THE EFFECT OF COMBINED MEDITATION WITH BIOFEEDBACK TRAINING PROGRAM ON THE STRESS, DEPRESSION AND CORTISOL LEVELS AMONG PEOPLE WITH MILD DEPRESSION DIABETES

BY

MRS. ORMANEE PATARATHIPAKORN

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

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ENTITLED

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was approved as partial fulfillment of the requirements for
the degree of the doctor of philosophy of nursing science
on May12, 2020

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Dissertation Title	THE EFFECT OF COMBINED MEDITATION WITH BIOFEEDBACK TRAINING PROGRAM ON THE STRESS, DEPRESSION AND CORTISOL LEVELS AMONG PEOPLE WITH MILD DEPRESSION DIABETES
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Academic Years	2020

ABSTRACT

Diabetes mellitus (DM) is a kind of chronic disease that causes adverse economic and social effects since it requires long-term treatment. In every phase of treatment, people are likely to have risks of acute and chronic complications, which may lead to disability or death. Significant adverse impacts can also occur after DM. These major negative impacts cause tension arising from the nature of those diseases, such as suffering for months, years, or a lifetime, receiving treatment in a hospital regularly, and feeling depressed or having subsequent complications. Studies have shown that the most frequent problems of people with diabetes include such connecting factors as psychological stress and depression. Identifying non-pharmaceutical self-regulation approaches for stress and depression is essential for improving outcomes. Biofeedback and meditation can impact diabetes people self-regulation. The stress, depression and cortisol levels of diabetes people will be examined in term of practice meditation alone, combination meditation with skin conductance (SC) and skin

temperature (ST) biofeedback, and those receive routine care. This study might benefit people with diabetes and offer support for new self-regulation approaches for stress and depression among people with diabetes. This research may provide evidence to support self- regulation approaches for stress and depression that can lead positively affects mental health in people with diabetes.

The sample group was composed of adult and older people who were diagnosed with type 2 diabetes mellitus with or without comorbidities that were treated at the General Practice Outpatient Department, Thammasat University Hospital (TUH) in Thailand. Additionally, the subjects were selected based on set characteristics and inclusion criteria, including the level of depression (mild level measured by BDI within a scoring range of 10-15 points). The participants were randomly assigned to one of the three RCT arms by using simple random sampling by lottery method (random assignment) as follows: 1) meditation (n = 34), 2) combined meditation with biofeedback (n = 34), and 3) a control group receive no training program (n = 34). All of three groups received routine care. Measurements were the Symptoms of Stress Inventory (SOSI), the SC and ST biofeedback instrument, and the Beck Depression Inventory (BDI). The researcher compared the differences in stress and depression among people that had meditated, people that had meditated and practiced the biofeedback program, and the control group. Data were analyzed using frequency, percentage, mean, standard deviation, MANOVA, and MANCOVA. The duration of the study was from June 2018 to October 2019.

For the results, the mean of the stress and depression of the control group was higher than the meditation and biofeedback group. The meditation only group had a higher mean for stress and depression than the meditation and biofeedback group with a statistically significant at the level of 0.05. According to the results, the people with diabetes that practiced meditation and biofeedback had a greater decrease in serum cortisol than those that practiced meditation alone. In the control group, the mean score of serum cortisol was increased with the statistical significance at the level of 0.05.

The research findings demonstrate the effectiveness of combined meditation with biofeedback program in reducing stress, depression and serum cortisol after the program was administered. The stress, depression and cortisol level of the

diabetic people were reduced after the people had participated in the program for six sessions at approximately 60-90 minutes per session and one session per week. The subjects practiced meditation at home in the same manner as their practice in the hospital, and they practiced every day for at least 20 consecutive minutes for six consecutive weeks. Accordingly, the biofeedback program is a program that is capable of helping people learn how to relax, as biofeedback instruments feed information back to people through on-screen visual signals, thus enabling people to learn about the progress and success in their practice. Moreover, people were able to recognize and distinguish among the emotions and feelings emerging during the training. Because these emotions were positive, positive reinforcement facilitated learning in regulating emotions and feelings toward relaxation. By repetitively engaging in this behavior, familiarization was achieved. Thus, people were able to train themselves without needing their training machines. Combined meditation with biofeedback should be arranged for diabetic people in hospitals so that people can handle their stress and depression, which will promote their physical, mental, and social adaptation. Consequently, this study could be public education to people with diabetes that combined meditation with biofeedback is effective in decreasing stress and depression. Moreover, biofeedback can be offered in the form of a mobile health application for yielding positive short-term outcomes on physiological and self-reported stress indicators through the use of mobile data and communication technology, namely wearable health care devices, mobile computers, and medical sensors.

Keywords: meditation training, biofeedback training program, stress levels, depression levels, cortisol levels, diabetes mellitus

ACKNOWLEDGEMENT

This dissertation is successfully developed with the kind support of Prof. Dr. Manyat Ruchiwit, major advisor, and Prof. Dr. Marlaine Smith, co-advisor. Both advisors play an essential role in sharing research knowledge and guidance, and inspiring researcher to maintain strong commitment and complete dissertation as scheduled. Also, the researcher is profoundly grateful for their kindness and mental support and would like to express appreciation to both advisors.

The researcher also would like to thank distinguished experts, which are Assoc.Prof.Dr.Thipaporn Tharavanit, Assoc. Prof. Dr. Tawanchai Jirapramupitak, Asst. Prof. Dr. Nuchanat Bunthumporn, Asst. Prof. Dr. Yaowarat Matchim and Asst. Prof. Dr. Phenphak Uthit, who gave advice and corrections in developing research tools required for all processes of the dissertation.

I would like to recognize Prof. Dr. Somchit Hanucharurnkul, Chairperson of the Dissertation Defense Committee as well as Assoc.Prof.Dr.Teeranut Harnirattisai and Asst. Prof. Dr. Rangsiman Sunthornchaiya, Dissertation Defense Committee who gave beneficial advice to make this dissertation complete.

I appreciated team head and personnel of the General Practice Outpatient Department and the Ear, Nose and Throat Ward, Thammasat University Hospital who facilitated data collection process, meditation program, meditation and biofeedback program for diabetic patients of Thammasat University Hospital.

I am so thankful for Assoc. Prof. Pharuhat Tor-Udom, the Director of Thammasat University Hospital who puts a high priority on people development and financial support for this dissertation.

I would express my profound gratitude to Mr.Chaipat Patarathipakorn and two sons who provided mental support and assistance in many ways to achieve academic goals.

Mrs.Ormanee Patarathipakorn

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER 1
INTRODUCTION

1.1 Background and significance

Diabetes is diagnosed as a chronic disease, causing adverse economic and social effects, requires long-term treatment. In every phase of treatment, people are likely to have risks of acute and chronic complications, which may lead to disability or death. The number of global people with diabetes continually increases. According to the World Health Organization, diabetes mellitus (DM) constitutes public health issues that require continuous, long-term management, including main health problem worldwide. The World Health Organization (WHO, 2016) presents type 2 diabetes is considered a severe challenge for the healthcare system of countries, and it includes approximately 90% of diabetic people. Also, the International Diabetes Federation has estimated that about 642 million people in the global population will have DM by the year 2040 (Sinclair, Dunning & Colagiuri, 2013). As previously mentioned, type 2 DM indicates in 90 percent of all diabetes people worldwide (Roglic, 2016). People with DM are at higher risk of micro and macrovascular damage in addition to lower life expectancy, diminished quality of life, and considerable morbidity (Roglic, 2016). One reliable source of data on Thailand's prevalence of chronic disease is Thailand's Ministry of Public Health. In 2014, Thailand's Bureau of Non-Communicable Diseases, Ministry of Public Health, addressed the people newly's rate diagnosed with DM per million people to have increased from 795.04 to 1,032 from 2010 to 2014 (Wanchai & Phrompayak, 2017).

The increased number of people with diabetes is a burden on society because DM causes several physical changes. DM leads to the malfunction of organs such as complications of the peripheral vascular system, causing damage to capillaries in several organs, i.e. capillary in the kidney and eyes, leading to kidney failure and vision loss (Ige et al., 2019). Also, complications occur in the arterial system and the nervous system. These complications cause people with diabetes to experience the degeneration of their physical fitness or to incur permanent disability. In the case of acute and severe complications, it may cause death. When some people have

difficulties, they are unable to work regularly and become dependent on their family members in terms of expenses and care (American Diabetes Association, 2019). Since it is a severe chronic disease and requires long- term treatment, it causes high expenditures in treatment, resulting in changes in the overall economy of the nation (Schofield et al., 2019).

Apart from the physical mentioned above, social and economic effects, diabetes also affects the mental health of people. According to the literature review, it was found that significant psychological impacts occurring subsequently after having been sick with diabetes. Psychological implications of diabetes in people are effects on self- esteem and self- image (Nguyen et al., 2019). They are less aware of their values because they can't work hard and feel fatigued due to high blood glucose levels. Some people have to quit their jobs for self-care (Alhaik et al., 2019). Illness-related stress is a common reaction to DM (Arasi et al., 2019; Armstrong et al., 2019). There are many reasons causing stress in people with diabetes, for example, conditions of chronic disease, treatment received, lifestyle change, economic situations, and change of social roles. Significant adverse impacts occur after DM, and these major negative impacts cause tension arising from the nature of those diseases, such as suffering for months, years or a lifetime, receiving treatment in a hospital regularly, and feeling depressed, or getting subsequent complications (Fernandez- Ruiz et al., 2019; Radzi et al., 2019). Besides, people with diabetes are faced with unavoidable mental stress, because this group of people is forced to cope with a chronic, potentially fatal disease requiring lengthy treatment, repeated complications and frequently aggressive therapy. It is evident that people with diabetes suffering from experience stress, leading to depression.

The World Health Organization (2017), reported depression could lead to psychological problem and an exhausting disorder presenting with symptoms such as fatigue, inability to feel pleasure, concentration deficit, reduced libido, sorrow, and hopelessness. At the same time, depression has also been seen to have adverse effects on health and compliance with treatment or therapy. People with diabetes are likely to experience a specific loss of self with noticeable sorrow and stress due to altered lifestyles caused by a diagnosis of chronic disease (Cleal et al., 2019; Lenzi et al., 2019). These limitations generally prevent people with chronic disease from

performing routine activities in their lives, leading to depression. Previous studies presented that depression is the most common problem of people with diabetes is (Winter et al., 2015; Park et al., 2015; Moulton et al., 2015; Berge & Riise, 2015; Nefs et al., 2015; Mirghani & Elbadawi, 2016; Rajput et al., 2016; Sun et al., 2016; Xiao et al., 2015; Manigault & BCACP, 2016; Chew et al., 2016; Fernandez-Ruiz et al., 2019; Hoogendoorn et al., 2019).

The prevalence of depression among PWDM had been reported at a high percentage from different parts of the world. The findings of some studies have posited the prevalence of depression to be three times higher in people with type 1 DM and two times higher in people diagnosed with type 2 DM in comparison to other healthy people in the global population. According to several studies conducted in western countries, depression has been found in the elderly at rates from 2.3 to 32.6% (Gallo & Lebowitz, 1999; DeGroot et al., 2001). Furthermore, the prevalence is higher among women than men (Anderson et al., 2001).

Apart from the findings of studies conducted in foreign countries, previous studies in Thailand have found the prevalence of depression to be between 10-30%. Moreover, most of the depression found in people with DM is found among the elderly (mean age = 60.2 ± 8.6 years). The study of Sitanan Poonpolsub et al. (2005) found DM people to have depression at a rate of 25.2%, while the study of Pra-ornthip Sutthisan (2007) in elderly DM people in Nongkhai Province, Thailand, found depression in 20.3% of all DM people. When categorized by age group, the elderly DM people aged 60 years were found to have depression at a rate of 17.8%. And according to the study of Nopparat Wacharakajornkul (2007) in DM people in Lampang Province, Thailand, depression was found in 38.8% of all elderly DM people. Pirunee Suppaso studied the prevalence of depression in people with type 2 DM and found the prevalence of depression to be 10.3%. A study by Somporn Rungreangkulkij et al. found the prevalence of depression in people with DM attending a primary health care center to be 15.83%. In contrast, Kattika Thanakwang et al. studied depression among older adults with DM in Thailand and found the rate of depression to be 32.5% in a sample of 330 people. In comparison, another 67.5% did not have depression, and most of the sample had mild depression (20.5%), moderate depression (9.6%) and severe depression (2.5%). Chaimongkol studied the prevalence and factors associated with

depression among type 2 diabetic people in Konsarn Hospital and found depression to occur in 16.18% of all people with mild depression at 12.06% and moderate depression at 4.12%. No severe depression was found. And in the another study of Supawadee Srirattanapraphan entitled "The Prevalence of Depression and Associated Factors in People with Diabetic Mellitus in Lahansai Hospital", the sample was found to have depression at a rate of 4.3%, whereby most had mild depression (2.8%), moderate depression (0.9%) and severe depression (0.6%).

As mentioned above, the primary physiological issue of people with diabetes is depression. People who those live alone with diabetes have less regular hospital admission and medicare hospital stay than people with diabetic. This situation leads to a loss of productivity and absence from work due to sickness (Cabeceira et al., 2019). Besides, people with diabetes and depression are related to a 4.5-fold increase based on health expenditure (Moulton et al., 2015; Moulton et al., 2019). As a result, it can be concluded that depressive symptoms represent a significant problem for DM people. Since it is a kind of severe chronic disease and requires long-term treatment, it causes high expenditures in treatment, resulting in the overall economy of the nation. These symptoms show a central point to cause high expenses in treatment, leading to the global economy of the nation. Concerning the underlying psychophysiological mechanisms behind DM, depression has been found to contribute to increased cortisol (Shomaker et al., 2018; Cheung et al., 2019).

Increasing cortisol secretion is a marker of the stress response. According to previous findings, the release of cortisol caused by an acute stressor plays a crucial role in health survival functions. Increasing cortisol levels causes elevating blood pressure and glycemic levels, in addition to the non-vital process in preserving energy by inhibiting the digestive, immune and reproductive systems. Long-term adrenaline and cortisol secretions can negatively affect glycemic levels and increase insulin resistance. Several clinical signs have been found to confirm the influence of the hypothalamus- pituitary- adrenal axis over depression. Depressed people exhibit increased cortisol values that are likely to involve higher secretions of hypothalamic CRH. This situation is leading to increased amounts of the adrenocorticotrophic hormone (ACTH) and cortisol levels (Joseph & Golden, 2017).

Furthermore, the levels of stress hormones such as cortisol are higher in people with diabetes. Changes in cortisol levels have been noted as ACTH, depression, and psychological stress levels change. Higher ACTH and cortisol are correlated with depressive symptoms whereby more substantial impact has been reported in older people who exhibit symptoms of psychotic or melancholic depression (Al-Mohaimeed, 2017; van Vuuren & Pillay, 2019; Shomaker et al., 2018). Cortisol plays vital roles, duties and functions in responding to stress in the body (Wichmann et al., 2017; Maduka & Ufelle, 2015). Changes in cortisol levels have been noted as ACTH, depression and psychological stress levels change (van Vuuren & Pillay, 2019). Surplus cortisol disturbs neurogenesis in the hippocampus, a sector involved in depression and DM (Joseph & Golden, 2017).

According to previous findings, the symptoms of people with diabetes that already suffer from depression will be exacerbated. For many people, managing DM requires the ability to make modifications aimed at adaptation. People with diabetes also have symptoms such as added depression, sorrow, despair, a need for comfort and a loss of dignity, etc. Importantly, effective treatment for stress and depression disorders requires paying attention to affective, behavioural, cognitive, and physiological processes. Several non-pharmacological interventions have been advanced as a means of helping people with diabetes. These programs are aimed at instructing people with diabetes about assessing psychological disorders and learning how to cope with harmful mental conditions (Ruchiwit, 2015; Massey et al., 2018). Hence, the adverse effects can be reduced by engaging in activities such as exercise, relaxation techniques, biofeedback programs, meditation, deep breathing exercises, guided imagery, yoga, and massage. Meditation and biofeedback are the primary focus of the present research.

Most current treatments for DM are geared toward palliative physical treatments, the prevention of exacerbation, and complications. People with diabetes may have to take medication for the rest of their lives. However, pharmacological treatment alone remains inadequate. Although emotional care is also vital in reducing the exacerbation of the disease, there is less attention to its importance (Mitchell et al., 2017; Massey et al., 2018). Consequently, several self-regulation techniques are available for emotional care. According to research, meditation plays an essential role in the improvement of negative mental states based on people with diabetes. Many

studies have addressed meditation in term of positive effects. The majority of these studies revealed the direct mediation effects on mood states and mindfulness (White bird et al ,2018.), immune function, sleep patterns, a wide variety of psychological, emotional, physical aspects of well-being (Mitchell et al., 2017; Shapiro & Carlson, 2017; Massey et al., 2018). In addition to lowering anxiety levels (Hoge et al., 2017; Ding et al., 2019, decrease blood pressure (Marchiori et al., 2015; Devi & Samaga, 2015), and boost immunity while managing pain and leading to general well-being (Massey et al., 2018; Priya & Kalra, 2018). Most importantly, meditation can help reduce stress and depression in people with diabetes (Skoranski et al., 2018; Priya & Kalra, 2018). As a supplement to meditation, biofeedback can be used for improving diabetic people' psychological condition including stress and depression (Latheef, 2017; Aaraji, Nosratabadi & Hoseinpourfard, 2018; Moss & Khazan, 2015; van der Zwan et al., 2015; Priya & Kalra, 2018). The applications of biofeedback are diverse in terms of health and preventing disease, particularly in cases involving the vital roles of psychological factors. As previously stated, biofeedback alone can yield positive outcomes. Nevertheless, combining biofeedback with other programs has proven to obtain even better results (Perera, Rathnarajah & Ekanayake, 2016).

Meditation is a system of thought which incorporates practices to reach bodily or mental control and well-being, as well as to help enlighten an individual through acceptance (Goldstein, 2017). While there are multiple approaches to meditation, transcendental meditation (TM) involves the use of chanting or mantras as focal points for concentration or attention. The objective of TM is to release the people's thoughts from current levels into a condition marked by minimum cognition. This condition is referred to as a state of heightened awareness, known as transcendental consciousness (Yogi, 1969; Shapiro & Carlson, 2017). In transcendental consciousness, the people's awareness senses the full potential of self and the unlimited potential of nature's intellect.

Consequently, cognition and activity suddenly grow in congruence with natural law. Besides, studies have shown that TM enhances attention regulation, positive emotion, intelligence, creative thinking, and perceptual ability while lowering

high blood pressure and illness rates (Ambavane et al., 2019). This evidence provides support for TM as a potentially useful technique for asthma, angina, and hypertension (Shader & Taylor, 2017; Schneider et al., 2019). Moreover, TM can help fight stress and depression (Priya & Kalra, 2018; Gathright el al., 2019).

Any consideration of the effects of TM on depression demands a look at the correlations among existing biological, behavioural, and cognitive structures of depression. By the etiology, depression is related to impaired cognition, leading to both positive (external factors) and adverse effects (internal, stable, and uncontrollable factors) (Seligman, 1975). Evidence derived from previous studies has shown how stress and depressive symptoms can affect the responses of the autonomic nervous system (Santhanam, Preetha & Devi, 2018; Pascoe & Crewther, 2017). With TM, the people's body achieves a deep rest state as mental activities decline. As a result, symptoms of stress are relieved, and the nervous system is re-energized (Yogi, 1969; Santhanam, Preetha & Devi, 2018; Pascoe & Crewther, 2017). In addition to lowering stress and anxiety levels, TM can help fight depression leading to general well-being (Gathright el al., 2019). The people that practices TM can learn about the advanced training to enhance his/her cognitive and active abilities as a result of the slightest, more powerful state of awareness (Bandy et al., 2019; Pascoe & Crewther, 2017; Priya & Kalra, 2018). In TM, the people gain considerable influence over rationality and positivity concerning their surroundings. This benefit further minimizes negative trends, while health positive social trends (Yogi, 1969; Priya & Kalra, 2018). Consequently, TM makes an individual confident, and he/she attempts to do everything to achieve a definite goal. It can be said, therefore, that TM is one of the most effective techniques available for reducing stress and depression.

Another intervention with potential value for stress and depression for people with diabetes is biofeedback. The skin conductance (SC) and skin temperature (ST) biofeedback programs are used to assess the physiological reactions to stress changes inside the body. SC and ST can contribute to the ability to maintain control over changes in skin conductance and skin temperature, which would otherwise be involuntary responses under the regulations of the autonomous nervous system. (Berge & Riise, 2015; Shader & Taylor, 2017). ST biofeedback is the process of using equipment to control body temperature through relaxation. The instruments

communicate feedback on the relaxation occurring by displaying the results on the face of the scale. The SC and ST biofeedback closes the gap between autonomic functions and awareness. Through SC and ST biofeedback, people can learn to control physiological processes that are usually controlled by the autonomic nervous system. Furthermore, biofeedback can decrease negative symptoms such as headache (Peters & Stepans, 2017; Kuo et al., 2019), stress (Perera, Rathnarajah & Ekanayake, 2016), stress and anxiety (Goessl et al., 2017), anxiety (Aritzeta et al., 2017; Shenefelt, 2017), chronic back pain (Sielski & Glombiewski, 2016), depression and anxiety (Fond et al., 2014; Gillihan & Foa, 2016), and depression (Choobforoushzadeh et al., 2015; Hamilton et al., 2016; Wiles et al., 2016).

Biofeedback is a feedback/reflection instrument that helps control stress and depression to the reduced level that people desired and self-regulation. Biofeedback has been combined with the following three programs:1) the biofeedback and relaxation techniques; 2) biofeedback and stress management; 3) biofeedback and meditation. Previous studies conducted in Thailand have focused on biofeedback with other programs aimed at relieving psychological stress (Ruchiwit et al., 2015; Ruchiwit, 2008), anxiety (Thammaraksa, 2008), aggressive behavior levels of amphetamine abusers (Raddussadee et al., 2014), and attention deficit hyperactivity disorder (Janmanee et al., 2013). Following a previous research study investigated by Thongkhum, Ruchiwit, and Somprasert (2015), the effect of meditation and biofeedback program on stress levels in chronic disease people was investigated. The findings were shown that the stress levels were lowered due to the meditation combine SC and ST biofeedback programs. In addition to previous studies conducted in Thailand, several studies have been carried out abroad concerning the positive effects of combining biofeedback with other programs (Hsu et al., 2016; Shiraishi et al., 2017; Voorham et al., 2017). Although previous researchers have conducted extensive research on the effect of biofeedback and meditation for improved psychological health, significant gaps continue to be found in the knowledge concerning understanding the effect of combined meditation with biofeedback on the cortisol levels among people with diabetes. Nevertheless, there is a dearth of research designs aimed at testing the effect of combined meditation with biofeedback program, as a means of lowering

cortisol levels, in addition to depressive symptoms and stress among people with diabetes in Thailand.

By applying biofeedback and meditation, people can learn how to gain cognitive control over the autonomic nervous system. Biofeedback represents a means of validating otherwise biased feelings of psychological stress, while meditation represents a singular therapeutic technique offering information to the state of biological processes. It is used to describe a technique which increases the ability of a person to voluntarily control physiological activities by being provided with information about those activities (Biofeedback Certification International Alliance, 2012). As a result, these people will be able to increase attention (Sun & Yeh, 2017; Loudon et al., 2017; Leyro et al., 2019) and cognitive effects (Kober et al., 2017). In conclusion, it is a critical point that the combination of biofeedback and meditation help people to monitor their physiological reactions for psychological stress as they learn how to control the responses above (Ratanasiripong et al., 2015; McKenna et al., 2015; Rush et al., 2017; De Witte et al., 2019).

While there is considerable evidence of the efficacy of meditation and biofeedback on the symptoms of DM, there have been no studies explicitly related to how these interventions affect stress, depression and serum cortisol. Therefore, closing the stated gap of knowledge can offer greater clarity and insight for healthcare providers involved in the care of people with diabetes. As previously stated, higher amounts of cortisol are correlated with stress and depressive symptoms (Joseph & Golden, 2017; Sudheimer et al., 2019; Chopra et al., 2019; Hoifodt et al., 2019; Skoranski et al., 2018). Studies on the biochemical parameters with psychometric variables for people with diabetes can contribute to filling in the gap of knowledge in this area. Also, there are few research designs aimed at testing the effect of combining meditation with biofeedback, as a means of lowering stress, deprssion and serum cortisol levels, in addition to depressive symptoms, among people with diabetes in Thailand.

Therefore, TM alone and combination meditation with biofeedback will be tested for their potential to affect the stress, serum cortisol, and depression in people with diabetes. The purpose is to discover ways to improve the psychological impact of

DM through self-regulation approaches that have the potential to enhance positive outcomes. This study might benefit people with diabetes and offer support for new practices to inform treatment for stress and depression.

1.2 Research objective

1.2.1 General purpose

To study the effect of combined meditation with biofeedback training program on the stress, depression and cortisol levels among DM people with mild depression.

1.3 Research questions

What are the differences in stress, depression and cortisol level of people with DM who received only routine care compare to those who received meditation only and combined meditation with biofeedback in addition to routine care?

1.4 Definition of the terms of the research

1.4.1 Treatment variables

1.4.1.1 The meditation program

The meditation program defines as an activating in which the meditator focuses his/her attention on a single issue or objects as part of a religious rite or as a relaxation method. Transcendental meditation (TM) involves the use of chanting or mantras as focal points for concentration or attention (Engert et al., 2017; Priya & Kalra, 2018). The TM techniques were introduced by a graduate of physics from Allahabad University in India in 1958, His Holiness Maharishi Mahesh Yogi.

1.4.1.2 The biofeedback program

The biofeedback program means an intervention in which people can learn to control specific physiological or psychological processes by applying the data recorded on the same processes. In this study, the physiological changes triggered by stressful events was measured by skin conductance (SC) and skin temperature (ST) biofeedback. The SC and ST biofeedback were used to teach people how to modify and control the body's vital functions by using electronic devices. SC is a function of perspiration gland activity as well as pore size. If a person becomes stress, the skin's conductance rapidly escalates within seconds because of increased perspiration. ST biofeedback involves the use of equipment in helping people practice body temperature control under mental control as a means of practicing relaxation by controlling changes in temperature. When stress is encountered, skin temperature decreases; and if the person relaxes, the skin temperature will increase.

1.4.1.3 Routine nursing care

Routine nursing care means individual consultation and group health education for people with diabetes in the control group in which people do not receive meditation program and do not receive combined meditation with biofeedback program. However, routine nursing care was provided to each experimental group in each hospital unit, also. Understandably, routine nursing care was not stable in the experimental group in this study.

1.4.2 Dependent variables

1.4.2.1 Stress

Stress defined as a condition that is triggered by a troublesome event or other difficult circumstances or situations. Hans Selye added a "physical response to positive or negative demand for adaptation" to this definition (Halter & Varcarolis, 2014). In a nutshell, stress can be defined as a reaction to a trigger or stressor that disrupts a person's physical, emotional or psychological conditions (Konduru,

2012). In the present study, the researcher measured stress by employing the Symptoms of Stress Inventory Self-Assessment (SOSI). The scale mentioned above can be employed for the measurement of physical, psychological and behavioral responses to stress over the month preceding data collection.

1.4.2.2 Serum cortisol

Cortisol is a hormone secreted from the outer adrenal gland. Cortisol plays vital roles, duties and functions in responding to stress in the body. In this study, cortisol in the blood of people with diabetes will be measured before and after the interventions. Blood specimen will be taken at the Medical Technology Laboratory of Thammasat University Hospital.

1.4.2.3 Depression

Depression means psychological disorder marked by long-term and severe discontent and anxiety (apprehensive and edgy or uneasy) that prevents the person from enjoying a healthy life during bouts of depression. Considered a common mental disorder, the presenting symptoms of depression are often encountered in the form of exhaustion, loss of pleasure, attention deficit, sexual dysfunction, deep sadness and despair. Factors associated with the etiology of depression include cognitive impairments causing both positive (external factors) and adverse effects (internal, stable, and uncontrollable factors). Due to the study, the Beck Depression Inventory (BDI) was conducted to test depression.

