indicated that mindfulness-based stress reduction can decrease symptoms such as fatigue, sleep disorder, stress, and anxiety and contribute to a better quality of life in cancer patients.

2.2 Palliative care in cancer

2.2.1 Definition of palliative care

To identify the meaning of palliative care, general and specific definitions were explored. Krouse et al. (2004) stated that “palliative care is an interdisciplinary team approach to care, with a focus on comfort and quality of life rather than prolongation of ‘cure’, for a patient and their loved ones”. Krongyuth, Campbell & Silpasuwan (2014) suggested that “palliative care is an inter-professional model of care used to guide and support patients and their families in their physical, psychosocial, and spiritual requirements over the trajectory of a life-threatening illness from diagnosis to death”. The World Health Organization (2014) defined palliative care as “an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual”. Jarrell (2016) identified palliative

care as “an approach to caring for patients and families of patients with life-threatening illnesses that focuses on improving quality of life”.

In summary, palliative care is an interdisciplinary team approach to care and support patients and their families in physical, psychosocial, and spiritual requirements throughout a life-threatening illness. Palliative care may be provided at any point along the cancer care continuum, from diagnosis to the end of life.

2.2.2 Palliative care from a worldwide perspective

Palliative care has been recognized as important to increase the quality of life for patients who have cancer and those with advanced or incurable disease (Krouse et al., 2004). The World Health Organization (WHO, 2014) has been promoting resources to provide and develop palliative care throughout the world by suggesting that all countries implement comprehensive palliative care to decrease suffering and increase quality of life in cancer patients or other life-threatening illness (Zimmermann et al., 2014).

In 2011, 58% of 234 countries had at least one palliative care service representing a 21% increase from 2006, especially in Africa (Lynch, Connor, & Clark, 2013). In Australia, palliative care is becoming more important, particularly in nursing. Nurses in Australia are interested in research concerning pain management of patients in palliative care settings (Wilkes, Tracy, & White, 2000).

In Germany, patients with terminal illness are considered for admission to IPD wards, palliative care wards, and palliative care-OPD wards. These three types of care begin after the patient is diagnosed with a life-threatening disease which cannot be cured. The health care team evaluates the health and takes care of the patient. If the patient is still alive after one month in a palliative care ward, he/she may be allowed to

go home or to a hospice for further care. In case of death, the health care team will also provide spiritual assistance to the patient's relatives (Phokhwang, 2017).

2.2.3 Palliative care in Thailand and Palliative Care Continuum

In recent years, the need for palliative care has increased rapidly due to an increasing global aging population. The aims of palliative care are to prevent and relieve pain and suffering, as well as promoting comfort and improving the well-being of patients and families (Zimmermann et al., 2014). This plays a significant role in cancer which grows and eventually spreads to vital organs. Proliferation of cancer cells has increased, while methods for improving treatment remain limited. The need for palliative care has escalated to become a major focus for patients and their families. As symptoms worsen, more attention is needed to help control them (American Cancer Society, 2008).

In Thailand, the leading cause of death is cancer. As a result, palliative care has become an important aspect of health care (Doorenbos et al., 2013). Cancer registrations showed incidence rates of 143 cases per 100,000 males and 132 cases per 100,000 females. In 2012, 112,392 new cases of cancer were reported in Thailand (Wilailak & Lertchaipattanakul, 2016).

Palliative care in Thailand is primarily provided by three types of organizations (Pokpalagon et al., 2016) as follows:

Religious-based organizations, these play a role in conducting palliative care and terminal illness care in Thailand. The aim of this care is neither to cure nor to relieve illness but to emphasize on developing spiritual harmony of the patient and their family to accept the illness and keep living life happily (Pokpalagon et al., 2016; Sintuvangnon, 2015). For example, psychological and spiritual care of HIV patients

and their families can encourage hope for life until death using Dhamma therapy (Sintuvangnon, 2015). However, there are limitations on medical staff, budgets, resources and accessibility to medicine, especially the opioids group for pain relief (Pokpalagon, 2016).

Home-based/Community-based care, this is conducted by a team of hospital staff or volunteers who visit the patient at home. This care emphasizes on servicing the basic necessities, health condition evaluation and care to control symptoms. Home care supports family members (Rabow et al., 2013) and focuses on participation of community members through qualified and appropriate care to encourage patients to take care of themselves and live freely with good quality of life (Hashmi et al., 2013). Salient points of this care include increase of patients' and relatives' satisfaction, control of pain and symptoms through home visits by the team of interdisciplinary staff and increase in participation by family members. However, limitations of this care can include caregiver burn out as well as lack of approval of some medicines and medical equipment (Pokpalagon, 2016).

Hospital-based services, these consist of interdisciplinary professions in hospitals which jointly care, promote and protect, patients with terminal illness. Most patients suffer from multifaceted problems which need action or treatment (Hashmi et al., 2013) through radiotherapy, chemical therapy, or relieving symptoms that cannot be done at home. However, some limitations of the hospital environment, for example, regulations of visits and activities between the patient and the family may not be sufficiently consistent with their psychological and spiritual needs (Pokpalagon, 2016).

Hospice refers to the place for taking care of patients with terminal illnesses. The concept of hospice is based on the belief in which the patient with

terminal illness should live the rest of their life with quality with family and friends (Pokpalagon, 2016). It emphasizes on caring for quality of life, relieving, and controlling pain and symptom of illness (Smith, Thai, Bakitas et al., 2013). It does not focus on recovering from illnesses but on having the patient and their family living with quality as the first priority, as well as looking after the family after their loss. The salient point of this care is that the patient's symptoms and quality of death will be better managed and controlled (Cagle, Pek, & Clifford et al., 2015). Severe medical procedures during the period before death, as well as the expenses in their last year of life, will also be decreased when compared with regular care (Obermeyer, Makar, & Abujaber et al., 2014).

Palliative care in Thailand is still in its infancy and available only in specific areas. Policy and guidelines in university and provincial hospitals do not include continuity and full options of care (Pokpalagon, 2016). There are too few health care teams to take care of all patients with terminal illness. Financial support from the government is lacking and treatment relies on donations (Sintuvangnon, 2015). No sector is responsible for coordination, while management is separated and disconnected among health care service providers. Limitation exist in management of medicine approval lists, especially the opioids group for pain relief and morphine in community-based settings (Pokpalagon, 2016; Sintuvangnon, 2015). Therefore, patient assessment for palliative care is necessary and important in Thailand (Krongyuth, Campbell, & Silpasuwan, 2014; Phokhwang, 2017). Palliative health care has not been practically integrated into overall health care and services differ in hospitals, hospices, home-based/community-based care, and religious-based organizations (Krongyuth, Campbell, & Silpasuwan, 2014; Phokhwang, 2017).

2.3 Importance of stress as a risk factor in cancer patients

2.3.1 Definition of stress

Stress definitions from dictionaries and the literature were explored. The Gale Encyclopedia of Mental Disorders (2003) defines stress as “a term that refers to the sum of the physical, mental and emotional strains or tensions on a person”.

Selye (2013) defines stress in terms of psychiatry as “a general adaptation syndrome in which a complex activation mechanism of the neuroendocrine system works to prepare the body to attack or escape behavior”. The Global Organization for Stress (2017) defines stress as “a physical, chemical, or emotional factor that causes bodily or mental tension and may be a factor in disease causation...and a state resulting from a stress is one of bodily or mental tension resulting from factors that tend to alter an existent equilibrium”.

In summary, stress is manifested as a response to a stressor that disturbs our physical, mental and emotional states. The inability to cope with stress can induce or worsen certain symptoms or diseases.

2.3.2 Causes of stress in cancer patients

Sources of stress are called stressors; these represent any real or perceived physical, social, or psychological event or stimulus that causes our bodies to react or respond (Glanz et al., 2008). Various factors associated with stress in cancer patients have been described as three interrelated antecedents as follows.

Patient Factors: Personality can influence cancer risk. Suppression of negative emotions increases cancer risks because stress responses disrupt the immune and endocrine systems and increase chronic inflammation (Hansel et al., 2010; Lemogne et al., 2013). People with different personalities, especially those who have a

strict visual personality, have difficulty in adapting to the role of a cancer patient and take more time to adjust (Khumtaveeporn, 2010). The mental state of patients with no psychological readiness, such as fear of treatment, fear of disappearance or fear of death increases difficulty in adapting to the role of a cancer patient. Cancer patients who are stressed are easily discouraged and disheartened and may refuse treatment (Khumtaveeporn, 2010). A patient with good knowledge and experience of cancer will be able to adapt, accept the illness better and improve their quality of life with confidence in the treatment outcome (Wiener, Weaver, Bell & Sansom, 2015). According to in the oncology setting cancer patients have high information needs with regard to their disease, procedures, and treatment. The patients who received those information will be increase stress and anxiety more than those who do not received information (Lock & Willson, 2016).

Cancer Factors: Symptom severity and treatment results or side effects can affect the stress levels of patients, and especially those in Stage II or III who undergo surgery or chemotherapy. Cancer treatment may have a strong negative impact on patients and lead to long-term physical effects such as pain and emotional distress (The American Cancer Society, 2017). Mercadante (2016) estimated that 44% of cancer patients reported pain with 10 to 20% suffering from unrelieved pain. In addition, diagnosis and treatment of side effects often trigger intense emotions that adversely affect daily quality of life (Waller, Williams, Groff, Bultz & Carlson, 2013). Many cancer treatments result in unfavorable side effects and suffering. Opasrattanakorn, Detprapon & Sumdaengrit (2015) reported that cancer patients who received chemotherapy and radiotherapy for at least three months showed a higher level of stress. Furthermore, stress can result in maladjustment over a prolonged period of

time at a sustained level. Increased levels of pain and feelings of chronic stress in cancer patients can cause severe depression which might influence the potential for suicide (Mercanoglu et al., 2015). Mols, Beijers, Vreugdenhil & van de Poll-Franse (2014) conducted a systematic review of 25 published studies of chemotherapy-induced peripheral neuropathy and its association with quality of life among cancer patients. Their results showed that 11 studies identified the association of chemotherapy on quality of life in cancer patients. Borisutbuathip & Kongpanvijit (2014) determined the major cause of death in cancer patients as fever resulting from low white blood cells due to complications of chemotherapy.

Environmental Factors: Cancer patients without psychological family support tend to be highly stressed and more desolate than those with family at their side (Sherman, Kasparian & Mireskandari, 2010). Health personnel that demonstrate attentive listening and willingness to assist cancer patients are better able to reduce stress levels. Financial problems, in particular patients with family responsibilities can increase stress levels (Goedendorp, Gielissen, Verhagen & Bleijenberg, 2009).

2.3.3 The stress response theory

Selye described stress response theory and systematically examined its relationship with health. He noted that several physiological adaptations occurred as a result of repeated exposures to stress that had pathological repercussions. Stress responds to physical and psychological behaviors which are detailed below.

First stage, Alarm reaction: Selye referred to collective changes as the general adaptation syndrome (GAS) whereby the body tries to accommodate and adapt to stress. He identified three stages of GAS. When one has stress, changes occur, especially in the autonomic nervous system (ANS). The ANS has two branches as the

sympathetic and parasympathetic nervous systems. Responses of the sympathetic nervous system to stress can be defined as a series of biochemical exchanges between different parts of the body. The hypothalamus, a structure in the brain, functions as the control center of the sympathetic nervous system and defines the overall reaction to stressors. When the hypothalamus perceives that extra energy is needed to fight a stressor, it releases the hormone epinephrine, also called adrenaline. Epinephrine induces more cardiac output by increasing the heart rate. Blood pressure dilates the airways in the lungs to increase oxygen intake, thereby increasing respiratory rate. Chronic stress is associated with prolonged activation of this stress response (Konduru, 2012).

Second stage, Resistance: The body tries to recover and revert to a state of physiological calmness or homeostasis by resisting the alarm response. However, because the perceived stressor still exists, the body does not achieve complete calm or rest and remains activated or aroused at a level that causes a higher metabolic rate in some organ tissues. If the stress continues, the individual's resources will eventually become depleted, leading to the next stage of GAS (Selye, 2013).

Third stage, Exhaustion: One or more target organs show signs of dysfunction. If the stress continues beyond the body's capacity, resources are exhausted and the patient becomes vulnerable to disease from oncoming cancer leading to death (Selye, 2013).

These changes show how stress contributes to the development of major diseases such as heart disease (Mercanoglu, 2015), diabetes (Thongkhum, 2015) or cancer (Waller, Williams, Groff, Bultz & Carlson, 2013). If continued long-term at a certain level, stress becomes maladaptive in cancer patients, with increasing pain

(Cormanique et al., 2015). For example, increased muscle tension around an area that is already sore is likely to worsen the pain. Moreover, stress also produces changes in the body's hormonal systems (Prasongsook et al., 2017). These changes are believed to affect the pain system, making it more sensitive (Martin & Lizzy, 2015). Thus, stress and pain are major symptoms that severely impact cancer patients and should be concerned for or prevented. If stress continues beyond the body's capacity, the organism exhausts its resources and becomes vulnerable to diseases from oncoming cancer to death (Selye, 2013).

Many studies have investigated the characteristics of Selye's stress response theory. Numerous nursing research intervention studies have been guided by the theory such as "Psychological support and outcomes for ICU patients" (Papathanassoglou, 2010) which explained the role of stress neuropeptides. Moreover, clinical practices have developed from the conceptualization of stress and response theory. Selye's stress response theory has greatly benefitted clinical practices and nursing research.

2.3.4 Stress Assessment Measures

Stress impacts on cancer patients and chronic stress can develop heart failure or depression that lead to thoughts of death (Mercanoglu et al., 2015). Stress assessment in cancer patients, including accurate and effective screening procedures for the initial stage of stress, are important for stress management (Narisa & Srisamorn, 2014). Two methods of stress assessment and screening include observation of expressions from emotions, thoughts, speech, and behavior such as anger, nervousness and insomnia through observation of physical symptoms such as muscle pain, anorexia and constipation (Gutgsell et al., 2013). Another form of assessment uses a questionnaire such as The

Perceived Stress Scale (PSS), a classic form of stress assessment developed in 1983. Assessment of emotions and thoughts during the past month are collected using 10 closed-ended questions with five levels (0-4) as a Likert scale based on the frequency of feeling where 0 means never, 1 means almost never, 2 means sometimes, 3 means often, and 4 means always. Total score of the questionnaire can vary from 10 to 40. Stress level is divided into three levels according to score range. Scores from 10 to 20 indicate low level of stress, scores from 21-31 indicate moderate level of stress, and scores from 32-40 indicate high level of stress (Suetrong, Danaidutsadeekul, Vanitkun & Hanprasertpong, 2016; Lee, Chung, Suh & Jung, 2015).

The stress assessment questionnaire of the Department of Mental Health (SPST-20) assesses stress through physical, emotional, and behavioral changes over the past six months using 20 questions. Scores are divided into five levels. The rating scale ranges from 0-100 with confidence coefficients greater than 0.7. Totals are divided into four levels as follows: score 0-24 indicates low stress, score 25-42 indicates moderate stress, score 43-62 indicates high stress, and score 63 and above indicates severe stress (Tongsawang, 2017).

The SOSI (Symptoms of Stress Inventory) developed by Leckie and Thompson (1979) and adapted from the Cornell Medical Index measures stress assessment by self-perception. SOSI was translated into Thai and used with Thai samples by Muecke (1994) to assess physical, mental, and behavioral responses to stress perceived by patients or emotional, behavioral, mental, and physical changes related to health and illness perceived by patients over the past one month. Physiological assessment considers physical manifestations such as cardiac stimulation symptoms, upper respiratory tract symptoms, neurotic symptoms, gastrointestinal

discomfort symptoms, and muscle tension. Psychological assessment measures habit, depression, anxiety, anger, and confusion. The questionnaire contains 107 closed-ended questions with five levels as a Likert scale. Scores for patients without any response to stress were 1 point and for patients with highest frequent response to stress 5 points. In Thailand, Taawapan (2001) used the questionnaire with myocardial infarction patients. He adapted and reduced the number of questions to 85 with confidence level set at .95. Kaewtha (2003) used the questionnaire with hypertension patients and set the confidence level at .96, while Ruchiwi and colleagues (2012) used the questionnaire with ischemic heart disease patients for a confidence level of .911. Assessment of stress should measure emotional, mental, and behavioral expression simultaneously to be most effective (Narisa & Srisamorn, 2014).

2.4 Importance of Pain as a major symptom in cancer patients

2.4.1 Definition of pain

General and specific definitions from dictionaries and the literature were explored for the meaning of “pain”. The Oxford Dictionary (2017) states, “Highly unpleasant physical sensation caused by illness or injury,” while the Medical Dictionary by Farlex (2017) defines pain as “an unpleasant feeling that is conveyed to the brain by sensory neurons”. Pain Community Center (2017) suggests, “Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.” Fields et al. (cited in Kumar & Elavarasi, 2016) states, “Pain is an unpleasant sensation localized to a part of the body. It is often described in terms of a penetrating or tissue-destructive process (e.g., stabbing, burning,

twisting, tearing, and squeezing) and/or of a bodily or emotional reaction (e.g., terrifying, nauseating, and sickening).”

To summarize, pain is experienced as increased muscle tension around an area and is related to stress and unpleasant feelings.

2.4.2 Concept and principle of pain

Pain experienced by cancer patients is mostly chronic, caused by pressure on the tumor. Cancer metastasis-induced nociceptors send nerve impulses through nerve fibers and the spinal cord to reticular formations in the brainstem. These impulses are processed in the limbic system which induces emotional responses by lowering endorphin levels which causes anxiety and increases pain as a continuous cycle (Juangpanich, Onbunreang, Khansorn, Khansorn & Vatanasapt, 2012). The gate-control theory of Melzack and Wall (1967) consists of four major components; 1. Spinal gate mechanism, 2. Central control system, 3. Central biasing system, and 4. Action system. Each system works collaboratively. Gate-control theory has also been described as three main systems by Leungsomnapa, Prasertsri, Chaiyasung, Suworawatanakul and Sananpanichkul (2015), Melzack and Wall (1967), Juangpanich, Onbunreang, Khansorn, Khansorn and Vatanasapt (2012), Srisaeng and Supornpun (2015) and Lohitthai, Chemama and Siriphan (2017) as follows:

1. The gate control system

This describes substantia gelatinosa (SG) as a gelatinous substance of the dorsal horn of the spinal cord. The dorsal horn acts as gate control sending pain information by transmission cells or T cells. If there is more stimulation in small nerve fibers than large nerve fibers, the T cells send pain information to the brain in two ways through neospinothalamic fibers to the ventrobasal and posterolateral thalamus as well

as to the somatosensory cortex and through medially coursing fibers to reticular formations, the medial intralaminar thalamus and the limbic system resulting in emotional pain or stress manifesting as physical pain.

2. The central control system

When large nerve fibers are stimulated, pain information is sent through the central control system or the brain. Some information is returned to the control system via the spinal cord (gate control system). The theory also describes interests, emotions and pain experienced in the past which affects opening or closing of pain gates at the spinal cord directly or inhibits descending pathways to adjust pain information through different fibers. A person perceives pain in the thalamus and forebrain which is evaluated in the cortex.

3. The action system

This responds to pain through reflex and minimizing pain behaviors. Pain is transmitted to the brain if the gate is opened wider and people usually experience high levels of pain. On the other hand, narrowing the pain gate reduces the pain being experienced (Leaungsomnapa, Prasertsri, Chaiyasung, Suworawatanakul & Sananpanichkul, 2015).

2.4.3 Pain Assessment Measures

Comprehensive pain assessment leads to appropriate and effective treatment with minimal side effects. In general, levels of pain are assessed by self-reporting which depends on several patient factors such as their mental health, emotions, insomnia or medications (Gelinis, Puntillo, Joffe & Barr, 2013). A good pain assessment tool should be easy to use, reliable and appropriate for the patient (Mosley,

Hartman, Tankovich & van de Poll-Franse, 2015). Several pain assessment tools are available.

1. Patient self-reporting and assessing their own pain levels requires setting up questions for them to answer or explain (Puntillo et al., 2014). The questions should cover pain stimuli, characteristics, position, intensity and pain-related activity. Self-reporting is the most reliable method because pain is individual or subjective and no one can describe pain better than the patients themselves (McCaffery, 1983).

2. Assessment of physiological changes such as heart rate, respiratory rate, blood pressure, perspiration and hypothermia are mostly used for patients with acute pain (Boonprakob et al., 2016).

3. Assessment of response behavior can be obtained from observation of facial expressions, gestures, tones of voice, movements, interaction with others as well as expression of emotions. However, this depends on individual factors (Mosley, Hartman, Tankovich & van de Poll-Franse, 2015).

A good pain assessment tool should consist of pain measurement to determine the intensity. There are two types of pain measurements (Chinachoti & Raksakietisak, 2015).

1. Pain assessment without using instruments including;

- 1.1 Simple descriptive scales: For example, a nurse can ask a patient if any pain is being experienced. If the answer is positive the nurse can ask the patient to describe the intensity such as mild, moderate or severe (Puntillo et al., 2014).

- 1.2 Numerical rating scales (NRS): These use numerical ratings as 0 for no pain and 10 for worst pain possible. Patients generally rate their pain scores as 1-2 = acceptable, 3-4 = mild and bearable, 5-6 = moderate. For pain scores above 6, treatment

should be provided along with using pain relief medications (Castarlenas, Jensen, von Baeyer & Miró, 2017; Puntillo et al., 2014; Ruskin et al., 2014).

2. Pain assessment using instruments: Visual analog scale (VAS), numerical rating scales (NRS), simple descriptor scales (SDS) and facial rating scales are all used.

2.1 Visual analog scales (VAS) are measured using a horizontal or vertical line, usually 10 cm in length to represent the actual pain indicated. This method is accurate, quick and easy (Zampelis, Ornstein, Franzén & Atroshi, 2014). However, there are some limitations among patients with mental disorders or visual impairment or patients who have recently awakened after general anesthesia (Thai Society of Clinical Oncology, 2016).

2.2 Numeric scales use a number along a horizontal or vertical line from 0-10 or 0-100 to provide more details of intensity. This method is fast and results can be used to calculate statistical values (Ruskin et al., 2014; Castarlenas, Jensen, von Baeyer & Miró, 2017; Sawangsri, 2017).

2.3 Simple pain scales use a horizontal or vertical line divided into six levels from 0-5 to rate the pain starting from no pain (0) and increasing to worse pain possible (5). This method is fast and easy; however, if the patient does not understand the meaning of each scale, usage of the tool becomes slower (Thai Society of Clinical Oncology, 2016).

2.4 Facial scales use pictures of facial expressions to indicate pain. A smiling and happy face represents no pain, a frowning face represents moderate or bearable pain and a crying face represents worst pain imaginable (Thai Society of Clinical Oncology, 2016). This method is used mostly for children, elders or those who

cannot communicate verbally (Sawangri, 2017). A nurse presents pictures of facial expressions to patients and asks them to point to the picture best describing their pain level at that moment. Scores indicated under the pictures are used for calculation (Techamuanwaiwit, 2015).

2.5 Effective and efficacious cancer-related interventions to mitigate stress and pain

2.5.1 Review of effective and efficacious cancer-related interventions

Non-pharmacologic cancer treatments have been well researched with the aim of reducing cancer-related stress (e.g., fear of diagnosis, treatment options and side effects, and consequences of their diagnosis on family, etc.) (Cormanique et al., 2015) and symptoms (e.g., pain, fatigue, nausea, vomiting, and diarrhea, edema, loss of appetite and weight loss) (Greenberg et al., 2015; Martin & Lizzy, 2015; Toccafondi et al., 2017).

The most common effective non-pharmacologic interventions include studies on: mindfulness meditation (Lengacher et al., 2012), cognitive behavioral therapy (Hofmann, Asnaani, Vonk, Sawyer & Fang, 2012), music (Gallagher et al., 2017), and biofeedback (Alvarez, Meyer, Granoff & Lundy, 2013).

Mindfulness is a practice of meditation that focuses mainly on inward and outward breaths to develop awareness of the present moment, promote relaxation and reduce stress and anxiety (Matchim, Armer & Stewart, 2011). Mindfulness can be used to develop presence of mind and reduce stress in patients with various diseases, especially cancer. Lengacher et al. (2012) conducted a study entitled “Mindfulness Based Stress Reduction in Post-Treatment Breast Cancer Patients: An Examination of

Symptoms and Symptom Clusters”. Results indicated that mindfulness-based stress reduction can decrease symptoms such as fatigue, sleep disorder, stress, and anxiety and contribute to a better quality of life in cancer patients. Piet, Würtzen and Zachariae (2012) also carried out a study entitled “The Effect of Mindfulness-Based Therapy on Symptoms of Anxiety and Depression in Adult Cancer Patients and Survivors: A Systematic Review and Meta-Analysis”. Their findings revealed that mindfulness-based therapy is related to reduction of stress, anxiety, and depression in cancer patients. In addition, a study entitled “The Efficacy of Mindfulness - Based Stress Reduction on Mental Health of Breast Cancer Patients: A Meta - Analysis” by Zainal, Booth and Huppert (2013) indicated that mindfulness - based stress reduction has a positive effect on mental health of breast cancer patients. Their results were similar to a study entitled “A Pilot Study Evaluating the Effect of Mindfulness-Based Stress Reduction on Psychological Status, Physical Status, Salivary Cortisol, and Interleukin-6 among Advanced-Stage Cancer Patients and Their Caregivers” by Lengacher et al. (2012) which suggested that mindfulness-based stress reduction is a useful intervention for reducing stress, anxiety and cortisol levels and is also beneficial to caregivers. Hilton et al. (2016) conducted a meta-analysis of 30 randomized controlled trials using the Hartung-Knapp-Sidik-Jonkman approach for random effects models to examine the evidence on efficacy and safety of mindfulness meditation interventions for the treatment of chronic pain in adults. Their findings revealed low-quality evidence for mindfulness meditation in decreasing pain. The authors noted the need for better designed, rigorous, large randomized controlled trials (RCTs) to provide “estimates of efficacy” of mindfulness mediation in controlling chronic pain. However, Cherkin et al. (2016) conducted a study in 342 adults who were experiencing low back pain and

reported that mindfulness-based stress reduction and cognitive behavioral therapy may be an effective treatment for patients who have pain at 26 weeks.