1.5 Theoretical framework

Selye's theory of stress and Beck's cognitive model ware used to guild this study as the stress and depression are the most common issue for diabetes people. Identifying non-pharmaceutical self-regulation approaches for stress and depression is essential for improving outcomes.

Selye, in his theory of stress, created the general adaptation syndrome (GAS), where he described the body's stress response according to the following three stages: alarm, exhaustion, together with resistance. The stress condition is a state of pressure against the body and mind that can be diagnosed only by specific symptoms. Caused by general physical responses to threats, the symptoms induce physical changes aimed at adapting to the threats through the hyperarousal or the acute stress response. The autonomic nervous system and adrenal glands are triggered by stress. Stress causes the people to exhibit physical, behavioural, cognitive, and emotional symptoms such as perspiration, headaches, accelerated heart rate, elevated blood glucose and pressure levels, insomnia, attention deficit, anger, and depression. Stress causes cortisol hormones to suppress the use of antagonized insulin (Weeger et al., 2019).

Selye (1976) categorized the variables of the reactions to stress according to the two following types: 1) endogenous conditioning factors such as genetics, age, gender, completeness, and existing damage to specific organs or each people's essential health; and 2) exogenous conditioning factors, which are new variables for individuals. These factors cause more tissue metabolism in the body, and the body responds to stimuli mostly from the automatic nervous system and the adrenal gland, causing the body to have pathologies, particularly at weak organs. Studies of cortisol hormones have shown that reactions to stress will be severe when cortisol hormone levels in the blood are at the highest level regardless of the cause of stress. Continuous or long-term release of stress hormones such as adrenaline and cortisol can negatively affect glycemic levels and increase insulin resistance. Surplus cortisol disturbs neurogenesis in the hippocampus, a sector involved in depression and DM (Joseph & Golden, 2017; Hackett et al., 2019; Siddiqui, 2019; Madkhali et al., 2019; van Vuuren & Pillay, 2019; Joseph & Golden, 2017).

According to Beck's cognitive model, automatic, cognitive errors, cognitive triad, and schemata are the critical components in developing and maintaining treatment of clinical depression. Suppose the schema (both consistent and dysfunctional with symptoms and or causes of depression can lead beliefs and thoughts) are triggered

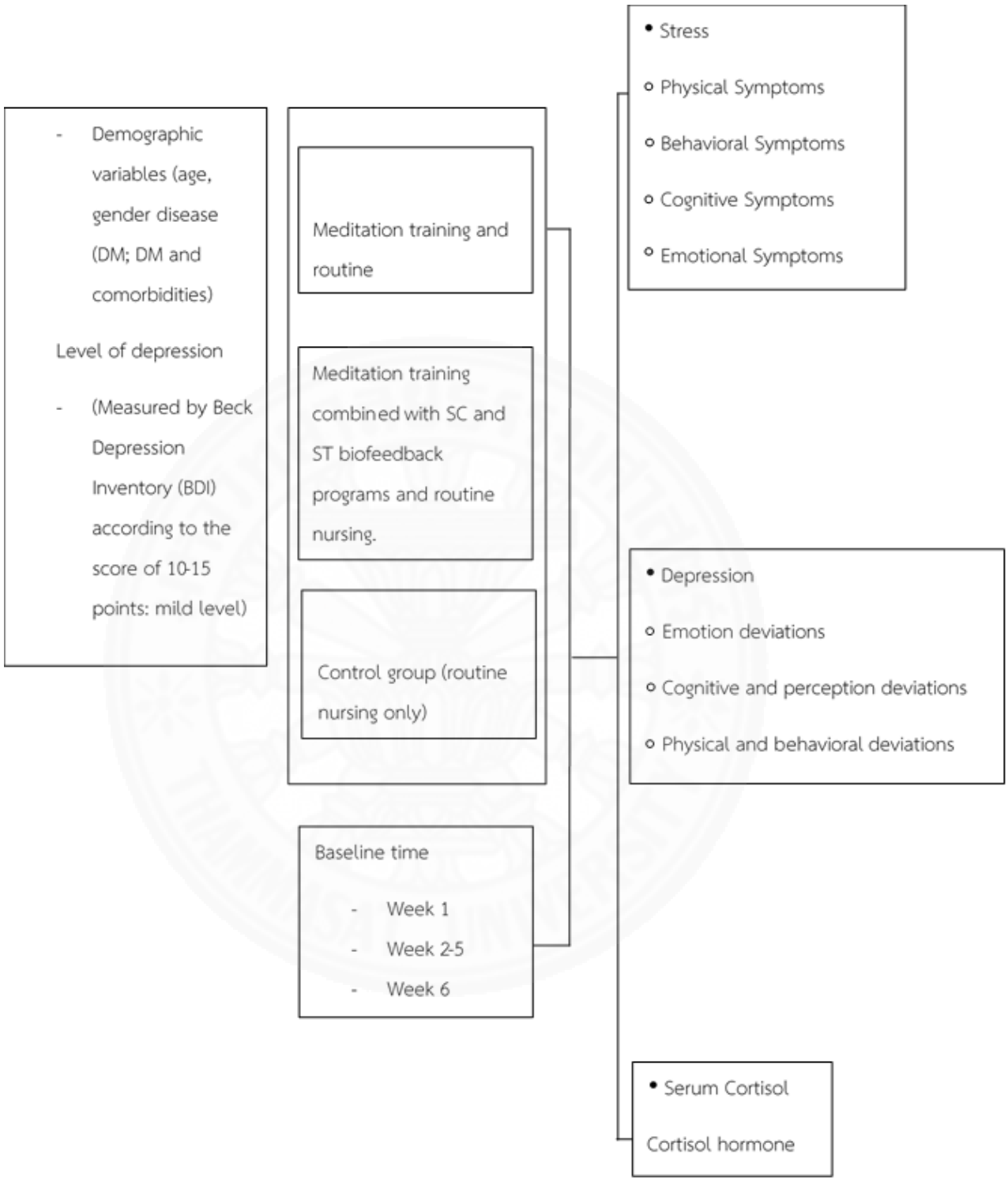
by stress. In that case, the frequently-encountered results are cognitive errors that eventually lead to depression. Beck stated that depression is a people's psychological reaction to crises or stressful situations expressed in the form of emotional deviations, cognitive deviations and perceived physical and emotional deviations. Each area had the following essential characteristics: emotional deviations consisted of sadness, depression, lack of interest and crying; cognitive and perception deviations. These deviations consisted of negative self-concept toward the environment and the future, deviations of the personal image from reality, lack of motivation, withdrawal behaviours, increased dependence on others, delayed thoughts, abnormal satisfaction, loss of sexual and physical drive; physical and behavioral deviations including withdrawal behaviors, loss of appetite, insomnia and slower performance of activities (Curl & Wilson, 2015).

Any consideration of the effects of meditation on the depression demands a look at the correlations among existing biological, behavioral, and cognitive structures of anxiety. When the multiple effects of biological, behavioral, and cognitive susceptibility are considered in terms of depression, several precise methods are available. Among these, meditation has been proven to have positive effects on depression relief. TM involves the use of a meaningless word or sound (chant or mantra) as the focal point for bringing the mind to a sense of calmness or cognitive peace until the quietude of transcendental consciousness is achieved (Priya & Kalra, 2018; Shader & Taylor, 2017). TM represents a physiological means for combating depression (Colosio et al., 2017; Gathright el al., 2019).

Apart from meditation, applications of biofeedback are diverse in terms of promoting health and preventing disease, particularly in cases involving the vital roles of psychological factors (Ruchiwit, 2015). Biofeedback represents a means of validating otherwise biased feelings of anxiety. In contrast, relaxation techniques represent a singular therapeutic technique offering information the state of biological processes and is used to describe a technique which increases the ability of a person to voluntarily control physiological activities by being provided with information about those

activities. Biofeedback contributes to the regulation of heightened emotionality. Hypothetically speaking, emotion-regulation techniques represent a correlation between emotion and actions based on the way people control their moods (Ruchiwit, 2015; Kennedy & Parker, 2019). In other words, regulating emotions is believed to affect actions due to the way it helps people achieve a positive mood allowing specific cognitive processes. In turn, these processes boost effort and perseverance in performing tasks. Thus, biofeedback offers vital information for people to understand and gain control (Ruchiwit, 2015; Kennedy & Parker, 2019).

As previously stated, biofeedback alone can yield positive outcomes. Interestingly, combining biofeedback with other programs has proven to obtain even better outcomes (Guzzetta, 1989; Nader et al., 2000; Rausch et al., 2006; Bonadonna, 2003; Perez-De-Albeniz & Holmes, 2000; Grossman et al., 2004; Patel & Carruthers, 1977; Seer, 1979; Yucha et al., 2001; Goodwin & Montgomery, 2006; Marcinkiw, 2003). From the investigation of previous studies, the combination of meditation and SC and ST biofeedback programs can be useful for DM people that have mild depression. In this study, combining meditation with SC and ST biofeedback programs will be conducted with the following four main objectives in mind (1) teaching people how to modify and control the body's vital functions by using electronic devices; (2) increasing the ability to identify cognitive distortions and sensibly appraise stressors; (3) promoting healthy lifestyles to increase the ability to cope with stress and depression disorders; and (4) promoting connections with self and others in a life with meaning and purpose. The mentioned types of interventions offer a framework for the achievement of essential self-regulation skills to cope with stress and depression disorders in people with diabetes.



Figfure 1.1 The framework of the Effect of combined Meditation with Biofeedback Training Program on the Stress, Depression and Cortisol Levels among People with Mild Depression Diabetes

1.6 Research hypotheses

1.6.1 Mean scores on stress, depression and cortisol level would be significantly lower in the meditation and combination of meditation with biofeedback group than those in the control group at six weeks after completion of the intervention.

1.6.2 Mean scores on stress, depression and cortisol level would be significantly lower in the combination of meditation with biofeedback group than those in the meditation group at six weeks after completion of the intervention.

1.7. Research boundary

This dissertation aims to study the effect of combining meditation with SC and ST biofeedback programs on the stress and depression levels of people with diabetes. The population of this study is people that diagnosed with Type 2 DM only or Type 2 DM with adult and older-aged as well as comorbidities that sought treatment at the General Practice Outpatient Department, Thammasat University Hospital (TUH) during March to June 2019.

1.8 Summary

Chronic disease has three prominent motives in Thailand, and DM is that one. Several studies have shown the stress and depression are the most common issue for diabetes people. Identifying non-pharmaceutical self- regulation approaches for stress and depression is essential for improving outcomes. Biofeedback and meditation can impact diabetes people' self-regulation. The stress and depression of diabetes people will be examined in term of practice meditation alone, combination meditation with SC and ST biofeedback, and those receive routine care. Two theories informed the research: 1) Selye's theory of stress; 2) Beck's cognitive model. This study might benefit people with diabetes and offer support for new self-regulation approaches for stress and depression among people with diabetes. This research may provide evidence

to support self- regulation approaches for stress and depression that can lead positively affects mental health in people with diabetes.

CHAPTER 2
REVIEW OF THE LITERATURE

This literature review aims to pinpoint and assess currently- existing knowledge about the effect of combined meditation alone with biofeedback on the stress, depression and cortisol levels among people with mild depression diabetes. Other reviewing is about both theoretical and empirical literature on stress, depression and serum cortisol and their linkages to diabetes and meditation as well as biofeedback, and find gaps in the available knowledge on the topic, and to clarify the research questions further.

The kinds of literature reviewed include thesis dissertations or reports on research findings; final reports submitted to research funding organizations, textbooks, and reputable medical journals and reports on medical conferences with medical research presentations computerized or in Internet databases. Cinahl Plus with Full Text, Clinical Key, Informa Health Care, Francis, Karger Online Journals, Ovid, Science Direct, ProQuest Dissertation and Theses Global, Springer Link, Koha and books, Sage Journals, Talor, as well as Wiley Online Library published in English were used as the sources for the studies by using a combination of set vocabulary and keywords. There are significant issues related to the research as the following:

2.1 Nature of diabetes mellitus and its impact on individual and family

2.2 Prevalence of depression among people with diabetes mellitus (PWDM) and consequence

2.3 Factor associate with depression among PWDM and research related

2.4 Theory of stress and stress and management

2.4.1 Theory of stress

2.4.2 Stress management

2.4.2.1 Relaxation technique

2.4.2.2 Meditation

2.4.2.3 Biofeedback

2.4.2.4 Combination of meditation and Sc & ST biofeedback

2.1 Nature of diabetes mellitus and its impact on individual and family

Diabetes mellitus is a group of metabolic diseases characterized by elevated levels of blood glucose resulting from defects in insulin secretion, insulin action, or both (WHO, 2020; (de Lima Filho et al., 2019; Latheef, 2017). DM can be diagnosed based on the following glucose testing. The first one is fasting plasma glucose levels of more than or equal to 126 mg/dl at least twice or random plasma glucose levels of more than or equal to 200 mg/dl in combination with symptoms of DM (frequent urination, excessive thirst, weight loss for unknown reasons). Secondly, plasma glucose at 2 hours after drinking a 75-gram glucose solution that is higher than or equal to 200 mg/dl at least twice. According to the World Health Organization, the Expert Committee on the Diagnosis and Classification of DM in 2000 categorized clinical classes into the following four types: 1) type 1 diabetes mellitus (type 1 DM); 2) type 2 diabetes mellitus (type 2 DM); 3) other specific types caused by disease or anomalies such as endocrinopathies, genetic defects of insulin action, drug or chemical-induced DM and infection, etc. and 4) gestational DM.

In terms of DM etiology, causes of DM include genetic factors such as beta-cell malfunction, faulty insulin action, drug, chemical induction and infections, endocrinopathies, exocrine pancreatic diseases, or endocrinopathies. Also included are conditions frequently discovered in practice such as gestational diabetes, both type 1 diabetes mellitus (type 1 DM) and type 2 diabetes mellitus. (type 2 DM) Meanwhile, type 1 DM is most frequently discovered in children and younger people but currently exists among older adult groups due to improved treatment and care. Due to the type 1 DM is marked by the destruction of pancreatic beta-cell, which leads to a significant

reduction or cessation of insulin production (Ragy and Ahmed, 2019). In some cases, an autoimmune process indicates that people are found to have type 1 DM

Nevertheless, in some unknown cases of the etiology of beta- cell destruction are vague. Generally speaking, approximately ten percent of diabetes people have type 1 DM, while a large majority of 90 percent have type 2 DM (van Vuuren &Pillay, 2019). A progressive metabolic disorder, type 2 DM, refers to a disease that has an increase of glycemic levels for responding to the body's failure to produce sufficient insulin. In the older adult group, the altered metabolic function can lead to lower metabolic rates, added storage distribution of fat and shrinking muscle mass. One of the consequences of the above changes puts people in this group at higher risk for the type 2 DM (Sun et al., 2016; Rajput et al., 2016). In the older adult group of people with diabetes and poorly managed glycemic control, potential symptoms include suppressed functionality and higher morbidity, hospitalization and mortality rates (de Lima Filho et al., 2019; Khan, Lutale & Moledina, 2019).

DM has a wide- ranging effect on people and families. People with complications from DM suffer an even more significant impact. These adverse effects are a problem in the lives of people with diabetes, causing people to need to adapt to problems to continue living with the disease. Success in adaptations is partly dependent on problem severity. Ultimately, severe effects from DM are another factor potentially causing people with diabetes to have stress and depressive symptoms (Khan, Lutale & Moledina, 2019; Deschenes, Burns & Schmitz, 2015; de Lima Filho et al.,2019; Madkhali et al., 2019; Habtewold et al., 2016; Zhou et al., 2017; Brown et al., 2019). Complications and effects from DM created difficulties and complications for people and families in every aspect, causing people to be at higher risk of disability and death. Furthermore, DM-related distress may cause people to have more negative perceptions of people health, causing people to feel more hopeless and bored, resulting in stress and depressive symptoms.

Furthermore, there are family impacts from diabetes cause people with diabetes to have fewer social activities and avoid meeting with others due to a need to control complications from diabetes and energy exceeding people requirements. This effect causes people to isolated from society, lose people roles and duties, lose ordinary living conditions and have uncertainties in life with effects on family and social

relationships (Lee et al., 2017; Saffari et al., 2019). Furthermore, economic effects cause people to spend a long time in treatment since DM is a chronic disease. This effect is causing people with diabetes to incur high medical costs and other related expenses such as travel expenses to meet a doctor, food costs for people and relatives, etc. (Zhou et al., 2017). In particular, people with diabetes with complications have higher medical costs. In addition to burdens from expenses on people and families, governments have to deal with significant budgetary expenditures to provide health services for people with diabetes. Thus, DM causes economic effects at the familial and national levels.

2.2 Prevalence of depression among people with diabetes mellitus (PWDM) and consequence

The American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders (DSM-5) defines depression as a "mood disorder that reunites several symptoms that alter the functionality of an individual" Based on DSM–5, the diagnostic criteria for a major depressive disorder are composed of a set of core symptoms such as a "down" or irritable mood or declining interest or pleasure), or both, combined with a minimum of the following four symptoms: guilt or worthlessness, fatigue or loss of energy, concentration problems, suicidal thoughts or thoughts about death, weight loss or gain (5% change in weight), psychomotor retardation or activation (change inactivity) and hypersomnia or insomnia (change in sleep) lasting for a minimum of two weeks. Such depression can be described as either a first, recurrent or chronic episode. It can also be either mild, moderate or severe and with or without psychotic characteristics. (Silverman et al., 2015).

Several evaluation forms are available to evaluate depression because depression represents a group of abnormal symptoms (syndromes) rather than a. single entity. Hence, concepts were originated to set different measurement criteria for each evaluation form, depending on the view of depression symptoms. Depression evaluation forms can be divided into two groups as follows: 1) Self-rating scales in which the people or subject of the evaluation completes the questionnaire. Results can be somewhat subjective, however, and some accuracy might be lost. However, the

benefit of this type of evaluation form is that it can be used to evaluate large numbers of people at low cost. Hence, it is frequently used to screen for illness. 2) Clinical rating scales are depression evaluation forms using measurement instruments. Questionnaire respondents complete the questionnaires based on structured interviews. Evaluations are made on each topic in the evaluation form. The example of theses evaluations includes Beck Depression Intervention (BDI) , Short expression- happiness scale (SDHS), Patient Health Questionnaire (PHQ), Hamilton rating scale for depression (HRSD) (Cassidy et al., 2018).

The prevalence of depression among PWDM had been reported at a high percentage from different parts of the world. The findings of previous studies have discovered moderate escalations in the incidence of pre- and undetected DM is some people. This escalation is even more evident in people who have been previously diagnosed with diabetes mellitus, particularly in comparison to groups of otherwise healthy people with normal blood glucose levels. The findings of some studies have posited the prevalence of bouts of depression to be three times higher in people with type 1 DM and two times higher in people diagnosed with type 2 DM in comparison to other healthy people in the global population. It is well-known that DM and depressive disorder are substantial public health issues across the globe.

Furthermore, projects have estimated these two public health conditions to be counted among the top five causes of the burden of disease by 2030. At present, depressive disorder and DM are ranked fourth and eighth among the causes of disability- adjusted life years, respectively. Moreover, estimates show approximately 90% of people with DM to have type two DM or T2DM. More recent studies have suggested a bidirectional link between type 2 DM and depression disorder. In a meta-analysis study, depressive symptoms were found to be correlated with 60- percent rise in the risk factors associated with type 2 DM. type 2 DM has also been found to be correlated with a 24-percent rise in the risks associated with depressive symptoms.

Over the past ten years, some studies have addressed DM and depression disorder. In the hospital- based study conducted in India, the prevalence of depressive symptoms was found to range from 8. 5 to 32. 5 percent, depending on what measurement scales were used. In people with diabetes mellitus, depressive symptoms are correlated with factors such as age, increased medication burden, neuropathy,

obesity, retinopathy and somatic symptoms among women with genital symptoms among men. In another study conducted in Bangladesh, the rates for the occurrence of depressive symptoms among people diagnosed with DM were found to range from 28-34 percent. The above study also discovered gender differences, namely a 22-percent prevalence rate among men and a 35-percent prevalence rate among women In Bangladesh, the risk factors involved were found to involve single marital status, ineffective glycemic control and use of insulin. In Pakistan, a systematic review of mental health studies discovered the mean prevalence of anxiety and depressive disorders in the community-based populations to equal 34 percent in general.

In other regions beyond Asia, namely Southwest Ethiopia, the prevalence of depressive symptoms and DM is 43.6%with 52.7% of this rate found among females and 36% among males. In terms of independent predictors of depression in people diagnosed with diabetes mellitus, a minimum of one diabetes mellitus-related complication and ages over 55 years were found to be correlated with this phenomenon. In an analysis of data obtained from the Australian National Diabetes Audit from adults with type 2 DM at 50 diabetes clinics, symptoms of depression were reported to have effects in 40% of the subjects. It can be summarized, therefore, that people diagnosed with DM are two to four times more likely to have depressive symptoms in comparison to healthy people in the general population.

Apart from the findings of studies conducted in foreign countries, previous studies in Thailand have found the prevalence of depression to be between 10-30%. Moreover, most of the depression found in people with DM is found among the elderly (mean age = 60.2 ± 8.6 years). The study of *Sitanan* Poonpolsub et al. (2005) found DM people to have depression at a rate of 25.2%, while the study of Pra-ornthip Sutthisan (2007) in elderly DM people in Nongkhai Province, Thailand, found depression in 20.3% of all DM people. When categorized by age group, the elderly DM people aged 60 years were found to have depression at a rate of 17.8%. And according to the study of Nopparat Wacharakajornkul (2007) in DM people in Lampang Province, Thailand, depression was found in 38.8% of all elderly DM people. Pirunee Suppaso studied the prevalence of depression in people with type 2 DM and found the prevalence of depression to be 10.3%. A study by Somporn Rungreangkulkij et al. found the prevalence of depression in people with DMattending a primary health care center to be 15.83%. In contrast, Kattika

Thanakwang and colleagues. studied depression among older adults with DMin Thailand and found the rate of depression to be 32.5% in a sample of 330 people. In comparison, another 67.5% did not have depression, and most of the sample had mild depression (20.5%), moderate depression (9.6%) and severe depression (2.5%). Chaimongkol studied the prevalence and factors associated with depression among type 2 diabetic people in Konsarn Hospital and found depression to occur in 16.18% of all people with mild depression at 12.06% and moderate depression at 4.12%. No severe depression was found. And in the study of Supawadee Srirattanapraphan entitled "The Prevalence of Depression and Associated Factors in people with Diabetic Mellitus in Lahansai Hospital", the sample was found to have depression at a rate of 4.3%, whereby most had mild depression (2.8%), moderate depression (0.9%) and severe depression (0.6%).

The consequence of stress and depressive symptoms has attracted interest. One of the main risk factors for depression is the occurrence of stressful events in life. In terms of physiology, increasing amounts of cortisol are released when a people is experiencing stress, whereas serotonin secretions are suppressed along with other neurotransmitters located in the brain. Long-term rises in cortisol are known to potentially inhibit new neuron growth in the hippocampus, thereby impairing emotional control and cognitive processes. In short, the initial onset and severity of cognitive decline are affected by stressful events and circumstances.

Furthermore, the interactions of neuronal circuitry with other neurotransmitters functioning in the brain offer an integrated method for addressing the many different biological mechanisms posited as the pathophysiology of depressive symptoms. The findings of previous studies have reported a definite correlation between depressive symptoms and stress. Moreover, stress triggers identify cognitive and biological vulnerabilities influencing the way people interpret events or circumstances and subsequent consequences while serving as the line between the above and the triggering of neurocognitive and neuro-hormonal reactions to depression. Based on the premise that stressors can predict depressive symptoms, it has been indicated that depressive symptoms are likely when a people's peopleality style "matches" a particular stressor (Beck, 1983).

2.3 Factors associate with depression among PWDM and research related

Pathological changes, symptoms and presenting symptoms of DM have the following physical, psychological and socio-economic effects on people. The first one is physical effects mostly caused by disease pathology, causing people to have high blood glucose. Extended high blood glucose causes death or permanent disability among people. The second one is psychological effects from incurable DM cause people have many changes in lifestyle such specific dietary restrictions, medication adherence for glycemic control and general physical healthcare. Besides, people are required to make more effort to change healthy lifestyles to lifestyles tailored for the disease. If people are unable to change or have difficulty changing lifestyles, people will experience stress. Furthermore, the fact that people required treatment to live with an incurable disease and confront uncertainties from diabetic symptoms each day usually causes people to become anxious, bored and hopeless with feelings. They are a burden to others in addition to having potential depression and lower self-esteem (Gharaibeh et al., 2016; Akena et al., 2015; Lee et al., 2017; Chlebowy et al., 2019).

The important factor for depression is self-esteem. Self-esteem causes a people to feel proud and positive feelings about themselves. This factor is essential for people coping with problems and adaptations, particularly during sickness. Because self-esteem causes a people to be motivated or feel empowered in performing self-care activities, the people will able to adapt to illness with positive effects on mental health. A people with low self-esteem or a negative self-image will feel powerless, causing a lack of motivation to perform self-care activities, poor adaptation to illness and potential for depression (Priya & Kalra, 2018). Furthermore, some studies have found self-esteem to be negatively correlated with depression among adolescents (Akena et al., 2015; Gharaibeh et al., 2016; Lee et al., 2017). Hence, self-esteem can predict depression in adolescents.

Apart from self-esteem, social effects from diabetes cause people with diabetes to have fewer social activities and avoid meeting with others due to a need to control complications from diabetes and energy exceeding peopleal requirements (Lee

et al., 2017; Saffari et al., 2019), and 4) economic effects cause people to spend a long time in treatment s, causing people with diabetes to incur high medical costs and other related expenses (Zhou et al., 2017). In particular, people with diabetes with complications have higher medical costs. In addition to burdens from expenses on people and families, governments have to deal with significant budgetary expenditures to provide health services for people with diabetes. Thus, DM causes economic effects at the familial and national levels.

DM is a chronic disease with wide-ranging effects on people and families. The effects, as mentioned above, include physical, psychological, social and economic effects. People with complications from DM or other chronic diseases suffer an even more significant impact. These adverse effects are a problem in the lives of people with diabetes, causing people to need to adapt to problems to continue living with the disease. Success in adaptations is partly dependent on problem severity. Therefore, illnesses with more severe effects will increase risk of failure in adapting to problems, causing stress and depression among people with diabetes (Khan, Lutale & Moledina, 2019; Deschenes, Burns & Schmitz, 2015; de Lima Filho et al.,2019; Madkhali et al., 2019; Habtewold et al., 2016; Zhou et al., 2017; Brown et al., 2019). Ultimately, severe effects from DM are another factor potentially causing people with diabetes to have stress and depressive symptoms. Complications and effects from DM created difficulties and complications for people and families in every aspect, causing people to be at higher risk of disability and death. Furthermore, DM-related distress may cause people to have more negative perceptions of people health, causing people to feel more hopeless and bored, resulting in stress and depressive symptoms.

Several depression studies among diabetes people were conducted overseas. The findings from a study conducted by Sampao (2005) found senior adults with many health problems to be more depressed. In the meantime, Jantarapat (2004) found the perceived severity of the illness to have a positive influence on depression among senior adults who were treated at hospitals. A study conducted by Suttisan (2007) among people with diabetes revealed most people with diabetes together with depression, had problems in life and were unable to solve problems. Therefore, the ability to confront issues is another factor capable of predicting depression in people with diabetes.

Moreover, Suttisan found social support to be a factor correlated with depression among diabetes people and demonstrated social support as a potential depression-related factor among Thai people with diabetes. Suttisan (2007) found the people with diabetes with no complications to be at lower risk for depressive symptoms than people with diabetes with complications. Thus, the fact that people with diabetes have complications should be a factor capable of predicting depression. The ability to confront problems is an essential factor correlated with depression due to effects on adaptation to problems, including illness. People with diabetes with problems in the area of adaptation to illness and other unsolvable problems were more probable to be depressed than people who adapted well to illnesses or were able to solve problems in life (Suttisan, 2007). In another study by Thongchat (2005), the findings found the ability to confront problems to be negatively correlated with depression in adolescents.

Findings from studies conducted overseas found complications from DM to be positively correlated with depression (Caluyong et al., 2015; Habtewold et al., 2016; Zhou et al., 2017; Khan, Lutale & Moledina, 2019; Deschenes, Burns & Schmitz, 2015; van Vuuren &Pillay,2019; de Lima Filho et al., 2019; Madkhali et al., 2019; Hoogendoorn et al., 2019). These complications consisted of macrovascular complications, nephropathy, neuropathy, retinopathy, and sexual dysfunction (Zhou et al., 2017). Past findings domestically and abroad have shown many factors to be related and capable of predicting depression in people with diabetes. The factors mentioned above include the length of illness with DM. Because DM is a chronic disease and prognosis usually worsens in line with physical deteriorations, prognosis continues to worsen the longer the body deteriorates. The findings from previous studies on the correlations between length of illness with DM and depression supported the positive relationship between the length of illness with diabetes and depression (AlBekairy et al., 2017).

Social support is another factor that should be given importance since social support is correlated with a people's physical and psychological health and illness. A people who lacks social support can easily have anxiety and depression. Social support will help minimize the impact of unpleasant events, including stress from illness. When confronted with stressful events, a people will adapt to stress in the adaptation process. Social support helps ease the severity of stressful events during the step of assessing

stress or interpreting events by reducing feelings of helplessness or feelings of less worth.

Furthermore, social support suppresses inappropriate stress confrontation behaviors. A people who receives excellent social support will adapt to events better than a people without social support (Lee et al., 2017; Kong et al., 2019; Saffari et al., 2019). The findings from studies conducted overseas supported the fact that the level of social support received by people with diabetes is negatively correlated with depression. This evidence means people with diabetes who received social support will be less likely to have depression than people with diabetes who do not receive social support (Zhang et al., 2015; Habtewold et al., 2016).

According to previous studies, the factors found to be correlated with depressive symptoms are female gender, low educational level, minimal family support, minimal physical activity, non- dietary control, sleep deficit, and limited physical activity (Lee et al., 2017). Activity in daily living competency is another factor capable of causing depression among people with diabetes. Activity in daily living competency is a factor enabling a people to perceive people power in controlling the environment. People who are unable to perform activities in daily life separately have to be dependent on others, causing the people to feel powerless and a burden which may lead to depression. According to the study, activity in daily living competency was able to predict depression among people with chronic obstructive pulmonary disease, senior adults who were treated in the hospital and people with cerebrovascular disease (van Vuuren &Pillay, 2019). A study conducted among people with diabetes found deficiencies in activities in daily living were found to be positively correlated with depression in diabetes people based on type 2 DM (Khambaty et al., 2017; Shomaker et al., 2018).

According to previous studies, depressive symptoms are correlated with some socio-demographic, behavioral and clinical symptoms. The rates of depression are usually higher among women and people with poor glycemic control, insulin therapy and long-term DM. Previous studies on the correlations between depressive symptoms/ age/ BMI/ level of education/ socio- economic status/ history of alcohol consumption and history of smoking (Aminu, Chandrasekaran & Nair, 2017; AlBekairy et al., 2017; Khambaty et al., 2017). Apart from the factors above, personal

characteristics represent another factor correlated with depression because different attributes in each person may have caused different adaptations to illness with effects on depression. Gender, age and level of education have been found to be correlated with depression and women were found to have higher rates of depression than men (Briganti et al., 2019; van Vuuren & Pillay, 2019; Lee et al., 2017). Therefore, personal characteristics may be another factor capable of predicting depression in patients with diabetes.

2.4 Theory of stress and stress management

2.4.1 Theory of stress

According to Hans Selye, numerous physiological adaptations are triggered when coping with stress. A highly complicated phenomenon, stress is generally triggered by perceived threats, whether mental or physical, to balance in life and body. The responses to these threats can be physiological, psychological or behavioral (Bali and Jaggi 2015). Possible sources of stress are numerous, including stress involving work, family and illnesses of all kinds. A mild bout of stress does not usually affect people in unhealthy or maladaptive ways. Severe bouts of stress, however, can become health-related severe risks when recovery is insufficient or incomplete. Stress in high degrees or long-lasting stress is common for many people. (American Psychiatric Association 2016).

In particular, Selye observed that a number of these adaptations are brought on by frequent stressful events and followed by pathological consequences. The physical and psychological responses to stress are as follows: 1) Alarm: According to Selye, the human body, exerts effort toward both accommodating and adapting to stressful situations in a set of changes known as GAS. GAS can be divided into three stages in which changes are brought about by stressful events or circumstances, particularly in the autonomic nervous system (ANS), including the sympathetic and parasympathetic nervous systems. The sympathetic nervous system responds to stress with a set of internal biochemical exchanges within the body in which the hypothalamus regulates the sympathetic nervous system and identifies the general reactions to stressful events or circumstances. If the hypothalamus perceives a need for additional

energy for combatting stress, epinephrine (AKA adrenaline) is secreted. As a result, cardiac and, therefore, the heart rate is increased. The airways within the lungs are enlarged for dilated by blood pressure, thereby increasing oxygen intake and respiratory rates. In cases involving chronic stress, the above response to stressors is correlated with long-lasting activation of the response (Konduru, 2012), 2) Resistance: At this stage, the body's attempts are aimed at recovery and return to physiological balance as it resists alarm.

Nevertheless, chronic stress means that the stressors persist to such an extent that the body is unable to bring about recovery and stays in an active state or a state of arousal, thereby leading to higher metabolic rates in some parts of the body. In cases where stress persists even longer, the resources to which the people has access will be exhausted, thereby leading to the next stage (Selye, 2013), and 3) Exhaustion: At this stage, one or multiple organs may present with symptoms of dysfunction. In cases where the degree of stress exceeds the people's physical capacity, the people's resources become depleted, thereby suppressing immunity and making the people susceptible to illness (Selye, 2013).

2.4.2 Stress management

Programs capable of effectively addressing the mentioned conditions need to cope with issues involving mental, physical, emotional, and spiritual well-being. Stress management courses are frequently offered in the form of workshops where people learn how to minimize the adverse effects of stress. The examples of stress management are exercise, relaxation techniques, massage, meditation, biofeedback, counselling, guided imagery, acupuncture, yoga, deep breathing exercises, involvement in social/ support groups and other types of lifestyle modification. In essence, stress management courses address the numerous factors contributing to mental, physical, intellectual, emotional and spiritual wellness (Tetrick & Winslow, 2015).

2.4.2.1 Relaxation techniques

Relaxation techniques are characterized as a part of freedom from skeletal muscle tension and anxiety. Relaxation is referred to as a sense of being at

peace or ease (Engert et al., 2017). Previous studies have produced and evaluated several interventions as a means of helping people with diabetes (Priya & Kalra, 2018; van Son et al., 2015; Whitebird et al., 2018; Khobragade et al., 2016; Yang et al., 2017; Hoge et al., 2017). The benefit of interventions is assessing psychological disorders, learning how to cope with adverse mental conditions (Latheef, 2017; van Son et al., 2015). These interventions cause decreasing stress and depression (Ebrahem & Masry, 2017; Jayaprasad, Bhatkule & Narlawar, 2018; Berge & Riise, 2015; Pascoe & Crewther, 2017), as well as reducing blood glucose (Priya & Kalra, 2018; Berge & Riise, 2015; Jayaprasad, Bhatkule & Narlawar, 2018; Xie & Deng, 2017).

Nevertheless, these positive effects can be even better when combined with other intervention, and when people learn how to assess events that trigger stress in their lives. Besides, relaxation techniques or biofeedback can be effective at lowering stress while improving the overall physical conditions of people. They also learn about skillsets for coping with daily stress and applying the skills they have learned in daily practice. Furthermore, the risk of recurrence for chronic stress can be reduced with relaxation. When combined with pharmacological therapy, relaxation can significantly reduce the risk of persistence stress more effectively than medication alone (Moss & Khazan, 2015; Pascoe & Crewther, 2017; Perera, Rathnarajah & Ekanayake, 2016; van der Zwan et al., 2015; Ebrahem & Masry, 2017).

2.4.2.2 Meditation

Meditation is the practice of focusing attention on one given entity or another over a continuous period. As previously stated, meditation is a cognitive process performed to achieve physical or mental control and well-being. It is also aimed at enlightening people through acceptance (Shader & Taylor, 2017).

According to the literature review, meditation plays a crucial role in positive physiological and psychological states in people with diabetes (Jung, Lee& Park, 2015; Tovote et al., 2015; Armani Kian et al., 2018; Khobragade et al., 2016; Hoge et al., 2017; Yang et al., 2017). Apart from its religious connotations, meditation has also been used as an effective way to maintain physical, mental, and even social well-being (Tovote et al., 2015; Engert et al., 2017; Priya & Kalra, 2018; Santhanam,

Preetha & Devi, 2018; Shader & Taylor, 2017). Despite the multiple approaches to meditation, the majority of meditation techniques can be categorized as either concentrative meditation or mindfulness meditation. Concentrative meditation emphasizes breathing, images or sounds (mantras or chanting) as the means of calming one's mind and allowing heightened awareness and clarity to occur Transcendental meditation (TM) involves the use of chanting or mantras as focal points for concentration or attention (Engert et al., 2017; Priya & Kalra, 2018). The TM techniques were introduced by a graduate of physics from Allahabad University in India in 1958, His Holiness Maharishi Mahesh Yogi. The technique is based on the idea that thought has the same potential for creating various energy levels as matter (Engert et al., 2017; Priya & Kalra, 2018). It is based on the practice of non-resistance and the absence of control over the mind (Engert et al., 2017; Priya & Kalra, 2018). Instead, the mind only has to be released in the right direction and to let it be as it is using natural methods. TM is a means of releasing the mind to achieve natural transcendence without effort. It can be concluded that regular practice of TM effectively rehabilitates people by relieving psychological stress (Engert et al., 2017; Priya & Kalra, 2018; Santhanam, Preetha & Devi, 2018; Shader & Taylor, 2017; Yang et al., 2017), anxiety (Engert et al., 2017; Shader & Taylor, 2017). Furthermore, TM leads to organizing brain function (Engert et al., 2017; Shader & Taylor, 2017; Jadhav et al., 2017), enhancing harmony (Colosio et al., 2017), and developing positive social interactions (Priya & Kalra, 2018).

People that regularly practice meditation training experience physiological changes. These physiological changes include decreased lower blood lactate levels, lower heart rate, oxygen consumption, blood pressure (Yang et al., 2017), decreased cortisol level (Kiran et al., 2017; Priya & Kalra, 2018). At the same time, regular practice of meditation increases alpha waves, and skin resistance (Pascoe & Crewther, 2017). Practitioners of meditation have been able to suppress unimportant cerebral networks to concentrate on the inner self and suppress irrelevant information (Priya & Kalra, 2018; Sedlmeier et al., 2017). According to the verification provided by electroencephalograms, people who practice meditation are capable of making changes in the brain waves. Muscle tension relief is related to the practice of meditation. Besides, meditation has the positive effects of practicing meditation on blood pressure (Pascoe & Crewther, 2017; Priya & Kalra, 2018), baseline cortisol (Kumar et al., 2018;

Kiran et al., 2017; Roglic, 2016), and cognitive function (Priya & Kalra, 2018). In addition to the positive physiological effects of meditation, the psychological effects have been verified. Meditation has also been found to be positively correlated with one's internal locus of control, enhanced self-actualization, and more positive feelings when faced with psychological stress (Sedlmeier et al., 2017; Hoge et al., 2017; Jung, Lee& Park, 2015; Kumar et al., 2018; BAnSAl, MittAl & Seth, 2016; Pascoe & Crewther, 2017; Santhanam, Preetha & Devi, 2018; Latheef, 2017). Also, meditation can reduce anxiety (Pascoe & Crewther, 2017; Kiran et al., 2017), anxiety, depression, and stress (Priya & Kalra, 2018; Skoranski et al., 2018; Winter et al., 2015), anxiety and depression (Priya & Kalra, 2018), and depression (Gerbarg et al., 2015; Rod, 2016; Tovote et al., 2015; Armani Kian et al., 2018). Findings support that the effects of meditation result in different physiological changes than the effects of a variety of other relaxation techniques manifesting what is known as the relaxation response. Research suggests that there is better mental health among people that practice meditation than among those that do not.

As previously stated, meditation may affect physical and psychological changes (Priya & Kalra, 2018; Gathright el al., 2019; Deo et al., 2015). The processes of meditation are effective in regulating mental and physical processes by employing the inner self. TM is one of the most effective techniques (Priya & Kalra, 2018; Gathright el al., 2019; Santhanam, Preetha & Devi, 2018; Shader & Taylor, 2017). When people practice TM, their bodies achieve a condition marked by deep relaxation in which fatigue and stress are eliminated, and brain function is orderly (Priya & Kalra, 2018; Santhanam, Preetha & Devi, 2018). Thus, the people that practice TM are generally healthier and more integrated (Berge & Riise, 2015; Priya & Kalra, 2018; Shader & Taylor, 2017). This benefit leads them to more successful dynamic activity. Also, TM contributes deep relaxation and control that enable the body's immune system and other healing processes to restore balance and healthy physiological function. The results are improved health and disease prevention because TM restores balance to the people's mind, body, and environment (Yogi, 1969)

In TM training, people achieve a state known as transcendental consciousness, where they experience unlimited awareness leading to better creativity and higher intelligence (Priya & Kalra, 2018). Practiced regularly, TM offers greater

coherence in brain function where the people's mind becomes more comprehensive, focused, creative, and intelligent (Jadhav et al., 2017; Priya & Kalra, 2018). TM makes the mind alert and comprehensive as both cognitive and physical activity improve self and others (Priya & Kalra, 2018). Many people that regularly practice TM have commented that they make fewer mistakes in their daily lives as they learn to live in harmony with natural law. In a nutshell, TM gives people inner strength, homeostasis, satisfaction, and awareness while relieving stress (Yogi, 1969).

Hence, regular practitioners of TM have better attention appreciation and love for self and others in their people and professional lives. Under these circumstances, any dependence on external factors or substance dissipates. Moreover, what is commonly referred to as transcendental consciousness accompanies successful TM. Transcendental consciousness leads to the absence of sensations such as fear, anxiety and feeling altogether (Priya & Kalra, 2018; Shader & Taylor, 2017). This restful alertness creates a calm, pleasurable self as a single people that is in the present and accepts what experiences that present has to offer in what is anticipated as a sense of well-being that makes it easy to take responsibility for the current situation (Priya & Kalra, 2018; Shader & Taylor, 2017).

Consequently, the potential advantages of TM are the realization of mental potential and improved health for chronic disease people (Priya & Kalra, 2018; Shader & Taylor, 2017; Berge & Riise, 2015; Gathright el al., 2019). Several studies have addressed the positive effects of medication on diabetes people. In Thailand, among the effects of meditation have been studied on stress (Charoensukmongkol, 2014), emotional well-being (Keawchaum, 2009; Charoensukmongkol, 2014). Promoting health behaviors (Phochaja, 2017) and blood sugar level (Kaewponpek, 2018; Nojai et al., 2018). Many aspects of this practice have been studied to determine their effects on other medical treatments and complementary therapies to improve quality of life as well as a health condition (Lindquist et al., 2014).

Concerning research beyond Thailand, meditation is as a tool for self-care of adaptation for people with diabetes (Tovote et al., 2015; Armani Kian et al., 2018; Gainey et al., 2016; Priya & Kalra, 2018; van Son et al., 2015). Meditation has been found to enhance attention regulation, self-awareness, emotional regulation,

and self-relaxation (Engert et al., 2017; Priya & Kalra, 2018; van Son et al., 2015). Meditation has also been found to be positively correlated with good psychological health in people with diabetes. Most of these studies revealed that meditation affected mood states (inclusiveness, exclusiveness, and mindfulness) (Kumar et al., 2018; Latheef, 2017; Skoranski et al., 2018; van Son et al., 2015). Moreover, a highly effective mediating factor in the stress treatment of people with diabetes shows meditation lead to lower stress levels in diabetes people (Kumar et al., 2018; Latheef, 2017; Skoranski et al., 2018).

Meditation can also help reduce depression (AlBekairy et al., 2017; Yoo et al., 2016), depression and anxiety (Jayaprasad, Bhatkule & Narlawar, 2018; Priya & Kalra, 2018; van Son et al., 2015; Haenen et al., 2016), stress and depression(Latheef, 2017), depression, anxiety and stress (Whitebird et al.,2018), as well as cortisol level (Kumr et al., 2018; Robb et al., 2019; Kiran et al., 2017; Skoranski et al.,2018). In a previous study by Piet. In a prior study by Sasikumar and Fathima Lathecf (2017), the study showed the effects of meditation reduced depression and stress in people with diabetes (Latheef, 2017).

Despite the multiple approaches to meditation, TM is one of the effective meditation techniques. TM is related to a wide variety of psychological, emotional, and physical manifestations of well-being. TM was found to be most effective among participants with the highest degrees of stress (Gathright el al., 2019; Pascoe & Crewther, 2017; Santhanam, Preetha & Devi, 2018). TM is associated with a physiological means for combating depression (Gathright el al., 2019). TM was found to be the most effective among participants with the highest degrees of anxiety (Priya & Kalra, 2018). Moreover, TM represents a physiological means for combating depression because it lowers the cortisol, plasma lactate, respiratory rate together with skin resistance levels (Pascoe & Crewther, 2017; Shader & Taylor, 2017). TM also offers long-range integration of the distal cortical-neural groups required in cognitive behaviors, motor, and sensory (Colosio et al., 2017). Besides, previous studies have shown that TM reduced anxiety, stress, and depression (Priya & Kalra, 2018; van Son et al., 2015). TM has been studied, and results revealed that it was a highly effective

mediating factor in the treatment of chronic diseases. Studies have shown that TM has been found to bring about positive psychological health in people with diabetes (Priya & Kalra, 2018; Gerbarg et al., 2015; Yang et al., 2017; Pavlov et al., 2015; Devi & Samaga, 2015).

2.4.2.3 Biofeedback

Biofeedback can be used for improving one's health condition. Biofeedback is a training method that allows people to perceive the changes occurring in their body during training (Perera, Rathnarajah& Ekanayake, 2016). The origin of biofeedback can be found in holistic self-care concepts where body and mind are one. Biofeedback originated from Selye's theory of stress which was created by Hans Selye, who explained how stressors act to trigger specialized reactions. This model is vital to gaining an understanding of the correlation between stress and health. Selye also created the GAS in which he described the body's stress response in the following three stages: alarm, resistance and exhaustion (Halte, 2017). The purpose of biofeedback is relaxation and control of physiological processes to guide people through modifications in their bodies to facilitate the regulation of physiological functions that are generally susceptible to the heightened neuroendocrine activity brought about by stress (Aaraji, Nosratabadi & Hoseinpourfard, 2018; Shenefelt, 2017; Schwartz & Andrasik, 2017; Ruchiwit, 2015).

As previously mentioned, biofeedback helps trainees learn to relax successfully and more quickly. People can adopt meditation in maintaining good people health in daily living without requiring biofeedback, as people would already have memorized their training experiences very well. As part of a category of models referred to as self-regulation theories, where people are instructed to regulate their autonomic nervous system activity, biofeedback can help people learn how to suppress this activity. Moreover, biofeedback is a critical educational instrument in educating people about methods for monitoring and altering both the frequency and amplitude of the electronic signals transmitted within the body by relaxing the physical regions where

electrodes are attached. With continued practice, people can be taught how to make sustainable changes with proper use of biofeedback instruments (Aaraji, Nosratabadi & Hoseinpourfard, 2018; Perera, Rathnarajah & Ekanayake, 2016; Shenefelt, 2017; Schwartz & Andrasik, 2017; Ruchiwit, 2015).

According to previous findings, biofeedback represents a means whereby people can learn how to improve their health and manage chronic disease symptoms for better self-care performance. The far-reaching health benefits of biofeedback, a process that monitors, measures, and immediately reports on its findings, are well-known. According to the literature review, some field studies and controlled trials support the validity of biofeedback therapy in facilitating relaxation as a means of treatment for specific functional disorders (Aaraji, Nosratabadi & Hoseinpourfard, 2018; Moss & Khazan, 2015; Shenefelt, 2017; van der Zwan et al., 2015; Seidi et al., 2016; Ratanasiripong, Ratanasiripong & Kathalae,2015). Interventions based on biofeedback principles can be implemented to promote health and prevent disease, mainly when psychological factors are significant contributors to people conditions (Aaraji, Nosratabadi & Hoseinpourfard, 2018; Perera, Rathnarajah & Ekanayake, 2016; Shenefelt, 2017). One of the more notable effects is the objective and physiological self-control achieved by people that use biofeedback. Initial studies of biofeedback were conducted to demonstrate voluntary self-control, as subjects showed the ability to change their heart rate, galvanic skin response, arterial dilation, and brain wave emissions (Perera, Rathnarajah & Ekanayake, 2016; Shenefelt, 2017; Ratanasiripong, Ratanasiripong & Kathalae, 2015). A wide range of physiological limitations can be overcome with training in biofeedback to relieve muscle tension, lower blood pressure, increased secretion of hydrochloric acid in the stomach, etc. (Aaraji, Nosratabadi & Hoseinpourfard, 2018; Shenefelt, 2017; Ruchiwit, 2015).

For people with chronic disease, the advantages of biofeedback include relief of emotional stress. In practice, biofeedback can be categorized into the following five categories: 1) simple relaxation with relief of stress, anxiety and depression as a means of overcoming psychosomatic symptoms (Shader & Taylor,

2017; van der Zwan et al., 2015); 2) overall relaxation aimed at treating psychosomatic disorders when the aforementioned simple relaxation methods have failed(Moss & Khazan, 2015; Perera, Rathnarajah & Ekanayake, 2016; Shader & Taylor, 2017; Seidi et al., 2016; Ratanasiripong, Ratanasiripong & Kathalae,2015); 3) technologically-supported relaxation therapy aimed at facilitating the release of physical tension and inner turbulence(Aaraji, Nosratabadi & Hoseinpourfard, 2018; Schwartz & Andrasik, 2017); 4) biofeedback, enabling people to control certain physical functions with the aim of achieving deep relaxation(Schwartz & Andrasik, 2017; Lindquist, Tracy & Snyder, 2018); and 5) audio-visual feedback, where people learn how to interpret and control physical (Moss & Khazan, 2015; Perera, Rathnarajah & Ekanayake, 2016; Shenefelt, 2017). Eventually, people learn how to interpret and control their physical responses without the use of instrumentation (Schwartz & Andrasik, 2017).

According to the findings, the positive effects produced by biofeedback are numerous. Biofeedback is wieldy implemented by healthcare providers. For example, researchers have conducted studies on the effects of biofeedback in training for relieving stress (Perera, Rathnarajah & Ekanayake, 2016), reducing anxiety, depression and better clinical outcome in dermatology (Shenefelt, 2017) as well as stress (van der Zwan et al., 2015). The instruments used in biofeedback offer readings on physiological functioning, such as cardiac, cerebral, and other physiological activities in addition to skin temperature and skin conductance.

In Thailand, wide ranges of biofeedback methods are employed. These methods include galvanic skin response, electroencephalography, electromyography, and heart rate variability. However, the method most frequently applied is electromyography, with some relaxation techniques aimed at stress and anxiety relief among chronic disease people, heart disease people, and alcohol addict people (Ruchiwit, 2015). In one quasi-experimental research randomized study, biofeedback focused on heart rate variability that promoted regulated respiration was able to reduce

the depression, among a group of adult people. The mentioned program also developed and improved the people's resourcefulness (Ngamlwes, 2015; Bunthumporn, 2012).

Furthermore, previous studies have been conducted on the use of biofeedback in the evaluation of relaxation and the effects of biofeedback on the progression of the chronic disease (Shader & Taylor, 2017; Aaraji, Nosratabadi & Hoseinpourfard, 2018; Moss & Khazan, 2015; Shenefelt, 2017; van der Zwan et al., 2015). The results revealed that biofeedback could improve relief in physiological stress of people with diabetes because the instruments continuously measure the level of stress and display the physiological function of the people. In this way, people become conscious and control the physical, behavioural, and cognitive levels through learning reinforcement (Zwan et al., 2015). At the same time, biofeedback is capable of helping those that use it to achieve skills for coping with emerging symptoms. In one study, biofeedback was able to increase the quality of life, reduce blood sugar and stress diabetes people (Aaraji, Nosratabadi & Hoseinpourfard, 2018).

2.4.2.4 The combination of meditation and SC & ST biofeedback

Biofeedback is a training method that will allow people to perceive the changes occurring in their body during training. Hence, biofeedback helps trainees to relax successfully and more quickly. People will already have the experience of adjusting their bodies so that they can regulate the physiological functions that are prone to increase metabolic activity caused by stress. Consequently, people can adopt meditation for maintaining good people health in daily living without requiring biofeedback. By applying biofeedback and meditation, people can learn how to gain cognitive control over their autonomic nervous system. Biofeedback represents a means of validating otherwise biased feelings of psychological stress. In contrast, meditation is used for achieving people's ability to voluntarily control physiological activities by being provided with information about those states of being active including it also represents a singular therapeutic technique offering information on the state of biological procedure. (Ruchiwit, 2015; Yu, Zhang & Fang, 2015; Shenefelt, 2017).

Another method involves body temperature control by using a biofeedback instrument for regulating body temperature through the skin. This finding can be explained in that meditation triggers the parasympathetic autonomic nervous system to dilate the peripheral arteries to increase blood flow to the hands and feet, resulting in increased skin temperature (Ruchiwit, 2015; Schwartz & Andrasik, 2017). Upon noticing movements in the dial needle, the trainee perceives his or her stress levels due to feedback from the GSR instrument. With frequent and repetitive training to achieve familiarization, the trainee becomes able to control the direction of the needle at will in the same manner as biofeedback for regulating the perspiration glands (Ruchiwit, 2015). It is clear that electrical resistance at the skin is correlated with the level of emotional stimulation and is indicative of relaxation-ranging from high to low levels based on the stimulating signals (Ruchiwit, 2015; Schwartz & Andrasik, 2017).

As mentioned above, biofeedback alone can yield positive outcomes. Nevertheless, combining biofeedback with other programs has led to positive outcomes in terms of improving psychological stress (Perera, Rathnarajah & Ekanayake, 2016), depression and anxiety (Seidi et al., 2016) anxiety and HbA1 (Seidi et al., 2016), stress and anxiety (Ratanasiripong, Ratanasiripong & Kathalae,2015; Edwards, 2016) blood glucose (Seidi et al., 2016), pain management (Wang et al., 2015), aggressive behaviour levels of amphetamine abusers (Raddussadee et al., 2014). By applying biofeedback-assisted meditation, people can learn how to gain cognitive control over the autonomic nervous system (Schwartz & Andrasik, 2017; Lindquist, Tracy & Snyder, 2018). As a result, these people will be able to lower their chronic stress, peripheral vasoconstriction, anxiety, and depression (Halter & Varcarolis, 2014; Sun et al., 2016; Perera, Rathnarajah & Ekanayake, 2016; van der Zwan et al., 2015).

At present, meditation and biofeedback are employed in association with pharmacological therapy for diabetes people, with the goals of improved treatment outcomes, decreased medication adherence, and no medication use in some people. The study of the effect of meditation, combined with Skin conductance (SC) and Skin conductance (ST) biofeedback programs, as a means of lowering

depressive symptoms and stress among people with diabetes, can be explained in principle as follows. The body can identify stress through the skin (galvanic skin resistance: GSR). Meditation triggers the function of the parasympathetic autonomic nervous system. It can bring a reduction in the amount of sweat in the palms and feet, with increased electrical resistance in the skin. When the mentioned training is used together with the biofeedback instrument to regulate perspiration gland function, with the trainee observing the dial needle move to the left and right, the trainee will perceive his or her stress level. With frequent training, the trainee becomes familiarized and can move the needle in the desired direction (Ruchiwit, 2015; Shenefelt, 2017; Schwartz & Andrasik, 2017; Shenefelt, 2017).