2.5.2 Music

2.5.2.1 Definition of music

The Cambridge Dictionary defines the meaning of music as, “a pattern of sounds made by musical instruments, voices, or computers, or a combination of these, intended to give pleasure to people listening to it.” The Oxford Dictionary definition is “Vocal or instrumental sounds (or both) combined in such a way as to produce beauty of form, harmony, and expression of emotion.” The Royal Institute Dictionary (2011) has, “Music means sound that consists of rhythm and the instrument of sound making emotional sensations or a sense of love or sadness or happiness, etc. through its rhythm.” Charernsook (1989) gives the meaning of music as, “Music is the matter of arts involving man-made sounds by copying the sounds of nature or whatever, then modifying it to become more systematic. More importantly, it must be an emotional medium to listeners. Linguists try to translate musical sounds and give them meanings that are generally well known. Music is a universal language”.

To summarize, music comprises vocal or instrumental sounds that consist of rhythm and the instrument of sound making emotional sensations.

2.5.2.2 Effects of music on brain response and stress reduction

The musical sounds that are created after passing through auditory apparatus will change emotions through the thalamus, cortex, and limbic areas of the brain (Iamsang, 2013). When a patient listens to music, musical sounds are sent as auditory signals to the thalamus and then to the auditory cortex (Guyton, 1986), which is connected to other areas of the brain and results in changes throughout the entire

body and behavior (Im-erb, Kongchoom & Rimsueb, 2014). This relies on the interconnecting functions of three major body systems as the psycho-neuroendocrine, autonomic nervous, and musculoskeletal systems (Wells-Federman et al., 1995). Musical sounds are sent from the brain's auditory cortex to the limbic system, which is the center for emotional behavior control, feelings, and taste (Guzzetta, 2000; Willis, 1993). The limbic system releases endorphins as hormones for neural signaling. These can change emotions and are created by neural cells for conduction. Endorphin secretion results in pleasant feelings throughout the body (Iamsmang, 2013). Music moves from the ear to the center of the brain and the limbic system which controls emotional responses. Suitable music stimulates the brain to release endorphins to ease the mind and reduce stress (Juangpanich, Onbunreang, Lunlud, Khansorn & Vatanasapt, 2012). Furthermore, music also affects the autonomic system by reducing sympathetic system functions of epinephrine and norepinephrine secretion. This lowers the heart rate, blood pressure and breathing rate (Guyton & Hall, 2000) and contributes to relaxation when hearing music. Music appropriate for reducing stress and worry should have a slow, constant rhythm of around 60-80 beats per minute (bpm) along with loudness of around 60-90 decibels (Juangpanich, Onbunreang, Lunlud, Khansorn & Vatanasapt, 2012; Permpech & Butsripoom, 2016).

2.5.2.3 Effects of music on the brain response, pain pathways and pain reduction

The use of music to sway patient emotional reception was based on the Gate Control Theory of Pain by Melzack & Wall. This states that the mechanisms of pain reception control are at the spinal level, which adjusts nerve impulses before pain transmission to the brain. If large dendrites have more nerve impulses than small

dendrites (pain reception), nerve impulses from large dendrites will stimulate SG cells in the spine to prevent nerve impulses from connecting to T-cells. Thus, nerve impulses will not be sent to the brain to acknowledge pain, equivalent to closing a door. However, small dendrites have more T nerve impulses which interrupt the function of SG cells, resulting in nerve impulse transmission to T cells to the brain, producing painful sensations as the equivalent of opening a door (Guzzetta, 2000; Wells-Federman et al., 1995). Patients listening to music will focus on the sounds. Thus, musical signals are comparable to positive stimulants that allow the brain to experience pleasant, fun, and relaxing signals instead of pain and worry. This is equivalent to closing the door that sends pain signals through musical stimulation. Thus, the brain does not sense pain, leading to reduction in worry and stress (Im-erb, Kongchoom & Rimsueb, 2014). Furthermore, the body naturally controls pain using chemical substances known as endorphins whose production can be stimulated by music. When the patient is listening to or playing their preferred music, endorphins are produced in the body leading to feelings of relaxation (Chiengchana & Trakranrung, 2015). Music used to reduce pain should be soft with a constant rhythm containing no sharp or hustling sounds. Music used for relaxation and to reduce worry should be played at a soft volume to maximize participation by the listener (Im-erb, Kongchoom & Rimsueb, 2014).

2.5.2.4 Relaxation music technique on stress and pain in cancer patients

Music positively stimulates the body, mind and emotions to reduce pain, stress and depression (Im-erb, Kongchoom & Rimsueb, 2014). Music is used to reduce stress and chronic pain of cancer patients by stimulating the nociceptors and sending nerve impulses along nerve fibers to the spinal cord and reticular formations in the brainstem which works together with the limbic system. Pain is reduced as endorphins

are released. The stress and pain will be increased as the repeated cycle (Juangpanich, Onbunreang, Khansorn, Khansorn & Vatanasapt, 2012).

Music influences changes in emotions through the thalamus, cortex and limbic system. When patients listen to music, sound is transferred as nerve impulses to the thalamus and auditory cortex (Guyton, 1986). These areas of the brain change body behavior through the working operations of three main systems of the body as the psychoneuroendocrine system, autonomic nervous system and musculoskeletal system. Music is transferred from the auditory cortex of the brain to the limbic system which is the control center of emotional behavior, feeling and taste (Guzzetta, 2000; Iamsaang, 2013) to stimulate the release of endorphins as neurotransmitters that affects emotions. T-cells are not activated and pain is reduced. According to pain theory, stress will be also reduced (Wells-Federman et al., 1995; Guzzetta, 2000; Juangpanich, Onbunreang, Khansorn, Khansorn & Vatanasapt, 2012). Moreover, music also affects the autonomic nervous system by slowing down the sympathetic nervous system and releasing epinephrine and norepinephrine. As a result, heart rate, blood pressure, and respiratory rate decrease (Guyton & Hall, 2000). Thus, the body relaxes when musical sounds are transferred as nerve impulses to the auditory cortex to deactivate the central nervous system. This relaxes the muscular system and reduces muscle rigidity (Wells-Federman et al., 1995).

2.5.3 Biofeedback Program

2.5.3.1 Definition of biofeedback

Biofeedback is defined in The Medical Dictionary defines biofeedback as “a patient guided treatment that teaches an individual to control muscle tension, pain,

body temperature, brain waves, and other bodily functions and processes through relaxation, visualization, and other cognitive control techniques”.

In the Cambridge Dictionary (2017) as “a method by which a person learns to control their heart rate and other physical or mental processing using recorded information”. In psychology, biofeedback is “a treatment technique in which people are trained to improve their health by using signals from their own bodies”. Ratanasiripong, Kaewboonchoo, Ratanasiripong, Hanklang and Chumchai (2015) defined biofeedback as “a mind-body, self-regulation process for improving performance and health. Through biofeedback equipment, the individual can become aware of his or her physiological function so that he or she can learn to modify thoughts, feelings, or behaviors to make positive changes to that physiological function”. Schwartz (2017) refers to biofeedback as “a process that enables an individual to learn how to change physiological activity for the purposes of improving health and performance”.

Here, biofeedback refers to non-pharmacological intervention in which patients are trained to self-regulate by practicing signals from their own bodies involving the use of EEG and EMG equipment.

2.5.3.2 Electroencephalograph (EEG) biofeedback program

An electroencephalograph (EEG) is used to examine brain function through changes in electrical brain waves signals. Brain waves appear to move up and down and are measured in units of rounds per second (Vittayakittipong, 2006). Examination of human brain waves was first undertaken by a German psychiatrist named Hans Berger in 1924. Later, he discovered alpha wave rhythms which disappear when

patients open their eyes or think. He was the first scientist to examine and interpret brain waves (Finger, 2001; Vittayakittipong, 2006) as differing between individuals.

Brainwaves are electromagnetic impulses generated by bio-chemical activities inside human brain cells which are measured by an electroencephalograph (EEG). Frequency units of these waves are measured as cycles per second or Hertz (Hz). The fundamental frequency of brainwaves can be changed based on the state of neuro activities inside the brain connecting to changes in emotion and consciousness. Brainwaves can be divided into four levels as follows: (Koelsch, 2014; Milicevic & Marymount, 2013; Ruchiwi, 2014; Wu, Zhang, Ding & Zhou, 2013).

Levels of Brainwaves

1. Beta waves. The fastest brainwaves, beta waves are basic level brainwaves with frequency above 13 cycles per second (Hz). They engage in linear-thinking mental activities. Frequency of beta waves is unevenly fast and they occur during the usual mental state of a person or when specific ideas are not focused. Beta waves can cause physical and mental uproar and confusion as well as short-term memory loss and learning difficulties. Beta brainwaves also indicate an uncomfortable state of mind.

2. Alpha waves. These range from 8 to 12 Hz. According to the alpha sleep report, this state is neither falling asleep nor awake but a semiconscious one under the active mind. It also refers to the moment a person is interested, emphasizes, and concentrates in doing any activity. Alpha waves are characteristic of a relaxed yet alert state of awareness and promote fast and easy learning.

3. Tetra waves. Frequencies of these brainwaves are 4 to 8 Hz. Tetra waves are generated during falling asleep and coming awake. During sleep, tetra waves

connect the brain to dreams while an awake state generates this wave type through creative thinking, imagination, clear images with eyes closed, and state of consideration for solving problems. These states are really important in terms of creative thinking as Tetra waves are generated by people who enjoy recreation and practice meditation.

4. Delta waves. Frequencies of these brainwaves are 0 to 4 Hz. Delta waves are involved in the deepest relaxation and generated when falling asleep with slow metabolism, low blood pressure, body temperature and heartbeat. Apart from the state of nearly asleep or falling asleep, the level of this brainwave is rarely generated with a person of other states but monk, hermit, priest, or practitioner who always creates a happier mind.

Sound waves can arouse changes in the state of human brainwaves when detected by listening to songs and electrical waves will then harmoniously synchronize with the frequency of each level of brainwaves. Delta waves arouse the brain to self-synchronize or connect to the rhythm of the music.

Electroencephalograph (EEG) biofeedback program procedure

The patient should lie flat on the bed or sofa in a comfortable position. The therapist measures their head to find the locations for electrode placement on the scalp. For example, the frontal lobe is associated with speech, personality, concentration, and decision-making. The parietal lobe is associated with sensory areas, understanding, and speech. The temporal lobe is associated with auditory and memory areas. The occipital lobe is associated with visual areas and the cerebral cortex is associated with the functioning of sensitive muscles such as eating food, use of finger digits, etc. (Ruchiwi, 2014). Scalp areas on which the electrodes will be placed are cleaned. The electrodes

are then attached at the desired locations and brain waves are recorded (Vittayakittipong, 2006).

2.5.3.3 Electromyography (EMG) biofeedback program

Electromyography (EMG) is a tool used to record electrical signals transmitted by motor units to reflect forces created from muscle contractions (Techatanawat & Tangtragoonpaisarn, 2014).

EMG biofeedback is used to train striated muscle states (stressed or relaxed) and allows a person to control muscle contraction and relaxation accurately (Ruchiwi, 2014) by recording the location of the frontalis muscle around the forehead following muscle contractions from headaches, the masseter muscle around jaws when it contracts from anger, and the trapezius muscle around the shoulders when it contracts due to stress (Ruchiwi, 2014; Techatanawat & Tangtragoonpaisarn, 2014).

EMG biofeedback program procedure

The patient should lie flat on the bed or sofa in a comfortable position. The researcher attaches electrodes to the muscles to be measured. The electrodes are divided into two types as needle electrodes and surface electrodes to indicate the weight of muscle contraction (Robinson, 2008). During measurement, this procedure is combined with relaxation techniques by having the subject tense their muscles and gradually relax them, whereupon the EMG displays images that indicate muscle contraction and relaxation states. This is repeated until achieving control of the contracted and relaxed states. Muscles in a relaxed state normally have a wave amplitude of between 3-5 microvolts (Ruchiwi, 2014; Techatanawat & Tangtragoonpaisarn, 2014).

Summary and Importance of the proposed study

Cancer induces painful suffering which ultimately leads to death. Furthermore, cancer also affects patients physically and mentally, especially through pain and stress. The feeling of pain generally found in cancer patients reduces their quality of life. Pain is one cause of suffering (Carr et al., 2002) and leads to worsening of the disease's condition. Stress induces feelings of worry. Cancer patients and their families will feel stress about the side effects of treatment, recurrence and prognosis leading to death as well as treatment costs. If the stress becomes chronic, it will also affect the lives of patients and their families (ASCO, 2017), leading to depression and possibly potentially self-harm (Mercanoglu et al., 2015).

A literature review indicated that therapeutic music and biofeedback program training are methods that patients can use to train and control their stress and pain levels without additional costs. This training can be done anywhere and anytime. Music has been shown to improve quality of life by relieving pain and reducing stress in cancer patients. Music affects the autonomic nervous system by stimulating the pituitary gland to release endorphins which induce pain relief and divert the patient's attention to the music. Research has shown that therapeutic music can be used to improve pain levels of cancer patients (Gutgsell, 2013; Kaliyaperumal & Subash, 2010), while biofeedback program training can induce bodily changes via emotional stress or pain control. Relaxation techniques can improve patients' awareness, thoughts, behaviors, and emotions related to bodily changes (Frank et al., 2010). Therapeutic music and biofeedback training have protective effects through stress and pain reduction for cancer patients as an important tool for reducing bodily and mental symptoms as stated. Studies of the effects of therapeutic music and biofeedback

program training for stress and pain reduction will help patients to approach stress appropriately, reduce death rates and costs, as well as offer guidelines to reduce undesired symptoms such as stress. Pain reduction in cancer patients can also be applied to nursing patients with other diseases.



CHAPTER III

METHODOLOGY

Introduction:

This chapter details the methodology used to conduct this research, beginning with a description of the research design and followed by the sample, sampling procedures, sample size calculations, and randomization protocols.

3.1 Research Design

This study included a between-group randomized controlled trial (RCT) repeated measure design (see Table 3.1). It is a true experimental design in which the participants were randomly assigned to one of four treatment groups comprising a music group, a biofeedback group, a music together with biofeedback group, and a control group. Random assignment was used to increase equality between the treatment groups. Meanwhile, RCT can reduce bias because the variables can be controlled for random allocation of subjects, which eliminates bias and creates comparable groups. The results are representative of the population studied (Lorraine K. A., Brettania Lopes, and Kristen Ricchetti-Masterson, 2015).

Table 3.1

Between Groups Randomized Control Trial repeated measure design

Randomized	Sample	First time	Fourth time	Eighth time
R	E ₁	O ₁₁	O ₁₂	O ₁₃
R	E ₂	O ₂₁	O ₂₂	O ₂₃
R	E ₃	O ₃₁	O ₃₂	O ₃₃
R	C	O ₄₁	O ₄₂	O ₄₃

R = random assignment to group

E₁ = experimental group 1 comprising Thai cancer patients who received music and routine nursing care provided by Thammasat Radiation Oncology Center (TROC) at THU.

E₂ = experimental group 2 comprising Thai cancer patients who received a biofeedback training program and routine nursing care provided by Thammasat Radiation Oncology Center (TROC) at THU.

E₃ = experimental group 3 comprising Thai cancer patients who received music together with a biofeedback training program as well as routine nursing care provided by Thammasat Radiation Oncology Center (TROC) at THU.

C = control group comprising Thai cancer patients who only received routine nursing care provided by Thammasat Radiation Oncology Center (TROC) at THU.

O₁₁ = stress response and pain response before receiving music and routine nursing care at TUH from the same nurse and same treatment for the first time

O₁₂ = stress response and pain response while receiving music and routine nursing care at TUH from the same nurse and same treatment for the fourth time

O₁₃ = stress response and pain response after receiving music and routine nursing care at TUH from the same nurse and same treatment for the eighth time

O₂₁ = stress response and pain response before receiving a biofeedback training program and routine nursing care at TUH from the same nurse and same treatment for the first time

O₂₂ = stress response and pain response while receiving music and routine nursing care at TUH from the same nurse and same treatment for the fourth time

O₂₃ = stress response and pain response after receiving a biofeedback training program and routine nursing care at TUH from the same nurse and same treatment for the eighth time

O₃₁ = stress response and pain response before receiving music together with a biofeedback training program and routine nursing care at TUH from the same nurse and same treatment for the first time

O₃₂ = stress response and pain response while receiving music and routine nursing care at TUH from the same nurse and same treatment for the fourth time

O₃₃ = stress response and pain response after receiving music together with a biofeedback training program and routine nursing care at TUH from the same nurse and same treatment for the eighth time

O₄₁ = stress response and pain response of the control group for the first time

O₄₂ = stress response and pain response of the control group for the fourth time

O₄₃ = stress response and pain response of the control group for the eighth time

3.2 Population and sample

3.2.1 Population

The study population included cancer patients with Stage IIB or III cancer who were in the process of receiving treatment and routine nursing care provided by Thammasat Radiation Oncology Center (TROC) at TUH in 2018.

3.2.2 Sample

The population under study comprised patients who suffered from either stage IIB or stage III cancer and were receiving treatment and routine nursing care provided by Thammasat Radiation Oncology Center (TROC). The cancer types at TUH included colorectal, lung, breast or cervical/ ovarian. Data was collected for four months between June and October 2018.

3.2.3 Selection sample

(1) The inclusion criteria were determined based on the following criteria: the person (a) is 18 years of age or older; (b) is able to speak, read, and write in Thai; (c) has either stage IIB or stage III cancer and being treated at Thammasat University Hospital (TUH); (d) has a moderate level of stress (scores between 44-137) and a mild to moderate level of pain score (score between 1-6); (e) enjoys listening to music; and (f) has no previous record of training with biofeedback training or music.

(2) The exclusion criteria were determined based on the following criteria: the person (a) has an existing record of experiencing complications that could potentially impede medical treatment; or (b) is deemed to be psychopathic or has a mental illness.

3.2.4 Sample size

The study sample size was calculated to ensure the theorized differences and relationships could be effectively detected 80% of the time. To determine the sample size required for this research power was 0.80, the level of confidence was set at 95%. That means the level of significance was set at 0.05. This study used the same effect size of 0.33, as this has been suggested and considered to be moderate according to “The effect of meditation training coupled with biofeedback training on the stress levels of chronic disease patients” (Thongkum, 2005). The sample size was determined using G*Power software Version 3.1.9.2, which suggested a sample size of 80 participants. The researcher then divided the 80 participants into four evenly sized groups of twenty participants. An additional eight participants were recruited to account for the potential loss of 10% of participants during the study. Thus, a total of 88 participants were used to represent the target population, who were then divided into four separate groups comprising 22 participants.

3.2.5 Sampling method

3.2.5.1 Enrollment

Participants were recruited in 2018 from the target patient population at Thammasat Radiation Oncology Center (TROC). At the time, patients were undergoing treatment for either stage IIB or stage III cancer. After the proposal was approved by the IRB of the university and the Ethics Committee of TUH, the researcher contacted the head of nursing and a physician at Thammasat Radiation Oncology Center (TROC) about matching similar types of cancer and treatment. Recruitment was undertaken for every month between May to October 2018 with random selection of candidates for the four study groups. The number of cancer patients was recorded in the enrollment

process. A computer-based randomization method was used to select participants for the chosen sample size. The 88 cancer patients were subsequently assigned to four mutually-exclusive groups comprising three experimental groups and one control group.

3.2.5.2 Random assignment

All participants were randomly assigned to one of the four treatment conditions (music and routine nursing care, biofeedback programs and routine nursing care, music together with biofeedback programs and routine nursing care, and routine nursing care only) using SPSS Version 24 random number generator to place an equal number of participants in each group to enhance the equivalence between the groups. To minimize the risk of predicting the treatment assignment for the next eligible participant, randomization was performed in permuted blocks of four using a random blocking number order by matching similar cancer types and treatments. Consequently, 22 participants from the sample of 88 participants were assigned to each of the four groups, namely experimental group 1 ($n = 22$), experimental group 2 ($n = 22$), experimental group 3 ($n = 22$), and the control group ($n = 22$).

3.2.5.3 Follow-up

The researcher visited the participants on a weekly basis to assess the pain and stress levels they were experiencing as well as to review their daily logs with them to inquire about whether they were having any difficulty listening to the music during the research. (see Figure 3.1).

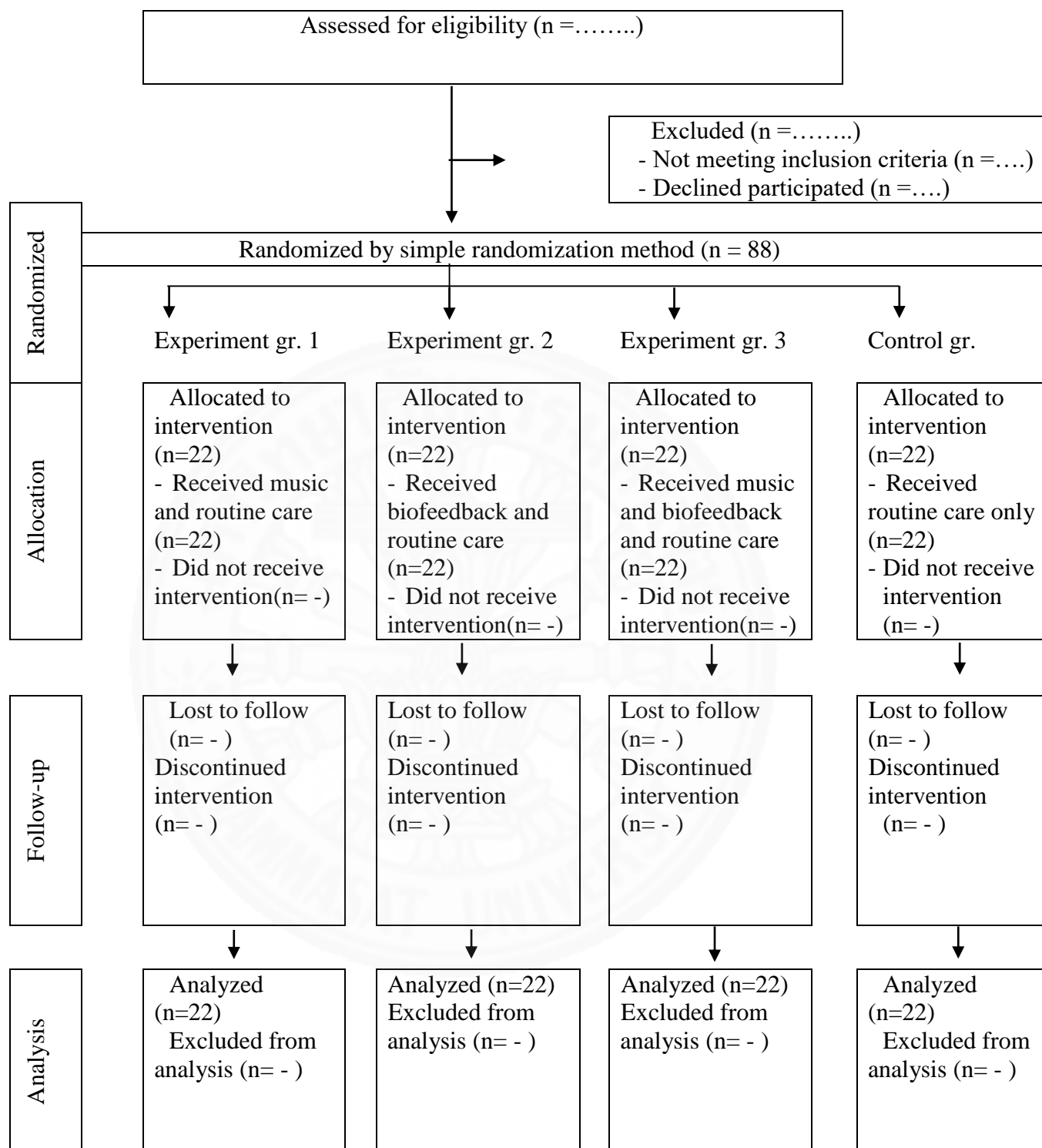


Figure 3.1 Consort flow diagram of A Randomized Controlled Trial Examining the Effects of a Music and Biofeedback Program on Thai Cancer Patients receiving Palliative Care

3.3 Instruments, questionnaires and materials used in the research

(1) A **socio-demographic data form** was used to collect data related to the characteristics of each cancer patient. Data related to medical history was assessed based on each patient's medical record. Personal data included the patient's gender, age, level of education and medical records detailing the type of cancer, the kind of medical treatment, the duration of illness (in years), the frequency at which the patient listened to music and the frequency of pain relief medication.

(2) **Modified Symptoms of Stress Inventory in Thai version (Modified SOSI)** is a method of assessment created by Leckie & Thompson (1979) which was subsequently translated into Thai and tested with Thai people by Marjorie A. Muecke (Muecke, 1994) using 107 questions. Thaophan (2001) ran an experiment with a sample of patients with myocardial infarction by modifying the questionnaire to only include 85 questions with reliability of .95, while Kaewtha (2003) applied the questionnaire to sample hypertensive patients and gained reliability of .96. Ruchiwi, Rugwongprayoon, Vuthiarpa, & Liagchawengwong (2012) applied the same questionnaire to a sample of heart disease patients and gained reliability of .91. Thongkhum (2015) took the modified questionnaire of 85 questions to test with a sample of patients with chronic illnesses including diabetes, hypertension and Ischemic heart disease, gaining reliability of .87. For this study, the researcher adapted the questionnaire by shortening the set of questions to only cover topics concerning the body, mind and behavior so as to be suitable for cancer patients, leading to the new set of 55 questions. After that, the researcher submitted the questionnaire to five experts and Marjorie A. Muecke, who created the SOSI questionnaire to check for content validity, the consistency of the contents, and the accuracy of the language as well as the item-objective congruence

(IOC) of the modified SOSI, which was found to be between 0.6-1.0 and improved the questionnaire based on feedback from the experts. The final questionnaire comprised 30 questions. In order to test for reliability, the researcher administered the modified SOSI to a select group of 30 cancer patients who were similar to the target sample in order to test their understanding of the questions in the questionnaire and compute the reliability of the questionnaire by measuring internal consistency with Cronbach's alpha coefficient. The purpose of this assessment was to measure the degree of response to stress of the body, mind and behavior during the previous month. The assessment consisted of closed-ended questions with possible answers in the form of a Likert Scale ranging from 5 to 1. On average, it took approximately 20-25 minutes to complete the assessment. The scale factors are given as follows:

1	=	Never
2	=	Rarely
3	=	Sometimes
4	=	Often
5	=	Very often

For this modified SOSI instrument, valid scores range between 30 and 150 and are divided into three ranges based on a normal distribution with a mean and a standard deviation.