Meditation, combined with biofeedback, has yielded positive treatment outcomes in chronic disease people. Previous studies conducted in Thailand have focused on biofeedback with other programs aimed at relieving stress depression, anxiety (Ruchiwit, 2015). A prior research study conducted by Thongkhum, Ruchiwit, and Somprasert (2015) investigated the effect of a meditation combined with the SC and ST biofeedback on the stress levels of people with diabetes by using the self-reported stress test: SOSI. The finding showed that the levels of stress among people with diabetes were lowered due to the implementation of meditation combined with the SC and ST biofeedback. Studies of heart disease people have focused on meditation used with biofeedback in the evaluation of stress, and the effects of meditation used together with biofeedback for health. A study was conducted by Ruchiwit and colleagues (2005) on the stress of heart disease and health status of people using SC and ST biofeedback combined with stress relief techniques involving meditation and imagery administered over eight weeks at 60 minutes per week. According to the findings, there were changes in the stress levels of the experimental group, which have resulted in a more significant reduction than the control group.

In addition to previous studies conducted in Thailand, as in other studies, have been investigated abroad concerning the positive effects of combining biofeedback with other programs. It was concerning studies involving meditation

combined with biofeedback for reducing stress and anxiety (Shader & Taylor, 2017; Edwards, 2016; Ratanasiripong, Ratanasiripong & Kathalae, 2015), decreasing stress (Perera, Rathnarajah & Ekanayake, 2016), improving self-regulation and relaxation (Moss & Khazan, 2015). The researcher gathered relevant research that supports the present study and found a study on the control of glycemic levels through the use of biofeedback and mindfulness in people with diabetes for eight sessions. According to the findings, biofeedback and mindfulness can improve glycemic control and lower anxiety and depression (Seidi et al., 2016).

Studies have shown that a combination of biofeedback and meditation can help people monitor their physiological reactions to stress as they learn how to control their responses (Seidi et al., 2016; Moss & Khazan, 2015; Perera, Rathnarajah & Ekanayake, 2016; Zwan et al., 2015). According to the finding, biofeedback and meditation can increase self-regulation and relaxation (Moss & Khazan, 2015), improve glycemic control, lower anxiety and depression (Seidi et al., 2016). People not only can recognize the signs and symptoms of physiological disorders, but they can learn to reduce the adverse effects (Ratanasiripong, Ratanasiripong & Kathalae, 2015). According to previous studies, biofeedback combined with meditation is effective in lowering levels of depression (Perera, Rathnarajah & Ekanayake, 2016), stress and anxiety (Edwards, 2016; Ratanasiripong, Ratanasiripong & Kathalae, 2015; Shader & Taylor, 2017).

According to the literature review, stress and depressive symptoms are frequently encountered in people with diabetes (Briganti et al., 2019; van Vuuren &Pillay, 2019; de Lima Filho et al.,2019; Khan, Lutale & Moledina, 2019; Islam, Rawal & Niessen, 2015; Jayaprasad, Bhatkule & Narlawar, 2018; Krishna, 2018; Rehman & Kazmi, 2015). Meditation represents a type of coping in which integrated practices are not only aimed at achieving physical or mental control and well-being but also at helping people with diabetes gain acceptance (Tovote et al., 2015; Armani Kian et al., 2018; Gainey et al., 2016; Latheef, 2017; Pascoe & Crewther, 2017). Apart from

meditation, biofeedback enables people with diabetes to manage multiple physical processes and can be an excellent supplement to mainstream chronic disease treatments. Next, people with diabetes are given the data yielded by the instruments to learn how to control their physiological functions willingly. By applying these types of interventions, people can learn how to gain cognitive control over the autonomic nervous system. As a result, these people will be able to lower their stress and decrease their depression. Therefore, these programs are practical in addressing the conditions of depression and stress to improve various dimensions such as mental, physical, emotional, and spiritual well-being. Besides, a combination of biofeedback and meditation can be useful in lowering stress and decreasing stress and depression among people with diabetes.

Studies on the biochemical parameters with psychometric variables for people with diabetes can contribute to filling in the gap of knowledge in this area. Therefore, closing the stated gap of knowledge can offer greater clarity and insight for healthcare providers involved in the care of people with diabetes. As previously stated, higher amounts of cortisol are correlated with stress and depressive symptoms (Joseph & Golden, 2017; Sudheimer et al., 2019; Chopra et al., 2019; Hoifodt et al., 2019; Skoranski et al., 2018). Therefore, studies on the serum cortisol levels for people with diabetes can contribute to filling in the gap of knowledge in this area.

However, there is rare research to test the effects of meditation with SC and ST biofeedback programs to reduce the depression and stress in diabetes people in Thailand. According to previous studies, the combination of meditation and biofeedback programs can be useful for people that have DM (Seidi et al., 2016; Zwan et al., 2015). This study is based on Hans Selye's theory of stress and Aaron T. Beck's cognitive model. People that train themselves to control their stress by using biofeedback together with meditation have a lower sympathetic nervous system and adrenal gland function with increased physiological responses, leading to increased skin resistance to electrical currents. These are because meditating people feel relaxed and have less sweat and higher body temperatures. These instruments show

measurements as number scales on the GSR display to inform people whether they are training correctly to relax and whether their stress levels have decreased. Once adept at appropriate management, people can control their psychological stress without requiring further use of instruments (Ruchiwit, 2015; Schwartz & Andrasik, 2017; Lindquist, Tracy & Snyder, 2018). The findings of the present study are expected to benefit people with diabetes in the area of the research and to provide guidance to ensure that they have proper management techniques for stress and depression.

CHAPTER 3
RESEARCH METHODOLOGY

Introduction

In this chapter is composed of the aspects of research design and followed by the sample, sampling procedures, sample size calculations, and randomization protocols.

3.1 Research Design

The present study was of a three-arm randomized controlled trial (RCT) approach, including a meditation group, a combination of meditation and SC & ST biofeedback group and a control group (Table 3.1). Applied RCT in this study can raise equality between groups. Also, it eliminates the selection bias by treatment allocation. Moreover, the findings of RCT are considered the guideline for evaluating efficacy in clinical research and constitute evidence for nursing treatment. (Spieth, Kubasch, Penzlin, Illigens, Barlinn, & Siepmann, 2016).

Table 3.1 Pre-test and post-test control group design

Randomization	Sample	Pre-test	Intervention	Post-test
R	M	O_{11}	X_1	O_{12}
R	M+BF	O_{21}	X_2	O_{22}
R	C	O_{31}	$\mathbf{X_3}$	O_{32}

When:

R = Randomization

M = The group obtained by matching pairs was set as experimental group 1and received meditation.

M+BF = The group obtained by matching pairs was specified to be experimental and received meditation with the SC and ST biofeedback programs.

C = The group obtained by matching pairs was specified to be the control group.

X1 = Meditation program (treatment 1) + routine nursing care

X2 = Meditation program in combination with the SC and ST biofeedback programs (treatment 2) + routine nursing care

X3 = Routine nursing care

O11 = Pre-test stress and depression scores for experimental group 1 before the meditation program

O12 = Post-test stress and depression scores for experimental group 1 after the 6-week meditation program

O21 = Pre-test stress and depression scores for experimental before the meditation program in combination with the SC and ST biofeedback programs

O22 = Post-test stress and depression scores for experimental after receiving the meditation program in combination with the SC and ST biofeedback programs for six weeks

O31 = Pre-test stress and depression scores in the control group

O32 = Stress and depression scores for the control group at week 6

3.2 Sample sampling and setting

3.2.1 Population

The population included adults and older adults diagnosed with type 2 diabetes mellitus (type 2 DM) or type 2 DM with comorbidities that sought treatment at the General Practice Outpatient Department, TUH in 2019.

3.2.2 Sample

The sample group was composed of the adult, and older adult people diagnosed with type 2 DM or type 2 DM with comorbidities that sought treatment at

the General Practice Outpatient Department, TUH. Data collection was carried out from March to June 2019. Sample selection, sample size, and sampling method are as follow:

3.2.3 Sample selection

(1) Inclusion criteria

The following consideration criteria were set to select the sample group:

1.1 Able to understand and read Thai

1.2 Age range of 35-75 years old

1.3 Blood glucose levels at 70 – 200 mg% (American Diabetes Association, 2019) for the last three months.

1.4 No mental symptoms or psychiatric disorders are obstructing the study, such as schizophrenia and other mental disorders (Kennedy, 1976; Lazarus, 1976).

1.5 Receiving BDI score 10-15 points (mild depression)

1.6 Agree to participate in this study, and able to provide inform consent.

(2) Exclusion criteria

The exclusion criteria for rejecting the subjects were as follows:

2.1 Having other comorbidities or medical complications, such as severe communicable diseases, dementia, and tuberculosis.

2.2 Receiving stress relaxants.

2.3 Having back anomalies preventing sitting for more than 20 minutes.

3.2.4 Sample size

Before conducting the present research, the researcher calculated the desired sample group using power analysis with a power of test set at .80 and a reliability score at 95 percent or a significance (α) at .05 (Polit & Hungler, 1999). A previous research study conducted by Thongkhum, Ruchiwit, & Somprasert (2012) investigated the effect of meditation and biofeedback training program on the stress levels of people with diabetes found Cohen's effect size (f = .33), a median level

(Cohen, 1969). With this effect size, the researcher estimated the sample size by using G* Power 3. 1. 5 to achieve a sample size of 92 subjects together with using a Multivariate Analysis of Covariance (MANCOVA). Since three sample groups were required, 31 subjects were placed in each group. During the study, the researcher increased the sample size for each group by ten percent to compensate for sample attrition. Hence, the total sample size was 102 subjects divided into three groups of 34 subjects each.

3.2.5 Sampling method

The consort flow diagram described the progression of the randomized experiment that was tracked the experimental and control groups consisting of the following four stages (Figure 3.1).

3.2.5.1 Enrollment

The sample group was recruited from the target people population at the General Practice Outpatient Department, TUH by using simple random sampling by drawing lots to obtain subjects for participation. The researcher selected subjects based on set characteristics and inclusion criteria by drawing lots to obtain 102 subjects for participation in the research project in line with the calculated sample size. Additionally, the subjects were selected based on the level of depression (mild level measured by BDI within a scoring range of 10-15 points).

Then the subjects were matched in pairs in three sample groups of 34 subjects per group based on similar characteristics for gender, age, and disease. As mentioned above, age, gender and disease are the variables found to be correlated with depression in people with diabetes (Sun et al., 2016; Rajput et al., 2016; Sardari & Pazokian, 2017; Lee et al., 2017; de Lima Filho et al., 2019). The matched-paired method was used to reduce the chances of extraneous variables influencing the results of this study. The matched-paired method is commonly used to compare treatments without using large numbers of randomized samples. The subjects will be matched in pairs in three sample groups based on similar characteristics for gender, age, and disease. To ensure that the results of the research, namely, the dependent variables, were consistent with the independent variables, the researcher wanted to conduct the study free from the influence of other extraneous variables occurring with some

independent variables. Hence, the extraneous variables were controlled by pairing subjects. In controlling extraneous variables by pairing subjects, the samples for the study were equal for any one or more given extraneous variables. The matching pair method was used to ensure that given extraneous variables were equal between each pair of subjects. Pair-matching is a method for controlling extraneous variables.

3.2.5.2 Random assignment

The participants were randomly assigned to one of the three RCT arms by using simple random sampling by lottery method (random assignment) as follows: 1) meditation and routine nursing care (n = 34), 2) combined meditation with biofeedback and routine nursing care (n = 34), and 3) a control group receiving routine care only (n = 34). By employing a randomized block design, the research was able to ensure directed random assignment to the treatment groups (2 intervention groups and one control group) in equal numbers. Following the inclusion, depression was assessed with the BDI in which mild depression was indicated within scoring ranges of 10 to 15 points. Thus, the group assignments were free from the influence of the baseline measurements. This research can be identified as a blinded experiment since participants do not know about the information on the experiment. They will know information when the experiment is done. The benefit of good blinding is to decrease experimental biases coming from an expectation of participants and other sources.

3.2.5.3 Follow-up

All three sample groups were subjected to the experiment together every week for six weeks. The consort flow diagram regarding the effect of combined meditation with biofeedback training programs on the stress, depression and cortisol levels among people with diabetes is shown in Figure 3.1 as follows.

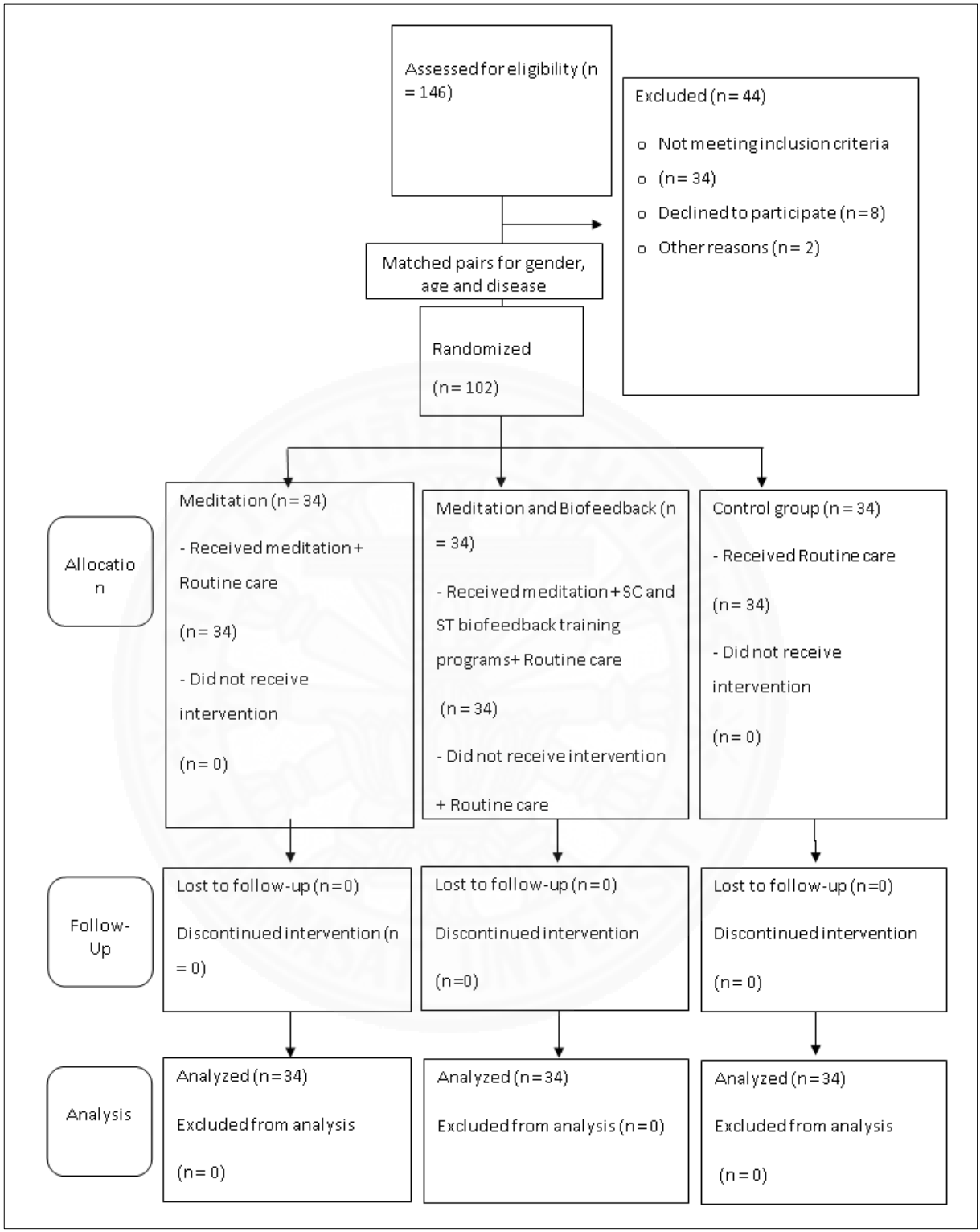


Figure 3.1 Consort flow diagram of the Effect of combined Meditation with Biofeedback Program on the Stress, Depression and Cortisol Levels among People with Mild Depression Diabetes. This diagram was used for each of the one cohort required to complete this research.

It was not feasible to randomize all of the participants at the same time because of 102 participants required to conduct this research. Therefore, the following table presents the number of participants selected for each cohort as well as the number of training hours per/week and the entire sample. As can be seen in Table 3.2, there was 1 number of the cohort with 510 hours with 3 of research assistants.

Table 3.2 Explanation of the cohort

Week 1-6			
Intervention	**N**	**Hours of Training Per/Week**	**Total Hours Overall**
Meditation	34	34	204
Meditation + BF	34	51	306
Control	34	0	0
Total	102	85	510

3.3 The instruments used in the research

3.3.1 Sample selection instruments

For obtaining the data, the following instruments were used for the data collection:

1) A personal questionnaire was used to gather information on the study samples' socio-demographic, including gender, age, and diseases. Five advisory professors and qualified experts performed the content validity testing of the personal questionnaire. This process was examining the content structure, language accuracy, and suitability and content consistency of the activity objectives. Five experts were composed of an endocrinologist and a psychiatrist from Faculty of Medicine, Thammasat University, two experts in the application of complementary therapies from Faculty of Nursing, Thammasat University, and an expert in the application of complementary therapies from Faculty of Nursing, Chulalongkorn University. The

responses of each expert were distributed for frequency using the percentage criteria of experts with concurring opinions at 80 percent and up. Clauses, where the percentage of the measuring behavioral objectives is below 80 percent, will be excluded or modified based on the recommendations received (Rovinelli & Hambleton, 1977).

2) Symptoms of Stress Inventory (SOSI) was 107 questionnaires developed by Leckie & Thompson in 1979 (adjusted from Cornell General Practice Index) and compiled into the Thai language by Marjorie A. Muecke in 1994. The SOSI has assessed the feelings perceived by people regarding health and illness over the preceding month by calculating mean scores obtained from each questionnaire. The items evaluate stress symptoms which are scored on a Likert scale of ranged from 1 to 5. The items are reverse scored whereby higher scores indicate a more significant presence of stress symptoms. Average score from 85 to 169 represents low stress, average stress score from 170 to 340 indicates moderate stress level, the average score from 341 to 425 indicates high-stress level, and average score up to 425 indicates the presence of severe level of stress.

In the previous study, a study was researched in people with ischemic heart disease by Ruchiwit and colleagues (2005), SOSI was carried out. The responses of five experts were distributed for frequency using the percentage criteria of experts with concurring opinions at 80 percent. With using Cronbach's alpha coefficient method, the researcher calculated the SOSI scores for instrument reliability. The results showed the reliability was 0.91. Thongkhum, Ruchiwit conducted another study, & Somprasert (2012) on the effect of meditation and biofeedback program on the stress levels in people who have diabetes mellitus, ischemic heart disease as well as hypertension. SOSI was implemented in 30 people with chronic diseases in one of the university hospitals. Afterwards, the scores were calculated for instrument reliability using Cronbach's alpha coefficient method, and the reliability was 0.87. In this study, SOSI was readjusted to use in people with Diabetes Mellitus. The researcher asked Marjorie A. Muecke for permission to implement SOSI to assess stress levels.

Five advisory professors and qualified experts performed the content validity testing of SOSI. This process was examining the content structure, language accuracy, and suitability and content consistency of the activity objectives. Five experts were composed of an endocrinologist and a psychiatrist from Faculty of Medicine,

Thammasat University, two experts in the application of complementary therapies from Faculty of Nursing, Thammasat University, and an expert in the application of complementary therapies from Faculty of Nursing, Chulalongkorn University. The responses of each expert were distributed for frequency using the percentage criteria of experts with concurring opinions at 80 percent and up. Clauses, where the percentage of the measuring behavioral objectives is below 80 percent, will be excluded or modified based on the recommendations received (Rovinelli & Hambleton, 1977).

The SOSI were tested for reliability by measuring internal consistency. The researcher experimented with 30 people with diabetes that had qualifications similar to the samples that were studied at a university hospital to determine that the instrument can measure with reliability. The scores were then calculated for instrument reliability using Cronbach's alpha coefficient method. If the reliability is higher than .80, the researcher will implement the instruments as the stress and depression assessment forms of the sample group (Polit & Hungler, 1999). The reliability of SOSI was 0.94.

3) The Beck Depression Inventory (BDI) is a depression measurement form created by Beck in 1982. (Beck et al., 1982). BDI has been used in the various study of physical and mental illness. In the previous study, the reliability of BDI was assessed in 598 in people and out people in psychiatric people. The alpha coefficient was .88 and .86, respectively (Beck & Steer, 1984). The BDI was also employed 24 people with type 2 diabetes, and internal reliability was .84 Chaicharoen, Nabkasorn, & Vatanasin, 2018).

BDI was compiled into the Thai language by Prof. Dr. Manyat Ruchiwit in 2005. The researcher asked Prof. Dr. Manyat Ruchiwit for permission to implement BDI to assess depression levels. The internal consistency for the evaluation form ranged from 0.73 -0.92, with a mean value of 0.86. Its reliability score was 0.88. The evaluation form contained 20 questions covering groups of statements for describing current feelings such as feelings or symptoms of physical, psychological and emotional depression. BDI was used to assess depressive disorders such as crying, changed appetite, discouragement, and guilt, loss of interest, sadness, self-confidence, difficulty breathing and suicidal ideation. Most of the above items evaluate symptoms of depression that are scored on a Likert scale ranging from 0 to 3. The cut-off ranking,

which suggests depression, is 10 points or more. The first 15 questions covered psychological symptoms, while the remaining 5 covered physical symptoms. Four choices were available for each item as points ranging from 0 to 3 or from no symptoms (0 points) to severe symptoms (3 points), and subjects were asked to one choice among them to measure depression symptoms. The questions were aimed at inquiring about feelings occurring within the past week. The BDI scoring indicates the depression levels as follows: the normal mood is indicated with 0-9 points; mild mood disturbance is indicated with 10-15 points; borderline clinical depression is indicated with 16-19 points; moderate depression is indicated with 20-29 points; severe depression is indicated with 30-60 points, extreme depression level is indicated with the score more than 60 points.

Five advisory professors and qualified experts performed the content validity testing of BDI. This process was examining the content structure, language accuracy, and suitability and content consistency of the activity objectives. Five experts were composed of an endocrinologist and a psychiatrist from Faculty of Medicine, Thammasat University, two experts in the application of complementary therapies from Faculty of Nursing, Thammasat University, and an expert in the application of complementary therapies from Faculty of Nursing, Chulalongkorn University. The responses of each expert were distributed for frequency using the percentage criteria of experts with concurring opinions at 80 percent and up. Clauses, where the percentage of the measuring behavioral objectives is below 80 percent, will be excluded or modified based on the recommendations received (Rovinelli & Hambleton, 1977).

The BDI was tested for reliability by measuring internal consistency. The researcher experimented with 30 people with diabetes that had qualifications similar to the samples that were studied at a university hospital to determine that the instrument can measure with reliability. The scores were then calculated for instrument reliability using Cronbach's alpha coefficient method. If the reliability is higher than .80, the researcher will implement the instruments as the stress and depression assessment forms of the sample group (Polit & Hungler, 1999). The reliability of the BDI was 0.73.

4) Cortisol level recording form was used to record the cortisol level. Cortisol level recording form included a column of research, number, date and result.

Cortisol is a steroid hormone that helps the body response to stress. The medical technologist drew the people the plasma cortisol at the Medical Technology Laboratory of Thammasat University Hospital according to the standard method of the certified clinical laboratory (BRIA Lab, Bangkok, Thailand). The morning level of cortisol (7-10 a.m.) is from 6.2 to 19.4 ug/dL. The evening level of cortisol (4-8 p.m.) is from 2.3 to 11.9 ug/dL (BRIA Lab, Bangkok, Thailand). The acceptable value of serum cortisol is between 6.2 to 19.4 ug/dL. Higher serum cortisol level indicates stress (Kontoangelos et al., 2015). In this study, serum cortical level was measured before and after the interventions. Thus, cortisol was tested twice in the present study. The first test was performed at approximately 07.30 am, and the second test was performed at about 11.30 am. In the present study, however, a condition was set requiring each people to take a blood test at the same time every day, because the researcher needs to divide people into sub-group. The first sub-group with 17 subjects had their intervention from 08:00–09:30 am, while the second sub-group, also with 17 subjects, had their intervention from 09:30–11:00 am.

5) The home meditation record form

The home meditation record form contained the following items: the date and period when the audio file was played and the meditation practice in addition to post-meditation cognition, feelings and physical changes. Moreover, participants were asked for their phone number and line id information to contact and follow them up during the study. The researcher encouraged the consistency of home meditation by using line group application.

3.3.2 Intervention instruments

3.3.2.1 The meditation program

The meditation program means the method for the minds of people with diabetes to be repaired. This study consists of the subjects which will be linked to a meditation program. The researcher is going to choose transcendental meditation (TM) based on the guidelines of Maharishi Mahesh Yogi by using the audio files of Mrs. Metta Schaffler, a qualified teacher with 45 years of experience from the Center

of TM in Thailand at the Rajapark Institute, to accompany meditation practice. With TM, participants begin by sitting in a comfortable position, closing his/her eyes, and concentrating on a single focal point such as one-word chanting or mantras. This technique is easy to learn and takes no more than 20 minutes morning and evening. As a result, the mind may gradually calm, and the participant may feel relaxed. The meditation program takes 20 minutes. The audio file was divided into two interventions in the present study to guide medication. The audio file was played for people receiving the meditation intervention only, and the audio file was played for people administered meditation in combination with SC & ST biofeedback. The researcher played a meditation audio file for 20 minutes and continued meditating for 10 minutes. If any people had limitations preventing the people from personally playing the audio file at home, the researcher gave instructions to the people's caregivers on playing the audio file for listening, checking and evaluating whether the audio file has been played for the people to hear during meditation.

Five advisory professors and qualified experts performed the content validity testing of the meditation program. This process was examining the content structure, language accuracy, and suitability and content consistency of the activity objectives. Five experts were composed of an endocrinologist and a psychiatrist from Faculty of Medicine, Thammasat University, two experts in the application of complementary therapies from Faculty of Nursing, Thammasat University, and an expert in the application of complementary therapies from Faculty of Nursing, Chulalongkorn University. The responses of each expert were distributed for frequency using the percentage criteria of experts with concurring opinions at 80 percent and up. Clauses, where the percentage of the measuring behavioral objectives is below 80 percent, will be excluded or modified based on the recommendations received (Rovinelli & Hambleton, 1977).

3.3.2.2 The biofeedback program

The origin of biofeedback research was conducted by Yogis and Zem master between 1950s and 1960s. They introduce a method for controlling autonomic function. The skin conductance (SC) and skin temperature (ST) biofeedback instruments were used to test the level of sweating on the skin's surface induced by stress responses. SC and ST biofeedback program is a program for learning physical

functions and using data from biofeedback machines as a signal for monitoring conditions. Biofeedback helps to control automatic physical functions of skin temperature and sweating using individual electrodes that use 1-20 microvolts attached to different parts of the body. ST biofeedback involves the use of equipment in helping people practice body temperature control under mental control as a means of practicing relaxation by controlling changes in temperature. SC biofeedback display physical responses to stress in another form using changes in the amount of sweat on the skin. The instruments will communicate for the people to gain feedback about the relaxation occurring. When relaxation is achieved, the numerical values on the face of the scale will increase, and the needle on the face of the scale will be on the left side. On the contrary, when the people feel stress, the numerical values on the face of the scale will decrease, and the need will move to the right.

The current accuracy of the SC and ST biofeedback machines was determined by using the known group technique. The researcher tried the instruments with five people with diabetes at a university hospital with similar characteristics to the subjects who were studied to determine the instrument sensitivity and stability during implementation by comparing images and audio indicating stress and relaxation.

Besides, the SC and ST biofeedback reliability testing in this study included a calibration of instrument standards. Also, the SC and ST biofeedback reliability testing in this study included calibration of instrument standards. The researcher subjected the standard calibration results of the biofeedback machine obtained from the biofeedback dealership company for repeat testing by experts at the General Practice Equipment Center of TUH. The testing was to verify the status, precision, deviations and changes and measurement uncertainties of the biofeedback machine to ensure high-quality meeting suitable specifications for use as an instrument capable of accurately, precisely and reliably taking measurements and performing tests for the research. The calibration of the biofeedback instruments was performed as follows: Before use, the functioning of various buttons and switches will be checked. Settings were made. The infrared finger sensor will also be checked. The calibration is

a critical process to ensure the device will functioning normally and that the infrared finger sensor is not dirty or wet. Pre-use calibration of SC and ST biofeedback instruments using GSR connected to the signaling apparatus with needles was done by adjusting the needle at zero every time. People who had overly rapid changes in the display were fit the switch by moving it forward to "1/2". In this study, two sets of GSR devices were used. One people used one GSR throughout the experimental phase by setting the numbers to direct the device specifically for each people. The researcher, who was trained in using GSR for this study, was the only people to read the results.

Five advisory professors and qualified experts performed the content validity testing of the biofeedback program. This process was examining the content structure, language accuracy, and suitability and content consistency of the activity objectives. Five experts were composed of an endocrinologist and a psychiatrist from Faculty of Medicine, Thammasat University, two experts in the application of complementary therapies from Faculty of Nursing, Thammasat University, and an expert in the application of complementary therapies from Faculty of Nursing, Chulalongkorn University. The responses of each expert were distributed for frequency using the percentage criteria of experts with concurring opinions at 80 percent and up. Clauses, where the percentage of the measuring behavioral objectives is below 80 percent, will be excluded or modified based on the recommendations received (Rovinelli & Hambleton, 1977).

3.3.2.3 The audio file

The audio file was divided into two interventions in the present study to guide medication. The audio file was played for people receiving the meditation intervention only, and the audio file was played for people administered meditation in combination with SC & ST biofeedback. The researcher played a meditation audio file for 20 minutes and continued meditating for 10 minutes. If any people had limitations preventing the people from personally playing the audio file at home, the researcher gave instructions to the people's caregivers on playing the audio file for listening, checking and evaluating whether the audio file has been played for the people to hear during meditation. Otherwise, a record was made in the home

meditation record form. The record form contained the following items: the date and period when the audio file was played and the meditation practice in addition to post-meditation cognition, feelings and physical changes. Moreover, participants were asked for their phone number information and line id to contact and follow them up during the study.

Table 3.3 The meditation program (Mrs. Metta Cheffer according to Maharishi Mahesh Yogi, 1958)

Week	Components	Time	Strategies	Activities
1	1. Relationship building	5 min	- Establishing good rapport - Creating a positive atmosphere	The researcher built a relationship with the participants, including greeting, introduction, sharing of objectives, practices, duration, and benefits of participation. The researcher also engaged with respondents by requesting information about their current symptoms.
	2. Knowledge sharing	10 min	- Sharing through a learning environment - Group interaction	The researcher shared her knowledge of stress and depression, as well as the benefits of meditation. The researcher distributed a stress management manual, meditation practice leaflets, and an audio file of meditation practice, a brief explanation of how to use SC and ST biofeedback.

Week	Components	Time	Strategies	Activities
	3. Pre-evaluation	40 min	- Evaluating pre-experiment data	The researcher measured SC and ST biofeedback and record the data by using BDI and SOSI evaluation tools before interpreting the data for the people.
	4. Practice process	30 min	- Skill practice - Self-regulation	The participants practiced meditation along with the audio file for 20 minutes, and then the researcher led a meditation for 10 minutes. The basic principles and methods of meditation were as follows: 4.1 Wear loose clothing. Find a quiet corner away from the noise and sounds to avoid outside disturbance with a proper temperature. Prepare a comfortable seat. For example, older people with bad knees can sit on chairs. 4.2 Do not eat until you are excessively full or leave yourself too hungry. 4.3 Sit in the most comfortable position possible that would not cause fatigue, even after an

Week	Components	Time	Strategies	Activities
				extended period of practice. Adjust your posture to stay relaxed and observe whether or not your body is tense. If tense, adjust and relax to avoid tension. 4.4 Breathe deeply, openly, gently and comfortably. Let go of whatever is on your mind. Temporarily let go of your worries. You might set a specific time in the mind you can dedicate to meditating. Bring contentment to your heart, because all you need to do to be content is to want to be content. If you can do that, you will immediately become content. Enjoy this practice of meditation. 4.5 Lightly close your eyes, so the eyelashes meet but do not close them tightly. Once you are comfortable, recite a mantra composed of one- and two-syllable words. Recite them in your mind and place your focus only on the

Week	Components	Time	Strategies	Activities
				sounds of these words. Repeat them over and over again in your mind. This activity will calm your mind into a state of concentration. 4.6 While you are training your mind, you might periodically encounter distractions or hear outside noises. If thoughts occur while you are practicing the mantra, you should focus on the mantra instead. The mantra is the vehicle that will transport your mind back inside. The mantra can change many things. Its rhythm might increase or slow down. Every case of change is a proper way to train your mind. However, proper mental training does not mean that the mantra has to be present all the times. Frequently the mantra and thoughts alternate. Do not resist your thoughts and let yourself go comfortably.

Week	Components	Time	Strategies	Activities
				4.7 If you begin to have a headache or physical discomfort while you are meditating, do not try to resist the practice. Just close your eyes and lie down for about five to ten minutes. It means that you will not maintain the same mantra or that you can change the rhythm of the mantra. Let it go naturally and do not resist your thoughts. 4.8 Once your mind has calmed, it will arrive at transcendental consciousness. You might experience odd sensations. These symptoms present themselves differently depending on the state of mind of each people, e.g. twitching, dozing off, drowsiness, becoming startled; feeling like your body is spinning, lightness of weight, shivering,

Week	Components	Time	Strategies	Activities
				goosebumps, and others. Just let go. 4.9 The proper way for you to exit your meditation is not to open your eyes for more than two minutes. Opening your eyes too quickly can cause a headache. During the two minutes that our eyes are still closed, we can move and slowly open our eyes.
1	5. Evaluation process	5 min	- Evaluating post-experiment data - Homework assignment - Sharing experiences - Group interaction	The participants were allowed to ask questions and share ideas. Then they were requested to practice meditation at home for 20 minutes daily, record their meditation practice, and submit the home meditation log forms to the researcher the next week. A review of the daily logs helped the researcher monitor the participant's fidelity to home meditation practice.
2-5	1. Relationship building	10 min	- Social support	The researcher started greeting the participants, ask about their illness, and

Week	Components	Time	Strategies	Activities
			- Encouraging activities - Group sharing	monitor their meditation record. Then the researcher asked for post-meditation feedback and encouraged the participants to practice daily.
	2. Practice process	30 min	- Skill practice - Self-regulation	The participants practiced meditation along with the audio file for 20 minutes, and then the researcher led meditation for 10 minutes.
	3. Evaluation	20 min	- Evaluation of post-experiment data - Social support - Encouraging activities	The participants were allowed to ask questions and share the idea. Then they were requested to practice meditation at home for 20 minutes daily, record their meditation practice, and submit the home meditation log forms to the researcher the next week. A review of the daily logs helped the researcher monitor the participant's fidelity to home meditation practice.
6	1. Relationship building	5 min	- Establishing good rapport - Creating a positive atmosphere	The researcher started greeting the participants, ask about their current symptoms and general topics and monitor their meditation

Week	Components	Time	Strategies	Activities
				record. Then the researcher asked about their feeling and perceived changes after practicing meditation for five weeks.
	2. Practice process	20 min	- Skill practice - Self-regulation	The participants practiced all procedures of meditation by themselves without using the audio file or the assistance of the researcher.
	3. Evaluation	45 min	- Evaluations post-experiment data - Social support - Addressing benefits - Encourage activities	The participants were allowed to ask questions and share ideas, and then measure their stress after experimentation by using SC and ST biofeedback and the record data by using the BDI and SOSI evaluation tools. The researcher interpreted the results for the participants and announced the completion of the research. The participants were encouraged to continuously practice meditation to reduce their stress in their daily lives and to promote both their physical and mental health.

Week	Components	Time	Strategies	Activities
	4. Meditation practice with biofeedback based on research ethics	20 min	- Skill practice - Self-regulation	The researcher identified changes after the practice and encouraged the participants to apply their experiences in their daily lives to controlling their psychological stress without using biofeedback.

Table 3.4 The Meditation with the SC and ST Biofeedback Programs

Week	Components	Time	Strategies	Activities
1	1. Relationship building	5 min	- Establishing good rapport - Creating a positive atmosphere	The researcher built a relationship with the participants, including greeting, introduction, sharing of objectives, practices, duration, and benefits of the participation. The researcher also engaged with the respondents by requesting information about their current symptoms.

Week	Components	Time	Strategies	Activities
	2. Knowledge sharing	5 min	- Sharing through a learning environment	The researcher shared her knowledge of DM, stress and depression The researcher distributed the stress management manual, meditation practice leaflets, and the audio file of meditation practice and a brief explanation of how to use SC and ST biofeedback.
	3. Pre-evaluation	35 min	- Evaluation of pre-experiment data	Before interpreting the data for the participants, this process required SC and ST biofeedback and the recording of data by using the BDI and SOSI evaluation tools.
	4.Practice process	30 min	- Skill practice - Self-regulation	The participants practiced meditation along with the audio file for 20 minutes, and then the researcher led meditation and SC and ST biofeedback for 10 minutes.
	5. Evaluation	15 min	- Evaluations post-experiment data - Social support - Addressing benefits	The researcher measured the participants' stress by using SC and ST biofeedback, recording the meditation practice, and interpreting the results to the participants. The

Week	Components	Time	Strategies	Activities
			- Encourage activities	participants were allowed to ask questions and share ideas, and they were requested to practice meditation at home for 20 minutes daily, record their meditation practice, and submit the home meditation log forms to the researcher the next week. A review of the daily logs helped the researcher monitor the participant's fidelity to home meditation practice.
2-5	1. Relationship building	5 min	- Establishing good rapport - Creating a positive atmosphere	The researcher started greeting the participants, ask about their illness, and monitor their meditation record, and then she asked for post-meditation feedback and encouraged the participants to practice daily.
	2. Pre-meditation measurement	10 min	- Evaluation of pre-experiment data	The researcher measured the participants' stress by using SC and ST biofeedback, and interpreting the results to the people.
	3. Practice process	30 min	- Skill practice - Self-regulation	The participants practiced meditation along with the

Week	Components	Time	Strategies	Activities
				audio file for 20 minutes, and then the researcher led meditation and SC and ST biofeedback for 10 minutes.
	4. Evaluation	15 min	- Evaluations post-experiment data - Social support - Addressing benefits - Encourage activities	The researcher measured the participants' stress by using SC and ST biofeedback, recording the meditation practice, and interpreting the results to the people. The participants were allowed to ask questions and share ideas, and they were requested to practice meditation at home for 20 minutes daily, record their meditation practice, and submit the home meditation log forms to the researcher the next week. A review of the daily logs helped the researcher monitor the participant's fidelity to home meditation practice.
6	1. Relationship building	5 min	- Establishing good rapport - Creating a positive atmosphere	The researcher started greeting the participants, asked about their current symptoms and general topics, and monitored their

Week	Components	Time	Strategies	Activities
				meditation record. Then the researcher asked about their feeling and perceived changes after practicing meditation for five weeks.
	2. Pre-meditation measurement	10 min	- Evaluation of pre-experiment data	The researcher measured the participants' stress by using SC and ST biofeedback, and interpreting the results to the people.
	3. Practice process	30 min	- Skill practice - Self-regulation	The participants practiced all of the methods of meditation by themselves without using the audio file or the assistance of the researcher. SC and ST biofeedback was applied.
	4. Evaluation	45 min	- Evaluations post-experiment data - Social support - Addressing benefits - Encourage activities	The researcher measured the participants' stress by using SC and ST biofeedback and recording the data by using the BDI and SOSI evaluation tools, recording their meditation practice, and interpreting the results to the people. The researcher announced the completion of the research and asked the

Week	Components	Time	Strategies	Activities
				participants about their feelings for 6 weeks. The participants were encouraged to continuously practice meditation to reduce the stress in their daily lives and to promote both their physical and mental health.

3.5 Routine care

Routine nursing care means individual consultation and group health education for people with diabetes in the control group in which people do not receive meditation and do not meditate together with SC and ST biofeedback program.

3.6 Ethical consideration

The researcher submitted the research proposal for the consideration of the Research Ethics and Research Methodology Subcommittee of the Faculty of Nursing (number of project code: 094/2018) and the Human Research Ethics Committee of Thammasat University Hospital, Thammasat University. The permission to use the General Practice record in this study was given by the Director of TUH, the head of the General Practice Outpatient Department, and participants. The researcher asked the participants to voluntarily participate in the study and given them enough time/study information to make the decision. To guarantee that the people comprehended the study, the researcher expressed communication to the participant in two ways, including written and verbal forms. The participants were informed of the details about the background and purpose of the research along with the procedures, including the

potential risks and benefits. The benefits of participating in this study concluded learning technique for self- regulation to reduce complications from stress and depression. In term of risk assessment of the engagement of the study, the researcher measures the people' readiness regarding physical and mental health regularly. If participants decided to take part in the study, they were asked to sign a consent form. The researcher allowed the participants to withdraw from the research project without any conditions. General Practice professors had approved all research procedures with expertise in the field of endocrinology and metabolism from the Department of Internal Medicine, Thammasat Hospital, who was a qualified expert in this study. If during the research project, the participants were found to have risk from abnormalities, the researcher provided support and referred people for immediate treatment in line with their treatment entitlements in addition to monitoring the participants until participants were safe.

After receiving permission from Thammasat University Hospital Director, the researcher preceded the experiment and collected data from the sample group. Before assembling the data and preceding the experiment, the sample group was informed about research objectives, details about study subjects' rights program throughout the research duration, and benefits of participating in the research program.

3.7 Data collection

3.7.1 Preparation for data collection

3.7.1.1 The researcher received training courses as follows; 1) three days course on stress relief using biofeedback program taught by Prof. Dr. Manyat Ruchiwit; 2) five days courses on TM taught by Mrs. Metta Cheffer (45 years experiences on meditation at Rajapark Institute, Thailand). After finished those courses, the researcher received a certificate for a three-day biofeedback program administered

by the Psychiatric Nurse Association of Thailand and a certificate for a five-day TM program administered by Rajapark Institute, Thailand.

3.7.1.2 The research assistants received training on how to utilize meditation and biofeedback by an expert who is a nursing professor of the Faculty of Nursing, Thammasat University.

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

3.7.1.4 The permission to conduct the study was given by the Director of Thammasat University Hospital.

3.7.1.5 The researcher gave information of this study to the head nurse and staffs of the General Practice Outpatient Department for their cooperation in data collection.

3.7.2 Data collection

3.7.2.1 The researcher established a good rapport. Then the researcher informed the purpose of the research along with the procedures, including the potential risks/hazards and benefits. All of the information stated in the documentation were provided explanations to the people. If participants did not agree to take part in the study, they were treated the same as other people in the hospital. It did not negatively affect their treatment. They were free to not participate in the study and change their mind at any point during the study without giving any reason. Information collected from participants and medical records were stored securely and kept confidentially, and only overall results were reported. If participants decided to take part in the study, they were asked to sign a consent form.

3.7.2.2 The 102 subjects were randomly allocated one of three RCT arms: 1) meditation (n = 34); 2) a combination of meditation and SC & ST biofeedback (SC & ST, n = 34) and 3) a control group (n = 34). All three groups received routine nursing care.

3. 7. 2. 3 Experimental group 1 concluded adults and older adults diagnosed with type 2 DM or type 2 DM with comorbidities that sought treatment at the General Practice Outpatient Department, TUH. The researcher played a meditation audio file for 20 minutes and continued meditating for 10 minutes. If any people had limitations preventing the people from personally playing the audio file at home, the researcher gave instructions to the people's caregivers on playing the audio file for listening, checking and evaluating whether the audio file has been played for the people to hear during meditation.

3. 7. 2. 4 Experimental group 2 received a meditation program in combination with biofeedback. The program took place consecutively over six weeks with one 90-minute session per week and at least 20 minutes of daily meditation at home. People were measured stress by using a biofeedback instrument with sweat control and skin temperature control. The researcher also explained the measurement results and the interpretation of the results. A stress evaluation form (SOSI) and a depression evaluation form (BDI) were used. Before people completed these forms, the researcher explained how to complete the forms to the people and gave opportunities for people to ask questions, and the researcher answered any questions the people raised. If a people was found to be unable to complete the evaluation forms personally, the people were interviewed instead. The research assistants collected data. After evaluation forms were completed, the researcher and the research assistant verified data entered in the evaluation forms. If data were found to be incomplete or inaccurate, the people concerned would be returned the forms for reevaluation until all required data were wholly entered. Afterwards, all data were recorded as pre-test data. This process required 35 minutes. The people have assessed the questionnaires and tests like the following: (a) socio-demographic data form; (b) SOSI; (c) BDI; (d) the SC and ST biofeedback score. Furthermore, the people were received a blood test to measure the serum cortisol level.

3.7.2.5 A record was made in the home meditation record form. The record form contained the following items: the date and period when the audio file was played and the meditation practice in addition to post-meditation cognition, feelings and physical changes. Moreover, participants were asked for their phone number and line id information to contact and follow them up during the study. The researcher encouraged the consistency of home meditation by using line group application.

3.7.2.6 The control group receive routine care based on the guidelines of TUH.

3.7.2.7 For post-test of the experiment, the people have assessed the questionnaires and tests like the following: (a) socio-demographic data form; (b) SOSI; (c) BDI; (d) the skin conductance (SC), and skin temperature (ST) biofeedback score; Furthermore, the people were received a blood test to measure the serum cortisol level.

3.7.2.8 These following factors are used to build good environment for patients namely, purpose clarity, possessing group interaction skills, good listening skills, proper physical environment, caring dispositions, and sufficient time.

3.8 Data analysis

In this study, data analysis was performed in the following three sections:1) data screening in which the researcher will test for normality and missing data; 2) reports on descriptive statistics and socio-demographic data after the intervention; 3) primary analysis and testing of one research hypothesis. Thus, all of the research questions were submitted to intent-to-treat (ITT) analysis to minimize reporting bias on treatment outcomes. This analysis increased the chance of generating a positive treatment bias effect (Shrier et al., 2014). This study used SPSS Version 24 Missing Analysis to evaluate the missing data's scope and patterns. As stated above, the data screening stage of the data analysis was conducted to test for normality and missing data. At this stage, the researcher assessed the normality assumptions with the use of Shapiro-Wilk and Q-Q plot (Hair et al., 2010; Field, 2009).

Next, the researcher employed an SPSS V24 Missing Value Analysis to assess the type and degree of data attrition. In terms of classification, data could be

categorized as missing completely at random (MCAR), missing at random (MAR), or not missing at random (NMAR). The degree and types of missing values determined how the data are to be attributed with the use of multiple imputations based on an entirely conditional Markov Chain Monte Carlo (MCMC) model. In such cases, a monotone protocol was utilized for more monotone types or monotone patterns (Allison, 2002). The researcher then assessed the stress and depression levels of the three sample groups. To determine whether there are significant variances between the two databases, the researcher performed a sensitivity analysis of the original data with missing values and imputed values for the ITT analysis across all relevant predictors and outcomes. As long as no significant variances were discovered in the sensitivity analysis, the researcher used the imputed ITT data to perform the primary analyses. However, if variances were found between the original data and the imputed ITT database, the researcher used both databases in the hypothesis testing of the hypothesis. Lastly, the researcher described any variances discovered in the research findings (Bell et al., 2014; Carpenter et al., 2007).

In this study, the socio-demographic and descriptive data were discussed in the form of a preliminary analysis using mean, frequency, and standard deviation. These findings also were categorized by treatment group. The researcher then employed one-way ANOVA as the method of testing for continuous variables on the baseline differences between the three treatment groups. Next, the researcher used chi-square testing to examine the differences in the categorical variables among the treatment groups (Field, 2009). Lastly, the researcher explored the variances in the socio-demographic variables and baseline dependent SOSI and BDI variables across groups, and SC and ST biofeedback values were explored.

3.8.1 Primary Analyses

In this section, the researcher described the methods of hypothesis testing

Hypothesis 1*:* Mean scores on stress, depression and cortisol level would be significantly lower in the meditation and the combination of meditation with biofeedback group than those in the control group at six weeks after completion of the intervention.

For this hypothesis, multivariate analysis of variance (MANOVA) was applied to each group to find the difference between the results of the pre-test stress, depression and cortisol in the same group. For comparison of the different post-test mean of stress, depression and cortisol, multivariate analysis of covariance (MANCOVA) was used to analyze the results of comparison by testing groups

Hypothesis 2: Mean scores on stress, depression and cortisol level would be significantly lower in the combination of meditation with biofeedback group than those in the meditation group at six weeks after completion of the intervention.

For this hypothesis, the researcher performed an analysis among the groups by employing measures MANOVA, which will enable investigation of the latent construct for the combined outcomes; namely, stress (SOSI) and depression (BDI). This method of analysis was capable of detecting potential variances possibly overlooked in the examinations of each construct.

The researcher discovered statistically-significant variances in the socio-demographic characteristics or baseline values. The researcher modified the MANOVA and ANOVA instruments. The modified versions then were used for hypothesis testing, after which the research retained any significant covariates in the model. The researcher then removed any variances exhibiting no statistical significance from the above model to enable the adoption of a more parsimonious model (Hair et al., 2010).

Regarding the outcomes for depression (BDI), stress (SOSI), and the differential effects of the treatment group were compared across measurement points from pre-test to post-test. Next, the researcher used ANOVA for the data analysis to determine any statistically-significant variances among the three treatment groups. In the analysis mentioned above, the dependent variable was to be a continuous interval or ratio measure. In contrast, the independent variables in the analysis were to be categorized as either nominal or ordinal variables. Next, the researcher was able to test the assumption of homogeneity of variances by employing instruments such as Levene's test.

The researcher used multivariate analysis of covariance (MANCOVA) to compare the varied scores in the linear combination of stress and depression measured by the SOSI and BDI among all of three groups and to determine

significant group differences while also controlling for type I error. The researcher used MANCOVA for further data analysis, aimed at evaluating the statistical differences in the multiple continuous dependent variables using an independent grouping variable while also enabling the control of the covariate. The assumptions for the MANCOVA are the same as those for the MANOVA except for the fact that one more assumption related to the covariate is added. In MANCOVA, the assumptions are that the independent variables are categorized, and the dependent variables must be either continuous or scaled. Hence, covariates can be continuous, ordinal, or dichotomous. Also, to be considered is the absence of multicollinearity. In other words, the dependent variables cannot be over-correlated; instead, the correlation should exceed r = .90. Next is normality, whereby multivariate normality needs to be reported in the data.

Moreover, the homogeneity of variance in which the variance between the groups has to be equal. Last are the correlations between the covariate(s) and dependent variables. When researchers selected covariates, they generally determined the existence of a statistical relationship between the covariate(s) and dependent variables. This analysis was carried out by applying the correlational analysis.

However, the analysis results for the serum cortisol by the group were used for the separate analysis. The results of the comparison between pre-test stress and depression indicated that each group had unequal pre-test stress and depression. Hence, the pre-test means of stress and depression were determined as a covariate for post-test analysis When considering correlations between depression and serum cortisol and between stress and serum cortisol, they had very low levels of correlation (r=0.12; 0.19). Multivariate analysis of variance (MANOVA) was suitable to analyze for stress and depression analysis, and MANCOVA was also used because of the covariate variables. Besides, Analysis of Variance (ANOVA) was conducted to examine the results of comparison by testing groups.

Based on the results of the normal distribution test using the Shapiro-Wilk test and the Q-Q plot, it was found the stress score measured by skin conductance and the skin temperature of both variables had no normal distribution. Non-parametric statistics were required for the analysis, where further data analysis needed to compare the stress score measured by skin conductance and skin temperature in the pre-test and post-test. Thus, the Wilcoxon signed-rank test was used for comparison analysis

between skin conductance and skin temperature during the pre-test and post-test in combined meditation with biofeedback program.

CHAPTER 4
RESULTS AND DISCUSSION

The study aimed to study the effect of combined meditation with biofeedback on the stress, depression and cortisol levels among people with mild depression diabetes. It was also a three-arm randomized controlled trial. Based on inclusion criteria, 102 subjects were divided and randomized into three groups of 34 each. Subjects in experimental group 1 were trained meditation, subjects in experimental group 2 were trained meditation in combination with the SC and ST biofeedback, and the control group did not have the. The quantitative findings were evaluated depression and stress scores by comparing the mean pre -and post-test among all three groups, the control group and the experimental group. Before and after the experiment, blood was collected to measure serum cortisol. This study had an experimentation period of six weeks. The findings are presented by using tables accompanied by descriptions in the order indicated below.

Part 1: The primary data of the research sample were categorized by gender, age, the highest level of education, marital status, monthly income, income sufficiency, occupation, treatment rights, diagnosis, and length of illness.

Part 2: Analysis to answer the research hypotheses

4.1 Part 1: The primary data of the research sample

Part 1: The research sample's primary data were categorized by gender, age, the highest level of education, marital status, monthly income, income sufficiency, occupation, treatment rights, diagnosis, and length of illness.

In this study, the 102 subjects were divided and randomized into experimental group 1, experimental group 2, and the control group with 34 subjects in each group.

1) The samples included three groups of respondents, 34 persons each, which were the experimental group 1, experimental group 2, and the control group. The subjects were selected in pairs based on identical profiles in terms of gender, age, and

disease. The mean age of all three groups was 59.49 (SD = 9.69). In all of three groups of diabetic people, over half (61.76%) were female with most participants (41.86%) fell into the 56-65 years of age group with equal percentages of the sample having diabetes (47.6%) and diabetes with hypertension (47.6%). About 76.5 % of the people had been sick for five years or less, while 71.57 % had been sick for longer than ten years. When using the chi-squared test, the findings showed that gender, age, level of education, marital status, monthly household income, income sufficiency, occupation, medical rights, and symptom diagnoses had no statistically-significant at the level of 0.05. This finding represents that the characteristics of primary data of meditation group, meditation and biofeedback group and control group are equal and suitable for testing in the next statistical test as shown in Table 4.1.

Table 4.1 The comparison of demographic data among three groups using Chi-square (n=34)

Personal Data		Meditation		Meditation with Biofeedback		Control		Total		Chi-Square		
		n	%	n	%	N	%	n	%	Value	*df*	*p*
Gender	Male	13	38.24	13	38.24	13	38.24	39	38.24	3.99	2	0.13
	Female	21	61.76	21	61.76	21	61.76	63	61.76			
	Total	34	100.00	34	100.00	34	100.00	102	100.00			
Age (years)	Under 45	5	14.71	5	14.71	5	14.71	15	14.71	8.34	8	0.40
	46 – 55	5	14.71	5	14.71	5	14.71	15	14.71			
	56 – 65	14	41.18	14	41.18	14	41.18	42	41.18			
	66 – 75	10	29.41	10	29.41	10	29.41	30	29.41			
	Mean (SD)		59.27 (10.51)		58.18 (10.25)		61.03 (8.30)		59.49 (9.69)			
	Total	34	100.00	34	100.00	34	100.00	102	100.00			
Educational level	No formal education	3	8.82	2	5.88	0	0.00	5	4.90	13.09	10	0.22
	Primary school	12	35.29	10	29.41	19	55.88	41	40.20			
	Secondary school	3	8.82	5	14.71	1	2.94	9	8.82			
	High school, Vocational certificate	4	11.76	8	23.53	4	11.76	16	15.69			
	High vocational certificate, Diploma	4	11.76	3	8.82	1	2.94	8	7.84			
	Bachelor's degree, Master's Degree	8	23.53	6	17.65	9	26.47	23	22.55			

Personal Data	Meditation		Meditation with Biofeedback		Control		Total		Chi-Square		
	n	%	n	%	N	%	n	%	Value	*df*	*p*
Total	34	100.00	34	100.00	34	100.00	102	100.00			

Table 4.1 The comparison of demographic data among three groups using Chi-square (n=34) (Cont.)