This modified SOSI instrument has a minimum score = 30, maximum score = 150, mean = 90, and a standard deviation = 47 (Tan and Michel, 2011; Mercer and Pullen, 2009).

The levels of stress can be determined as follows:

Average score between	33-43	=	low level of stress
Average score between	44-137	=	moderate level of stress
Average score between	> 137	=	high level of stress

Since the focus of this study was on cancer patients with moderate levels of stress, only those patients with average scores between 44 and 137 were invited to participate in this study.

(3) Pain score is measured using a numerical rating scale by TUH to help determine the level of pain on a scale of 0 to 10 with 0 being painless and 10 being the most severe pain (Krebs, Carey, & Weinberger, 2007; Sawangsri, 2017). By using a pain score, the participants could accurately identify the levels of pain they were experiencing. The interpretation of numbers and categorical scale is as follows:

0	=	No pain
1-3	=	Mild pain
4-6	=	Moderate pain
7-9	=	Severe pain
10	=	Severe and unbearable pain

Since the focus of this study was on cancer patients with mild-to-moderate levels of pain, only those patients with pain scores ≤ 6 were invited to participate in the study.

(4) Biofeedback training programs involve the use of EEG and EMG. EEG biofeedback is a method for detecting the electrical activity of the brain in the form of brainwaves, which can be represented as waveforms of various amplitudes and frequencies. In this study, EEG biofeedback was used to measure the electrical activity

of the temporal lobe, which is the main part of the brain responsible for auditory perception. The results of the measurements were desynchronized patterns generated during feelings of stress and excitement, which are responsible for occurrences of beta frequencies in the brain (Jena, 2015; Ruchiwit, 2014). In this study, alpha waves in frequencies ranging between 8 and 12 hertz were tracked and recorded. EMG biofeedback can be used to measure muscle tension. Muscle tension of more than 3-5 microvolts, especially in the trapezius and generated as a result of stress, was measured via EMG (Ruchiwit, 2014). During EEG and EMG biofeedback training, the participants could visualize graphical diagrams corresponding to their brain waves and muscle tension on Procom Infiniti. Experimental Group 2 received EEG and EMG biofeedback training one day per week over a period of eight weeks, with one session lasting approximately 45-60 minutes.

(5) **Music** comprises various choices in terms of music genres that can be used in music therapy, including but not limited to classical, jazz, royal and Thai instrumental music as well as relaxing nature sounds, all of which have similar rhythms of roughly 60 to 66 beats per minute in common. Music has the ability to increase the generation of alpha waves in the brain and increase feelings of relaxation in cancer patients. A committee of five professionals, consisting of a psychiatric mental health nurse instructor, a psychiatrist, a doctor, and two professional music therapists, reviewed the choices of music to be administered to the participants. For each individual, the piece of music that triggered the generation of alpha waves in the brain within the shortest period of time was selected. The participants from the intervention group were made to listen to their music of choice with headphones connected to an MP3 player, which was played twice a day (15-30 min per session), once early in the

morning (5 a.m.–11 a.m.) and once in the evening (6 p.m.–11 p.m.) for at least 15 minutes each.

(6) **Guidelines for stress and pain management** for cancer patients included a sufficient amount of knowledge on the causes, effects and advice on how to manage stress and pain in cancer patients.

(7) **A personal home music record**, which keeps track of how frequently a patient listens to music at home, was kept for each patient.

3.4 Monitoring the quality of tools

3.4.1 Content validity

Monitoring was performed to establish the content validity of the data form, the home music recording form, the music, the biofeedback training program, and the stress and pain management guidelines. This was primarily done through a committee of five specialists consisting of a psychiatric mental health nurse instructor, a psychiatrist, a doctor, and two professional music therapists, who examined the nature and consistency of the contents as well as the language accuracy. All items were required to obtain inter-rater agreement from the specialists at a rate greater than or equal to 80%. Scores on the index of item-objective congruence (IOC) of the Symptoms of Stress Inventory (SOSI) were found to lie between 0.6-1.0, with a significant level of .05. After the committee approved the content validity, the tools were tested using the known group technique on a very select group of five cancer patients (at Bang Khayaeng Health Promoting Hospital), who shared a reasonably high degree of similarity (inter-rater agreement) with the participants to check their suitability and determine whether the tools could be used safely with the study participants.

3.4.2 Reliability

The author used Cronbach's Alpha coefficient in an experiment conducted with a trial group of 30 cancer patients (at 4th Health Region Promotion Center) who shared a reasonably high degree of similarity with the sample participants ($\alpha = 0.906$) in order to test and evaluate the reliability of the SOSI and pain score tools.

3.4.3 Calibration of biofeedback instruments

Since the calibration of EEG and EMG biofeedback instruments normally requires advanced skills and knowledge, the researcher and research assistants received training from biofeedback specialists on the correct use of the instruments, how they are calibrated, and how to check their validity.

3.5 Action research data collection

3.5.1 Preparations

(1) The researcher and research assistants (three people) were trained by a biofeedback specialist to use music combined with biofeedback training. Practice was undertaken in conjunction with a biofeedback training specialist. The researcher received a certificate for a three-day biofeedback training program administered by the Psychiatric Nurse Association of Thailand.

(2) The proposal was approved by the Institutional Review Board of the University Ethics Committee and the Ethics Committee of TUH.

(3) A letter of recommendation from the Faculty of Graduate Studies, Thammasat University, was submitted to the directors asking for permission to conduct the study.

(4) The researchers met the head of the out-patient ward at TUH to explain the objectives and nature of the study in order to garner their cooperation for data collection.

3.5.2 Implementation of data collection

(1) The patients were recruited from the out-patient ward, and patients meeting the study criteria were approached.

(2) The researcher introduced herself and explained the study purpose and methodology, while emphasizing that the data would be used confidentially and anonymously. Verbal informal consent was provided after the explanation, before a formal written consent form was subsequently provided.

(3) The participants were asked to answer a number of questionnaires and tests in the following order: (a) socio-demographic data form; (b) Symptoms of Stress Inventory (SOSI); (c) pain score; (d) electroencephalograph (EEG) and electromyography (EMG) score; and (e) vital signs.

(4) After completing the data collection, all the questionnaires were checked to ensure that each questionnaire item was answered and to verify data completeness.

(5) After completion of the baseline data collection, the 88 participants that had satisfied the selection criteria were randomized into one of the three experimental groups or the control group, resulting in 22 participants in each group.

(6) Experimental group 1 included cancer patients who received music and routine nursing care provided by Thammasat Radiation Oncology Center (TROC) at TUH. This group listened to music through headphones connected to an MP3 player twice a day (15-30 min per session), once in the early morning between 5 a.m. and 11

a.m. and once in the evening between 6 p.m. and 11 p.m. for at least 15 minutes. Patients were also given a form to record the frequency that they took pain relief medication, detailing the date, time, and type of pain relief medication taken.

(7) Experimental group 2 included cancer patients who received biofeedback training and routine nursing care provided by Thammasat Radiation Oncology Center (TROC) at TUH. A medication tracking form was used to record the frequency of pain relief medication used, including the date, time, and type of pain relief medication. Group 2 received biofeedback training one day per week for a total of eight training sessions.

(8) Experimental group 3 included cancer patients who listened to music together with biofeedback training and also received routine nursing care provided by Thammasat Radiation Oncology Center (TROC) at TUH. This group listened to music through headphones connected to an MP3 player every day. They also completed a form to record the frequency with which they took pain relief medication, detailing the date, time, and type of pain relief medication. Group 3 received music together with biofeedback training one day per week for a total of eight training sessions.

(9) The control group only received routine nursing care and used a form to record the frequency with which they took pain relief medication, detailing the data, time, and type of pain relief medication.

(10) By the end of the experiment, the groups had completed eight sessions. The participants from all experimental groups and the control group were asked to complete questionnaires to determine post-test scores.

3.6 Protection of rights for sample participants

This study was submitted to the Institutional Review Board of the University Ethics Committee and the Ethics Committee of TUH. All objectives and research plans were explained to the head nurse of TUH. All participants were informed about the study objectives and methodology, as well as about how the data was collected and their right to confidential use of their personal information. The benefits for the participants in taking part in the research included learning about how to manage stress and pain. Such information could help to reduce their chances of having a relapse or incurrent diseases, as well as lowering treatment costs. For the risks associated with participating in the research, the researchers assessed the readiness of the patients continuously in terms of their physical and mental health. If a condition arose unexpectedly, the patient was immediately placed under the care of a doctor. Communication between the researchers and participants was expressed in both written and verbal forms to ensure that the participants truly understood the study and their participation in it. Subsequently, the participants were asked if they would like to participate in the study. A process of informed consent was completed prior to the data collection process. Participants were informed that their decision to participate in the study would have no influence on their treatment or hospital services. The subjects were assured of their confidentiality and that they were free to discontinue participation in the study at any time throughout the data collection process. The researchers looked closely for any changes in the patients during the experiment. If any medical problems of congenital diseases arose, whether physical or mental, assistance was provided immediately. Discontinuation criteria were used either upon completion of the data collection or when a patient left the program.

3.7 Data analysis

Data analysis was undertaken in three sections. First, the researcher screened the data to test for normality. Missing data was also assessed. The second stage focused on reporting the socio-demographic and descriptive statistics by intervention. The final data analysis stage was the primary analysis, which focused on analyzing the four research hypotheses. An intent to treat (ITT) analysis was conducted on all the research questions to reduce the bias of reporting results for the participants considering that they continued to have treatment, which increased the likelihood of creating a positive treatment bias effect (Shrier et al., 2014). Screening: Normality and Missing data was assessed in the data screening phase of the data analysis plan. Assumptions of normality were assessed using histograms, skewness, and kurtosis. Either the Shapiro-Wilk test or Kolmogorov-Smirnov test was used as well.

SPSS Version 24 Missing Value Analysis was used to assess the patterns and extent of the missing data. Data may be missing completely at random (MCAR), missing at random (MAR), or not missing at random (NMAR). Depending on the extent and patterns of the missing values, missing data was imputed using multiple imputation with a fully conditional MCMC model. The monotone protocol was utilized if the patterns were more monotone (Allison, 2002). Sensitivity analysis was conducted between the original data that included the missing values, as well as for the imputed values of the ITT analysis across all relevant predictors and outcomes. If there was no significant difference between the two databases, the imputed ITT data was used during the primary analyses. If there was a difference between the original data and the imputed ITT database, both databases were used to analyze the four hypotheses and the

differences in the findings were described (Bell et al., 2014; Carpenter, Kenward, and White, 2007).

The preliminary analysis reported socio-demographic and descriptive data disaggregated by treatment group, such as means, standard deviations, and frequencies. Two-way ANOVA was used to test baseline differences between the four treatment groups for the continuous variables, while Chi-square investigated the treatment group differences on categorical variables (Field, 2018). Group differences for both the socio-demographic variables and the baseline dependent variables of SOSI, EEG, EMG, VS, as well as the biofeedback results from the pain score and pain relief medication frequency, were explored.

Primary Analyses

Hypothesis 1: Patients who receive music and biofeedback will have a more significant decrease in pain compared to the music only group, biofeedback only group, and control group. This hypothesis was tested using a between-groups repeated measure ANOVA, which is the most appropriate technique for this analysis since the outcome variable was measured multiple times and is continuous with a categorical independent variable (music and routine nursing care, biofeedback programs and routine nursing care, music together with biofeedback programs and routine nursing care, and routine nursing care only). To assess the group differences, both Bonferroni multiple comparison correction and contrast will be used (Field, 2018; Steven, 2009).

Hypothesis 2: Patients receiving music and biofeedback will have a more significant decrease in stress compared to the music only group, biofeedback only group, and control group. This hypothesis will also be tested using a between-groups repeated measure ANOVA with Bonferroni correction and contrast.

Hypothesis 3: Patients receiving music and biofeedback training will have a more significant decrease in the construct of healthy functioning as measured by a linear combination of SOSI, pain score, EEG, EMG, and vital signs compared to the music only group, biofeedback only group, and control group. To test this hypothesis, repeated measures between factors MANOVA was used for changes in this latent construct utilizing several correlated dependent variables (stress and pain). The researcher favored a single, overall statistical test for this set of variables. In some cases, the more important reason for this was to explore how the independent variables (the treatments of the four groups) influenced some of the response patterns of the dependent variables (stress and pain) (Carey, 1998).

CHAPTER IV

RESULTS

Effects of music together with biofeedback training were investigated with respect to self-reported pain and stress, and relief of pain and stress among a population of cancer patients who received treatment and routine nursing care provided by Thammasat Radiation Oncology Center (TROC) between June and October, 2018. The sample consisted of 88 cancer patients who met the inclusion/exclusion criteria. The study purpose was explained and patients consented to participate. The experiment consisted of a between groups randomized controlled trial repeated measure design, with four equal groups of 22 participants as three experimental groups and a control group for 8 measurements in total. Experimental group 1 comprised cancer patients that received music and routine nursing care provided by Thammasat Radiation Oncology Center (TROC) at TUH. Experimental group 2 comprised cancer patients that received biofeedback and routine care provided by Thammasat Radiation Oncology Center (TROC) at TUH. Experimental group 3 comprised cancer patients that received music together with biofeedback training and routine nursing care provided by Thammasat Radiation Oncology Center (TROC) at TUH and the control group comprised cancer patients that received routine nursing care only. Findings are shown in the tables and figures with results described as follows:

Part I Sociodemographic characteristics of the samples.

Part II Comparison of SOSI score, pain score, EEG, EMG, and vital signs between patient groups who received music only, biofeedback only, music and biofeedback training, and the control group.

Part I A socio-demographic characteristics of the samples

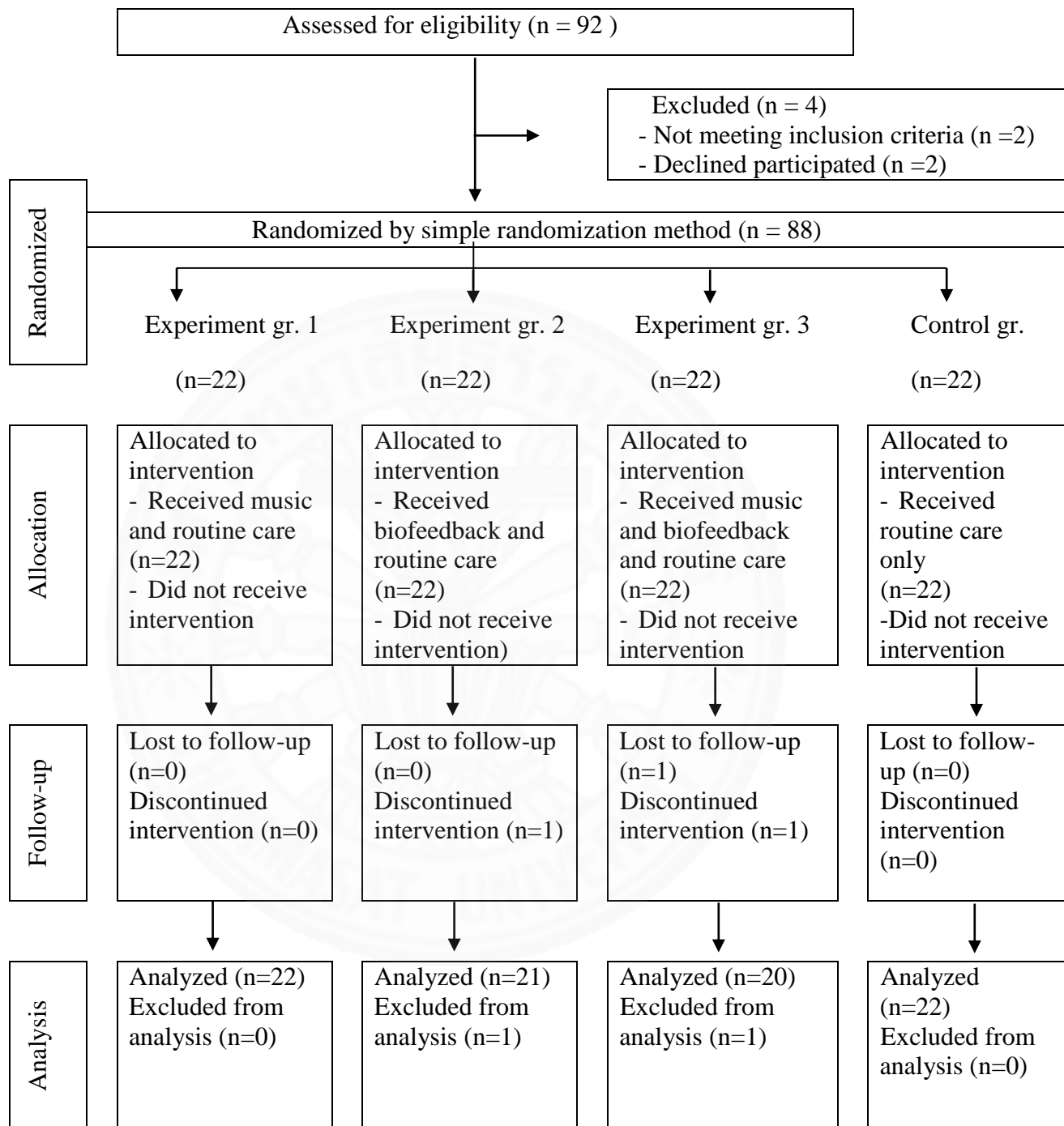


Figure 4.1: Consort flow diagram

This study was based on a between-group randomized controlled trial (RCT) of repeated measure design. Participants assigned to experimental group 1 listened to music through headphones connected to an MP3 player twice a day for 15-30 minutes per session in the morning (5 a.m.-11 a.m.) and again in the evening (6 p.m.-11 p.m.). Experimental group 2 participated in a biofeedback program twice a week for 8 times in total. Experimental group 3 listened to music through headphones connected to an MP3 player twice a day and received a biofeedback training program twice a week for 8 times in total. During the course of the experiment, the researcher visited the participants twice a week to assess the pain and stress levels they were experiencing, review their daily logs and inquire whether they were having any difficulty listening to the music during the research. Participants were informed about the objectives, procedures, time periods and benefits of study participation and stress and pain levels were evaluated by Modify Symptoms of Stress Inventory (modify SOSI) together with pain scores. Physiological effects of stress were measured using electroencephalography (EEG) and electromyography (EMG) biofeedback instruments. Both modified SOSI, pain scores, EMG and EEG measurements were evaluated and measured a total of 3 times, during the first time, the fourth time and the eighth time period of the experiment.

Initially, 92 patients were selected with stage IIB and III cancer; however, 2 patients did not meet the inclusion criteria, and another 2 declined to participate because they could not attend all 8 measurement times. The remaining 88 participants were equally assigned (n=22) to one of four treatment groups as experimental group 1, experimental group 2, experimental group 3 and the control group. After the second time period, 21 participants remained in experimental groups 2 and 3, as one participant

in each group was affected by the treatment. Two participants were elderly, and very exhausted after receiving chemotherapy, and discontinued participation in the study. During the third time period, one participant in experimental group 3 passed away leaving only 20 participants (Figure 4).

Pretest and posttest dependent testing allowed recognition of the individual traits of each participant and increased the ability to assess differences between the groups (Campbell & Stanley, 1963).

Table 4.1: A socio-demographic characteristics of the four treatment groups

A socio-demographic characteristics	Experiment Gr 1		Experiment Gr 2		Experiment Gr 3		Control Group		Value	df	χ^2
	n	%	n	%	n	%	n	%			
	Gender										
Male	8	36.4	7	31.8	7	31.8	8	36.4	.202	3	.977
Female	14	63.6	15	68.2	15	68.2	14	63.6			
Age											
Range	40-72		47-70		32-70		32-72		11.390	9	.250
Mean	57.4		63.59		60.54		57.6				
S.D.	6.91		2.72		2.26		6.55				

A socio-demographic characteristics	Experiment		Experiment		Experiment		Control		Value	df	χ^2
	Gr. 1		Gr. 2		Gr. 3		Group				
	n	%	n	%	n	%	n	%			
Marital Status											
Single	1	4.5	1	4.5	2	9.1	0	0.0	14.110	12	.294
Married	17	77.3	13	59.1	16	72.7	16	72.7			
Widowed	3	13.6	7	31.8	4	18.2	3	13.6			
Divorced	1	4.5	0	0	0	0.0	0	0.0			
Separated	0	0.0	0	0.0	0	0.0	3	13.6			
Education											
Uneducated	1	4.5	1	4.5	0	0.0	1	4.5	19.948	15	.174
Elementary	12	54.4	18	81.8	9	40.9	16	72.7			
education											
Secondary	1	4.5	1	4.5	4	18.2	1	4.5			
education											
Vocational/high	3	13.6	2	9.1	5	22.7	1	4.5			
vocational / Diploma											
Undergraduate	5	22.7	0	0.0	4	18.2	2	9.1			
Postgraduate	0	0.0	0	0.0	0	0.0	1	4.5			
Type of Cancer											
Colorectal	5	22.7	5	22.7	5	22.7	5	22.7	3.200	15	.999
Breast	10	45.5	10	45.5	10	45.5	10	45.5			
Cervical/Ovarian	4	18.2	4	18.2	4	18.2	4	18.2			
Lymphoma	1	4.5	2	9.1	1	4.5	1	4.5			
Laryngeal	2	9.1	1	4.5	1	4.5	1	4.5			
Prostate	0	0	0	0	1	4.5	1	4.5			

A socio-demographic characteristics	Experiment		Experiment		Experiment		Control		Value	df	χ^2
	Gr. 1		Gr. 2		Gr. 3		Group				
	n	%	n	%	n	%	n	%			
Stage of cancer											
Stage IIB	9	40.9	11	50	9	40.9	12	54.54	1.233	3	.745
Stage III	13	59.1	11	50	13	59.1	10	45.45			
Illness Duration											
Less than / equal to 1 years	20	90.9	21	95.5	19	86.4	17	77.3	4.026	6	.673
More than 2-3 years	1	4.5	1	4.5	2	9.1	3	13.6			
More than 3 years	1	4.5	0	0.0	1	4.5	2	9.1			
Type of Treatment											
Chemotherapy	2	9.1	2	9.1	2	9.1	2	9.1	.566	3	.904
Radiation	9	40.9	9	40.9	9	40.9	9	40.9			
Radiotherapy	3	13.6	4	18.1	3	13.6	5	22.73			
together with chemotherapy		3		8		3					
Surgery together with radiotherapy	6	27.2	7	31.8	6	27.2	6	27.27			
Radiotherapy, chemotherapy and surgery	2	9.1	0	0.0	2	9.1	0	0.0			

*p > .05

Data in Table 4.1 show that the four treatment groups contained similar cancer and treatment types; 10 patients in each group had breast cancer (45.5%); 5 patients in each group had colon cancer (22.7%); 4 patients in each group had cervical cancer (18.2%) and 3 patients in each group had other types of cancer including prostate, lymphoma, and laryngeal cancer.

In terms of treatment methods, 9 participants (40.9%) in each group were treated by only radiotherapy, 2 participants (9.1%) in each group were treated by only chemotherapy, 11 participants as 50% of each group were treated by more than one treatment method, for example, radiotherapy together with chemotherapy (Gr.1, Gr.3 = 3 participants, Gr.2 = 4 participants, Gr.4 = 5 participants) and surgery together with radiotherapy (Gr.1, Gr.3, Gr.4 = 6 participants, Gr.2 = 7 participants) and radiotherapy, chemotherapy and surgery (only Gr.1 and Gr.3 = 2 participants).

In terms of age, Gr.1 ranged from 40 to 72 years, mean age was 57.4 (S.D. = 7.42), Gr.2 ranged from 47 to 70, mean age was 63.59 years (S.D. = 2.72), Gr.3 ranged from 32 to 70 mean age was 60.54 (S.D. = 2.26), and the control group ranged from 32 to 72, mean age was 57.6 (S.D. = 6.55). Age comparison between the four treatment groups indicated no significant statistical differences ($p > .05$) (Table 1 shown in Appendix B).

For stage of cancer, 9 participants (40.9%) of Gr.1 and Gr.3, 11 participants (50%) of Gr.2 and 12 participants (54.54%) of the control group had stage IIB cancer, Most participants in all groups were female (66%) and 70.4% were married Period of time before cancer diagnosis was around 1 year for most participants as 90.9% for Gr. 1, 95.5% for Gr. 2, 86.4% for Gr. 3, and 77.3% for the control group. All participants liked listening to music; average frequency was around 4-6 days per week and average

period was around 15-30 minutes per day. Basic information comparison between the four treatment groups indicated no significant statistical differences ($p > .05$), with similar general natures among participants.

Part II Comparison of SOSI score, pain score, EEG, EMG, and vital signs between patients who received music only, biofeedback only, music and biofeedback and the control group.

1) Normal distribution testing for ANOVA assumption

Normal distribution testing using Kolmogorov-Smirnov statistics and a QQ-plot determined that the first time period was normally distributed with statistical significance at the level of .05 (Kolmogorov-Smirnov=0.08, $p=0.20$). The fourth and eighth time period were not normally distributed with statistical significance at the level of .05 (Kolmogorov-Smirnov=0.10, $p=0.03$; Kolmogorov-Smirnov=0.20, $p=0.00$); however, when analyzed by QQ-plot the findings revealed normal distribution (Appendix B). Therefore, stress during the three time periods was normally distributed (Table 4.2) (The figure 1 in Appendix B).

Table 4.2: Test of normal distribution

Variable	Kolmogorov-Smirnov	df	p
1 st stress	0.07	85	0.20
2 nd stress	0.10	85	0.03
3 rd stress	0.20	85	0.00

* $p < .05$

2) Analysis of variance matrix equilibrium in each period of time and homogeneity of variance

Homogeneity of stress variance in each time period determined that variance of the 1st stress was distinct without statistical significance at the level of .05 ($F= 1.37$, $df1= 3$, $df2= 81$, $p= 0.26$). The 2nd stress was not statistically significantly different at .05 ($F= 1.10$, $df1= 3$, $df2= 81$, $p= 0.36$) while the 3rd stress was dissimilar with statistical significance at .05 ($F= 5.09$, $df1= 3$, $df2= 81$, $p = 0.00$). However, when considering standard deviation the difference did not exceed 10 times (Hair, Black, Babin, Anderson & Tatham (2010). Therefore, data variance was considered suitable for the next phase of study (Table 4.3).

Table 4.3: Analysis of variance homogeneity

Variable	F	df1	df2	p
1 st stress	1.37	3	81	.26
2 nd stress	1.10	3	81	.36
3 rd stress	5.09	3	81	.00

3) Analysis of experimental group variable and stress interaction

Analysis of experimental group and stress interaction was performed using two-way ANOVA. Experimental group variable and stress in each time period interacted and reached statistical significance ($F=40.31$, $p=0.00$). This indicated that the experimental group changed over time for each stress measurement as shown in Table 4.4.

Table 4.4: Analysis of experimental group variable and 1st stress interaction

Variable	Type III Sum of Squares	df	Mean Square	F	p
Experimental group variable and stress	20.53	3.00	6.84	40.31	0.00

*p < .05

4) Comparison of the 1st stress with experimental groups

Comparative analysis of the 1st stress with experimental groups before the experiment found no statistically significant difference at .05 (F=1.62; p=0.19). This indicated that all groups were equal before the analysis as shown in Table 4.5.

Table 4.5: Analysis of stress covariance and comparison of pair mean

Dependent variable	F	p	Pair comparison
1 st stress	1.62	0.19	-

*gr1=music; gr2=biofeedback; gr3=music & biofeedback; gr4=control

5) Comparative analysis of stress in each time period between experimental groups

Comparative analysis of stress in each time period for the four treatment groups as music, biofeedback, music and biofeedback, and control was performed using repeated measure ANOVA with one independent variable as group (music, biofeedback, music and biofeedback, and control), and a dependent variable as stress.

Results indicated that the 3rd experimental group (music and biofeedback) had highest mean score during the time before the experiment. Mean values continuously decreased with lowest in the 3rd stress. In addition, the 1st experimental group (music) and 2nd experimental group (biofeedback) showed decreasing mean scores, while the control group had higher stress mean scores in every time measurement period, with the 3rd stress mean as the highest (The figure 2 in appendix B).

6) Comparative analysis of SOSI, EEG, and EMG in each time period between experimental groups

A repeated measures MANOVA analysis was used to answer the research questions. Repeated-measures MANOVA has the ability to test for multiple dependent variables simultaneously, with the added ability to determine whether these variables interact with each other (Mertler & Vannatta, 2017). Before computing the statistical tests, assumptions were checked as follows: a) first assumption; variables should be measured at interval or ratio level, and b) second assumption; normality must be verified to ensure that data represent a normal distribution. A normality test via a QQ-plot indicates whether data is linear or not, thus providing a quick visual of normality,

while Kolmogorov-Smirnov Z statistics show significance that distribution is normal. Here, results suggested that SOSI, EEG and EMG data were normally distributed. Details of the transformed data are presented as Appendix B.

Table 4.6: Mauchly's test of sphericity

Variable	Measure	Mauchly's W	Approx. Chi-square	df	p	Epsilon		
						Greenhouse-Geisser	Huynh-Feldt	Lower-bound
Time	SOSI	.526	51.434	2	.000	.678	.711	.500
	EEG	.424	68.596	2	.000	.635	.664	.500
	EMG	.116	172.118	2	.000	.531	.552	.500

***p < .05**

Note: Mauchly's test of sphericity evaluates the null hypothesis that the error covariance matrix of orthonormalized transformed dependent variables is proportional to an identity matrix.

Mauchly's test of sphericity showed that the assumption of sphericity was violated by SOSI, $\chi^2(2) = 51.434$, $p < 0.01$; EEG, $\chi^2(2) = 68.596$, $p < 0.01$, and EMG, $\chi^2(2) = 172.118$, $p < 0.01$. To gain further insight into the magnitude of the sphericity violation, epsilon values for each dependent variable were examined. Generally, the Greenhouse-Geisser correction is recommended for use, especially if estimated epsilon (ϵ) is less than 0.75. Here, Huynh-Feldt was used to determine the degree to which each dependent variable violated sphericity. Errors were SOSI ($\epsilon = .711$), EEG ($\epsilon = .664$) and EMG ($\epsilon = .522$).

Table 4.7: Descriptive statistics for all variables

Variables	Gr 1		Gr 2		Gr 3		Gr 4	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
SOSI: Time 1	56.19	14.15	61.00	14.81	62.30	10.08	66.27	9.34
Time 2	44.24	8.30	46.14	6.90	38.35	7.34	68.09	11.21
Time 3	53.29	13.17	53.38	10.20	51.20	5.71	66.36	8.67
EEG: Time 1	38.96	20.85	34.98	13.37	50.07	23.49	38.84	19.04
Time 2	13.24	7.13	14.31	9.41	11.74	6.57	50.01	28.08
Time 3	25.55	12.01	25.10	9.53	27.18	9.05	44.73	20.07
EMG: Time 1	0.42	0.19	0.62	0.30	0.65	0.25	0.35	0.28
Time 2	0.44	0.23	0.55	0.29	0.31	0.21	0.71	0.23
Time 3	0.39	0.20	0.58	0.31	0.57	0.30	0.49	0.27

Table 4.7 shows mean SOSI scores, EEG and EMG for time 1 to time 3 of the experimental groups.

Table 4.8: Repeated measures MANOVA within-subjects and between-subjects

Effect	Wilks' Lambda	F	Hypothesis df	Error df	p	Partial Eta Squared
Group	.512	6.777	9.00	192.416	.000	.200
Time	.263	35.52	6.00	76.000	.000	.737
Time * Group	.269	7.081	18.00	215.446	.000	.355

*p < .05

Results of data analysis in Table 4.8 show interaction between time and group for SOSI, EEG and EMG (Wilks' lambda = .269, F = 7.081, $p < .01$). Variables vary with time and group.

Hypothesis 1: Patients treated by music together with biofeedback program should have greater significant decrease in pain compared with those treated by only music or biofeedback program and the control group treated by routine care only.

According to research, 90% of patients with Stage IIB or III cancer have very low or no pain (level 0-1 of pain scale) which is tolerable without medicine. Therefore, these pain levels are not able to be compared by experiment.

Hypothesis 2: Patients treated by music together with biofeedback program should have a greater significant decrease in stress compared with those treated by only music or biofeedback program and the control group treated by routine care only.

Results in Tables 4.2- 4.5 show that experimental group 3 had the highest mean during the time before the experiment. Mean values continuously decreased, with lowest mean recorded in the 3rd stress. In addition, experimental group 1 and experimental group 2 were likely to have decreasing means, while the control group had higher stress means in every measurement period. However, the mean of the 3rd stress was the highest. Patients treated with only music or biofeedback programs showed more significant decrease in stress than the control group, while those treated by music together with biofeedback showed the most significant decrease in stress.

Hypothesis 3: Patients treated by music together with biofeedback program will have a greater significant decrease in the construct of healthy functioning as measured by linear combination of SOSI, pain scores, EEG, EMG, and vital signs compared with those treated by only music or biofeedback program and the control group treated by routine care only.

Results in Tables 4.6 - 4.8 show that patients treated by music together with a biofeedback program had a greater significant decrease in the construct of healthy functioning as measured by linear combinations of SOSI, pain score, EEG, EMG, and vital signs compared with those treated by only music or a biofeedback program and the control group treated by routine care. Results showed that SOSI, EEG, and EMG gave significant differences in mean scores from time 1 to time 2, and time 2 and time 3 in groups 1, 2 and 3 (SOSI, EEG and EMG (Wilks' lambda = .269, F = 7.081, p < .01). Group 4 was not significantly different.

Results indicated that music and biofeedback can reduce stress in cancer patients. When these two variables were combined, emotions showed significant reduction with a corresponding decrease in stress.

CHAPTER V

DISCUSSION

This randomized control repeated measure design study investigated the effects of music alone compared with music and a biofeedback program to decrease pain and stress of Thai adult patients who received treatment and routine nursing care provided by Thammasat Radiation Oncology Center (TROC) with either Stage IIB or Stage III cancer.

The sample comprised 88 cancer patients randomly assigned into four equal groups of 22 consisting of a control group treated with only routine nursing care, experimental group 1 treated with music and routine nursing care, experimental group 2 treated with a biofeedback program and routine nursing care, and experimental group 3 treated by music and a biofeedback program together with routine nursing care. The study period was from June to October 2018.

Instruments, questionnaire and materials used in the research

(1) Instruments for data collection comprised a socio-demographic data form, Modify Symptoms of Stress Inventory (modify SOSI), pain scores from TUH, EEG and EMG biofeedback.

(2) Instruments for the experiments comprised a biofeedback program, MP3 player, a personal home music recorder, and guidelines for cancer patients regarding stress and pain management.

To assess content validity, five specialist committee members consisting of a psychiatric mental health nurse instructor, a psychiatrist, a doctor, and two professional music therapists examined the nature, consistency and language accuracy of the questionnaire. All items were required to achieve at least 80% inter-rater

agreement for acceptance. SOSI scores in the index of item-objective congruence (IOC) ranged between 0.6 and 1.0. Once content validity was approved, the tools were tested using a known technique to select a group of five cancer patients (at Bang Khayaeng Health Promoting Hospital) with a reasonably high degree of similarity (inter-rater agreement) with sample participants to check their suitability and determine whether the tools could be safely applied.

To assess the reliability of SOSI and pain score tools, Cronbach's alpha coefficient was determined for a trial group of 30 cancer patients (at 4th Health Region Promotion Center) who shared a reasonably high degree of similarity with the sample participants ($\alpha = .906$).

Data collected from the three experimental groups were divided into three time periods as before, during, and after the experiments. Experimental groups 2 and 3 were treated with biofeedback twice a week for 30 minutes per session as 8 sessions in total. Experimental groups 1 and 3 were treated daily with music via an MP3 player for at least 15 minutes per day twice a week for 8 times in total. Quantitative information was analyzed by the Statistical Packages for the Social Sciences (SPSS) and level of significance was fixed at .05.

1. Preliminary analysis yielded socio-demographic and descriptive data.
2. Two-way ANOVAs were applied to test baseline differences of the continuous variables (e.g stress scores in each time period) among the four treatment groups.
3. Chi-square was applied to examine differences between treatment groups and categorical variables (e.g type, stage of cancer).

4. Between groups, repeated measures ANOVA was applied to test stress using the Bonferroni correction to make adjustments.

5. Between factors, repeated measures MANOVA was applied to change latent constructs for several correlated dependent variables (stress and pain).

Research results

1. Basic information of the four treatment groups, each comprising 22 participants, was equally divided by matching similar types of cancer and treatment. Results indicated that most participants (45.5%) experienced breast cancer. In 2017, the two most common types of cancer in females were breast cancer and cervical cancer as 41.96% and 14% of new female cases. For males, the second most common type was colon cancer as 16.29% of new male cases (Boonrat, Benjakul, Kengganpanich & Kengganpanich, 2018). The WHO reported breast cancer as the most common type, accounting for 11.6% of all incident cancers. The second most common types were colon cancer and anal cancer as 10.2% of all incident cancers. All participants were instructed in self-care health education by the same nurse and treated by similar procedures. Most samples (66%) were female and 70.4% were married, which corresponded to the 2017 survey of the National Cancer Institute of Thailand that recorded 2,135 females as new cancer cases registered at hospitals together with 1,475 male cases. More males than females were found among worldwide cancer cases (9.5 million males and 8.6 million females). In Asia, new cases were registered as males 49.2% and females 47.5% of the total (Bray, Ferlay, Soerjomataram, Siegel, Torre & Jemal, 2018) out of the Thai population of 51% females and 49% males. Most participants (87.5%) were diagnosed with cancer after 1 year. All participants liked

listening to music, with average frequency of around 4-5 days per week (52.3% of the total) and average music listening time 15-30 minutes per day (44.3% of the total). Basic information between the four groups indicated no statistically significant differences ($p > .05$), with similar general natures among the participants.

2. Comparative analysis of pain in each time period between the four experimental groups found that 90% of patients with Stage IIB or III cancer had very low or no pain (level 0-1 of pain scale) which was tolerable without medicine. Both Stage IIB and III cancers indicate that larger cancers or tumors have spread into the lymph nodes or nearby tissues but not to other parts of the body (Vineis & Wild, 2014). In the early stages this may be painless; however, if cancer spreads to the bones or nerves it generates strong pain, often found in patients with metastatic disease; between 50% and 90% of these individuals experience moderate to severe pain (Mercadante & Cuomo, 2016; Prasongsook et al., 2017). Meanwhile, 80.6% of patients with end-stage cancer referred to the Quality of Life Care Unit at Mahavjiralongkorn Thanyaburi Hospital experienced pain, with 43.1% at moderate levels and 50% with neuropathic pain. In terms of the effect of music on pain, Jasemi, Eghtedar, Aghakhani, Khodabandeh, & Sayadi (2013) determined that music therapy reduced the intensity of pain among patients who had moderate pain scores and those at the terminal stage. An integrative review by Keenan & Keithley (2015) investigating the effects of music on cancer pain in adults showed that among five studies, two gave significant differences in self-reported pain using music, depending on pain level and type of disease in mostly elderly samples. Alterations with aging of the neurobiology of pain impacted on pain threshold, tolerance and treatment. Yezierski (2012) studied "The effects of age on pain sensitivity: preclinical studies" and found that sensitivity in sensory systems reduced

with age. The aging process affects the functional operation of the peripheral nervous system, while reduction of major myelin proteins contributes to a loss in myelinated and unmyelinated nerve fibers. Nerve conduction and endoneural blood flow also decrease with advancing age, related to reduction in peripheral nerve function.

3. Comparative analysis of stress in each time period between the three experimental groups found that experimental group 3 (music and biofeedback) had the highest mean during the time before the experiment. Means continuously decreased, with lowest mean in the eighth time period. Experimental group 1 (music) and experimental group 2 (biofeedback) gave decreasing means, while the control group recorded higher stress means in all measurement periods. Patients treated with only music or biofeedback programs showed more significant decrease in stress than the control group, while those treated by music together with biofeedback showed the most significant decrease in stress. This occurred because musical sounds, created after passage through the auditory apparatus, change emotions when passing through the thalamus, cortex, and limbic areas of the brain (Iamsmang, 2013). When a patient listens to music, sounds are transmitted as auditory signals to the thalamus and then to the auditory cortex (Guyton, 1986). This is connected to other areas of the brain and results in behavior changes throughout the entire body (Im-erb, Kongchoom & Rimsueb, 2014). These changes rely on the interconnecting functions of three major body systems as the psycho-neuroendocrine, autonomic nervous, and musculoskeletal systems (Wells-Federman et al., 1995). Musical sounds are sent from the brain's auditory cortex to the limbic system, which is the center for emotional behavior control, feelings, and taste (Guzzetta, 2000; Willis, 1993). The limbic system releases endorphins as substances for neural signaling which change emotions and are created

and conducted by neural cells. Endorphin secretion results in pleasant feelings throughout the body (Iamsang, 2013). Musical sounds are transmitted from the ear to the center of the brain and the limbic system which controls emotional responses. Suitable music then stimulates the brain to release endorphins which ease the mind and reduce stress (Juangpanich, Onbunreang, Lunlud, Khansorn & Vatanasapt, 2012). Furthermore, music also affects autonomic system functions by reducing sympathetic system functions of epinephrine and norepinephrine secretion. This process lowers heart rates, blood pressure and breathing rates (Guyton & Hall, 2000) and thus contributes to relaxation when listening to music. Various researchers determined the effectiveness of music in reducing stress. Malgorzata Monika Stanczyk (2011) investigated music therapy to show use of music and present the integration of music as a supportive care for cancer patients. Results showed that music was very beneficial for cancer patients and can be used to reduce stress and anxiety, improve mood and enhance relaxation. Lee, E. H., & Choi, S. E. (2012) studied the effects of self-selected music listening on stress relief in terminal stage cancer patients. Results showed significant reduction in stress levels before and after listening to their favorite music ($p=0.001$). The results showed favorite music listening reduced stress in terminal cancer patients. Patients were able to benefit from the biofeedback program based on the learning model of psychophysiological psychotherapy (Ruchiwi, 2014). Patients learned to control their stress by developing awareness of their physiological reactions. Through reinforced biofeedback training, patients learned how to control their emotions. Eventually, they no longer needed a biofeedback instrument (Frank, Khorshid, Kiffer, Moravec, & McKee, 2010; Lemaire et al., 2011; Tsai, 2007).

Therefore, treating patients with music together with a biofeedback program encouraged them to develop more effective stress management.

4. Comparative analysis for each time period between experimental groups showed that SOSI, EEG, and EMG were significantly different in mean scores between each time period in Gr. 1, Gr.2 and Gr.3. However, Gr. 4 was not significantly different in mean scores between each time period. Electroencephalography (EEG) is used to examine brain functions through changes in electrical signals of brainwaves which oscillate up and down and are measured in units of rounds per second (Vittayakittipong, 2006). Jena (2015), who studied “Examination stress and its effect on EEG” found that stress can be expressed through brainwaves and measured through EEG. Hou, Sourina, Tan, Wang, & Mueller-Wittig (2015) and Jun & Smitha (2016) used EEG measurements to examine stress through brainwaves. Sound waves can also arouse the state of human brainwave changes. Sound waves can be detected by listening to music and this electrical wave harmoniously synchronizes with each frequency level of brainwaves. This arouses the brain to self-synchronize or connect to the rhythms of the music, especially alpha waves which characterize a relaxed yet alert state of awareness and promote fast and easy learning.

Electromyography (EMG) biofeedback is used to train striated muscle states (stressed or relaxed). This allows a person to control muscle contractions and relaxation accurately (Ruchiwi, 2014). When patients listen to music, sounds are transferred via listening nerve impulses to the thalamus and auditory cortex (Guyton, 1986). These cranial structures change behavior by three main systems comprising the psycho neuroendocrine system, the autonomic nervous system, and the musculoskeletal system.

From the auditory cortex in the brain, music is transferred to the limbic system as the control center of emotional behavior, feeling and tasting (Guzzetta, 2000; Iamsmang, 2013). This stimulates the release of endorphins as neurotransmitters which affect the emotions and make the body feel relaxed. Music is transferred as nerve impulses to the auditory cortex, which then deactivates the central nervous system and induces relaxation through reduced muscle rigidity (Wells-Federman et al., 1995). Thus, treating patients with music together with a biofeedback program directly affects brainwaves which transit to the muscular system and promote relaxation. Lemaire, Wallace, Lewin, Grood, & Schaefer (2011) studied “The effect of a biofeedback-based stress management tool on physician stress: a randomized controlled clinical trial”. They found that biofeedback had a positive effect on stress management and may also be an easy and effective stress-decrease strategy for Healthcare Providers. Alvarez, Meyer, Granoff, & Lundy (2013) showed that EEG biofeedback can reduce negative emotions and attitudes of cancer patients to treatment, while an article entitled “The Power of Music to Reduce Stress” by Collingwood, J. (2016) explained that music has both psychological and physiological powers, to reduce stress management. Music can be used together with biofeedback to play an important role in the treatment of people who suffer from stress.

Results indicated that music and biofeedback can reduce stress in cancer patients. When these two variables were combined, emotions were significantly reduced with a corresponding decrease in stress.

Research limitations

Most of the samples were patients with breast cancer, colorectal cancer, and cervical cancer and did not represent all types of cancer.

Limitation of the experiment included practicing listening to music together with a biofeedback program. The researcher could not control the length of time for listening to the music and the patient's practice at home. Principles of practicing through a biofeedback program involved 8 times of correct practice with the researcher until the patients were able to self-control stress and implement the technique of relaxation by listening to the music for controlling and reducing stress effectively without using the tools.

Limitation of sample selection existed, as there were not enough patients to select as samples of 4 experimental groups in every month throughout the 3 months of the experiment.

Recommendations

Results showed that treatment with music combined with a biofeedback program positively decreased stress levels as brainwaves induce a relaxed state and muscle tone in cancer patients. Therefore recommendations are as follows:

Policy recommendations

Administrators and related staff in hospitals should be aware of and emphasize on the stress of cancer patients. There should be an evaluation of the level of patients' stress during treatment in hospital by considering the implementation of

listening to music together with a biofeedback program to reduce the stress of cancer patients.

Practical recommendations

1. Patterns or activities of evaluating and managing the stress of cancer patients should be developed during treatment in hospitals to reduce and prevent mental problems. Training on operating these activities should also be provided for related staff.

2. The technique of listening to music together with a biofeedback program should be implemented for cancer patients during treatment in hospital or any patients with other sickness to evaluate and prevent stress.

Recommendations for further research

1. Future research should include a posttest follow-up to ensure that participants remained confident to utilize stress management on a permanent basis.

2. Future research design should be extended to study patients with end-stage cancer who are experiencing significant pain level to examine the hypothesis and determine whether music treatment with a biofeedback program resulted in pain decrease.

3. This research design can be extended to patients' families or caregivers as they also experience stress issues.

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Appendix



Appendix A

The instruments

1. Modified Symptoms of Stress Inventory in Thai version (Modified SOSI)

Instruction

1

แบบวัดความเครียด Symptoms of stress inventory (SOSI)

คำชี้แจง

1. แบบวัดนี้มีข้อคำถามทั้งหมด 30 ข้อ (โปรดตอบทุกข้อ)
2. โปรดทำเครื่องหมาย ✓ ลงในช่องว่างที่ตรงกับการเปลี่ยนแปลงทางร่างกาย อารมณ์ ความคิด และพฤติกรรมของท่านมากที่สุด ในช่วง 1 เดือนที่ผ่านมาจนถึงปัจจุบัน
3. ความหมายของลักษณะการเปลี่ยนแปลง

ไม่เคย	หมายถึง	ไม่มีการเปลี่ยนแปลงเหล่านี้เลยในช่วง 1 เดือนที่ผ่านมา
นาน ๆ ครั้ง	หมายถึง	การเปลี่ยนแปลงดังกล่าวเกิดขึ้นกับท่านประมาณ 1-2 ครั้ง / เดือน
บางครั้ง	หมายถึง	การเปลี่ยนแปลงดังกล่าวเกิดขึ้นกับท่านประมาณ 1 ครั้ง / สัปดาห์
บ่อยครั้ง	หมายถึง	การเปลี่ยนแปลงดังกล่าวเกิดขึ้นกับท่านประมาณ 2-3 ครั้ง / สัปดาห์
บ่อยมาก	หมายถึง	การเปลี่ยนแปลงดังกล่าวเกิดขึ้นกับท่านเป็นประจำทุกวัน

✚

การเปลี่ยนแปลงทางร่างกาย อารมณ์ ความคิด และพฤติกรรม	ลักษณะการเปลี่ยนแปลง					สำหรับผู้วิจัย
	ไม่เคย	นาน ๆ ครั้ง	บางครั้ง	บ่อยครั้ง	บ่อยมาก	
คุณเคยมีอาการเหล่านี้หรือไม่:						
1. อาการคันอย่างรุนแรง/มีผื่นตามผิวหนัง						
2. รู้สึกร้อนๆ หนาวๆ						
ทั้งที่ไม่ได้ออกกำลังกายหรือแม้กระทั่งอยู่เฉยๆ คุณเคยมีอาการเหล่านี้หรือไม่:						
3. เจ็บบริเวณหน้าอกหรือหัวใจ/ใจสั่น/หัวใจเต้นเร็วหรือแรงกว่าปกติ						
4. หายใจเร็ว หายใจไม่ออก หายใจลำบาก						
คุณเคยมีภาวะดังต่อไปนี้หรือไม่:						
5. เป็นหวัดพร้อมอาการแทรกซ้อน (เช่น หลอดลมอักเสบ)						
6. เวียนศีรษะ ตาพร่า รู้สึกหน้ามืดคล้ายจะเป็นลม						
คุณเคยมีภาวะดังต่อไปนี้หรือไม่:						
7. ปวดศีรษะแบบเป็นพักๆ ปวดตื้อๆ ข้างใดข้างหนึ่งหรือ ปวดศีรษะเหมือนถูกบีบรัดบริเวณขมับ หน้าผาก ท้ายทอย หรือ ปวดบริเวณโหนกแก้ม หน้าผาก จมูกตรงระหว่างคิ้ว และหัวตา						

การเปลี่ยนแปลงทางร่างกาย อารมณ์ ความคิด และพฤติกรรม	ลักษณะการเปลี่ยนแปลง					สำหรับ ผู้วิจัย
	ไม่เคย	นานๆ ครั้ง	บางครั้ง	บ่อยครั้ง	บ่อยมาก	
คุณเคยประสบปัญหาต่อไปนี้หรือไม่:						
8. ท้องอืด ท้องเฟ้อ แน่นท้อง						
9.						
10.						
11.						
12.						
13.						
14.						
15.						
16.						
คุณรู้สึกว่:						
17. กังวลกับโรคหรือปัญหาสุขภาพของคุณ						
18. เครียด กระวนกระวายใจ						
19.						
20.						
21.						
22.						
23.						
24.						
25. ไม่มีสมาธิในการทำงาน						
คุณรู้สึกว่:						
26. มีความรู้สึกเหนื่อยล้า						
ตอนเครียดคุณเคยรู้สึกต่อไปนี้หรือไม่:						
27. โดดเดี่ยว ว้าเหว่						
28.						
29.						
30. รู้สึกเศร้าหมอง						

2. A socio-demographic data form

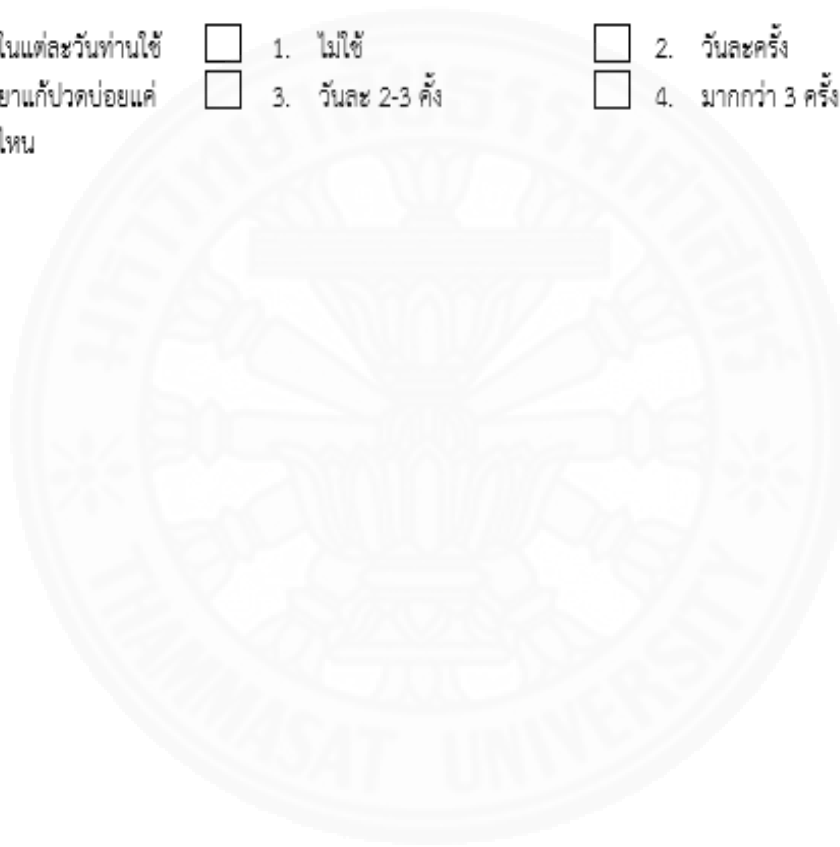
แบบสอบถามข้อมูลทั่วไป

คำชี้แจง กรุณาทำเครื่องหมาย ✓ ลงในช่อง ในแต่ละข้อเพียงช่องเดียว ตามความเป็นจริงให้ครบถ้วนทุกข้อ