	Personal Data	Meditation (n=34)		Meditation with Biofeedback (n=34)		Control (n=34)		Total		Chi-Square		
		n	%	n	%	N	%	n	%	Value	*df*	*p*
Marital Status	Single	3	8.82	4	11.76	3	8.82	10	9.80	2.89	8	0.94
	Married	26	76.47	25	73.53	26	76.47	77	75.49			
	Widowed	2	5.88	4	11.76	3	8.82	9	8.82			
	Divorced	1	2.94	1	2.94	1	2.94	3	2.94			
	Separated	2	5.88	0	0.00	1	2.94	3	2.94			
	Total	34	100.00	34	100.00	34	100.00	102	100.00			

	Personal Data	Meditation (n=34)		Meditation with Biofeedback (n=34)		Control (n=34)		Total		Chi-Square		
		n	%	n	%	N	%	n	%	Value	*df*	*p*
Household Monthly Income	Under 10,000	16	47.06	13	38.24	12	35.29	41	40.20	1.06	2	0.59
	Over 10,000	18	52.94	21	61.76	22	64.71	61	59.80			
	Total	34	100.00	34	100.00	34	100.00	102	100.00			
Income Sufficiency	Sufficient	16	47.06	13	38.24	12	35.29	41	40.20	1.06	2	0.59
	Insufficient	18	52.94	21	61.76	22	64.71	61	59.80			
	Total	34	100.00	34	100.00	34	100.00	102	100.00			

Table 4.1 The comparison of demographic data among three groups using Chi-square (n=34) (Cont.)

Personal Data		Meditation (n=34)		Meditation with Biofeedback (n=34)		Control (n=34)		Total		Chi-Square		
		n	%	n	%	n	%	n	%	Value	df	p
Occupation	Unemployed	10	29.41	5	14.71	5	14.71	20	19.61	11.29	8	0.19
	Government/state enterprise employee	14	41.18	14	41.18	13	38.24	41	40.20			
	Self-employed/private company employee	2	5.88	6	17.65	7	20.59	15	14.71			
	Merchant/business owner	7	20.59	8	23.53	4	11.76	19	18.63			
	Agriculturist	1	2.94	1	2.94	5	14.71	7	6.86			
	Total	34	100.00	34	100.00	34	100.00	102	100.00			
Rights to medical care	At their own expense	5	14.71	5	14.71	3	8.82	13	11.76	4.46	6	0.61
	Claimable medical fee	21	61.76	19	55.88	26	76.47	66	64.71			
	Universal coverage ID card	3	8.82	2	5.88	2	5.88	7	6.86			
	Social Security	5	14.71	8	23.53	3	8.82	16	15.69			

	Personal Data	Meditation (n=34)		Meditation **with** Biofeedback (n=34)		Control (n=34)		Total		Chi-Square		
		n	**%**	**n**	**%**	**n**	**%**	**n**	**%**	Value	d*f*	p
	Total	34	100	34	100	34	100	102	100			
Comorbidity	Diabetes	16	47.06	16	47.06	16	47.06	48	47.06	6.03	6	0.41
	Diabetes and ischemic heart disease	1	2.94	1	2.94	1	2.94	3	2.94			
	Diabetes and hypertension	16	47.06	16	47.06	16	47.06	48	47.06			
	Diabetes, ischemic heart disease and hypertension	1	2.94	1	2.94	1	2.94	3	2.94			
	Total	34	100.00	34	100.00	34	100.00	102	100.00			

4.2 Part 2: Analysis for answering the research hypotheses

4.2.1 Analysis results for the comparison of stress, depression and serum cortisol among three groups

4.2.1.1 Preliminary data analysis of the variables

When the results of the preliminary data analysis of the variables were categorized by sample, the findings revealed the sample in the meditation group and the meditation and biofeedback group to have lower mean post-test scores for the variables than mean pre-test scores for every variable. Only serum cortisol in the control group had a higher mean post-test score that the pre-test score for the variable. When testing with meditation was considered for stress (pre-test: M = 188.29, SD = 22.15: post-test: M = 183.94, SD = 21.49), depression (pre-test: M = 12.35, SD = 1.39: post-test: M = 11.68, SD = 1.32) and serum cortisol (pre-test: M = 10.97, SD = 3.09: post-test: M = 10.79, SD = 3.43), the mean post-test scores were lower than the pre-test scores.

When testing with meditation and biofeedback was considered for stress (pre-test: M = 180.50, SD = 16.77: post-test: M = 173.56, SD = 16.62), depression (pre-test: M = 11.97, SD = 1.11: post-test: M = 10.62, SD = 0.78) and serum cortisol (pre-test: M = 12.89, SD = 3.72: post-test: M = 11.52, SD = 3.62), the mean post-test score was also lower than the pre-test score when testing with meditation.

When testing with the control for stress, the mean post-test score for the variable was lower than the mean pre-test score (pre-test: M = 215.35, SD = 11.65: post-test: M = 214.18, SD = 10.96), and depression had only a slightly higher mean post-test score than the pre-test score for the variable (pre-test: M = 12.82, SD = 11.36: post-test: M = 12.85, SD = 1.54), whereas serum cortisol had a higher mean post-test score for the variable than the pre-test score, which differed from other variables (pre-test: M = 10.46, SD = 3.07: post-test: M = 11.32, SD = 3.20). These results were presented in Table 4.2.

Table 4.2 Mean scores of stress, depression, and cortisol level at pre- and post- test among 3 groups (n = 34)

Testing	Meditation				Meditation&biofeedback				Control			
	Min	Max	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean	SD
Stress												
Pre-test	156	247	188.29	22.15	146	214	180.50	16.77	199	242	215.35	11.65
Post-test	147	239	183.94	21.49	144	205	173.56	16.62	191	241	214.18	10.96
Depression												
Pre-test	10	15	12.35	1.39	10	14	11.97	1.11	10	15	12.82	1.36
Post-test	10	14	11.68	1.32	10	12	10.62	0.78	10	15	12.85	1.54
Serum cortisol												
Pre-test	6.27	19.47	10.97	3.09	8.61	22.42	12.89	3.72	6.69	18.67	10.46	3.07
Post-test	6.21	20.03	10.79	3.43	6.88	21.00	11.52	3.62	6.00	19.20	11.32	3.20

4.2.1.2 Analysis of primary research objectives

(1) Analysis of correlation between variables

When considering correlations between depression and serum cortisol and between stress and serum cortisol, they had very low levels of correlation (r=0.12; 0.19). Multivariate analysis of variance (MANOVA) was suitable to analyze for stress and depression analysis, and MANCOVA was also used because of the covariate variables. However, the analysis results for the serum cortisol by the group were used for further separate analysis.

Table 4.3 Correlation coefficient between depression and serum cortisol, between stress and serum cortisol, and between stress and depression

Variable	Stress	Depression	Serum cortisol
Stress	1		
Depression	0.50*	1	
Serum cortisol	0.19	-0.12	1

* $p < 0.05$

(2) Comparison between pre-test stress and depression by group

According to the findind of the comparison between pre-test stress and depression categorized by meditation, meditation together with SC and ST biofeedback, and control group by MANOVA, it was found that the stress and depression mean vectors were different, with a statistical significance at the level of 0.05 (Pillai's trace = 0.61, p = 0.00), using Pillai's trace for multivariate analysis as Pillai's trace was the most powerful statistic for the mean difference analysis. In the case of conflict of primary agreement concerning unequal covariance (Hair, Black & Babin, 2010), when analyzing the variance by variables and analysis of variance, it was found that every variable was different by testing groups with a statistical significance at the level of 0.05. When comparing the mean in pairs, it was found that the stress in the control group was higher than in the meditation group and the stress in the control group was higher than

meditation and biofeedback group with statistical significance at the level of 0.05. In terms of depression, it was found that depression in the control group was higher than in the meditation and biofeedback group with statistical significance at the level of 0.05.

The results of the comparison between pre-test stress and depression indicated that each group had unequal pre-test stress and depression. Hence, the pre-test means of stress and depression were determined as a covariate for post-test analysis, as shown in Table 4.4.

Table 4.4 Analysis of variable variance

Statistics	**Value**	***F***	**Hypothesis df**	**Error *df***	***p***
Pillai's trace	0.61	21.64	4	198	0.00
between-subjects effects Test					
Source	**Dependent variable**	**Type III SS**	***df***	***MS***	***F***	***p***	**Pair comparison**
Variable	Stress	4.19	2	2.10	52.93	0.00	Control > Meditation Control > Meditation and biofeedback
	Depression	0.21	2	0.11	27.02	0.00	Control > Meditation and biofeedback

*** p < 0.05**

(3) Comparison between post-test stress and depression by group

Based on the mean comparison post-test between stress and depression by group, multivariate analysis of covariance was used due to the mean difference test of the pre-test groups. It was shown that the mean scores were different, with a statistical significance for each pre-test group. Thus, the test enabled the control of the covariate, and it was found that the variance-covariance matrix of variables in each group was different with a statistical significance of the level of 0.05 (*Box's M* = 35.81, *F* = 5.79, *df1* = 6, *df2* = 244271,

$p = 0.00$). This result was not in accordance with the preliminary agreement, but as these analytic statistics had the potential to violate the agreement. The analysis could be used for Pillai's trace (Tabachnick, Fidell, & Osterlind, 2007). When considering the correlation of dependent variables, it was found that both post-test variables had statistically significant correlation at the level of 0.05 (Approx. Chi-Square = 28.14, df = 1, p = 0.00). The results showed that both variables were suitable for the MANCOVA, as seen in Table 4.5.

Table 4.5 Primary statistics of post-test stress and depression measurement by group

Testing Group	n	Stress		Depression	
		M	*SD*	*M*	*SD*
Control	34	214.18	10.96	12.85	1.54
Meditation	34	183.94	21.49	11.68	1.32
Meditation and biofeedback	34	173.56	16.62	10.62	0.78
Remark	*Box's M* = 35.81, *F* = 5.79, *df 1* = 6, *df2* = 244271, *p* = 0.00 Bartlett's test: Approx. Chi-Square = 28.14, *df* = 1, *p* = 0.00 Levene's test: Stress- *F* = 1.41, *df1* = 2, *df2* = 99, *p* = 0.25, Depression *F* = 1.60, *df1* = 2, *df2* = 99, *p* = 0.21				

According to the results of the MANCOVA by using the pre-test score as a covariate, it was presented that the mean vectors of post-test stress and depression of each group were different with a statistical significance at the level of 0.05. When analyzing variance by variables and comparison of paired means, it was found that stress and depression were different by group with a statistical significance at the level of 0.05 (Pillai's trace=0.31, p=0.00). When considering the control group, the mean of stress and depression was higher than in the other groups. Due to the meditation group, the mean of stress and depression was higher than in the meditation and biofeedback group with a statistical significance at the level of 0.05. Table 4.6 displays the results.

Table 4.6 Analysis of variance of post-test stress and depression elements by multivariate group

	Pillai's trace	***F***	**Hypothesis *df***	**Error *df***	***p***
Pre-test stress	0.89	402.00	2	96	0.00
Post-test depression	0.17	10.03	2	96	0.00
Testing group	0.31	8.88	4	194	0.00

Analysis of between-subjects effects

Source	**Dependent Variable**	**Type III SS**	***df***	***MS***	***F***	***p***
Pre-test stress	Post-test stress	3.42	1	3.42	803.71	0.00
	Post-test depression	0.00	1	0.00	0.31	0.58

Between-subjects effects Analysis

Source	**Dependent Variable**	**Type III SS**	***df***	***MS***	***F***	***p***
Pre-test depression	Post-test stress	0.00	1	0.00	0.10	0.76
	Post-test depression	0.06	1	0.06	19.53	0.00
Testing group	Post-test stress	0.10	2	0.05	12.04	0.00
	Post-test depression	0.08	2	0.04	12.05	0.00

Tests of between-subjects effects						
Source	**Dependent Variable**	**Type III SS**	***df***	***MS***	***F***	***p***
Error	Post-test stress	0.41	97	0.00		
	Post-test depression	0.32	97	0.00		
Corrected total	Post-test stress	8.11	101			
	Post-test depression	0.60	101			

4.2.2 Analysis results for comparison of pre-test and post-test serum cortisol by group

Based on the analysis results for the pre-test and post-test serum cortisol of each group using dependent t-test, when considering the meditation group, it was found that the pre-test and post-test serum cortisol of the meditation group were not different with a statistical significance at the level of 0.05 (t=0.58, p=0.57). When considering the meditation and biofeedback group, it was found that the pre- test and post-test serum cortisol of the meditation and biofeedback group were different with a statistical significance at the level of 0.05 (t=4.13, p=0.00). When considering the control group, it was found that the pre-test and post-test serum cortisol of the control group were different with a statistical significance at the level of 0.05 (t=-2.38, p=0.02).

Experimental group 1 had 34 people with diabetes. After six weeks of meditation, the subjects were found to have lower mean post-test serum cortisol scores (M = 10.79, S.D. = 3.43) than their pre-test scores (M = 10.97, S.D. = 3.09) but not met at a statistical significance at the level of 0.05 (t=0.58, p=0.57). Experimental group 2 had 34 people with diabetes. After six weeks of meditation training and biofeedback,

the subjects were found to have lower mean post-test serum cortisol scores (M = 11.52, SD = 3.62) than their pre-test scores (M = 12.89, SD = 3.72) with a statistical significance at the level of 0.05 (t=4.13, p=0.00).

Control group had 34 people with diabetes. After six weeks, the subjects were found to have higher mean post-test serum cortisol scores (M = 11.32, S.D. = 3.20) than their pre-test scores (M = 10.46, S.D. = 3.07) with a statistical significance at the level of 0.5 (t=-2.38, p=0.02). This finding suggested that the mean for the post-test serum cortisol in the control group was higher than the pre-test mean, as shown in Table 4.7.

Table 4.7 Comparison of mean scores on serum cortisol level between pre-test and post-test among three groups

Variable	*M*	*SD*	*t*	*df*	*p*
Pre-test of meditation group	10.97	3.09	0.58	33	0.57
Post-test of meditation group	10.79	3.43			
Pre-test of meditation and biofeedback group	12.89	3.72	4.13	33	0.00
Post-test of meditation and biofeedback group	11.52	3.62			
Pre-test of control group	10.46	3.07	-2.38	33	0.02
Post-test of Control group	11.32	3.20			

For comparison of the different mean of serum cortisol between pre-test and post-test, Analysis of Variance (ANOVA) was used to analyze the results of the comparison by testing groups. It was found that different mean scores of serum cortisol in each group were different with statistical significance at the level of 0.05. In meditation and biofeedback group, mean scores of serum cortisol were decreased more than meditation group with the statistical significance at the level of 0.05, as shown in Table 4.10. According to the results, the people with diabetes that practice meditation and biofeedback had a greater decrease in serum cortisol than those that practice

meditation alone. In the control group, the mean score of serum cortisol was increased with the statistical significance at the level of 0.05

Table 4.8 Analysis of variance of different serum cortisol by group

Different Score of Serum cortisol	Sum of Squares	*df*	*MS*	*F*	*p*	Comparison Result
Between groups	84.89	2	42.44	11.05	0.00	Meditation and biofeedback > Meditation
Within groups	380.17	99	3.84			
Total	465.06	101				

4.2.3 Analysis results of the comparison between skin conductance and skin temperature during both post and pre-test in meditation and biofeedback

4.2.3.1 Normal distribution test of stress measured by skin temperature and conductance and meditation and biofeedback

(1) According to the normal distribution test of Shapiro-Wilk and the Q-Q plot, it was found that the stress scores measured by skin conductance in the pre-test (Shapiro-Wilk =0.74, p=0.00) and the stress scores measured by skin conductance in the post-test (Shapiro-Wilk = 0.73, p=0.00) had no normal distribution with a statistical significance at the level of 0.05, as shown in Table 3 (Appendix A). When considered using the Q-Q plot, it was found that the data characteristics had no normal distribution, as shown in Figure 3 (Appendix A).

(2) The Shapiro-Wilk test and the Q-Q plot are used to investigate the testing of normal distribution, the stress scores measured by skin temperature were found in the pre-test (Shapiro-Wilk =0.74, p=0.00) and the stress scores measured by skin temperature in the post-test (Shapiro-Wilk = 0.73, p=0.00) had no normal distribution, with a statistical significance at the level of 0.05, as shown in Table 7

(Appendix A). When considered by Q-Q plot, there is no normal distribution of both variables, as shown in Figure 7 (Appendix A).

Based on the results of the normal distribution test using the Shapiro-Wilk test and the Q-Q plot, it was found the stress score measured by skin conductance and the skin temperature of both variables had no normal distribution. Non-parametric statistics were required for the analysis, where further data analysis needed to compare the stress score measured by skin conductance and skin temperature in the pre-test and post-test. Thus, the Wilcoxon signed-rank test was used for the analysis.

4.2.3.2 Comparison between skin conductance and skin temperature in the pre-test and post-test in meditation and biofeedback

(1) According to the research results of the stress mean measured by skin conductance between the pre-test and post-test using the Wilcoxon signed-rank test, it was found that the stress scores measured by skin conductance in the pre-test and post-test were different with a statistical significance at the level of 0.05 (Z=-3.45, p=0.00). Mostly, the scores measured by skin conductance tended to increase on the left side or counter clockwise rotation.

(2) Based on the stress score measured by skin temperature using biofeedback, it was found that the scores of skin temperature in the pre-test and post-test were different with a statistical significance at the level of 0.05 (Z=-3.57, p=0.00). Mostly, the scores measured by skin temperature tended to increase on the left side or counter clockwise rotation, as shown in Table 4.9. The results implied that the stress score decreased after training with biofeedback program.

Table 4. 9 Results of the comparison between stress means measured by skin conductance and skin temperature during the pre-test and post-test of the groups

Variable	**Med (IQR)**	***M* (*SD*)**	**Z**	**p-value**
Stress score measured by pre- test skin conductance	0.129 (0.455)	0.28 (0.24)	-3.45	0.00

Stress scores measured by post-test skin conductance	0.121 (0.502)	0.29 (0.26)		
Stress scores measured by pre- test skin temperature	0.131 (0.45)	0.28 (0.22)	-3.57	0.00
Stress scores measured by post-test skin temperature	0.129 (0.49)	0.29 (0.25)		

* **p < 0.05**

4.3 Discussion of the findings

The combination of meditation and biofeedback are nursing activities organized to increase people's stress management skills to reduce exacerbations or complications caused by stress and depression from having a disease. This study compared three sample groups, with 34 subjects in each group, consisting of the control group, which provide only routine treatment, and two experimental groups. The activities for experimental group 1 included meditation with the researcher once a week for 90 minutes per session. The activities performed by experimental group 2 consisted of meditation and biofeedback with the researcher once a week for 90 minutes per time. Both experimental groups had to return to meditate at home every day for 20 minutes a day and exchange their experience during the next week. The pre- and post-test stress and depression in all three groups were assessed by using SOSI, BDI and SC and ST biofeedback. Before and after the intervention, the participants were measured for plasma cortisol concentration. This experiment had a length of six weeks.

4.3.1 Sample group characteristics

The samples included three groups of respondents, 34 persons each, which were the experimental group 1, experimental group 2, and the control group. The subjects were selected in pairs based on identical profiles in terms of gender, age, and disease. The mean age of all three groups was 59.49 (SD 9.69). In all of three groups of

diabetic people, over half (61.76%) were female with most participants (41.86%) fell into the 56-65 years of age group with equal percentages of the sample having diabetes (47.6%) and diabetes with hypertension (47.6%). About 76.5 % of the people had been sick for five years or less, while 71.57 % had been sick for longer than ten years. When using the chi-squared test, the findings showed that gender, age, level of education, marital status, monthly household income, income sufficiency, occupation, medical rights, and symptom diagnoses had no statistically-significant at the level of 0.05. This finding represents that the characteristics of primary data of meditation group, meditation and biofeedback group and control group are equal and suitable for testing in the next statistical test as shown in Table 4.1.

4.4 Effectiveness of the meditation alone and combined meditation with biofeedback

In this study, combined meditation with biofeedback was conducted under the following two research hypothesis.

Hypothesis 1: Mean scores on stress, depression and cortisol level would be significantly lower in the meditation and the combination of meditation with biofeedback group than those in the control group at six weeks after completion of the intervention.

The people with diabetes in the meditation group were found to have significantly lower mean scores on stress, depression and cortisol level than the people in the control group at six weeks after completion of the intervention.

The findings answered with research hypothesis 1.

Meditation originated from Selye's Theory of Stress that was identified by Hans Selye, who explained how stressors act to trigger specific reactions. Based on Hans Selye's theory of stress, stress is a state of pressure against the body and mind that can be diagnosed only by specific symptoms. Stress causes the body to become unbalanced due to many changes, most importantly, the automatic nervous system and the endocrine system (Schwartz & Andrasik, 2017). Especially the adrenal gland and

the sympathetic nervous system are correlated with energy, actions, and survival or "fight or flight" behaviors. This happening causes the limbic part of the brain to send emotional impulses to the hypothalamus, thereby stimulating the sympathetic nervous system and the adrenal glands to secrete adrenaline and cortisol (Madkhali et al., 2019; van Vuuren & Pillay, 2019; Wichmann et al., 2017; Roelfsema et al., 2017; Ruchiwit, 2015). The incident causes the patient to exhibit physical, behavioral, cognitive, and emotional symptoms such as perspiration, headaches, accelerated heart rate, elevated blood glucose and pressure levels, insomnia, attention deficit, anger, and depression (Halter & Varcarolis, 2014).

When people practice transcendental meditation (TM), their bodies achieve a condition marked by deep relaxation in which fatigue and stress are eliminated, and brain function is orderly. Thus, the bodies of people who practice TM are generally healthier and more integrated. During deep TM, breathing becomes shallower, the heart rate slows, and the person's entire cardiovascular system achieves deep relaxation, which is the opposite of the fight or flight response. The levels of various chemical indicators of stress, such as blood lactate and cortisol, become significantly reduced (Pascoe & Crewther, 2017; Kumar et al., 2018; Kiran et al., 2017). Also, the body's muscle systems spontaneously relax in various parts of the body. Consequently, deeply-rooted stress, tension, and fatigue dissipate, while the immune system strengthens and the nervous system achieves balance. When the people meditated regularly, they felt more relaxed, thereby increasing their skin temperature and decreasing skin conductance (Lindquist, Tracy & Snyder, 2018).

The people with diabetes that meditated at home every day for six weeks can be explained to have reduced their automatic nervous system and endocrine system functions. These effects cause the body to secrete less adrenaline and noradrenaline and to secrete endorphins, causing the mind to be comfortable and stress-free (Priya & Kalra, 2018; Santhanam, Preetha & Devi, 2018). During deep transcendental meditation, as the mind proceeds to experience a finer level of thought that makes the mind empty and

idle, the whole body becomes calm and quiet (Gathright el al., 2019; Santhanam, Preetha & Devi, 2018; Shader & Taylor, 2017).

Furthermore, regular home meditation for at least 20 minutes is beneficial for one's perceptions, feelings, and one's body. Meditation also helps people relieve and reduce their stress, feel relaxed, reduce distractions, promote peaceful conditions, and reduce their anxiety. People can broaden their perspectives, make accurate decisions, understand themselves, be mindful, be aware of their feelings, be optimistic, live happy lives, be willing to interact and support others. Moreover, they feel relaxed and have a clear mind. To ensure successful meditation, people need faith, perseverance, commitment, and discipline to practice regularly.

According to the home meditation, experimental group 1 and experimental group 2 were found to have meditated every day for 20 minutes per time. Experimental group 1 meditated before dawn (2 subjects or 5.89%) and at night before sleep (32 subjects or 94.11%). Experimental group 2 meditated before dawn (1 subject or 2.94%) and before sleep (33 subjects or 97.06%). Most of the subjects meditated before sleep because it was a time when the subjects were free and peaceful, thereby allowing them to meditate longer. Most of the people chose an appropriate time, particularly in the morning or evening; and based on visits to the people's homes, the people were found to be able to meditate in line with the distributed audio file and booklets. Some people reported a lack of concentration initially and had to take occasional breaks until the third week before they were able to meditate consistently. The researcher advised and encouraged them in their practice from the first to the last week. Most of the people reported feeling relaxed, comforted, and rested from sleep, causing them to have enthusiasm in attending group activities every time. This finding concurred with the work of Thongkhum, 2015, who found people that participated in the meditation project to be satisfied with the method of relieving stress by meditation. Thus, the findings from the experiment concurred with the other studies that people who received meditation had less stress. (Priya & Kalra, 2018; Latheef, 2017; Santhanam, Preetha & Devi, 2018; Shader & Taylor, 2017; van Son et al., 2015).

The people with diabetes in the combined meditation with biofeedback group were found to have significantly lower mean scores on stress level than the people in the control group at six weeks after completion of the intervention.

When the people practiced meditation with the biofeedback every week by using SC biofeedback and ST biofeedback, they learned to discern the differences between their feelings during stress and relaxation. Biofeedback originated from Selye's Theory of Stress that was identified by Hans Selye, who explained how stressors act to trigger specific reactions. The aim of biofeedback is controlling physiological processes to facilitate regulation of autonomic nervous system activity, which is ordinarily susceptible to heightened metabolic activity brought about by stress (Aaraji, Nosratabadi & Hoseinpourfard, 2018; Shenefelt, 2017; Schwartz & Andrasik, 2017; Ruchiwit, 2015). Meditation caused the people to relax, thereby resulting in psycho-physiological changes. Besides, the people received feedback data during the biofeedback from the GSR machine's monitor. Consequently, and people were able to perceive their stress levels and control or reduce them. This finding occurred because the brain memorized relaxation during training. Thus, the people learned and were able to distinguish between the differences in stress and relaxation.

When the people practiced meditation with the SC and ST biofeedback every week, they learned to control their physical reaction by using their mind. When the people returned home, they meditated every day, thereby resulting in more effective stress control than the people that only meditated as a result of experience from meditation and feedback from the biofeedback without continually relying on instruments for measurement. When the people were assessed with the SOSI based on their pre- and post-test perception, the people with diabetes that received combined meditation with biofeedback were found to have significantly lower mean scores on stress level than the people in the control group at six weeks after completion of the intervention These findings concurred with the results of a study by Thongkhum (2015), who found meditation with biofeedback to be able to relieve stress in people better than meditation alone.

Foe meditation training, the people with diabetes in the combined meditation with biofeedback group were found to have significantly lower mean scores on depression level than the people in the control group at six weeks after completion of the intervention.

According to Aaron T. Beck's cognitive model, schemata, cognitive errors, cognitive triad, and automatic thoughts are the key components in developing and maintaining the treatment of clinical depression (Beck, 1976). In this study, the sample group with a mild level of depression was included. A mild level of depression is marked by sadness and lack of freshness. Furthermore, the person has less enthusiasm about work, reduced interested in the environment, and is more prone to crying than usual (Khan, Lutale & Moledina, 2019; Madkhali et al., 2019; Bener et al., 2017; Bener, Ozturk & Yildirim, 2017; Albikawi, Abuadas & Al-Jabery, 2015; Jayaprasad, Bhatkule & Narlawar, 2018; Khambaty et al., 2017; Krishna, 2018; Rehman & Kazmi, 2015). Depression management for people with diabetes includes encouraging to enhance their self-awareness, focus on their current situation, and never allow their minds to be influenced by triggers, be realistic in assessing their situation, interpret or think to understand their problems. Moreover, they should have a flexible perception, eliminate negative emotions, handle situations with rationales, and promote their mindfulness (Rehman & Kazmi, 2015).

TM can be defined as a process of directing a person's attention toward the core of his or her inner being at cognitive levels as the person's mind experiences the finest state of cognition as the person reaches the origin of cognition. Practiced regularly, TM offers greater coherence in brain function, where the person's mind becomes more comprehensive, focused, and creative and intelligent. TM gives people inner strength, homeostasis, and satisfaction and awareness while relieving stress (Gathright el al., 2019; Santhanam, Preetha & Devi, 2018; Shader & Taylor, 2017). During deep transcendental meditation, the people have the power of concentration, increasing willpower and enhancing the ability to maintain inner peace. In TM training, practitioners achieve a state known as transcendental consciousness where the practitioner experiences unlimited awareness leading to better creativity and higher intelligence (Priya & Kalra, 2018; Santhanam, Preetha & Devi, 2018; Shader & Taylor, 2017; van Son et al., 2015).

As a result of strengthening the conscious mind, better coordination between the mind and the nervous system is established, and the smooth and efficient functioning of the body is the natural result. When people practice transcendental meditation, their bodies achieve a condition marked by deep relaxation in which fatigue and stress are eliminated. That is, meditation practice allows the body to take a rest deeply and fully. Deep rest causes physical stress relief (Pascoe & Crewther, 2017; Shader & Taylor, 2017). Meditation helps the parasympathetic nervous system to work better, which means that the patient's mind will calm down and be free from stress. The heart rate and blood pressure are lowered.

The people with diabetes who meditated at home every day for six weeks can be explained to have reduced automatic nervous system and endocrine system functions. Meditation leads to the body to secrete less adrenaline and noradrenaline and secrete endorphins, causing the mind to be comfortable and stress-free. When the people meditated regularly, they felt more relaxed, thereby increasing electrical resistance at the skin and temperature at peripheral skin (Thongkhum, 2015; Ruchiwit, 2015). Moreover, it decreases other emotional responses such as fear, anger, and sadness etc. (Tovote et al., 2015; Priya & Kalra, 2018; Santhanam, Preetha & Devi, 2018). The findings of this research concur with work by Armani Kian and colleague, in a study of people with type 2 diabetes. In that study, the experiment was conducted over eight sessions of meditation, and it turned out that the meditation effectively lower depression scores with statistical significance ($p<0/05$) after the administration of the program. Thus, the study shows that meditation is a program capable of reducing depression symptoms.

For biofeedback training, the people with diabetes in the combined meditation with biofeedback group were found to have significantly lower mean scores on depression level than the people in the control group at six weeks after completion of the intervention.

When the people practiced combined meditation with biofeedback every week by using SC biofeedback to check their sweat gland function and ST biofeedback to check their body temperature at the skin, the people learned effective methods for relaxing from stress. Combined meditation with biofeedback helped the brain to

remember stress and relaxation. Consequently, the meditating people learned to discern the differences between their feelings during stress and relaxation because of the biofeedback instruments communicated for the person to gain feedback about the relaxation occurring. If the people feel relaxed, the needle on the monitor will turn to the left and numerical values will rise. And if people feel stressed, the needle on the monitor will turn to the right or counter clockwise rotation, and numerical values will drop.

From the first stage of the experiment, the people began to perceive stress levels and to familiarize themselves with the program in next weeks until they had completion of d the six-week program. The people were able to perceive their stress levels and control or reduce them. The values displayed on the GSR monitors indicated the people's physical reactions to stress during the program (Ruchiwit, 2015). The people's feelings of practical relaxation training from the displays of physical changes via the biofeedback machines gave them the strength to practice relaxing and to continue to reduce their stress. (Ruchiwit, 2015; Thongkhum, 2015; Moss & Khazan, 2015; Schwartz & Andrasik, 2017; Seidi et al., 2016; Edwards, 2016).

Combined meditation with biofeedback for the weekly monitoring of sweat glands and skin temperature for six weeks, together with practicing meditation at home at least 20 minutes a day, made people learn from their practice until they became familiar with practicing. Moreover, they received positive reinforcement from their positive behavior caused by coherent emotions and thoughts. This practice allows people to learn and adapt their thoughts, perceptions, feelings, behavior properly, resulting in peacefulness, relaxation, and freedom from stress and depression. The people with diabetes in the combined meditation with biofeedback group were found to have significantly lower mean scores on depression level than the people in the control group at six weeks after completion of the intervention. (Priya & Kalra, 2018; Latheef, 2017; Santhanam, Preetha & Devi, 2018; Shader & Taylor, 2017; van Son et al., 2015).

The people with diabetes in the meditation group were found to have significantly lower mean scores on cortisol level than the people in the control group at six weeks after completion of the intervention.

The people with diabetes in the meditation group were found to have significantly lower mean scores on cortisol level than the people in the control group at six weeks after completion of the intervention. People with diabetes can be described as having physical, psychological, and social stressors. According to Hans Selye, stress is the body's response to threats. Stress causes the body to become unbalanced due to many changes, most importantly, the automatic nervous system and the endocrine system (Schwartz & Andrasik, 2017). Especially the adrenal gland and the sympathetic nervous system are correlated with energy, actions, and survival or "fight or flight" behaviors. These changes cause the limbic part of the brain to send emotional impulses to the hypothalamus, thereby stimulating the sympathetic nervous system and the adrenal glands to secrete adrenaline and cortisol (Madkhali et al., 2019; van Vuuren & Pillay, 2019; Wichmann et al., 2017; Roelfsema et al., 2017; Ruchiwit, 2015). Cortisol plays vital roles, duties, and functions in responding to psychological stress in the body (McCullough et al., 2015).

Psychological stress triggers the the hypothalamic-pituitary-adrenal (HPA) axis and the sympathetic nervous system (SNS). Once an acute stressor triggers the HPA axis, the neuropeptide hormone corticotrophin-releasing hormone (CRH) is hyper-secreted by the hypothalamus. Next, the CRH goes to the anterior pituitary gland, where the secretion of the adrenocorticotrophic hormone (ACTH) is triggered and released into the person's bloodstream. Consequently, cortisol secretion is triggered (Bechtoldt & Schneider, 2016; Kala & Nivsarkar, 2016; Walvekar, Ambekar & Devaranavadagi, 2015). In people with diabetes suffering from stress and depression, the indicators of HPA-axis hyperactivity are at higher cortisol levels (Madkhali et al., 2019; Kumar et al., 2018).

According to the findings, the levels of serum cortisol among the people with diabetes were lowered due to the implementation of meditation. The practitioners of TM can learn about the advanced practice to enhance their cognitive and active abilities as a result of the slightest, more powerful state of awareness. TM makes the mind alert and comprehensive as both cognitive and physical activity. TM provides

deep relaxation and control that enable the body's immune system and other healing processes to restore balance and healthy physiological functioning. At the same time, the activity of the mind and the nervous system is acutely balanced and steady; thus, the mind becomes quiet and calm. This condition is marked by the absence of sensations such as fear, anxiety, stress, and depression (Gathright el al., 2019; Santhanam, Preetha & Devi, 2018; Shader & Taylor, 2017; van Son et al., 2015). Meditation helps reduce the response from the adrenal glands allowing the adrenal gland to produce less adrenalin hormone, noradrenalin hormone and cortisol hormone, which are hormones associated with stress. Meditation causes the adrenal cortex to produce fewer cortisol hormones. (Madkhali et al., 2019; Kumar et al., 2018). The findings concurred with a cluster-randomized trial study conducted by Hee Young Jung and colleagues (2015) that studied the effect of meditation on serum cortisol levels of people with diabetes mellitus after receiving the meditation program. The study, as mentioned above, found people' cortisol levels in the experimental group to be a significant reduction (Jung, H. Y., Lee, H., & Park, J; 2015).

The people with diabetes in the combined meditation with biofeedback group were found to have significantly lower mean scores on cortisol level than the people in the control group at six weeks after completion of the intervention.

Combined meditation with biofeedback, people can learn and control their physical reactions by using their mind. During initial practice, biofeedback is a tool that allows the people to become familiar with their feelings linked with their bodily functions, and this helps them experience their emotions and understand how to control their body functions (Perera, Rathnarajah & Ekanayake, 2016; Schwartz & Andrasik, 2017). Besides, psychological stress has been known to result in unpleasant physiological effects such as cortisol levels (McCullough et al., 2015; Bechtoldt & Schneider, 2016; Kala & Nivsarkar, 2016). Meditation causes the adrenal cortex to produce fewer cortisol hormones. When using combined meditation with biofeedback, people feel more relaxed. Cortisol hormone levels in the blood are at a lower level regardless of reducing stress (Wichmann et al., 2017; Maduka., Neboh & Ufelle, 2015; Joseph & Golden, 2017) and depression (Jain et al., 2018; Wichmann et al., 2017; Melin et al., 2017; Moica et al., 2016).

Hypothesis 2: Mean scores on stress, depression and cortisol level would be significantly lower in the combination of meditation with biofeedback group than those in the meditation group at six weeks after completion of the intervention.

The people with diabetes in the combined meditation with biofeedback group were found to have significantly lower mean scores on stress, depression and cortisol level than the people in the meditation group at six weeks after completion of the intervention. The findings supported the research hypothesis 2.

The research findings demonstrate the effectiveness of the meditation and biofeedback in reducing stress, depression and serum cortisol after the meditation and biofeedback were administered. The stress, depression and serum cortisol of the diabetic people were noticeably reduced after the people had participated in the program for six sessions at approximately 60-90 minutes per session and one session per week. The subjects practiced meditation at home in the same manner as their practice in the hospital, and they practiced every day for at least 20 consecutive minutes for six consecutive weeks.

Daily transcendental meditation practice for six weeks can cure the psychological effects of people with diabetes. As the practitioner concentrates during TM, awareness becomes acute in a state of restful alertness, referred to as transcendental consciousness. TM improves concentration, prevents over-thinking, and allows people to focus on reality by using a mantra (Priya & Kalra, 2018; Santhanam, Preetha & Devi, 2018; Shader & Taylor, 2017; van Son et al., 2015). TM allows people to be aware of the present moment, to recognize, understand, accept, and let go of the distress that has occurred to themselves rather than trying to change and challenge what has happened (Priya & Kalra, 2018; Santhanam, Preetha & Devi, 2018; Shader & Taylor, 2017; van Son et al., 2015). TM can train the practitioner to control his or her mind for heightened awareness and accepting-without-judgment stressful events or conditions. TM will enable people to separate their thoughts and reality and recognize the changes that happen when having their thoughts until such thoughts are gone. After practice, people will become more peaceful and manage their negative thoughts better. Their mind will become peaceful and become self-aware until the stress is decreased

(Priya & Kalra, 2018; Santhanam, Preetha & Devi, 2018; Shader & Taylor, 2017; van Son et al., 2015). Besides, awareness allows for good emotional health, mitigates anger, antisocial behavior, stress, and depression as well (Tovote et al., 2015; Gathright el al., 2019; Priya & Kalra, 2018; Santhanam, Preetha & Devi, 2018; Xu, Jia, Liu, & Hofmann, 2016). The findings concurred with a study conducted by Robin Whitebird and colleagues (2018) that studied to investigate diabetes distress of people with diabetes mellitus after receiving the meditation program. This study indicated that people' stress and depression after receiving meditation was a significant improvement (Whitebird, R. et al.; 2018).

TM not only allows people to have less stress and depression, but it also enables them to control their lives and develop their flexibility when they have to face any crisis in future. Also, TM allows people to face and resolve their problems systematically and effectively. According to the Maharishi, the TM process involves an extension of consciousness while tapping both creative energy and intelligence. Meditation can train the practitioner to control his/her mind to minimize his/her anxiety with a coping mechanism that is a calm and non-destructive reaction to stressful events. In this way, TM can employ meditative skills to form a detachment from anxiety, which is commonly found together with major depressive disorder. Consequently, people will receive good results and have less stress and depression (Jung, Lee & Park, 2015; Kumar et al., 2018; BAnSAl, MittAl & Seth, 2016; Jayaprasad, Bhatkule & Narlawar, 2018; Gathright el al., 2019; Latheef, 2017; Priya & Kalra, 2018; Santhanam, Preetha & Devi, 2018; Williams-McGahee, 2015).

Additionally, TM enables people to consider cause and effect relationships better. The reasoning is a mental mechanism that allows people to accept the reality that they have encountered so that they will try to eliminate their grief and create positive situations through meditation. Depressive disorder people tend to be unable to think thoroughly and systematically. This effect results in difficulties with problem-solving, even if it is just a small issue. Some people feel desperate about solving problems. A

study conducted among DM people by Gagan Priya and Sanjay Kalra, the finding revealed that most DM people with depression to be people that had problems in life and that were unable to solve their problems (Priya & Kalra, 2018).Moreover, TM leads to better creativity, higher intelligence, organizing brain function, enhancing harmony, and developing positive social interactions. Additionally, people will learn how to react appropriately to the situations they are facing. It is considered mental development to be free from distress.

Furthermore, the lack of social skills and interpersonal skills is associated with depression. It was reported that DM people with depression feel disappointed with their self and do not feel enjoyment with their situation environment, such as family, friends, work, and activities (Jayaprasad, Bhatkule & Narlawar, 2018; Priya & Kalra, 2018; van Son et al., 2015). TM makes the mind alert and comprehensive, as both cognitive and physical activities improve self and others. TM increases creativity and intelligence, self-confidence, self-esteem, and self-assertiveness and inner control. Thus, TM boosts the social skills of people, and their depression will, therefore, be decreased (Gathright el al., 2019; Priya & Kalra, 2018; Santhanam, Preetha & Devi, 2018; Shader & Taylor, 2017).

Apart from psychological changes, people that regularly practice meditation are known to undergo physiological changes. There are many physiological changes generated by meditation practice. When patient practice transcendental meditation, their bodies achieve a condition marked by deep relaxation, in which fatigue and stress are eliminated, and brain function is orderly. That is, meditation practice allows the body to take a deep and full rest and this results in physical stress relief. Meditation helps the parasympathetic nervous system to achieve balance, which means that the patient's mind will calm down and be free from stress (Priya & Kalra, 2018; Shader & Taylor, 2017; Tovote et al., 2015).

The fact that people meditated regularly caused them to be calm and to be able to perceive their emotions (Ruchiwit, 2015). Meditation causes the body to secrete adrenaline and noradrenaline less and making their minds feel comfortable (Ruchiwit, 2015; Priya & Kalra, 2018; Lindquist, Tracy & Snyder, 2018). Also, psychological

stress has been known to result in unpleasant physiological effects, such as cortisol levels. Psychological stress triggers the HPA axis and the SNS. Once an acute stressor triggers the HPA axis, the CRH is hyper-secreted by the hypothalamus. Next, the CRH goes to the anterior pituitary gland where the secretion of the ACTH is triggered and released into the person's bloodstream, which takes it to the adrenal cortex where cortisol secretion is triggered (McCullough et al., 2015; Bechtoldt & Schneider, 2016; Kala & Nivsarkar, 2016). In people with diabetes suffering from stress and depression, the indicators of HPA-axis hyperactivity are at higher cortisol levels (Bechtoldt & Schneider, 2016; Kala & Nivsarkar, 2016; Walvekar, Ambekar & Devaranavadagi, 2015). As a person meditates, breathing becomes shallower, and the heart rate slows, and the cardiovascular system achieves a state of intense rest. Levels of various chemical indicators of stress, such as blood lactate and cortisol, become significantly reduced (Tovote et al., 2015; Pascoe & Crewther, 2017; Shader & Taylor, 2017). Moreover, meditation decreases other emotional responses, such as fear, anger, sadness, etc.

Besides, TM affects brain functioning. It has been found that there are changes in the limbic system, which is the emotional control center of the body. TM causes changes in one's feeling, and such changes will be recorded in the emotional control system later, which then will be forwarded to the hypothalamus, which is the center for the integration of various emotional media signals based on neurotransmitters. Catecholamine is a neurotransmitter creating sympathetic activity. During meditation, catecholamine is decreased. Also, meditation practice results in better functioning of the left hemisphere and more positive emotional development. Moreover, meditation generates alpha waves to the brain, including increased secretion of endorphins, a substance that lets the body and mind stay relaxing. All of these changes offer lowered stress and depression (Ruchiwit, 2015; Priya & Kalra, 2018; Lindquist, Tracy & Snyder, 2018). These changes concurred with Sasikumar and Fathima (2017) that found people with type 2 diabetes that participated in the meditation program to be satisfied with the method of relieving stress. It was found that meditation effectively lower stress and depression scores with statistical significance ($p<0/05$) after the intervention ($p<0.000$) (Latheef, F; 2017).

Biofeedback originated from Selye's Theory of Stress that was identified by Hans Selye that explained how stressors act to trigger specific reactions. This model is vital to gaining an understanding of the correlation between stress and health. Selye also created the GAS in which he described the body's stress response in the following three stages: alarm, resistance and exhaustion (Halte, 2015). The aim of biofeedback is relaxation and control of physiological processes to guide people through modifications in their bodies to facilitate regulation of physiological functions that are usually susceptible to the heightened metabolic activity brought about by stress.

Accordingly, the biofeedback is a program that is capable of helping people learn how to relax, as biofeedback instruments feed information back to people through on-screen visual signals, thus enabling people to learn about the progress and success in their practice. While practicing using the instruments, a dial was visible on-screen to let people know whether or not their practice was effective. If a patient meditated consistently and continuously and experienced emotional relaxation, the machine would display higher scores as a reward for the practicing people. The mechanism of biofeedback affects the central nervous system leading to physiological adjustments. When the body learns from experience, and people achieve expertise and desired goals, they are no longer dependent on biofeedback.

The meditation and biofeedback using the biofeedback device for weekly monitoring sweat glands and skin temperature for 6 weeks, together with practice at home at least 20 minutes a day, therefore makes people learn from their training until they become familiar with and receive positive reinforcement from the positive behavior, which is caused by coherent emotions and thoughts, and they reinforce each other. These people have lower sympathetic nervous system and adrenal gland function with increased physiological responses leading to increased skin resistance to electrical currents. This occurrence is because meditating people feel relaxed with less sweat and higher body temperatures. The instruments above show measurements as number scales on the GSR display to inform people whether or not they are training correctly to relax and whether or not stress levels have decreased. The findings concurred with a randomized controlled study conducted by Alison Mackay and colleagues (2015) who studied the effect of biofeedback with another program, including mindfulness as a

psychological intervention. The study mentioned above found that the addition of biofeedback improved the stress levels.

Moreover, people were able to recognize and distinguish among the emotions and feelings emerging during the training. Because these emotions were positive, positive reinforcement facilitated learning in regulating emotions and feelings toward relaxation. By repetitively engaging in this behavior, familiarization was achieved. (Aaraji, Nosratabadi & Hoseinpourfard, 2018; Shenefelt, 2017; Schwartz & Andrasik, 2017; Ruchiwit, 2015; Ngamlwes, 2015). The people's feelings of effective relaxation training from the displays of their physical changes via the biofeedback instrument gave the people strength to practice relaxing so that they could continue to reduce their stress (Aaraji, Nosratabadi & Hoseinpourfard, 2018; van der Zwan et al., 2015; Thongkhum, Ruchiwit & Somprasert, 2015). This practice allows people to learn and adapt their thoughts, perceptions, feelings, and behavior properly, resulting in peacefulness, relaxation, and freedom from stress and depression (Priya & Kalra, 2018; Shader & Taylor, 2017; van Son et al., 2015.

In addition, it provided alternatives to people handling their stress and depression by creating their inner peace and self-control. When people have to deal with an uncomfortable situation, they will automatically realize their stress and be able to apply the stress relief techniques from the practice in order to manage their stress properly, and learn how to resolve the collective stress in their body and mind appropriately (Ruchiwit, 2015; Thongkhum, Ruchiwit & Somprasert, 2015; Schwartz & Andrasik, 2017). The people with diabetes that received the meditation and biofeedback were found to have lower mean post-test depression scores than the people that received meditation only (Priya & Kalra, 2018; Latheef, 2017; Santhanam, Preetha & Devi, 2018; Shader & Taylor, 2017; van Son et al., 2015). The meditation and biofeedback allowed people to learn and adapt their thoughts, perceptions, feelings, and behavior properly, resulting in peacefulness, relaxation, and freedom from stress and depression (Priya & Kalra, 2018; Shader & Taylor, 2017; van Son et al., 2015).When using meditation with biofeedback techniques, people feel more relaxed while serum cortisol is at a lower level regardless of reducing stress (Wichmann et al., 2017; Maduka., Neboh & Ufelle, 2015; Joseph & Golden, 2017) and depression (Jain et al., 2018; Wichmann et al., 2017; Melin et al., 2017; Moica et al., 2016).

Therefore, assessments using SOSI forms based on the people perceptions found self-report on stress wasn't significantly correlated with serum cortisol. Nevertheless, after the experiment, most of the values of plasma cortisol are within normal range with a statistically significant difference. The acceptable value of serum cortisol is between 6.2 to 19.4 ug/ Dl. The sensitivity of cortisol with one or two points of different values is very sensitive. This finding concurred with Anuj Bansal and colleges (2016) who found the mean serum cortisol level in pre-test was 14.83 while in the mean serum cortisol level in post-test after the meditation was 10.59. The results of the study showed a significant reduction in plasma cortisol within the normal range (Anuj Bansal et al., 2016). In this study, the researcher advised and encouraged people in their practice from the first to the last week. Most of the people reported feeling relaxed, comforted, and rested from sleep, causing them to have enthusiasm in attending group activities every time. This finding concurred with the observation from the researcher that found people that participated in the project to be satisfied with the method of relieving stress. The impact of changes in various fields, including the perception and translation of events, especially the rapid changes in the environment, results in factors of stress. This study is a randomized controlled trial which limitations. It is not possible to control the changing of environmental stress all the time during the experiment. Besides, other factors cause stress such as developmental stress, biological stress and stress from perception. Further research should conduct a mix-method to apply qualitative research to more in-depth studies covering all dimensions related to stress and cortisol serum of diabetic patients.

CHAPTER 5
CONCLUSIONS AND RECOMMENDATIONS

The present study used a three-arm randomized controlled trial approach involving meditation, combined meditation with biofeedback, and a control group. Experimental group 1 received the meditation program, experimental group 2 received combined meditation with the SC and ST biofeedback, and the control group received no training program. All three groups received routine care to study the effects of combined meditation with biofeedback on the levels of stress, depression and cortisol level of people with diabetes. Blood was collected to measure the serum cortisol before and after the experiment. The sample group was composed of adult and older adult people diagnosed with type 2 diabetes mellitus or type 2 diabetes mellitus with comorbidities that had mild level of depression and sought treatment at the General Practice Outpatient Department, TUH. The sample was composed of 102 adults with an age range of 35-75 years. The interventions were carried out for six weeks, with a total of four sessions per week from March to June 2019.

The subjects were specified DM with mild depression. The subjects were matched in pairs in three sample groups based on the similar characteristics of gender, age, and disease. including type 2 diabetes mellitus (type 2 DM) and type 2 DM with comorbidities. The samples were divided into three groups, 34 persons each experimental group 1 received meditation program, experimental group 2 received meditation program together with the SC and ST biofeedback programs. In contrast, the control group received no training program for the duration of the experiment. All three groups received routine care, and blood was collected to measure serum cortisol before and after the experiment.

The data collection tools included Symptoms of Stress Inventory (SOSI), the Beck Depression Inventory (BDI), a skin conductance (SC) biofeedback instrument, and a skin temperature (ST) biofeedback instrument. The experiment tools included the

meditation program for experimental group 1 and meditation program with the SC and ST biofeedback programs for experimental group 2.

The research instruments were validated by five qualified experts to examine the content validity of the questionnaire to gather demographic information, the home meditation form, the brochures, and the meditation program together with the SC and ST biofeedback programs. These methodologies were tested with five diabetic people whose profiles were identical to the target samples. The known-group technique was used to measure the concurrent validity of the SC and ST biofeedback machines by applying the method with five diabetic people whose profiles were identical to the target samples. And also compare the characteristics of needle appearing on the screen and practice. The result showed that there is a relationship. From the trial run, it found that the score that the patient received after the training was higher than before the training. It can be concluded that the machine is ready and suitable for use. SOSI and BDI were used to measure reliability by applying the technique with 30 diabetic people whose patterns were similar to the target samples. Then the results were calculated to measure the validity of research tools by using Cronbach's alpha coefficient method. The reliability of SOSI was 0.944, and the reliability of BDI was 0.732. The pre-use calibration of the SC and ST biofeedback instruments using GSR connected to the signalling apparatus with needles can be done by adjusting the needle to zero every time.

This study was based on Hans Selye's theory of stress and Aaron T. Beck's cognitive model. Stress is a state of pressure against the body and mind that can be diagnosed only by specific symptoms. Caused by general physical responses to threats, the symptoms induce physical changes aimed at adapting to the threats through the fight or flight response. (Halter & Varcarolis, 2014). Another theory is Beck's cognitive model. According to this model, schemata, cognitive errors, cognitive triad, and automatic thoughts are the key components in developing and maintaining the treatment of clinical depression (Beck, 1976).

The quantitative data were analyzed using a statistical program at a 0.05 statistical significance.

1) The demographic profiles of the respondents were analyzed by using descriptive statistics and chi-squared statistics.

2) The means of stress scores from SOSI and depression scores from the BDI for both pre- and post-experiments of experimental group 1 and experimental group 2 were analyzed by using mean and standard deviation.

3) The means of stress scores from SOSI and depression scores from the BDI for both the pre- and post-experiment of the experimental group 1 and experimental group 2 and the control group were compared by using dependent t-test.

4) All three groups were compared in terms of the mean pre- and post-test scores regarding the stress and depression of people with diabetes before and after the experiments by using multivariate analysis of covariance (MANCOVA).

5) For comparison of the different mean of serum cortisol between pre-test and post- test, Analysis of Variance (ANOVA) was applied to analyze the results of comparison by testing groups.

6) The stress scores measured by skin conductance and skin temperature in the pre-test and post-test were compared by using the Wilcoxon signed-rank test.

The research findings are as follows:

1) The samples included three groups of respondents, 34 persons each, which were the experimental group 1, experimental group 2, and the control group. The subjects were selected in pairs based on identical profiles in terms of gender, age, and disease. The mean age of all three groups was 59.49 *(*SD = 9.69). The three groups of diabetic people over half (61.76%) were female with most participants (41.86%) fell into the 56-65 years of age group with equal percentages of the sample having diabetes (47.6%) and diabetes with hypertension (47.6%). About 76.5 % of the people had been sick for five years or less, while 71.57 % had been sick for longer than ten years. When using the chi- squared test, the findings showed that the data difference between the three groups showed no statistical significance ($p > 0.05$), implying that the three groups of respondents had the same or similar profiles.

2) Based on the results of the MANCOVA by using the pre-test score as a covariate, it was found that the mean vectors of post-test stress and depression of each group were different with a statistical significance at the level of 0.05. When analyzing variance by variables and comparison of paired means, it was found that stress and depression were different by group with a statistical significance at the level of 0.05 (Pillai's trace=0.31, p=0.00*)*. When considering the control group, the mean of stress and depression was higher than in the other groups. For the meditation group, the mean of stress and dpression was higher than in the meditation and biofeedback group with a statistical significance at the level of 0.05.

3) The mean stress score from the SOSI after the experiment among all three groups of people with diabetes were found to be different with a statistical significance at 0.05. When the differences in the mean scores were compared in pairs, the mean stress scores of the SOSI of people with diabetes that received meditation program (M = 183.94, SD = 21.49) were lower than those of the people that received routine care only (M = 214.18, SD = 10.96) with a statistical significance at 0.05. The mean stress scores of the SOSI of people with diabetes that received meditation program with the biofeedback program (M = 173.56, SD = 16.62) were lower than those of the people receiving routine care only (M = 214.18, SD = 10.96) with a statistical significance at 0.05. The mean stress scores of the SOSI of the people with diabetes that received meditation program (M = 183.94, SD = 21.49) were higher than those of the people that received meditation program with the biofeedback program (M = 173.56, SD = 16.62) with a statistical significance at .0.05.