ข้อมูลส่วนบุคคลของผู้ตอบแบบสอบถาม				สำหรับผู้วิจัย
1. เพศ	<input type="checkbox"/> 1. ชาย	<input type="checkbox"/> 2. หญิง	<input type="checkbox"/>	
2. อายุ	<input type="checkbox"/> 1. ตั้งแต่ 18-32 ปี	<input type="checkbox"/> 2. ตั้งแต่ 33-46 ปี	<input type="checkbox"/>	
	<input type="checkbox"/> 3. ตั้งแต่ 47-60 ปี	<input type="checkbox"/> 4. มากกว่า 60 ปีขึ้นไป		
3. สถานภาพสมรส	<input type="checkbox"/> 1. โสด	<input type="checkbox"/> 2. คู่	<input type="checkbox"/>	
	<input type="checkbox"/> 3. หม้าย	<input type="checkbox"/> 4. หย่า		
	<input type="checkbox"/> 5. แยกกันอยู่			
4. ระดับการศึกษา	<input type="checkbox"/> 1. ไม่ได้เรียนหนังสือ	<input type="checkbox"/> 2. ประถมศึกษา	<input type="checkbox"/>	
	<input type="checkbox"/> 3. มัธยมศึกษา	<input type="checkbox"/> 4. ปวช./ ปวส./ อนุปริญญา		
	<input type="checkbox"/> 5.ปริญญาตรี	<input type="checkbox"/> 6. สูงกว่าปริญญาตรี		
5. ชนิดของโรคเมะเร็งที่เป็น	<input type="checkbox"/> 1. มะเร็งลำไส้	<input type="checkbox"/> 2. มะเร็งตับ	<input type="checkbox"/>	
	<input type="checkbox"/> 3. มะเร็งเต้านม	<input type="checkbox"/> 4. มะเร็งปากมดลูก/ รังไข่		
	<input type="checkbox"/> 5. อื่นๆ ระบุ.....			
6. ระยะเวลาการเจ็บป่วย	<input type="checkbox"/> 1. น้อยกว่าหรือเท่ากับ 1 ปี	<input type="checkbox"/> 2. มากกว่า 2-3 ปี	<input type="checkbox"/>	
	<input type="checkbox"/> 3. มากกว่า 3 ปีขึ้นไป			
7. การรักษาที่ได้รับขณะนี้(ตอบได้มากกว่า 1 ข้อ)	<input type="checkbox"/> 1. เคมีบำบัด	<input type="checkbox"/> 2. ฉายแสง	<input type="checkbox"/>	
	<input type="checkbox"/> 3. ผ่าตัด	<input type="checkbox"/> 4. อื่นๆ ระบุ.....		
8. ท่านชอบฟังเพลงหรือไม่ (ถ้าใช่ตอบข้อ9-10)	<input type="checkbox"/> 1. ชอบ	<input type="checkbox"/> 2. ไม่ชอบ	<input type="checkbox"/>	
	<input type="checkbox"/> 3. เฉยๆ			

สำหรับผู้วิจัย

9. ใน 1 สัปดาห์ท่านฟัง 1. 1-3 วันต่อสัปดาห์ 2. 4-6 วันต่อสัปดาห์
เพลงป๊อปแคไทย 3. ทุกวัน
10. ระยะเวลาในการฟัง 1. น้อยกว่า 15 นาที 2. มากกว่า 15 นาที – 30 นาที
เพลงแต่ละครั้ง 3. มากกว่า 30 นาที
11. ในแต่ละวันท่านใช้ 1. ไม่ใช่ 2. วันละครั้ง
ยาแก้ปวดป๊อปแค 3. วันละ 2-3 ครั้ง 4. มากกว่า 3 ครั้งต่อวัน
ไทย



3. Program of music and biofeedback training

Experimental group 1 consisted of cancer patients receiving music and routine nursing care, with the music selection comprised of classical, jazz, royal music, natural sound music, Thai instrumental music, or their favorite music. Relaxing nature sound music was included as it can increase the generation of alpha waves in the brain and increase feelings of relaxation in cancer patients. For each individual patient, the select piece of music that triggered the generation of alpha waves (ranging from 8 to 12 hertz) in the brain within the shortest period of time was selected. The cancer patients listened to the music through MP3 players twice per day, for a duration between approximately 15-30 minutes per time. The first session was in the morning, between 5 a.m. and 11 a.m., and the second was in the evening between 6 p.m. and 11 p.m..The period of listening was required to be a minimum of 15 minutes, for a total time period of eight times. The procedure of the activity was as follows:

First session: 60 minutes

The sample group participants were informed of the objectives, procedures, time period, and the benefits of participating in the project, including through obtaining knowledge related to managing the stress and pain caused by cancer, information about the causes and impacts of stress, and an understanding of how music can be used to reduce stress and pain. The patients were then evaluated for stress and pain levels using a 30-item stress assessment form, and the pain level evaluation was assessed by the researcher based on the participants' question responses. Next, a stress assessment was performed by electroencephalograph (EEG) biofeedback instruments and electromyography (EMG) biofeedback instruments, while an evaluation of their vital signs was also performed. For each individual, the piece of music that triggered

the generation of alpha waves (ranging from 8 to 12 hertz) in the brain within the shortest period of time was selected. The researcher thoroughly explained and demonstrated how measurements would be taken, including how the results would be translated for the sample (15 minutes), and then allowed the participants to practice listening to the music. Following this, the participants were given the music recording form so that they could record the date, time, and type of songs they listened to each day at home. They were also provided with a form to record their frequency of pain relief medication, noting down the date, time, and type of pain relief medication they took. Finally, the sample participants returned their form records to the researcher in sessions four, six and eight. In addition, the researcher also visited the participants on a weekly basis to assess the levels of pain and stress that they were experiencing and review their daily logs with them and inquire whether they were having any difficulty listening to the music.

Second and fourth sessions: 30 minutes

For the second and fourth sessions, the participants were required to listen to the music for two times per day as in the first session. However, the required duration of music listening was changed from between 15 and 30 minutes in the first session, to at least 30 minutes for the second and fourth sessions. Meanwhile, during these sessions the researcher also asked the participants to share their opinions on any problems or difficulties they had listening to the music.

Eighth session: 60 minutes

Patients practiced listening to self-healing music, and their stress and pain levels were then evaluated using the stress level and pain level assessment forms. Their stress levels were further evaluated using EEG biofeedback instruments and EMG

biofeedback instruments, meanwhile their vital signs were also evaluated. Finally, the results were translated and the project summarized to the participants upon completion of the project.

Experimental group 2 included cancer patients receiving biofeedback training and routine nursing care. A practicing EEG biofeedback program and EMG biofeedback program twice per week, as well as a once weekly vital sign evaluation for a total of eight times over four weeks. The procedure of the activity was as follows:

First session: 60 minutes

The sample group participants were informed of the objectives, procedures, time period, and benefits of participating in the project, obtaining knowledge related to managing the stress and pain caused by cancer, and information about the causes and impacts of stress. The patients then had their pain and stress levels evaluated using a 55-item stress assessment form, while the pain level evaluation was assessed by the researcher based on the participants' question responses. Next, the stress assessment was performed by EEG and EMG biofeedback instruments. The researcher thoroughly explained and demonstrated how the measurements would be taken, including how the sample results would be translated. The participants were then provided with a form to record the frequency of taking pain relief medication, to record the date, time, and type of pain relief medication. The sample participants returned the records to the researcher in sessions four, six and eight.

Second session - seventh session: 60 minutes

The sample group received practice in the EEG and EMG biofeedback programs for approximately 60 minutes before the results were translated for the participants. The researcher then asked the sample group to exchange their opinions

about the problems and difficulties they had in the practice. Finally, the patients were given the same recording forms as before for them to return to the researcher the following week.

Eighth session: 60 minutes

The sample group were given practice with the EEG and EMG biofeedback programs for 30 minutes, and their stress and pain levels were then assessed using the stress and pain assessment forms to evaluate their stress levels and then used the EEG biofeedback instruments and EMG biofeedback instruments. They also underwent a vital sign evaluation. Finally, the results were translated and the project concluded.

Experimental group 3 consisted of cancer patients receiving music together with biofeedback training and routine nursing care. The choice of music included, but were not limited to classical, jazz, royal and Thai instrumental music as well as relaxing nature sounds, which can increase the generation of alpha waves in the brain and increase the feeling of relaxation in cancer patients. For each individual, the piece of music that triggered the generation of alpha waves (ranging from 8 to 12 hertz) in the brain within the shortest period of time was selected. The participants were required to listen to the music through MP3 players twice per day for approximately 15 to 30 minutes each time, first in the morning between 5 a.m. and 11 a.m. and then in the evening between 6 p.m. and 11 p.m.. This music listening was combined with practicing EEG and EMG biofeedback programs, and a weekly vital sign evaluation for a total of eight sessions. The procedure of the activity was as follows:

First session: 60 minutes

The sample group participants were informed of the objectives, procedures, time period, and benefits of participating in the project, including through obtaining

knowledge related to managing the stress and pain caused by cancer, information about the causes and impacts of stress, and an understanding of how to use music to reduce stress and pain. The patient's stress and pain levels were then evaluated using a 30-item stress assessment form, while the pain level evaluation was assessed by the researcher based on their question responses. Next, the stress assessment was performed using EEG and EMG biofeedback instruments. The choice of music included those previously detailed, and for each individual, the piece of music that triggered the generation of alpha waves (ranging from 8 to 12 hertz) in the brain within the shortest period of time was selected. A vital sign evaluation was also undertaken. The researcher thoroughly explained and demonstrated how the measurements would be taken, including how the results would be translated and the patients were given an opportunity to practice listening to the music. After that, the participants were given the music recording form for the participants to record at home the date, time, and type of songs listened to each day and also a form to record their frequency of pain relief medication, which recorded the date, time, and type of pain relief medication. The completed forms were returned by the sample participants to the researcher in sessions four, six and eight. The researcher also visited the participants on a weekly basis to assess the levels of pain and stress that they were experiencing and review their daily logs with them and inquire whether they were having any difficulties listening to music.

Second session - seventh session: 60 minutes

The sample group were given practice in the EEG and EMG biofeedback programs along with music which involved listening to classical music, jazz music, royal music, natural sound music, Thai instrumental music, or their favorite music for approximately 60 minutes. The results were then translated for the patients. After that,

the researcher spoke with the sample group to exchange their opinions about the problems or difficulties they had in the practice to prepare them to listen to the music two times per day (approximately 15-30 minutes per time). The daily music listening schedule was as follows, first in the morning between 5 a.m. and 11 a.m., and then in the evening between 6 p.m. and 11 p.m. Finally, the patients were given the music recording forms to record the date, time, and type of music listened to at home each day, which were then returned to the researcher the following week.

Eighth session: 60 minutes

The sample group had practice in the EEG b and EMG biofeedback program together with listening to the music, and then their stress and pain levels were assessed using the stress and pain assessment forms to evaluate their stress levels after using the EEG and EMG biofeedback instruments. They also underwent a vital sign evaluation. Finally, the results were translated and the project was concluded.

The control group consisted of a group of cancer patients who would receive only routine nursing care. The control group received routine nursing care eight times, while they also underwent a pretest and posttest in sessions one and eight (approximately 60 minutes each time) at the Health Promotion Center, Faculty of Nursing, Thammasat University. The procedure of the activity was as follows:

First time: 60 minutes

The sample group participants were informed of the objectives, procedures, time period, and benefits of participating in this project, including obtaining knowledge about managing the stress and pain caused by cancer, information regarding the causes and impacts of stress, and an understanding of how to use music to reduce stress and pain. The patients' stress and were assessed using a 30-item stress assessment form,

while their pain levels were assessed by the researcher based on their question responses. Next, the stress assessment was performed using EEG and EMG biofeedback instruments and their vital signs were also evaluated. Additionally, the participants were provided with a form to record their frequency of taking pain relief medication in which they recorded the date, time, and type of pain relief medication. The researcher then thoroughly explained and demonstrated how the results would be translated for the sample group

Second session: 60 minutes

The sample group participants stress and pain levels were assessed using the stress assessment form and pain assessment form along with EEG and EMG biofeedback instruments. Their vital signs were also evaluated. Finally, the results were translated and the project concluded.

Appendix B: Normal distribution testing

Table 1

Table 1. Age comparison between the four treatment groups

A socio-demographic characteristics	Experiment		Experiment		Experiment		Control		Value	df	χ^2
	Gr. 1		Gr. 2		Gr. 3		Group				
	n	%	n	%	n	%	n	%			
Age											
18 - 32 years old	0	0.0	0	0.0	1	4.5	1	4.5	11.390	9	.250
33 - 46 years old	5	22.7	0	0.0	2	9.1	3	13.6			
47 - 60 years old	7	31.8	6	27.3	3	13.6	7	31.8			
More than 60 years old	10	45.5	16	72.7	16	72.7	11	50			

Data in Table 1 show that the four treatment groups contained similar Age indicated no significant statistical differences ($p > .05$)

Normal distribution testing

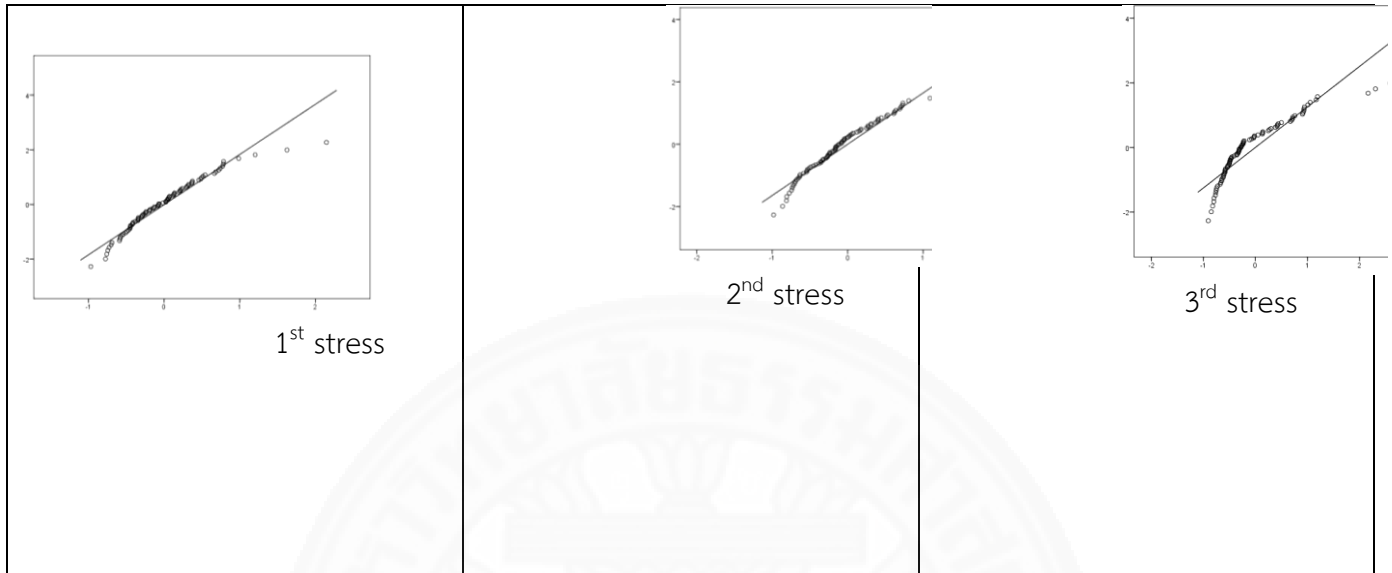


Figure 1: QQ plot Analysis of stress at each time

QQ-plot the findings revealed normal distribution. Therefore, stress during the three time periods in this research was normally distributed

Comparative analysis of stress in each period of time between experimental groups

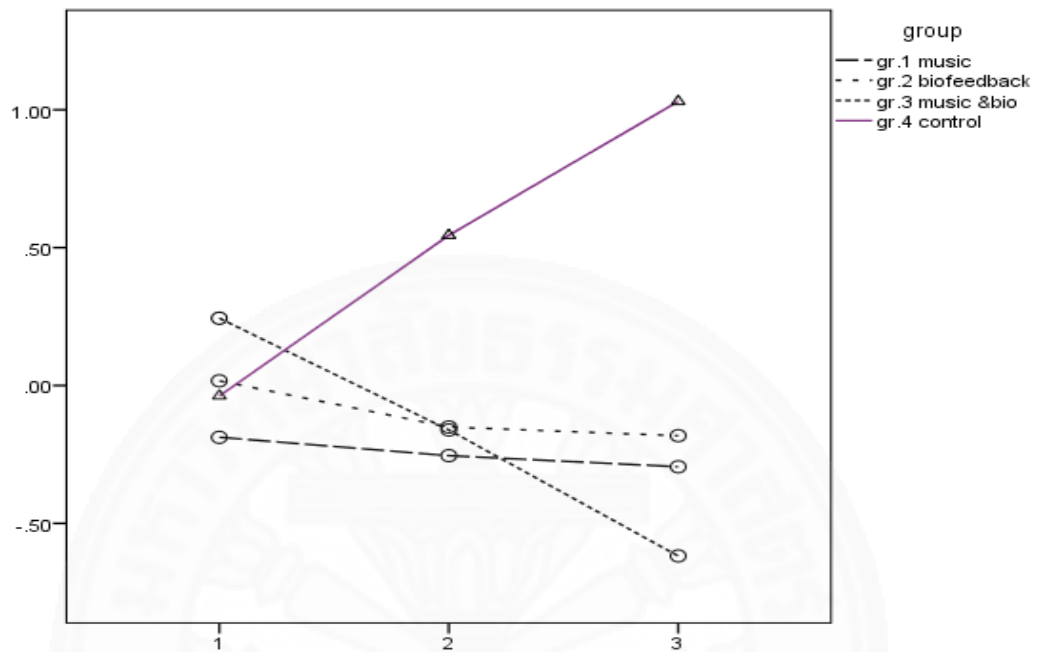


Figure 2: Comparative analysis of stress in each time period among the four treatment groups

Results indicated that the 3rd experimental group (music and biofeedback) had the highest mean score during the time before the experiment. Mean values continuously decreased with lowest in the 3rd stress. In addition, the 1st experimental group (music) and the 2nd experimental group (biofeedback) showed decreasing mean scores, while the control group had higher stress mean scores in every time measurement period, with the 3rd stress mean as the highest.

Comparative analysis of SOSI, EEG, and EMG in each time period between experimental groups

Table 2 Summary of Skewness and Kurtosis for SOSI

Time	Statistic	Standard Error	Shapiro-Wilk	Smirnov Z
Time1	Skewness	.32	.257	.194
	Kurtosis	.624	.508	.116
Time2	Skewness	.03	.261	.342
	Kurtosis	.625	.517	.054
Time3	Skewness	.902	.261	.815
	Kurtosis	0.077	.517	.003

The SOSI data shows approximate normality for the Time1 with skewness of 1.32 (SE = .257) and a kurtosis of 2.624 (SE = .508). After the experiment in time 2, the variable was distributed. The skewness is equal to 1.03 (SE = .261) and kurtosis is equal to .625 (SE = .517). After the third experiment, it was found that the variables were not uniformly distributed. The skewness is equal to .902 (SE = .261) and kurtosis is equal to -.077 (SE = .517). The variables data sets show a small positive skewness indication a slight skew to the right of the data set. Further, SOSI data sets show a close to normal kurtosis.

The Q-Q plots for SOSI in Figures 3 – 5 visually represent a normal approximation.

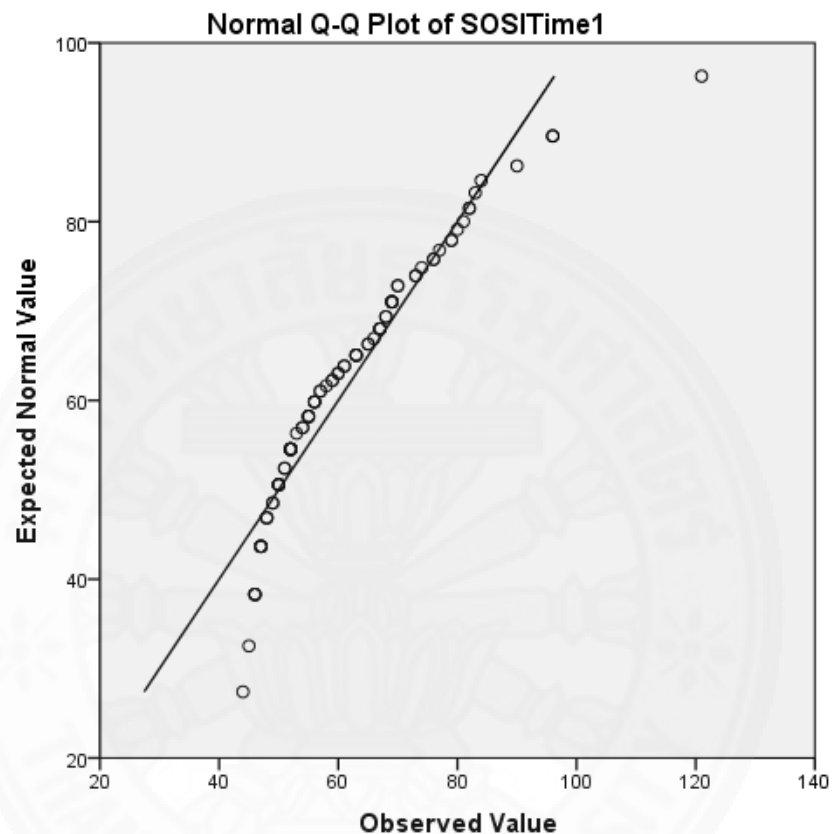


Figure 3. Q-Q Plot for the SOSI baseline (Time1) data.

The following Q-Q Plot in Figure 3 represent the SOSI baseline (Time1) data and are consistent with the finding that the SOSI data exhibits a close approximation to normal. The results show that the SOSI baseline (Time1) data are normally distributed.

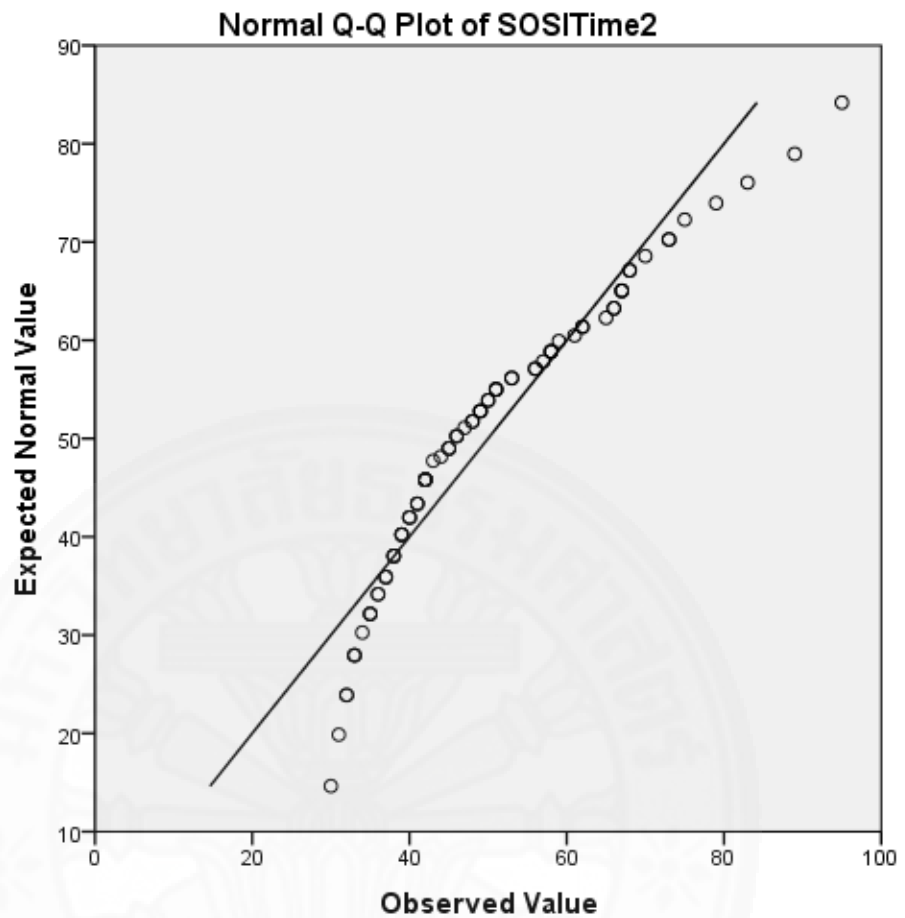


Figure 4. Q-Q Plot for the SOSI (Time2) data.

The following Q-Q Plot in Figure 4 represent the SOSI Time2 data and are consistent with the finding that the SOSI data exhibits a close approximation to normal. The results show that the SOSI Time2 data are normally distributed.

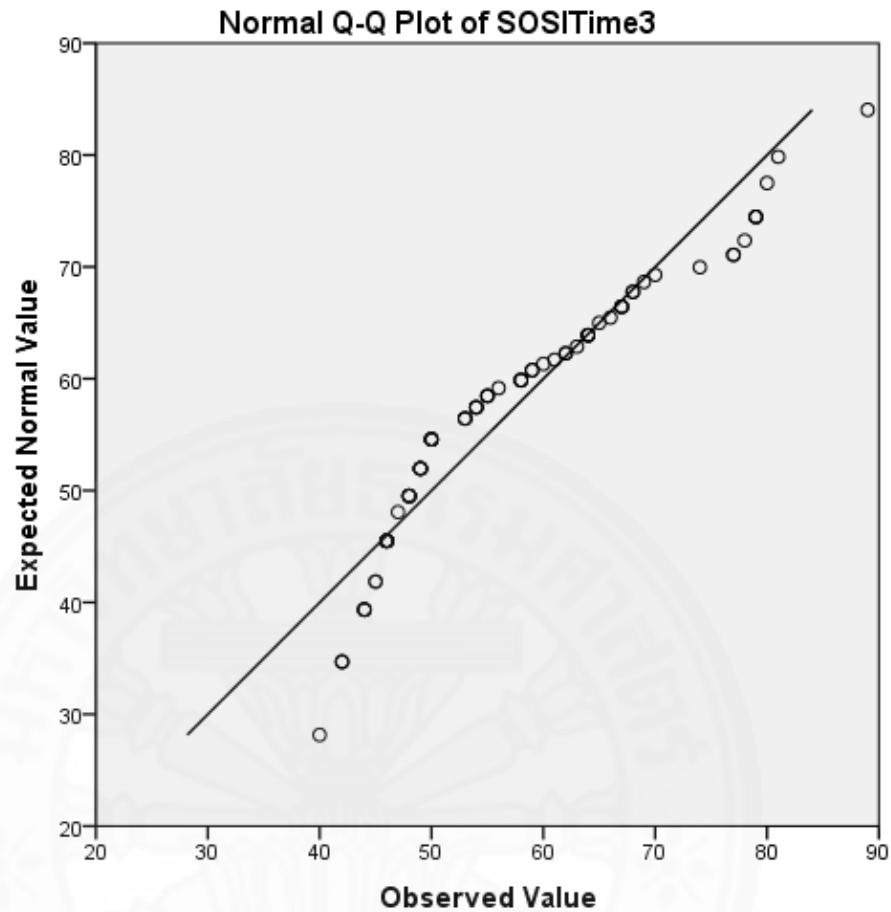


Figure 5. Q-Q Plot for the SOSI (Time3) data.

From Figure 5, it was found that the variables were not normally distributed. The results of the above tests show that SOSI data for the baseline and all training treatments were approximately normally distributed as assessed by visual inspection of normal Q-Q Plots. I proceeded with caution to conduct the MANOVA analysis on the productivity data considering the interpretation of outcomes may exhibit some minor error.

The distribution test is the normal curve of EEG

Table 3 Summary of Skewness and Kurtosis for EEG

Time	Statistic	Standard Error	Kolmogorov-Smirnov Z		
Time1	Skewness	.98	.257	.017	252
	Kurtosis	.268	.508		
Time2	Skewness	.206	.261	.060	000
	Kurtosis	.013	.517		
Time3	Skewness	.288	.261	.288	073
	Kurtosis	.842	.517		

The EEG data shows approximate normality for the Time1 with skewness of .98 (SE = .257). After the experiment in time 2, variable distribution is not normal. The skewness is equal to 2.206 (SE = .261) and kurtosis is equal to 5.013 (SE = .517). After the third experiment, it was found that the variables are normally distributed. The skewness is equal to 1.288 (SE= .261) and kurtosis is equal to 1.842 (SE = .517).

The Q-Q plots for EEG in Figures 6 – 8 visually represent a normal approximation.

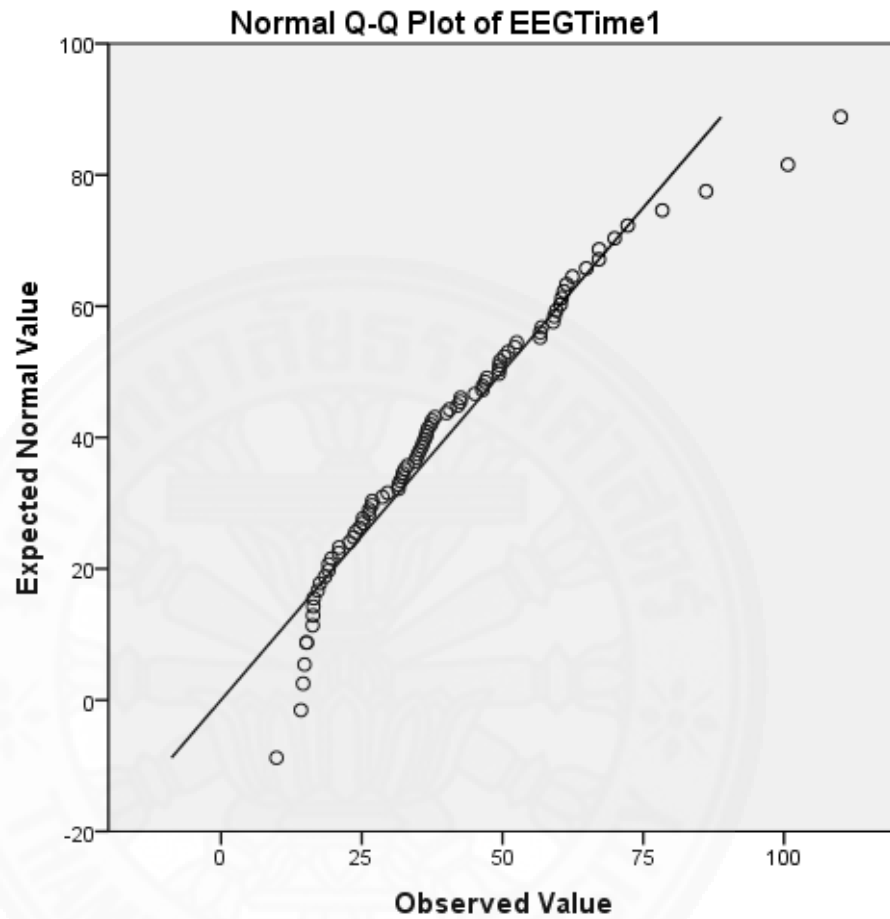


Figure 6. Q-Q Plot for the EEG baseline (Time1) data

From Figure 6, it was found that the variables were distributed into normal curves.

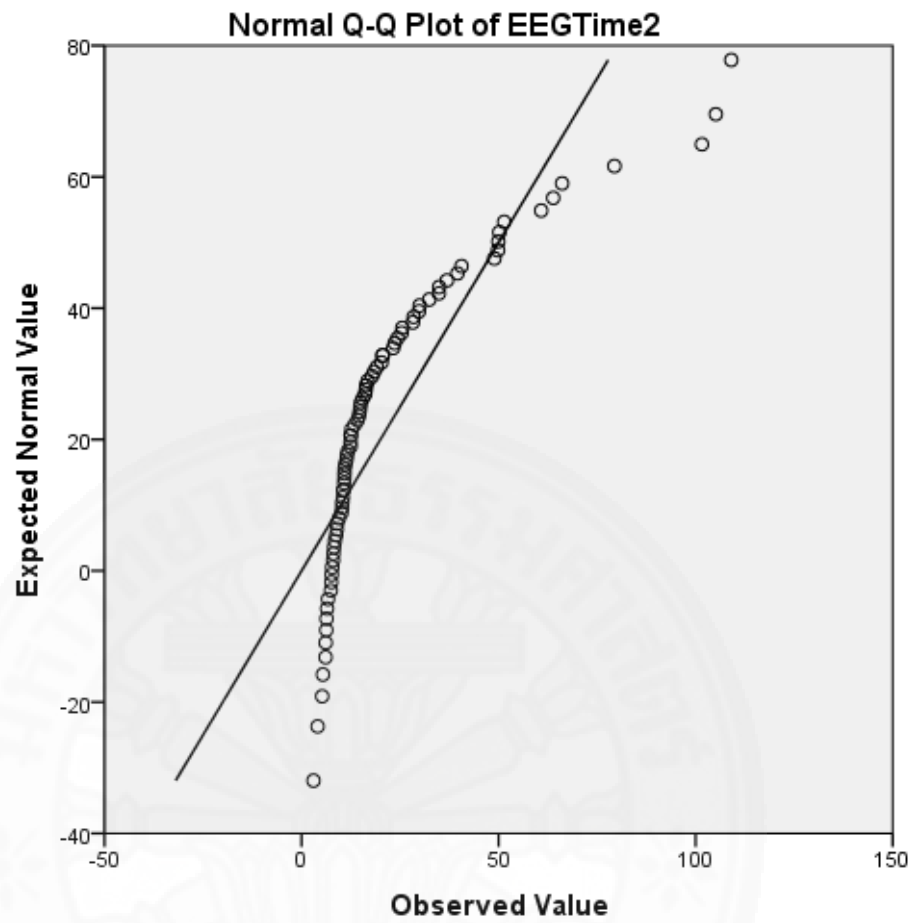


Figure 7. Q-Q Plot for the EEG Time2 data.

From Figure 7, it was found that the variables were not uniformly distributed.

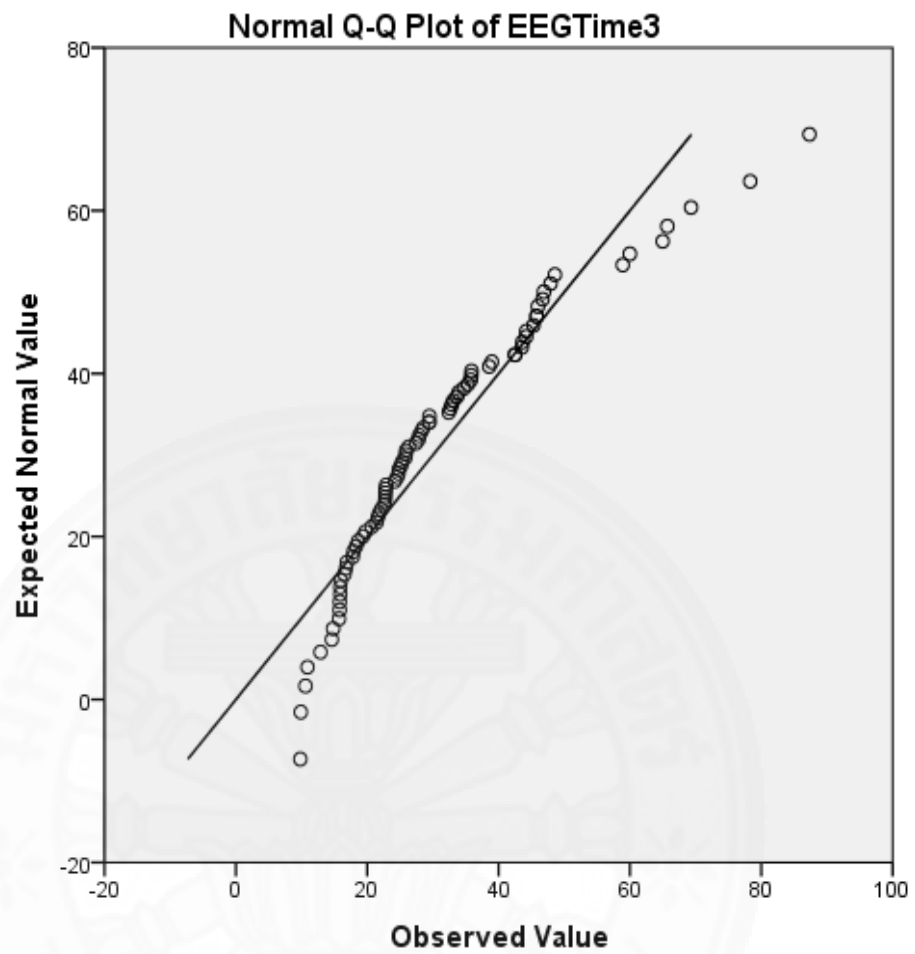


Figure 8. Q-Q Plot for the EEG Time3 data.

From Figure 8, it was found that the variables were distributed into normal curves. The distribution test is the normal curve of EMG

Table 4 Summary of Skewness and Kurtosis for EMG

Time	Statistic	Standard Error	Kolmogorov-Smirnov Z	Significance	
Time1	Skewness	.398	.257	.243	.000
	Kurtosis	3.723	.508		
Time2	Skewness	.234	.261	.025	.001
	Kurtosis	.856	.517		
Time3	Skewness	.075	.261	.651	.009
	Kurtosis	4.466	.517		

The EEG data shows approximate normality for the Time1 with skewness of .98 (SE = .257). After the experiment in time 2, variable distribution is not normal. The skewness is equal to 2.206 (SE = .261) and kurtosis is equal to 5.013 (SE = .517). After the third experiment, it was found that the variables are normally distributed. The skewness is equal to 1.288 (SE= .261) and kurtosis is equal to 1.842 (SE = .517).

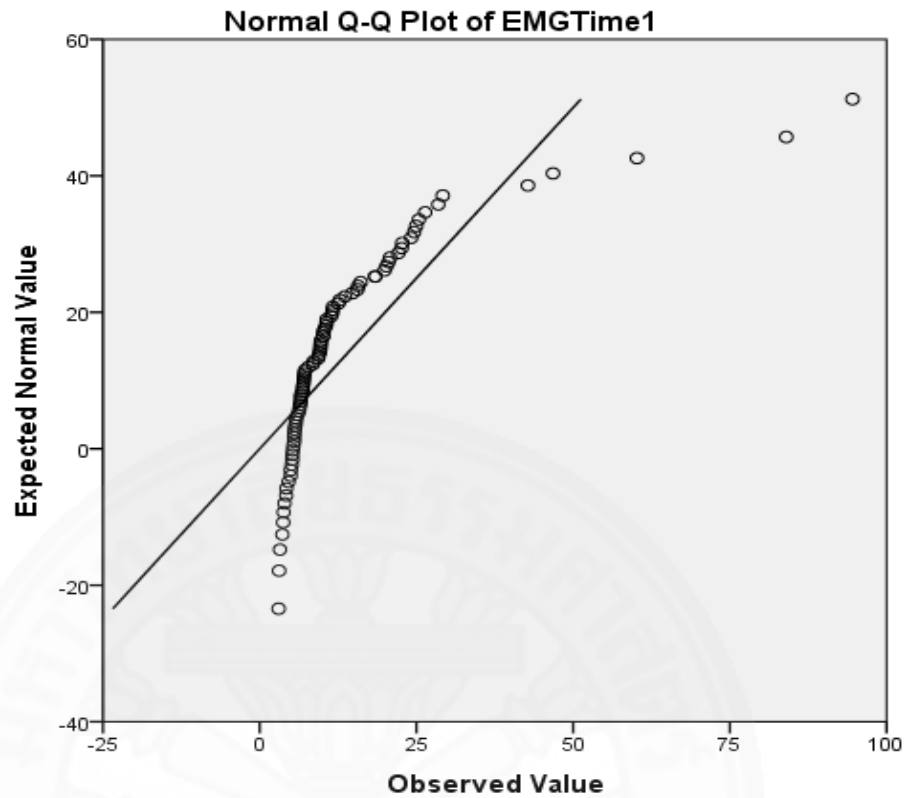


Figure 9. Q-Q Plot for the EMG Time1 data.

The following Q-Q plot in figure 9 represent the EMG time1 data is consistent with the finding that the EMG data exhibits non-normality and requires a closer review for outliers

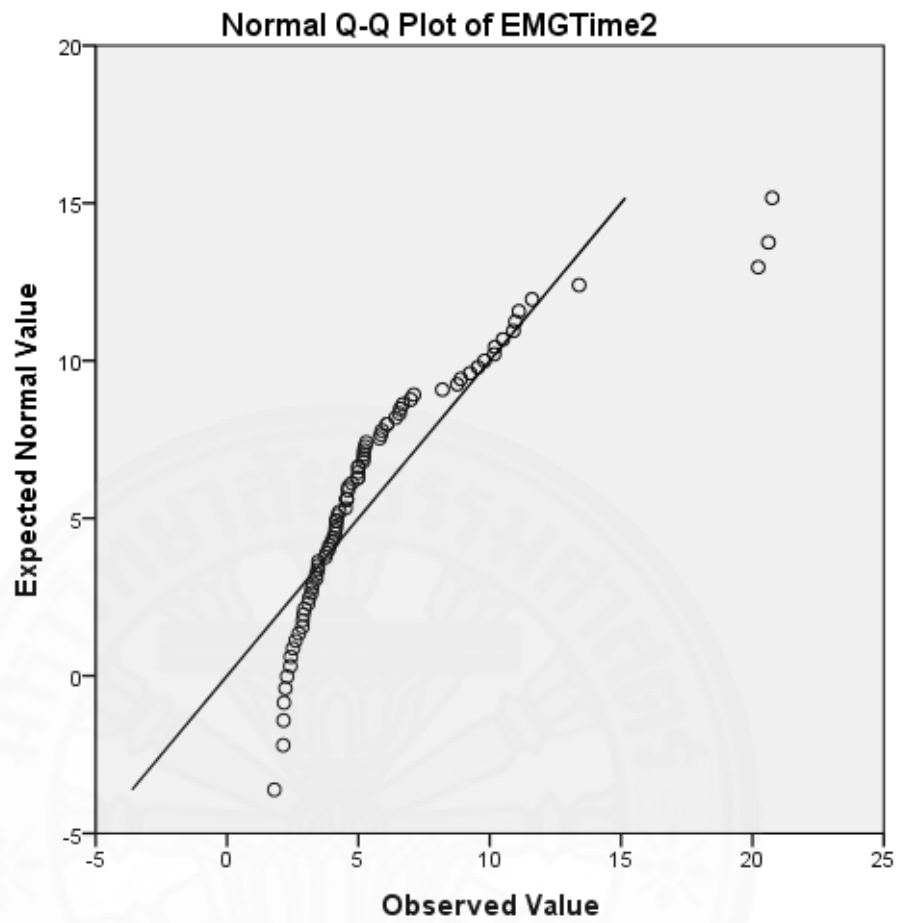


Figure 10. Q-Q Plot for the EMG Time2 data.

The following Q-Q plot in figure 10 represent the EMG time2 data is consistent with the finding that the EMG data exhibits non-normality and requires a closer review for outliers.

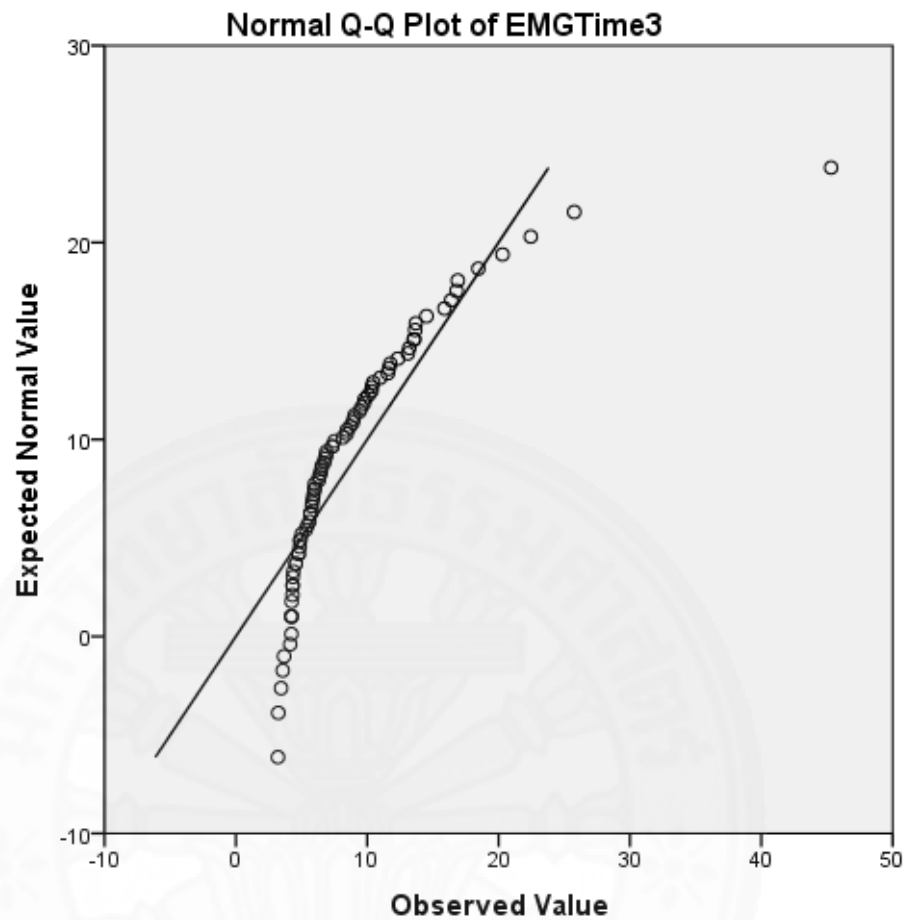


Figure 11. Q-Q Plot for the EMG Time3 data.

The following Q-Q plots in Figure 11 represent the EMG time3 data and is consistent with finding that the EMG time3 data exhibits non-normality and requires a closer review for outliers.

Marginal mean plots (Figure 12) support the stated conclusions that SOSI marginal means were different between treatments. Magnitude of difference is shown by the slope of the connecting lines from data point to data point.

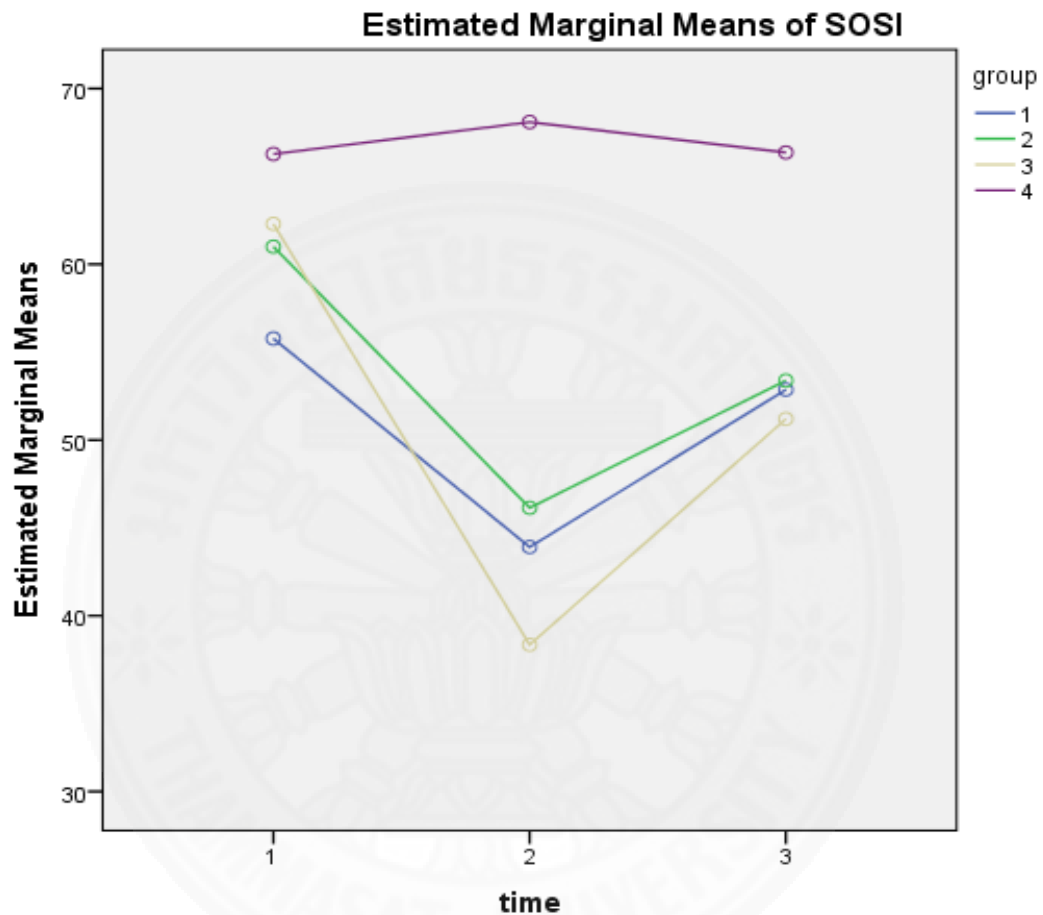


Figure 12: Estimated marginal means for SOSI

SOSI marginal means, as shown in Figure 12 suggest significant difference in mean scores from time1 to time2, and time2 and time3 in groups 1, 2 and 3. Group 4 was not significantly different.

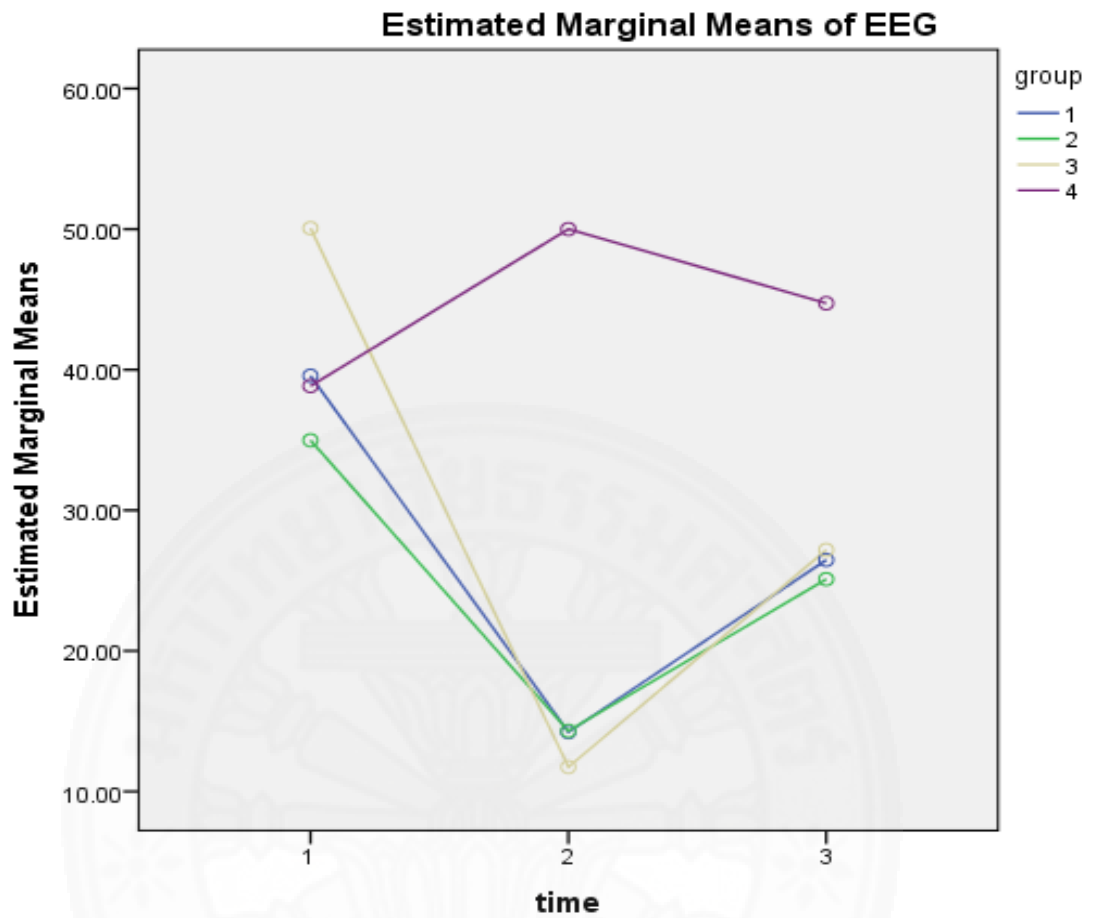


Figure 13: Estimated marginal means for EEG

EEG marginal means, as shown in Figure 13 suggest significant difference in mean scores from time1 to time2, and time2 and time3 in groups 1, 2 and 3. Group 4 was not significantly different.

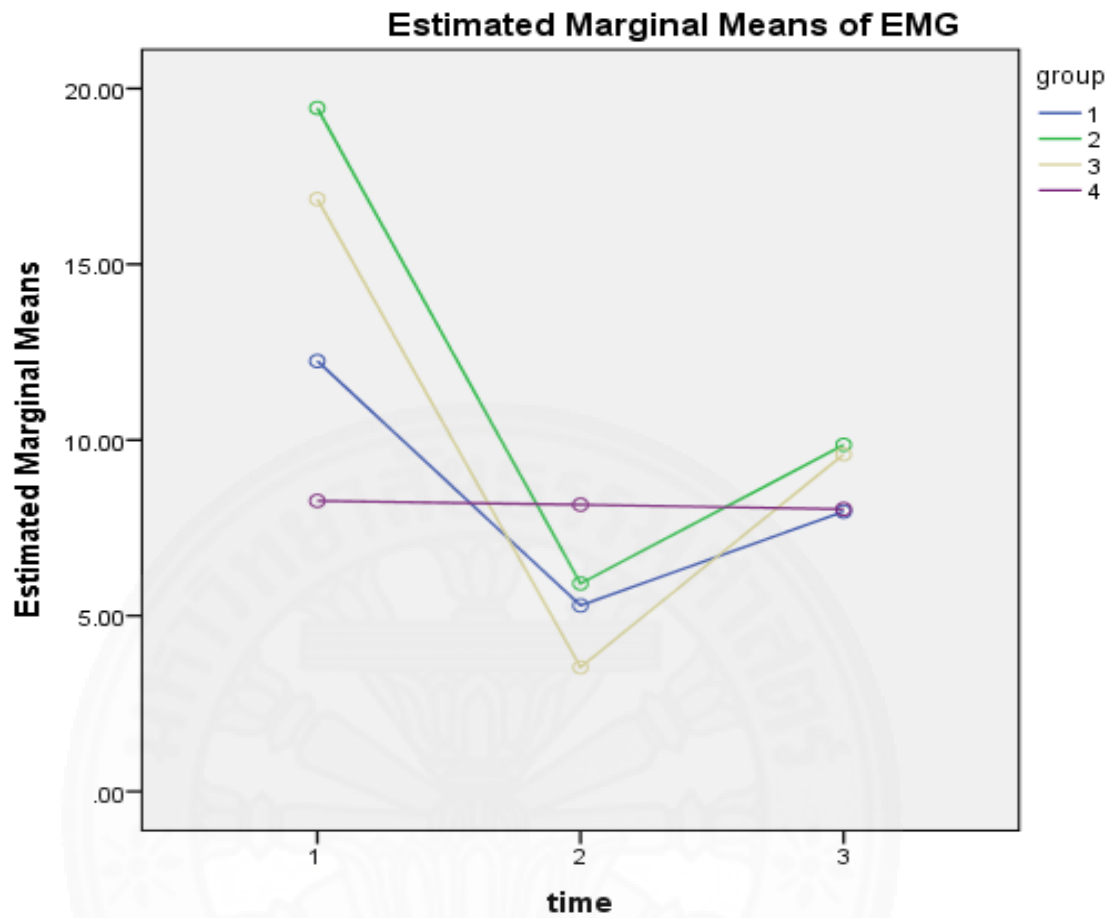


Figure 14: Estimated marginal means for EMG

EMG marginal means, as shown in Figure 14 suggest significant difference in mean scores from time1 to time2, and time2 and time3 in groups 1, 2 and 3. Group 4 was not significantly different.

Appendix C

The Institutional Review Board of the University Ethics



The Ethics Review Sub-Committee for Research Involving Human Research Subjects of
Thammasat University, No. 3 (Faculty of Health Sciences and Science and Technology)
Rachasuda Building ,1 Floor, Research and Behavior Center, Faculty of Nursing, Pratumthani
12121, Thailand, Tel: 0-2986-9213 Fax: 0-2516-5381 E-mail: cesctu3@nurse.tu.ac.th

COA No. 060/2561

Certificate of Approval

Project No. : 060/2561
Title of Project : ผลของดนตรีและโปรแกรมไบโอฟีดแบคในผู้ป่วยมะเร็งระยะประคับประคอง
 : A Randomized Controlled Trial Examining the Effects of a Music and Biofeedback Program for Thai Cancer Patients within Palliative Care
Principle Investigator : Mrs. Tipsuda Sunneangsator
Place of Proposed Study/Institution: Faculty of Nursing, Thammasat University

The Ethics Review Sub-Committee for Research Involving Human Research Subjects of Thammasat University, No. 3 (Faculty of Health Sciences and Science and Technology), Thailand, has approved, constituted in accordance with the International Conference on Harmonization - Good Clinical Practice (ICH-GCP), the above study project

Signature: *Pranom Othaganont* Signature: *Laksana Laokiat*
 (Prof. Dr. Pranom Othaganont) (Asst.Prof.Dr. Laksana Laokiat)
 Chairman of the Human Ethics Sub-Committee Secretary of the Human Ethics Sub-Committee of
 of Thammasat University, No. 3 Thammasat University, No. 3

Date of Approval : 4 June 2018

Approval Expire date : : 3 June 2019

Progressing Report Due : 24 December 2018

The approval documents including

- 1) Research proposal
- 2) Patient/Participant Information Sheet and Informed Consent Form
- 3) Researcher
- 4) Other research tools eg: Questionnaire
- 5) Other relevant documents

Appendix D

1. Informed Consent Form

AF 05_07

หนังสือแสดงความยินยอมเข้าร่วมการวิจัยของอาสาสมัครวิจัย Informed Consent Form

คำแนะนำ: โปรดปรับข้อความให้สอดคล้องกับโครงการวิจัยของท่าน²

ทำที่.....

วันที่.....เดือน.....พ.ศ.

เลขที่ อาสาสมัครวิจัย.....

ข้าพเจ้า ซึ่งได้ลงนามท้ายหนังสือนี้ ขอแสดงความยินยอมเข้าร่วมโครงการวิจัย
ชื่อโครงการวิจัย ผลของดนตรีและโปรแกรมไบโอฟีดแบคในผู้ป่วยมะเร็งระยะประคับประคอง
ชื่อผู้วิจัย ผู้ช่วยศาสตราจารย์ ทิพย์สุดา สำนึงเสนาะ
ที่อยู่ติดต่อ บ้านเลขที่ 90 ม. 4 ต.บางชะแยง อ.เมือง จ.ปทุมธานี
โทรศัพท์ 081-6491571

ข้าพเจ้า **ได้รับทราบ**รายละเอียดเกี่ยวกับที่มาและวัตถุประสงค์ในการทำวิจัย รายละเอียด
ขั้นตอนต่างๆ ที่จะต้องปฏิบัติหรือได้รับการปฏิบัติ ความเสี่ยง/อันตราย และประโยชน์ซึ่งเกิดขึ้นจาก
การวิจัยเรื่องนี้ โดยได้อ่านรายละเอียดในเอกสารชี้แจงอาสาสมัครวิจัยโดยตลอด และ**ได้รับคำอธิบาย**
จากผู้วิจัยจนเข้าใจเป็นอย่างดีแล้ว

ข้าพเจ้าจึง**สมัครใจ**เข้าร่วมในโครงการวิจัยนี้ ตามที่ระบุไว้ในเอกสารชี้แจงอาสาสมัครวิจัย
โดยข้าพเจ้ายินยอมสละเวลา (ตอบ แบบประเมินความเครียดจำนวน 30 ข้อ, ประเมินระดับความ
ปวด การประเมินความเครียดด้วยเครื่องมือไบโอฟีดแบคแบบผ่านคลื่นสมอง (An
electroencephalograph) และไบโอฟีดแบคที่แสดงถึงการตึงตัวของกล้ามเนื้อ (An
electromyography) รวมถึงการประเมินสัญญาณชีพ โดยใช้เวลาประมาณ 45 นาที) เมื่อ
เสร็จสิ้นการวิจัยแล้วข้อมูลที่เกี่ยวข้องกับอาสาสมัครวิจัย จะถูกทำลาย

ข้าพเจ้ามีสิทธิถอนตัวออกจากการวิจัยเมื่อใดก็ได้ตามความประสงค์ **โดยไม่ต้องแจ้งเหตุผล**
ซึ่งการถอนตัวออกจากการวิจัยนั้น จะไม่มีผลกระทบในทางใดๆ ต่อข้าพเจ้าทั้งสิ้น (ระบุเป็นต้นว่า**ไม่มี**
ผลกระทบต่อการดูแลสุขภาพ/ ผลต่อการศึกษา/ ผลต่อการเรียน)

ข้าพเจ้าได้รับคำรับรองว่า ผู้วิจัยจะปฏิบัติตามข้าพเจ้าตามข้อมูลที่ระบุไว้ในเอกสารชี้แจง
อาสาสมัครวิจัยและข้อมูลใดๆ ที่เกี่ยวข้องกัข้าพเจ้า ผู้วิจัยจะ**เก็บรักษาเป็นความลับ** โดยจะ
นำเสนอข้อมูลการวิจัยเป็นภาพรวมเท่านั้น ไม่มีข้อมูลใดในการรายงานที่จะนำไปสู่การระบุตัวข้าพเจ้า

หากข้าพเจ้าไม่ได้รับการปฏิบัติตรงตามที่ได้ระบุไว้ในเอกสารชี้แจงอาสาสมัครวิจัย ข้าพเจ้าสามารถร้องเรียนได้ที่: คณะอนุกรรมการจริยธรรมการวิจัยในคน มหาวิทยาลัยธรรมศาสตร์ ชุดที่ 3 อาคารราชสุดา ชั้น 1 ศูนย์ส่งเสริมสุขภาพ คณะพยาบาลศาสตร์ มหาวิทยาลัยธรรมศาสตร์ ศูนย์รังสิต โทรศัพท์ 02-986-9213 ต่อ 7373 โทรสาร 02-5165381

ข้าพเจ้าได้ลงลายมือชื่อไว้เป็นสำคัญต่อหน้าพยาน ทั้งนี้ข้าพเจ้าได้รับสำเนาเอกสารข้อมูลสำหรับอาสาสมัครวิจัย และสำเนาหนังสือแสดงความยินยอมเข้าร่วมการวิจัยของอาสาสมัครวิจัยไว้แล้ว

ลงชื่อ..... (.....) ผู้วิจัยหลัก วันที่...../...../.....	ลงชื่อ..... (.....) อาสาสมัครวิจัย วันที่...../...../.....
ลงชื่อ..... (.....) พยาน วันที่...../...../.....	ลงชื่อ..... (.....) พยาน วันที่...../...../.....

2. Participant Information Sheet

AF 04_07

ข้อมูลสำหรับอาสาสมัครวิจัย (Participant Information Sheet) กลุ่มที่ 1

โครงการวิจัยที่ ชื่อเรื่อง ผลของดนตรีและโปรแกรมไบโอฟีดแบคในผู้ป่วยมะเร็งระยะ
ประคับประคอง

ชื่อผู้วิจัย ทิพย์สุดา สำเนียงเสนาะ ตำแหน่ง ผู้ช่วยศาสตราจารย์
สถานที่ติดต่อผู้วิจัย

(ที่ทำงาน) คณะพยาบาลศาสตร์ มหาวิทยาลัยธรรมศาสตร์

(ที่บ้าน) บ้านเลขที่ 90 ม. 4 ต.บางชะแมง อ.เมือง จ.ปทุมธานี

โทรศัพท์มือถือ 081-6491571 E-mail: tip_sit@hotmail.com

อาจารย์ที่ปรึกษาวิทยานิพนธ์ ศาสตราจารย์ ดร. มรรยาท รุจิวิเศษณ์

สถานที่ติดต่อ อาคารนิยชาติ ชั้น 10 คณะพยาบาลศาสตร์ มหาวิทยาลัยธรรมศาสตร์

เบอร์โทรศัพท์ 02-9869213 ต่อ 7311 ในวันและเวลาราชการ

การเชิญท่านเข้าร่วมในการวิจัยก่อนที่ท่านจะตัดสินใจเข้าร่วมในการวิจัย มีความจำเป็นที่
ท่านควรทำความเข้าใจว่างานวิจัยนี้ทำเพราะเหตุใด และเกี่ยวข้องกับอะไร กรุณาใช้เวลาในการอ่าน
ข้อมูลต่อไปนี้อย่างละเอียดรอบคอบ และสอบถามข้อมูลเพิ่มเติมหรือข้อมูลที่ไม่ชัดเจนได้ตลอดเวลา

ตามที่ดิฉัน ผู้ช่วยศาสตราจารย์ ทิพย์สุดา สำเนียงเสนาะ นักศึกษาหลักสูตรปรัชญาดุษฎีบัณฑิต
สาขาวิชาพยาบาลศาสตร์ (หลักสูตรนานาชาติ) คณะพยาบาลศาสตร์ มหาวิทยาลัยธรรมศาสตร์ ได้จัดทำ
โครงการวิจัยเรื่อง “ผลของดนตรีและโปรแกรมไบโอฟีดแบคในผู้ป่วยมะเร็งระยะประคับประคอง”
โดยมีวัตถุประสงค์เพื่อศึกษาผลของดนตรีบำบัดและโปรแกรมการฝึกไบโอฟีดแบคเพื่อลดอาการปวด
และความเครียดในผู้ป่วยโรคมะเร็ง และเพื่อเปรียบเทียบความแตกต่างของระดับความปวด,
ความเครียด, ระดับคลื่นสมอง, ค่าการดึงตัวของกล้ามเนื้อ และค่าสัญญาณชีพในผู้ป่วยมะเร็งที่มี
ความเครียด และความปวด ทั้งนี้ ผู้วิจัยจะทำการสุ่มผู้ป่วยโรคมะเร็งที่รักษาตัวที่โรงพยาบาล
ธรรมศาสตร์เฉลิมพระเกียรติเพื่อเข้าร่วมโครงการ ซึ่งผลที่ได้จากการวิจัยครั้งนี้จะเป็นประโยชน์กับตัว
ท่านเพื่อเป็นแนวทางเพื่อใช้ป้องกันและลดอาการแสดงที่ไม่พึงประสงค์เช่น ความเครียด ลดความ
ปวดที่เกิดขึ้นได้

เหตุผลที่เชิญชวนให้ท่านเข้าร่วมโครงการนี้ เนื่องจาก ท่านเป็นเสมือนตัวแทนผู้ป่วย
โรคมะเร็งที่รักษา ณ โรงพยาบาลธรรมศาสตร์เฉลิมพระเกียรติ ที่จะช่วยให้ทราบระดับความเครียด
และความปวดที่จะมีผลต่อคุณภาพชีวิต ซึ่งจะเป็นข้อมูลที่ดีที่จะนำไปสู่แนวทางการพัฒนารูปแบบการ
ป้องกันและลดอาการแสดงที่ไม่พึงประสงค์เช่น ความเครียด ลดความปวดที่เกิดขึ้นได้ ให้มี
ประสิทธิภาพต่อไป

โดยการเข้าร่วมโครงการวิจัยครั้งนี้ ท่านจะได้รับการฟังดนตรี ผ่านเครื่องเล่น MP3 โดยฟัง
เพลงวันละ 2 เวลา (ประมาณ 15 - 30 นาที ต่อครั้ง) ครั้งแรกช่วงเช้า (ตั้งแต่ช่วงเวลาประมาณตี 5

น.- 11 น.) ครั้งที่ 2 ช่วงเย็น (ตั้งแต่ช่วงเวลาประมาณ 18 น. – 23 น.) อย่างน้อยวันละ 30 นาที รวมระยะเวลา 8 สัปดาห์ และจะได้รับการประเมินความเครียดประเมินความเครียดด้วยเครื่องมือไปโอพิดแบบคบบผ่านคลื่นสมอง และไปโอพิดแบบที่แสดงถึงการตั้งตัวของกล้ามเนื้อ ในสัปดาห์ที่ 1 และ 8 ณ ศูนย์ส่งเสริมสุขภาพ คณะพยาบาลศาสตร์ มหาวิทยาลัยธรรมศาสตร์

ในขณะที่เข้าร่วมโครงการ ท่านจะได้รับการพยาบาลตามปกติ ทั้งนี้ ท่านต้องไม่ใช้วิธีการผ่อนคลายความเครียดและความปวดด้วยวิธีอื่นร่วมด้วย

เนื่องจากการเข้าร่วมโครงการวิจัย ท่านจะได้รับการประเมินความเครียดในสัปดาห์แรก หากพบว่าท่านมีภาวะเครียดอยู่ในระดับที่ต้องรีบทำการรักษา ผู้วิจัยจะรีบดำเนินการส่งพบแพทย์เพื่อทำการรักษาทันที และในขณะที่ดำเนินโครงการหากท่านมีอาการกำเริบหรือเกิดภาวะแทรกซ้อน ผู้วิจัยจะรีบดำเนินการช่วยเหลือและส่งต่อเพื่อให้การรักษาทันที ทั้งนี้การเข้าร่วมโครงการนี้มีความเสี่ยงน้อยมาก การฝึกทุกอย่างไม่ก่อให้เกิดอันตรายหรือมีผลเสียต่อร่างกายใดๆทั้งสิ้น

โดยข้อมูลที่ตอบจะถูกเก็บเป็นความลับ **โดยจะไม่ระบุชื่อของผู้ที่ตอบแบบสอบถามที่เก็บรวบรวมข้อมูล ผู้วิจัยจะสร้างรหัสลับ และจะเก็บไว้ในสถานที่มิดชิด มีเพียงแต่ผู้วิจัยและอาจารย์ที่ปรึกษาเท่านั้นที่สามารถเข้าถึงข้อมูลนี้ได้** การเผยแพร่ข้อมูลหรือการตีพิมพ์ในหนังสือหรือวารสารทางการแพทย์และการพยาบาล จะนำเสนอในลักษณะเป็นภาพรวม เพื่อประโยชน์ทางวิชาการเท่านั้น

ในการเข้าร่วมโครงการวิจัยในครั้งนี้ ท่านจะได้รับของตอบแทนในการให้ข้อมูลต่างๆ เป็นค่าเดินทางแต่ละครั้ง 100 บาท รวมถึงมีอาหารว่างให้รับประทานในแต่ละครั้ง และขอยืนยันว่าการเข้าร่วมงานวิจัยนี้ไม่มีความเสี่ยงไม่ก่อให้เกิดอันตรายใดๆ แก่ท่าน และจะไม่เกิดผลกระทบต่อนานทั้งในหน้าที่ การงานและด้านส่วนตัว หากเกิดภาวะแทรกซ้อนใดๆ ที่มีสาเหตุจากการวิจัย ท่านจะได้รับค่าชดเชยตามความเหมาะสม

หากท่านมีข้อสงสัยหรือต้องการทราบข้อมูลเพิ่มเติมเกี่ยวกับโครงการวิจัย สามารถติดต่อผู้วิจัยได้ที่ บ้านเลขที่ 90 ม. 4 ต.บางชะแยง อ.เมือง จ.ปทุมธานี หมายเลขโทรศัพท์ 081-6491571 หรืออาจารย์ที่ปรึกษาวิทยานิพนธ์ คือ ศาสตราจารย์ ดร. มรรยาท รุจิวิชญ์ สามารถติดต่อได้ที่ คณะพยาบาลศาสตร์ มหาวิทยาลัยธรรมศาสตร์ เบอร์โทรศัพท์ 02-9869213 ต่อ 7311 ในวันและเวลาราชการ

การตอบแบบสอบถามของท่านมีความสำคัญอย่างยิ่งที่จะช่วยให้การวิจัยนี้สำเร็จลุล่วง เพื่อเป็นแนวทางในการพัฒนารูปแบบการป้องกันและลดอาการแสดงที่ไม่พึงประสงค์เช่น ความเครียด ลดความปวดที่เกิดขึ้นได้ ให้มีประสิทธิภาพต่อไป

ท่านมีสิทธิ์ในการปฏิเสธการตอบแบบสอบถามนี้ และมีสิทธิ์ที่จะบอกเลิกการเข้าร่วมการวิจัยนี้เมื่อใดก็ได้ถ้าปรารถนาโดยไม่มีผลกระทบใดๆ ทั้งสิ้นต่อท่านและบุคคลที่เกี่ยวข้อง

“หากท่านไม่ได้รับการปฏิบัติตามข้อมูลดังกล่าวสามารถร้องเรียนได้ที่: คณะอนุกรรมการจริยธรรมการวิจัยในคน มหาวิทยาลัยธรรมศาสตร์ ชุดที่ 3 อาคารราชสุดา ชั้น 1 ศูนย์ส่งเสริมสุขภาพ คณะพยาบาลศาสตร์ มหาวิทยาลัยธรรมศาสตร์ ศูนย์รังสิต โทรศัพท์ 02-986-9213 ต่อ 7373 โทรสาร 02-5165381”

ข้อมูลสำหรับอาสาสมัครวิจัย (Participant Information Sheet) กลุ่มที่ 2

โครงการวิจัยที่ ชื่อเรื่อง ผลของดนตรีและโปรแกรมไบโอฟีดแบคในผู้ป่วยมะเร็งระยะ
ประคับประคอง

ชื่อผู้วิจัย ทิพย์สุดา สำเนียงเสนาะ ตำแหน่ง ผู้ช่วยศาสตราจารย์
สถานที่ติดต่อผู้วิจัย

(ที่ทำงาน) คณะพยาบาลศาสตร์ มหาวิทยาลัยธรรมศาสตร์

(ที่บ้าน) บ้านเลขที่ 90 ม. 4 ต.บางชะแยง อ.เมือง จ.ปทุมธานี

โทรศัพท์มือถือ 081-6491571 E-mail: tip_sit@hotmail.com

อาจารย์ที่ปรึกษาวิทยานิพนธ์ ศาสตราจารย์ ดร. มรรยาท... จุจิวิษณุ

สถานที่ติดต่อ อาคารปิยชาติ ชั้น 10 คณะพยาบาลศาสตร์ มหาวิทยาลัยธรรมศาสตร์

เบอร์โทรศัพท์ 02-9869213 ต่อ 7311 ในวันและเวลาราชการ

การเชิญท่านเข้าร่วมในการวิจัยก่อนที่ท่านจะตัดสินใจเข้าร่วมในการวิจัย มีความจำเป็นที่
ท่านควรทำความเข้าใจว่างานวิจัยนี้ทำเพราะเหตุใด และเกี่ยวข้องกับอะไร กรุณาใช้เวลาในการอ่าน
ข้อมูลต่อไปนี้อย่างละเอียดรอบคอบ และสอบถามข้อมูลเพิ่มเติมหรือข้อมูลที่ไม่ชัดเจนได้ตลอดเวลา

ตามที่ดิฉัน ผู้ช่วยศาสตราจารย์ ทิพย์สุดา สำเนียงเสนาะ นักศึกษาหลักสูตรปรัชญาดุษฎี
บัณฑิต สาขาวิชาพยาบาลศาสตร์ (หลักสูตรนานาชาติ) คณะพยาบาลศาสตร์ มหาวิทยาลัยธรรมศาสตร์
ได้จัดทำโครงการวิจัยเรื่อง “ผลของดนตรีและโปรแกรมไบโอฟีดแบคในผู้ป่วยมะเร็งระยะ
ประคับประคอง” โดยมีวัตถุประสงค์เพื่อศึกษาผลของดนตรีบำบัดและโปรแกรมการฝึกไบโอฟีดแบค
เพื่อลดอาการปวด และความเครียดในผู้ป่วยโรคมะเร็ง และเพื่อเปรียบเทียบความแตกต่างของระดับ
ความปวด, ความเครียด, ระดับคลื่นสมอง, ค่าการดึงตัวของกล้ามเนื้อ และค่าสัญญาณชีพในผู้ป่วย
มะเร็งที่มีความเครียด และความปวด ทั้งนี้ ผู้วิจัยจะทำการสุ่มผู้ป่วยโรคมะเร็งที่รักษาตัวที่โรงพยาบาล
ธรรมศาสตร์เฉลิมพระเกียรติเพื่อเข้าร่วมโครงการ ซึ่งผลที่ได้จากการวิจัยครั้งนี้จะเป็นประโยชน์กับตัว
ท่านเพื่อเป็นแนวทางเพื่อใช้ป้องกันและลดอาการแสดงที่ไม่พึงประสงค์เช่น ความเครียด ลดความ
ปวดที่เกิดขึ้นได้

เหตุผลที่เชิญชวนให้ท่านเข้าร่วมโครงการนี้ เนื่องจาก ท่านเป็นเสมือนตัวแทนผู้ป่วย
โรคมะเร็งที่รักษา ณ โรงพยาบาลธรรมศาสตร์เฉลิมพระเกียรติ ที่จะช่วยให้ทราบระดับความเครียด
และความปวดที่จะมีผลต่อคุณภาพชีวิต ซึ่งจะเป็นข้อมูลที่ดีที่จะนำไปสู่แนวทางการพัฒนารูปแบบการ
ป้องกันและลดอาการแสดงที่ไม่พึงประสงค์เช่น ความเครียด ลดความปวดที่เกิดขึ้นได้ ให้มี
ประสิทธิภาพต่อไป

โดยการเข้าร่วมโครงการวิจัยครั้งนี้ ท่านจะได้รับการฝึกโปรแกรมไบโอฟีดแบคโดยผ่านคลื่น
สมอง และไบโอฟีดแบคที่แสดงถึงการดึงตัวของกล้ามเนื้อ รวมถึงการประเมินสัญญาณชีพ สัปดาห์ละ
1 ครั้งรวมระยะเวลา 8 สัปดาห์ และจะได้รับการประเมินความเครียดประเมินความเครียดด้วย

เครื่องมือไปโอพีดีแบบคอคแบบผ่านคลื่นสมอง และไปโอพีดีแบบคอคที่แสดงถึงการติ่งตัวของกล้ามเนื้อในสัปดาห์ที่ 1 และ 8 ณ ศูนย์ส่งเสริมสุขภาพ คณะพยาบาลศาสตร์ มหาวิทยาลัยธรรมศาสตร์

ในขณะที่เข้าร่วมโครงการ ท่านจะได้รับการพยาบาลตามปกติ ทั้งนี้ ท่านต้องไม่ใช้วิธีการผ่อนคลายความเครียดและความปวดด้วยวิธีอื่นร่วมด้วย

เนื่องจากในการเข้าร่วมโครงการวิจัย ท่านจะได้รับการประเมินความเครียดในสัปดาห์แรก หากพบว่าท่านมีภาวะเครียดอยู่ในระดับที่ต้องรีบทำการรักษา ผู้วิจัยจะรีบดำเนินการส่งพบแพทย์เพื่อทำการรักษาทันที และในขณะที่ดำเนินโครงการหากท่านมีอาการกำเริบหรือเกิดภาวะแทรกซ้อน ผู้วิจัยจะรีบดำเนินการช่วยเหลือและส่งต่อเพื่อให้การรักษาทันที ทั้งนี้การเข้าร่วมโครงการนี้มีความเสี่ยงน้อยมาก การฝึกทุกอย่างไม่ก่อให้เกิดอันตรายหรือมีผลเสียต่อร่างกายใดๆทั้งสิ้น

โดยข้อมูลที่ตอบจะถูกเก็บเป็นความลับ **โดยจะไม่ระบุชื่อของผู้ที่ตอบแบบสอบถามที่เก็บรวบรวมข้อมูล ผู้วิจัยจะสร้างรหัสลับ และจะเก็บไว้ในสถานที่มิดชิด มีเพียงแต่ผู้วิจัยและอาจารย์ที่ปรึกษาเท่านั้นที่สามารถเข้าถึงข้อมูลนี้ได้** การเผยแพร่ข้อมูลหรือการตีพิมพ์ในหนังสือหรือวารสารทางการแพทย์และการพยาบาล จะนำเสนอในลักษณะเป็นภาพรวม เพื่อประโยชน์ทางวิชาการเท่านั้น

ในการเข้าร่วมโครงการวิจัยในครั้งนี้ ท่านจะได้รับของตอบแทนในการให้ข้อมูลต่างๆ เป็นค่าเดินทางแต่ละครั้ง 100 บาท รวมถึงมีอาหารว่างให้รับประทานในแต่ละครั้ง และขอยืนยันว่าการเข้าร่วมงานวิจัยนี้ไม่มีความเสี่ยงไม่ก่อให้เกิดอันตรายใดๆ แก่ท่าน และจะไม่เกิดผลกระทบต่อท่านทั้งในหน้าที่ การงานและด้านส่วนตัว หากเกิดภาวะแทรกซ้อนใดๆ ที่มีสาเหตุจากการวิจัย ท่านจะได้รับค่าชดเชยตามความเหมาะสม

หากท่านมีข้อสงสัยหรือต้องการทราบข้อมูลเพิ่มเติมเกี่ยวกับโครงการวิจัย สามารถติดต่อผู้วิจัยได้ที่ บ้านเลขที่ 90 ม. 4 ต.บางชะแยง อ.เมือง จ.ปทุมธานี หมายเลขโทรศัพท์ 081-6491571 หรืออาจารย์ที่ปรึกษาวิทยานิพนธ์ คือ ศาสตราจารย์ ดร. มรรยาท รุจิวิชญ์ สามารถติดต่อได้ที่ คณะพยาบาลศาสตร์ มหาวิทยาลัยธรรมศาสตร์ เบอร์โทรศัพท์ 02-9869213 ต่อ 7311 ในวันและเวลาราชการ

การตอบแบบสอบถามของท่านมีความสำคัญอย่างยิ่งที่จะช่วยให้การวิจัยนี้สำเร็จลุล่วง เพื่อเป็นแนวทางในการพัฒนารูปแบบการป้องกันและลดอาการแสดงที่ไม่พึงประสงค์เช่น ความเครียด ลดความปวดที่เกิดขึ้นได้ ให้มีประสิทธิภาพต่อไป

ท่านมีสิทธิ์ในการปฏิเสธการตอบแบบสอบถามนี้ และมีสิทธิ์ที่จะบอกเลิกการเข้าร่วมการวิจัยนี้เมื่อใดก็ได้ถ้าปรารถนาโดยไม่มีผลกระทบใดๆ ทั้งสิ้นต่อท่านและบุคคลที่เกี่ยวข้อง

“หากท่านไม่ได้รับการปฏิบัติตามข้อมูลดังกล่าวสามารถร้องเรียนได้ที่ คณะอนุกรรมการจริยธรรมการวิจัยในคน มหาวิทยาลัยธรรมศาสตร์ ชุดที่ 3 อาคารราชสุดา ชั้น 1 ศูนย์ส่งเสริมสุขภาพ คณะพยาบาลศาสตร์ มหาวิทยาลัยธรรมศาสตร์ ศูนย์รังสิต โทรศัพท์ 02-986-9213 ต่อ 7373 โทรสาร 02-5165381”

ข้อมูลสำหรับอาสาสมัครวิจัย (Participant Information Sheet) กลุ่มที่ 3

โครงการวิจัยที่ ชื่อเรื่อง ผลของดนตรีและโปรแกรมไบโอฟีดแบคในผู้ป่วยมะเร็งระยะ
ประคับประคอง

ชื่อผู้วิจัย ทิพย์สุดา สำเนียงเสนาะ ตำแหน่ง ผู้ช่วยศาสตราจารย์
สถานที่ติดต่อผู้วิจัย

(ที่ทำงาน) คณะพยาบาลศาสตร์ มหาวิทยาลัยธรรมศาสตร์

(ที่บ้าน) บ้านเลขที่ 90 ม. 4 ต.บางชะแยง อ.เมือง จ.ปทุมธานี

โทรศัพท์มือถือ 081-6491571 E-mail: tip_sit@hotmail.com

อาจารย์ที่ปรึกษาวิทยานิพนธ์ ศาสตราจารย์ ดร. มรรยาท... จุฬิวิษณู

สถานที่ติดต่อ อาคารปิยชาติ ชั้น 10 คณะพยาบาลศาสตร์ มหาวิทยาลัยธรรมศาสตร์

เบอร์โทรศัพท์ 02-9869213 ต่อ 7311 ในวันและเวลาราชการ

การเชิญท่านเข้าร่วมในการวิจัยก่อนที่ท่านจะตัดสินใจเข้าร่วมในการวิจัย มีความจำเป็นที่
ท่านควรทำความเข้าใจว่างานวิจัยนี้ทำเพราะเหตุใด และเกี่ยวข้องกับอะไร กรุณาใช้เวลาในการอ่าน
ข้อมูลต่อไปนี้อย่างละเอียดรอบคอบ และสอบถามข้อมูลเพิ่มเติมหรือข้อมูลที่ไมชัดเจนได้ตลอดเวลา

ตามที่ดิฉัน ผู้ช่วยศาสตราจารย์ ทิพย์สุดา สำเนียงเสนาะ นักศึกษาหลักสูตรปรัชญาดุษฎี
บัณฑิต สาขาวิชาพยาบาลศาสตร์ (หลักสูตรนานาชาติ) คณะพยาบาลศาสตร์ มหาวิทยาลัยธรรมศาสตร์
ได้จัดทำโครงการวิจัยเรื่อง “ผลของดนตรีและโปรแกรมไบโอฟีดแบคในผู้ป่วยมะเร็งระยะ
ประคับประคอง” โดยมีวัตถุประสงค์เพื่อศึกษาผลของดนตรีบำบัดและโปรแกรมการฝึกไบโอฟีดแบค
เพื่อลดอาการปวด และความเครียดในผู้ป่วยโรคมะเร็ง และเพื่อเปรียบเทียบความแตกต่างของระดับ
ความปวด, ความเครียด, ระดับคลื่นสมอง, ค่าการดึงตัวของกล้ามเนื้อ และค่าสัญญาณชีพในผู้ป่วย
มะเร็งที่มีความเครียด และความปวด ทั้งนี้ ผู้วิจัยจะทำการสุ่มผู้ป่วยโรคมะเร็งที่รักษาตัวที่โรงพยาบาล
ธรรมศาสตร์เฉลิมพระเกียรติเพื่อเข้าร่วมโครงการ ซึ่งผลที่ได้จากการวิจัยครั้งนี้จะเป็นประโยชน์กับตัว
ท่านเพื่อเป็นแนวทางเพื่อใช้ป้องกันและลดอาการแสดงที่ไม่พึงประสงค์เช่น ความเครียด ลดความ
ปวดที่เกิดขึ้นได้

เหตุผลที่เชิญชวนให้ท่านเข้าร่วมโครงการนี้ เนื่องจาก ท่านเป็นเสมือนตัวแทนผู้ป่วย
โรคมะเร็งที่รักษา ณ โรงพยาบาลธรรมศาสตร์เฉลิมพระเกียรติ ที่จะช่วยให้ทราบระดับความเครียด
และความปวดที่จะมีผลต่อคุณภาพชีวิต ซึ่งจะเป็นข้อมูลที่ดียิ่งจะนำไปสู่แนวทางการพัฒนารูปแบบการ
ป้องกันและลดอาการแสดงที่ไม่พึงประสงค์เช่น ความเครียด ลดความปวดที่เกิดขึ้นได้ ให้มี
ประสิทธิภาพต่อไป

โดยการเข้าร่วมโครงการวิจัยครั้งนี้ ท่านจะได้รับการฟังดนตรี ผ่านเครื่องเล่น MP3 โดยฟัง
เพลงวันละ 2 เวลา (ประมาณ 15 - 30 นาที ต่อครั้ง) ครั้งแรกช่วงเช้า (ตั้งแต่ช่วงเวลาประมาณตี 5
น.- 11 น.) ครั้งที่ 2 ช่วงเย็น (ตั้งแต่ช่วงเวลาประมาณ 18 น. - 23 น.) อย่างน้อยวันละ 30 นาที
ร่วมกับการฝึกโปรแกรมไบโอฟีดแบคโดยผ่านคลื่นสมอง และไบโอฟีดแบคที่แสดงถึงการดึงตัวของ

กล้ามเนื้อ รวมถึงการประเมินสัญญาณชีพ สัปดาห์ละ 1 ครั้งรวมระยะเวลา 8 สัปดาห์ และจะได้รับ การประเมินความเครียดประเมินความเครียดด้วยเครื่องมือไปโอพีดแบบคคแบบผ่านคลื่นสมอง และไป โอพีดแบบที่แสดงถึงการตั้งตัวของกล้ามเนื้อ ในสัปดาห์ที่ 1 และ 8 ณ ศูนย์ส่งเสริมสุขภาพ คณะ พยาบาลศาสตร์ มหาวิทยาลัยธรรมศาสตร์

ในขณะที่เข้าร่วมโครงการ ท่านจะได้รับการพยาบาลตามปกติ ทั้งนี้ ท่านต้องไม่ใช่วิธีการผ่อน คลายความเครียดและความปวดด้วยวิธีอื่นร่วมด้วย

เนื่องจากการเข้าร่วมโครงการวิจัย ท่านจะได้รับการประเมินความเครียดในสัปดาห์แรก หากพบว่าท่านมีภาวะเครียดอยู่ในระดับที่ต้องรีบทำการรักษา ผู้วิจัยจะรีบดำเนินการส่งพบแพทย์เพื่อ ทำการรักษาทันที และในขณะที่ดำเนินโครงการหากท่านมีอาการกำเริบหรือเกิดภาวะแทรกซ้อน ผู้วิจัยจะรีบดำเนินการช่วยเหลือและส่งต่อเพื่อให้การรักษาทันที ทั้งนี้การเข้าร่วมโครงการนี้มีความ เสี่ยงน้อยมาก การฝึกทุกอย่างไม่ก่อให้เกิดอันตรายหรือมีผลเสียต่อร่างกายใดๆทั้งสิ้น

โดยข้อมูลที่ตอบจะถูกเก็บเป็นความลับ **โดยจะไม่ระบุชื่อของผู้ที่ตอบแบบสอบถามที่เก็บ รวบรวมข้อมูล ผู้วิจัยจะสร้างรหัสลับ และจะเก็บไว้ในสถานที่มิดชิด มีเพียงแต่ผู้วิจัยและอาจารย์ ที่ปรึกษาเท่านั้นที่สามารถเข้าถึงข้อมูลนี้ได้** การเผยแพร่ข้อมูลหรือการตีพิมพ์ในหนังสือหรือ วารสารทางการแพทย์และการพยาบาล จะนำเสนอในลักษณะเป็นภาพรวม เพื่อประโยชน์ทาง วิชาการเท่านั้น

ในการเข้าร่วมโครงการวิจัยในครั้งนี้ ท่านจะได้รับของตอบแทนในการให้ข้อมูลต่างๆ เป็น ค่าเดินทางแต่ละครั้ง 100 บาท รวมถึงมีอาหารว่างให้รับประทานในแต่ละครั้ง และขอยืนยันว่า การเข้าร่วมงานวิจัยนี้ไม่มีความเสี่ยงไม่ก่อให้เกิดอันตรายใดๆ แก่ท่าน และจะไม่เกิดผลกระทบต่อ ท่านทั้งในหน้าที่ การงานและด้านส่วนตัว หากเกิดภาวะแทรกซ้อนใดๆ ที่มีสาเหตุจากการวิจัย ท่าน จะได้รับค่าชดเชยตามความเหมาะสม

หากท่านมีข้อสงสัยหรือต้องการทราบข้อมูลเพิ่มเติมเกี่ยวกับโครงการวิจัย สามารถติดต่อ ผู้วิจัยได้ที่ บ้านเลขที่ 90 ม. 4 ต.บางชะแยง อ.เมือง จ.ปทุมธานี หมายเลขโทรศัพท์ 081-6491571 หรืออาจารย์ที่ปรึกษาวิทยานิพนธ์ คือ ศาสตราจารย์ ดร. มรรยาท รุจิวิชชญ์ สามารถ ติดต่อได้ที่ คณะพยาบาลศาสตร์ มหาวิทยาลัยธรรมศาสตร์ เบอร์โทรศัพท์ 02-9869213 ต่อ 7311 ในวันและเวลาราชการ

การตอบแบบสอบถามของท่านมีความสำคัญอย่างยิ่งที่จะช่วยให้การวิจัยนี้สำเร็จลุล่วง เพื่อ เป็นแนวทางในการพัฒนารูปแบบการป้องกันและลดอาการแสดงที่ไม่พึงประสงค์เช่น ความเครียด ลด ความปวดที่เกิดขึ้นได้ ให้มีประสิทธิภาพต่อไป

ท่านมีสิทธิ์ในการปฏิเสธการตอบแบบสอบถามนี้ และมีสิทธิ์ที่จะบอกเลิกการเข้าร่วมการ วิจัยนี้เมื่อใดก็ได้ถ้าปรารถนาโดยไม่มีผลกระทบใดๆ ทั้งสิ้นต่อท่านและบุคคลที่เกี่ยวข้อง

“หากท่านไม่ได้รับการปฏิบัติตามข้อมูลดังกล่าวสามารถร้องเรียนได้ที่: คณะอนุกรรมการ จริยธรรมการวิจัยในคน มหาวิทยาลัยธรรมศาสตร์ ชุดที่ 3 อาคารราชสุดา ชั้น 1 ศูนย์ส่งเสริมสุขภาพ คณะพยาบาลศาสตร์ มหาวิทยาลัยธรรมศาสตร์ ศูนย์รังสิต โทรศัพท์ 02-986-9213 ต่อ 7373 โทรสาร 02-5165381”

ข้อมูลสำหรับอาสาสมัครวิจัย (Participant Information Sheet) กลุ่มที่ 4

โครงการวิจัยที่ ชื่อเรื่อง ผลของดนตรีและโปรแกรมไบโอฟีดแบคในผู้ป่วยมะเร็งระยะ
 ประคับประคอง

ชื่อผู้วิจัย ทิพย์สุดา สำเนียงเสนาะ ตำแหน่ง ผู้ช่วยศาสตราจารย์
 สถานที่ติดต่อผู้วิจัย

(ที่ทำงาน) คณะพยาบาลศาสตร์ มหาวิทยาลัยธรรมศาสตร์

(ที่บ้าน) บ้านเลขที่ 90 ม. 4 ต.บางชะแยง อ.เมือง จ.ปทุมธานี

โทรศัพท์มือถือ 081-6491571 E-mail: tip_sit@hotmail.com

อาจารย์ที่ปรึกษาวิทยานิพนธ์ ศาสตราจารย์ ดร. มรรยาท... จุฬิชาธร

สถานที่ติดต่อ อาคารปิยชาติ ชั้น 10 คณะพยาบาลศาสตร์ มหาวิทยาลัยธรรมศาสตร์

เบอร์โทรศัพท์ 02-9869213 ต่อ 7311 ในวันและเวลาราชการ

การเชิญท่านเข้าร่วมในการวิจัยก่อนที่ท่านจะตัดสินใจเข้าร่วมในการวิจัย มีความจำเป็นที่
 ท่านควรทำความเข้าใจว่างานวิจัยนี้ทำเพราะเหตุใด และเกี่ยวข้องกับอะไร กรุณาใช้เวลาในการอ่าน
 ข้อมูลต่อไปนี้อย่างละเอียดรอบคอบ และสอบถามข้อมูลเพิ่มเติมหรือข้อมูลที่ไม่ชัดเจนได้ตลอดเวลา

ตามที่ดิฉัน ผู้ช่วยศาสตราจารย์ ทิพย์สุดา สำเนียงเสนาะ นักศึกษาหลักสูตรปรัชญาดุษฎี
 บัณฑิต สาขาวิชาพยาบาลศาสตร์ (หลักสูตรนานาชาติ) คณะพยาบาลศาสตร์ มหาวิทยาลัยธรรมศาสตร์
 ได้จัดทำโครงการวิจัยเรื่อง “ผลของดนตรีและโปรแกรมไบโอฟีดแบคในผู้ป่วยมะเร็งระยะ
 ประคับประคอง” โดยมีวัตถุประสงค์เพื่อศึกษาผลของดนตรีบำบัดและโปรแกรมการฝึกไบโอฟีดแบค
 เพื่อลดอาการปวด และความเครียดในผู้ป่วยโรคมะเร็ง และเพื่อเปรียบเทียบความแตกต่างของระดับ
 ความปวด, ความเครียด, ระดับคลื่นสมอง, ค่าการดึงตัวของกล้ามเนื้อ และค่าสัญญาณชีพในผู้ป่วย
 มะเร็งที่มีความเครียด และความปวด ทั้งนี้ ผู้วิจัยจะทำการสุ่มผู้ป่วยโรคมะเร็งที่รักษาตัวที่โรงพยาบาล
 ธรรมศาสตร์เฉลิมพระเกียรติเพื่อเข้าร่วมโครงการ ซึ่งผลที่ได้จากการวิจัยครั้งนี้จะเป็นประโยชน์กับตัว
 ท่านเพื่อเป็นแนวทางเพื่อใช้ป้องกันและลดอาการแสดงที่ไม่พึงประสงค์เช่น ความเครียด ลดความ
 ปวดที่เกิดขึ้นได้

เหตุผลที่เชิญชวนให้ท่านเข้าร่วมโครงการนี้ เนื่องจาก ท่านเป็นเสมือนตัวแทนผู้ป่วย
 โรคมะเร็งที่รักษา ณ โรงพยาบาลธรรมศาสตร์เฉลิมพระเกียรติ ที่จะช่วยให้ทราบระดับความเครียด
 และความปวดที่จะมีผลต่อคุณภาพชีวิต ซึ่งจะเป็นข้อมูลที่ดียิ่งจะนำไปสู่แนวทางการพัฒนารูปแบบการ
 ป้องกันและลดอาการแสดงที่ไม่พึงประสงค์เช่น ความเครียด ลดความปวดที่เกิดขึ้นได้ ให้มี
 ประสิทธิภาพต่อไป

โดยการเข้าร่วมโครงการวิจัยครั้งนี้ ท่านจะได้รับการประเมินความเครียดประเมิน
 ความเครียดด้วยเครื่องมือไบโอฟีดแบคแบบผ่านคลื่นสมอง และไบโอฟีดแบคที่แสดงถึงการดึงตัว
 ของกล้ามเนื้อในสัปดาห์ที่ 1 และ 8 ณ ศูนย์ส่งเสริมสุขภาพ คณะพยาบาลศาสตร์
 มหาวิทยาลัยธรรมศาสตร์

ในขณะที่เข้าร่วมโครงการ ท่านจะได้รับการพยาบาลตามปกติ ทั้งนี้ ท่านต้องไม่ใช้วิธีการผ่อนคลายความเครียดและความปวดด้วยวิธีอื่นร่วมด้วย

เนื่องจากในการเข้าร่วมโครงการวิจัย ท่านจะได้รับการประเมินความเครียดในสัปดาห์แรก หากพบว่าท่านมีภาวะเครียดอยู่ในระดับที่ต้องรีบทำการรักษา ผู้วิจัยจะรีบดำเนินการส่งพบแพทย์เพื่อทำการรักษาทันที และในขณะที่ดำเนินโครงการหากท่านมีอาการกำเริบหรือเกิดภาวะแทรกซ้อน ผู้วิจัยจะรีบดำเนินการช่วยเหลือและส่งต่อเพื่อให้การรักษาทันที ทั้งนี้การเข้าร่วมโครงการนี้มีความเสี่ยงน้อยมาก การฝึกทุกอย่างไม่ก่อให้เกิดอันตรายหรือมีผลเสียต่อร่างกายใดๆทั้งสิ้น

โดยข้อมูลที่ตอบจะถูกเก็บเป็นความลับ **โดยจะไม่ระบุชื่อของผู้ที่ตอบแบบสอบถามที่เก็บรวบรวมข้อมูล ผู้วิจัยจะสร้างรหัสลับ และจะเก็บไว้ในสถานที่มิดชิด มีเพียงแต่ผู้วิจัยและอาจารย์ที่ปรึกษาเท่านั้นที่สามารถเข้าถึงข้อมูลนี้ได้** การเผยแพร่ข้อมูลหรือการตีพิมพ์ในหนังสือหรือวารสารทางการแพทย์และการพยาบาล จะนำเสนอในลักษณะเป็นภาพรวม เพื่อประโยชน์ทางวิชาการเท่านั้น

ในการเข้าร่วมโครงการวิจัยในครั้งนี้ ท่านจะได้รับของตอบแทนในการให้ข้อมูลต่างๆ เป็นค่าเดินทางแต่ละครั้ง 100 บาท รวมถึงมีอาหารว่างให้รับประทานในแต่ละครั้ง และขอยืนยันว่าการเข้าร่วมงานวิจัยนี้ไม่มีความเสี่ยงไม่ก่อให้เกิดอันตรายใดๆ แก่ท่าน และจะไม่เกิดผลกระทบต่อท่านทั้งในหน้าที่ การงานและด้านส่วนตัว หากเกิดภาวะแทรกซ้อนใดๆ ที่มีสาเหตุจากการวิจัย ท่านจะได้รับค่าชดเชยตามความเหมาะสม

หากท่านมีข้อสงสัยหรือต้องการทราบข้อมูลเพิ่มเติมเกี่ยวกับโครงการวิจัย สามารถติดต่อผู้วิจัยได้ที่ บ้านเลขที่ 90 ม. 4 ต.บางชะแยง อ.เมือง จ.ปทุมธานี หมายเลขโทรศัพท์ 081-6491571 หรืออาจารย์ที่ปรึกษาวิทยานิพนธ์ คือ ศาสตราจารย์ ดร. มรรยาท รุจิวิชญ์ สามารถติดต่อได้ที่ คณะพยาบาลศาสตร์ มหาวิทยาลัยธรรมศาสตร์ เบอร์โทรศัพท์ 02-9869213 ต่อ 7311 ในวันและเวลาราชการ

การตอบแบบสอบถามของท่านมีความสำคัญอย่างยิ่งที่จะช่วยให้การวิจัยนี้สำเร็จลุล่วง เพื่อเป็นแนวทางในการพัฒนารูปแบบการป้องกันและลดอาการแสดงที่ไม่พึงประสงค์เช่น ความเครียด ลดความปวดที่เกิดขึ้นได้ ให้มีประสิทธิภาพต่อไป

ท่านมีสิทธิ์ในการปฏิเสธการตอบแบบสอบถามนี้ และมีสิทธิ์ที่จะบอกเลิกการเข้าร่วมการวิจัยนี้เมื่อใดก็ได้ถ้าปรารถนาโดยไม่มีผลกระทบใดๆ ทั้งสิ้นต่อท่านและบุคคลที่เกี่ยวข้อง

“หากท่านไม่ได้รับการปฏิบัติตามข้อมูลดังกล่าวสามารถร้องเรียนได้ที่: คณะอนุกรรมการจริยธรรมการวิจัยในคน มหาวิทยาลัยธรรมศาสตร์ ชุดที่ 3 อาคารราชสุดา ชั้น 1 ศูนย์ส่งเสริมสุขภาพ คณะพยาบาลศาสตร์ มหาวิทยาลัยธรรมศาสตร์ ศูนย์รังสิต โทรศัพท์ 02-986-9213 ต่อ 7373 โทรสาร 02-5165381”

BIOGRAPHY

Name	Mrs. Tipsuda Sumneangsator
Date of birth	12 June 1977
Educational Attainment	Mahidol University, 1996-1999 Bachelor of Science (Nursing) Mahidol University, 2001-2004 Master of Nursing Science (Psychiatric and Mental Health Nursing) Thammasat University, 2015-Present The Doctor of Philosophy Program in Nursing Science (International Program)
Work Position	1999-2001, Ramathibodi Hospital; Faculty of Medicine, Mahidol University 2004-Present, Faculty of Nursing, Thammasat University Position: Assistant professor
Scholarship	The Royal Golden Jubilee Ph.D. Programme (RGJ)

Publications

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