4) The mean depression scores from the BDI after the experiment among all three groups of people with diabetes were found to be different with a statistical significance at 0.05. When the differences in the mean scores were compared in pairs, as seen in Table 4.5, the mean depression scores of the BDI of people with diabetes that received meditation program (M = 11.68 SD =1.32) were lower than those of the people that received routine care only (M = 12.85, SD =1.54) with a statistical significance at 0.05. The mean depression scores of the BDI of people with diabetes that received meditation program with the biofeedback program (M = 10.62 SD =0.78) were lower than those of the people receiving routine care only (M = 12.85 SD =1.54) with a statistical

significance at 0.05. The mean depression scores of the BDI of people with diabetes that received meditation program (M = 11.68 SD =1.32) were higher than those of the people that received meditation program with the biofeedback program (M = 10.62 SD =0.78) with a statistical significance at 0.05. The pre-test and post-test serum cortisol of the meditation group were different with a statistical significance at the level of 0.05 (t=0.58, p=0.57).

5) The different mean scores of serum cortisol in each group were different with statistical significance at the level of 0.05. In combined meditation with biofeedback group, mean scores of serum cortisol were decreased more than meditation group with the statistical significance at the level of 0.05, as shown in Table 4.10. According to the results, the people with diabetes that practiced meditation and biofeedback had a greater decrease in serum cortisol than those that practiced meditation alone. In the control group, the mean score of serum cortisol was increased with the statistical significance at the level of 0.05.

The pre-test and post-test serum cortisol of the meditation group were not different with a statistical significance at the level of 0.05 (t=0.58, p=0.57). When considering the meditation and biofeedback group, it was found that the pre-test and post-test serum cortisol of the meditation and biofeedback group were different with a statistical significance at the level of 0.05 (t=4.13, p=0.00). When considering the control group, it was found that the pre-test and post-test serum cortisol of the control group were different with a statistical significance at the level of 0.05 (t=-2.38, p=0.02).

Experimental group 1 had 34 people with diabetes. After six weeks of meditation program, the subjects were found to have lower mean post-test serum cortisol scores (M = 10.79, S.D. = 3.43) than their pre-test scores (M = 10.97, S.D. = 3.09) but not met at a statistical significance at the level of 0.05 (t=0.58, p=0.57). Experimental group 2 had 34 people with diabetes. After six weeks of meditation program and biofeedback, the subjects were found to have lower mean post-test serum cortisol scores (M = 11.52, SD = 3.62) than their pre-test scores (M = 12.89, SD =

3.72) with a statistical significance at the level of 0.05 (t=4.13, p=0.00). Control group had 34 people with diabetes. After six weeks, the subjects were found to have higher mean post-test serum cortisol scores (M = 11.32, S.D. = 3.20) than their pre-test scores (M = 10.46, S.D. = 3.07) with a statistical significance at the level of 0.5 (t=-2.38, p=0.02). This result suggested that the mean for the post-test serum cortisol in the control group was higher than the pre-test mean

6) Based on the mean stress scores from the SC and ST biofeedback of people with diabetes that received meditation and biofeedback program, it was found that the stress scores measured by skin conductance in the pre-test and post-test were different with a statistical significance at the level of 0.05 (Z=-3.45, p=0.00). Mostly, the scores measured by skin conductance tended to increase. Based on the stress score measured by skin temperature using biofeedback, it was found that the scores of skin temperature in the pre-test and post-test were different with a statistical significance at the level of 0.05 (Z=-3.57, p=0.00). Mostly, the scores measured by skin temperature tended to increase, as shown in Table 4.9. The results implied that the stress score decreased after training with biofeedback program.

A summary of the findings shows that meditation program with the SC and ST biofeedback programs can reduce the stress and depression of diabetic people. Meditation can effectively alleviate stress and depression, while the biofeedback program helps people to be aware of their stress and to learn how to manage their stress effectively. When using meditation techniques with the biofeedback program, the people feel more relaxed. Moreover, it decreases cortisol hormone, which is hormones associated with stress. By comparing the mean pre- and post-test scores on stress and depression for the people with diabetes before and after experimental group 1 meditated, experimental group 2 meditated and participated in the biofeedback program and the control group received routine care, the findings can be seen as follows. The people with diabetes receiving both meditation and biofeedback had the greatest reduction in the linear combination of stress and depression compared to the mediation only and control groups. Besides, the people with diabetes that practiced both meditation and biofeedback experienced a greater decrease in stress than those that practiced meditation alone and those receiving routine care. Apart from stress, the people with diabetes that practiced meditation and biofeedback experienced a greater

decrease in their depression than those that practiced meditation alone and those receiving routine care. As a result, it can be seen that using biofeedback together with meditation is an effective way to relieve people' stress and depression.

5.1 Research Limitations

The study was aimed to study the effects of combined meditation with biofeedback training program on stress, depression and cortisol level among people with diabetes. The findings showed that these programs could significantly alleviate stress and depression. Concerning the limitations regarding combined meditation with biofeedback, the researcher did not control the treatment of the people at home. Those people had to be treated appropriately by using SC and ST biofeedback for six weeks to ensure that they could control their stress without using the tools. This treatment allows people to apply stress alleviation techniques from meditation to minimize the stress in their daily lives effectively.

5.2 Recommendations

The researcher recommends the application of the research findings as follows:

5.2.1 Policy recommendation

Executives of organizations and related staff at all levels should be aware of the stress and depression of diabetic people in hospitals and evaluate their stress and depression. People should be treated using both meditation and biofeedback programs to alleviate stress and depression.

5.2.2 Applications

5.2.2.1 Based on the findings, meditation and biofeedback programs together can reduce stress and depression, and rehabilitation programs should be provided for diabetic people with mild depression by combining meditation and

biofeedback programs to support the emotional well-being of diabetic people. In terms of the barrier, the advantages to be gleaned from biofeedback can be impeded by practitioner factors. Some examples of these factors include the generally high prices of the devices required, the complexity of implementation, and training opportunities. The principles of biofeedback have been added to the curriculum of graduate students in nursing and psychology. Moreover, senior leaders should support the nurses or medical staff that treat diabetic people to gain knowledge, understanding, and training to enhance expertise and to ensure effective and skilful treatment for stress and depression management.

5.2.2.2 Combined meditation with biofeedback should be arranged for diabetic people in hospitals so that people can handle their stress and depression, which will promote their physical, mental, and social adaptation. Moreover, this study could be public education to people with diabetes that combined meditation with biofeedback is effective in decreasing stress and depression.

5.2.2.3 Hospitals should support the work of diabetes clubs or networks by applying peer-to-peer approaches. Meditation courses can be offered in the form of group activities to promote learning and to motivate people to take care of their health.

5.2.3 Recommendations for further study

5.2.3.1 It should be stated, however, that there are limitations in terms of generalizability or applications in other and diverse contexts. Research should be generalized by including other physiological variables such as Hemoglobin A1C (HbA1C).

5.2.3.2 Research should be monitored in the long run; the researcher can extend the duration of the follow-up to the experiment to ensure that the people can apply meditation to reduce their stress without using tools.

5.2.3.3 The findings on meditation and biofeedback programs should be generalized to other groups of respondents, such as people of different ages or those that have other chronic diseases.

5.2.3.4 A mixed-methods design is required to understand the subjective experiences of these approaches.

5.2.3.5 Regardless, initial evidence supports the benefits of using biofeedback in improving psychological and physiological stress indicators. It has also been indicated that the method of biofeedback can be used as a readily accessible, less expensive component of interventions aimed at coping with or relieving stress. Additional studies should be conducted on the effectiveness of various components of biofeedback interventions. Furthermore, future studies should address the development of innovative technology such as eHealth, etc., in the practices of medication and biofeedback. Along these lines, more research is required on the identification of which biofeedback components have proven to have positive effects on stress and depression. Furthermore, the effects of psychophysiological assessments need to be evaluated to determine whether this part of biofeedback is an application to interventions aimed at managing stress. Biofeedback can be offered in the form of a mobile health application for yielding positive short-term outcomes on physiological and self-reported stress indicators through the use of mobile data and communication technology, namely wearable health care devices, mobile computers, medical sensors (De Witte et al., 2019).

5.3 Summary

The research findings demonstrate the effectiveness of combined meditation with biofeedback program in reducing stress, depression and serum cortisol after the program was administered. The stress depression and cortisol level of the diabetic people were reduced after the people had participated in the program for six sessions at approximately 60-90 minutes per session and one session per week. The subjects practiced meditation at home in the same manner as their practice in the

hospital, and they practiced every day for at least 20 consecutive minutes for six consecutive weeks. Accordingly, the biofeedback program is a program that is capable of helping people learn how to relax, as biofeedback instruments feed information back to people through on-screen visual signals, thus enabling people to learn about the progress and success in their practice. While practicing using the instruments, a dial was visible on-screen to let people know whether or not their practice was effective. If people meditated consistently and continuously and experienced emotional relaxation, the machine would display higher scores as a reward for people.

Moreover, people were able to recognize and distinguish among the emotions and feelings emerging during the training. Because these emotions were positive, positive reinforcement facilitated learning in regulating emotions and feelings toward relaxation. By repetitively engaging in this behavior, familiarization was achieved. Thus, people were able to train themselves without needing their training machines

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APPENDICES

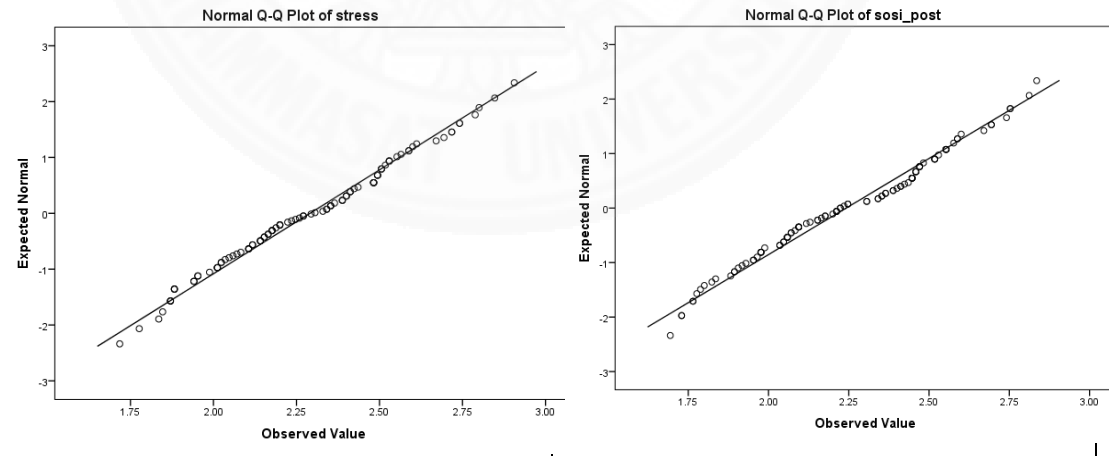
APPENDIX A
ANALYSIS OF ASSUMPTION IN PART 2

1. Normal distribution of stress and depression

According to normal distribution by Shapiro-Wilk test and Q-Q plot, it was found that the characteristics of stress in the pre-test (Shapiro-Wilk =0.98, p=0.30) had no normal distribution with statistical significance at the level of 0.05. But when considering by Q-Q plot, it was found that the data characteristics had normal distribution. Thus, it can be concluded that stress in both periods had normal distribution, as shown in Table 1 and Figure 1.

Table 1 Normal distribution of stress

Variable	Shapiro-Wilk	df	p
Pre-test stress	0.98	102	0.30
Post-test stress	0.98	102	0.05



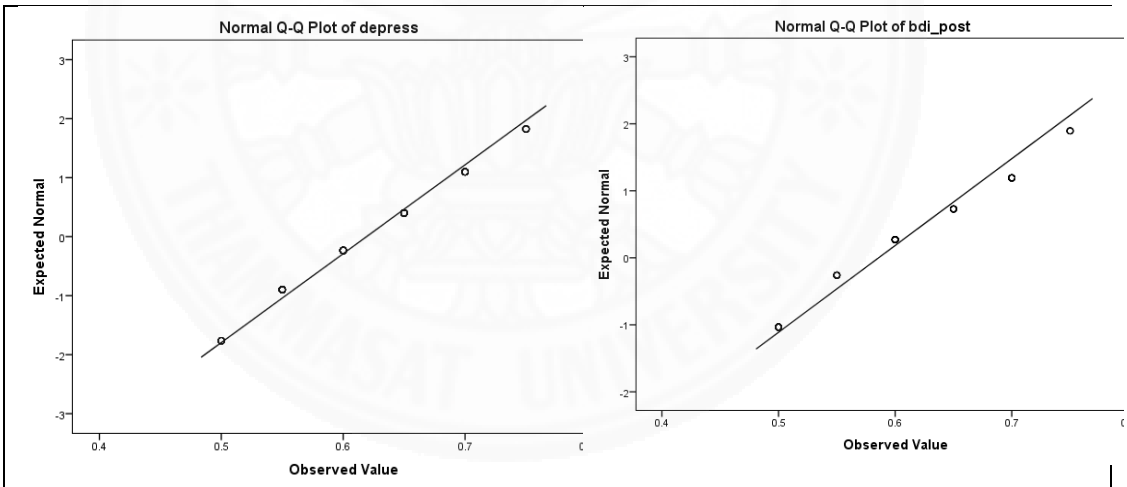
Pre-test Stress	Post-test Stress

Figure 1: Presenting Q-Q of stress in each period

According to normal distribution by Shapiro-Wilk test and Q-Q plot, it was found that the characteristics of depression in the pre-test (Shapiro-Wilk =0.93, p=0.00) and depression in the post-test (Shapiro-Wilk = 0.88, p=0.00) had no normal distribution with statistical significance at the level of 0.05. But when considering by Q-Q plot, it was found that the data characteristics had normal distribution. Thus, it can be concluded that depression in both periods had normal distribution as shown in Table 2 and Figure 2

Table 2 Normal distribution of depression

Variable	Shapiro-Wilk	df	p
Pre-test depression	0.93	102	0.00
Post-test depression	0.88	102	0.00



Pre-test Depression	Post-test Depression

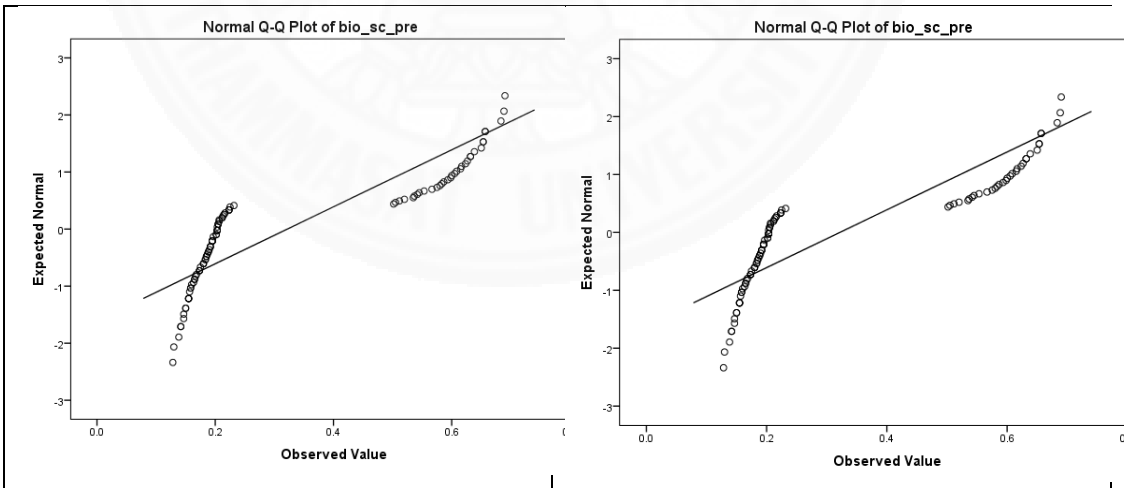
Figure 2: Presenting Q-Q plot of depression in each period

2. Normal distribution test of stress measured by skin conductance and skin temperature in meditation training with the biofeedback program

According to the normal distribution test of Shapiro-Wilk and the Q-Q plot, it was found that the stress scores measured by skin conductance in the pre-test (Shapiro-Wilk =0.74, p=0.00) and the stress scores measured by skin conductance in the post-test (Shapiro-Wilk = 0.73, p=0.00) had no normal distribution with a statistical significance at the level of 0.05. However, when considered using the Q-Q plot, it was found that the data characteristics had no normal distribution, as shown in Table 3 and Figure 3.

Table 3 Testing of normal distribution of stress measured by skin conductance

Variable	Shapiro-Wilk	df	p
Stress scores measured by pre-test skin conductance	0.74	102	0.00
Stress scores measured by post-test skin conductance	0.73	102	0.00



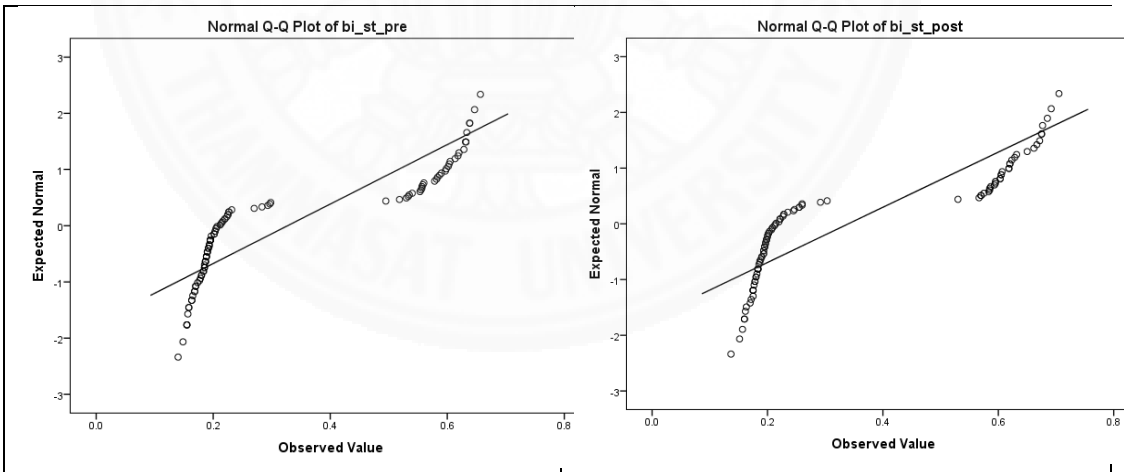
Stress scores measured by pre-test skin conductance	Stress scores measured by post-test skin conductance

Figure 3: Presenting Q-Q plot of stress measured by skin conductance

According to the testing of normal distribution using the Shapiro-Wilk test and the Q-Q plot, it was found the stress scores measured by skin temperature in the pre-test (Shapiro-Wilk =0.74, p=0.00) and the stress scores measured by skin temperature in the post-test (Shapiro-Wilk = 0.73, p=0.00) had no normal distribution, with a statistical significance at the level of .05. When considered by Q-Q plot, it was found that both variables had no normal distribution, as shown in Table 4 and Figure 4

Table 4 Normal distribution test of stress measured by skin temperature

Variable	Shapiro-Wilk	df	p
Stress score measured by pre- test skin temperature	0.74	102	0.00
Stress score measured by post- test skin temperature	0.73	102	0.00



Stress score measured by pre-test skin temperature	Stress score measured by post-test skin temperature

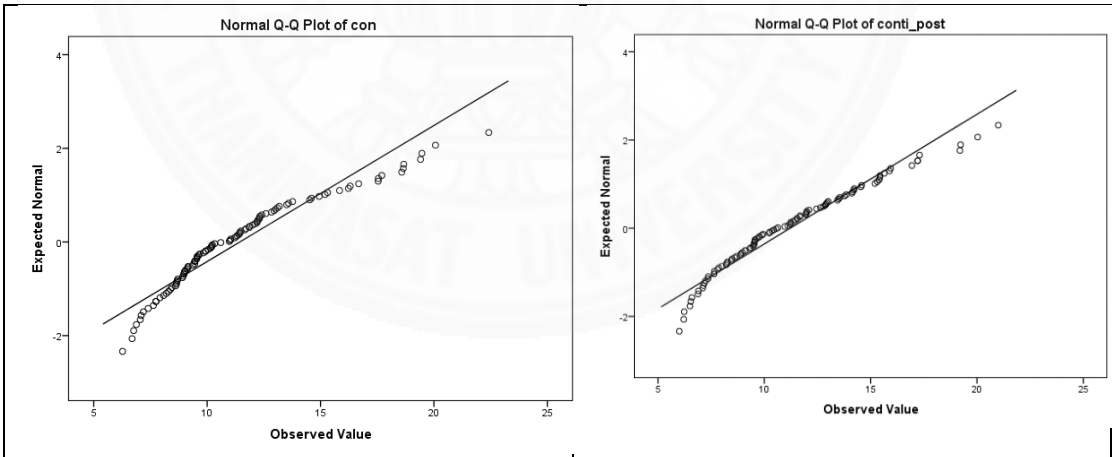
Figure 4: Presenting Q-Q plot of Stress measured by skin temperature

3. Normal distribution of serum cortisol

According to normal distribution by Shapiro-Wilk test and Q-Q plot, it was found that the characteristics of serum cortisol in the pre-test (Shapiro-Wilk =0.92, p=0.00) and the post-test (Shapiro-Wilk = 0.96, p=0.00) had no normal distribution with statistical significance at the level of 0.05. But when considering by Q-Q plot, it was found that the data characteristics had normal distribution. Thus, it can be concluded that serum cortisol score in both periods had normal distribution as shown in Table 5 and Figure 5

Table 5 Normal distribution of serum cortisol

Variable	Shapiro-Wilk	df	p
Pre-test serum cortisol	0.92	102	0.00
Post-test serum cortisol	0.96	102	0.00



Pre-test Serum cortisol	Post-test Serum cortisol

Figure 5: Presenting Q-Q plot analysis of serum cortisol in each period

APPENDIX B
THE MEDITATION TRAINING PROGRAM

This program was administered in 34 patients with diabetes mellitus (DM). The patients received the meditation training program at the meeting room of the Ear, Nose and Throat Ward of Thammasat University Hospital. The patients were divided into two groups of 17 patients each. Activities took place from 8:00 a.m. – 9:30 a.m. and 9:30 a.m. – 11:00 p.m. every week for a total of six weeks, with each session lasting 90 minutes. Also, patients were required to train at home for at least 20 minutes daily. The activities are described as follows:

General Objective: To provide patients with the meditation program for patients to feel relaxed.

Methodology

Week 1 (Program Training Time 1): 90 minutes total.

Topics

1. Holding conversations to establish good rapport and explain the training objectives.

2. Educating patients about stress and depression in patients with diabetes mellitus and stress and depression management guidelines.

3. Explaining the method and benefits of the meditation training program on patients with diabetes mellitus and reminding patients to practice meditation at home.

4. Explaining the principles of biofeedback instrument and instructing patients to engage in training.

5. Assessing stress levels in patients using a biofeedback instrument with sweat control and skin temperature control and a stress evaluation form

(SOSI), and evaluate depression levels using a depression evaluation form (BDI) to collect pre-experiment data.

Behavioral Objectives

1. Diabetic patients understand the purpose of this research and have a good relationship with the researcher.

2. Patients successfully describe the method and benefits of the meditation training program

3. Patients can perform the meditation training program according to procedures.

4. Patients practice meditation training at home every day

Training Procedures

Introduction: 15 minutes.

1 . The researcher established a good relationship with patients by discussing with patients about general illness conditions, knowledge, causes, mechanisms of causation and impacts of stress and depression in patients with diabetes, including the importance of stress relief in diabetic patients and the benefits of the meditation training following the guidelines of Maharishi Mahesh Yogi in diabetic patients, and used pamphlets to accompany discussions. The details are as follows:

Diabetes mellitus is caused by abnormal function of the pancreas in the production of insulin and glucagon. With diabetes mellitus, the body's metabolism dysfunction occurs, and blood glucose is left unutilized. When stress occurs, the use of blood glucose by the body is suppressed, and the cortisol hormone is secreted by the adrenal glands, leading to diabetes or high blood glucose levels. Long-term impacts include complications in the body's organs such as the cardiovascular system, nervous system, eyes, kidneys and others. Chronic diabetes creates risks for severe complications that could lead to disability or death. Moreover, diabetes has been found to impact the mental health of patients. Patients with diabetes tended to feel stressed by

the continuous nature of their treatments, chronic illness, self- care burdens and complications. Symptoms might cause patients to perceive their health more negatively, leading to stress, despair, disinterestedness, discouragement and feelings of unsafety and uncertainty in life. With increased feelings of worthlessness, patients can experience symptoms of depression.

Stress is a condition that puts pressure on the mind and body and is caused by threats. For adapting in the face of these threats, the body produces general responses. Changes occur in the adrenal glands, and the autonomic nervous system is triggered. These changes leading to an exhibition of thoughts, emotions, behaviors and physical symptoms such as perspiration, chills, increased rate and force of the heartbeat, headaches, poor concentration, insomnia, raised blood glucose and pressure levels, anger, anxiety, depression and others. Significant symptoms of depression include feelings of hopelessness, worthlessness, self-criticism, loss of interest in daily activities or things that happened or the environment in which the person used to express interest, loss of energy in activities, irritability, anger and dietary and weight changes.

Additionally, physical symptoms might also be present such as many experiences of nausea, stomachache, backache, neck ache and shoulder ache that cannot be explained by physical causes. If depression is severe, suicidal ideologies could arise. Depression in diabetic patients can exacerbate symptoms because patients have decreased interest in healthcare.

Furthermore, dietary changes in patients caused by depression might influence blood glucose levels in diabetic patients. Comparisons involving diabetic patients without depression found that diabetic patients with depression are accompanied by more prolonged duration of illness, the more significant number of days of hospitalization, increased frequency of access of hospital treatments and the higher rate of death. Thus, it is clear that these conditions impact the physical, psychological, social and economic aspects of diabetic patients. Therefore, psychological care plays an essential role in reducing the exacerbation of the disease. Accordingly, there are many stress management methods such as imagination training,

breathing training, muscle relaxation, meditation training, biofeedback training and others. Presently, patients with diabetes have been found to adopt meditation and biofeedback training in accompaniment with medication treatments, so medication usage has decreased or is no longer necessary in some patients, while treatment outcomes improved.

Meditation training is a beneficial self- management method for diabetic patients. This benefit is because medication leads to focus that induces happiness, peace and comfort. And humans can create this immense joy on their own. An advantage of meditation on mental health is improved quality of the mind. Consequently, elaborate, the mind becomes clear, clean, pure, calm, relaxed, open, uncluttered, light and comfortable with improved memory and wisdom. In terms of mental enhancement, it also promotes fast and correct thinking and choices made only in favor of good things.

Moreover, it relieves stress and is a useful tool for enhancing physical performance while boosting physical health since the body and mind influence each other. If the mind is strong, resistance to illnesses increases. Studies have found that meditation training benefits diabetic patients in many different ways. For example, it decreases the stimulation of the central region of the brain. It suppresses the autonomic nervous system from secreting neurotransmitters and hormones that directly affect the cardiovascular system, leading to reduced heart rate and lower blood glucose and pressure levels. Thus, the researcher applied the meditation training guidelines of the Maharishi Mahesh Yogi. In doing so, the researcher used the meditation training audio files following the guidelines of Mrs. Metta Sheffer, an expert with over 45 years of experience in the meditation training with the Transcendental Meditation Training Center, Rajapark Institute, to accompany the biofeedback meditation training with sweat control (SC) and skin temperature control (ST). The biofeedback instrument could indicate changes in stress levels. While stressed, the body secretes while the hands and feet will be cold, due to the autonomic nervous system, which carries out instructions from the brain. These physical symptoms make it possible to measure stress, and stress

is measured by the numbers shown on the screen of the skin electrical resistance measurement instrument. If a trainee feels relaxed, the instrument's needle will point toward the left of the number zero, and if the training feels stressed, the stress could be indicated by the rightward pointing of the needle from the number zero. Stress management in trainees occurs through practice until trainees are skilled enough that the trainees can perceive and manage with their stress immediately without continuing to rely on any instrument.

2. The researcher provided explanations and built understanding with patients regarding the communication and instruction to accompany home meditation such as about the audio files for the meditation training following the guidelines of Mrs. Metta Sheffer, stress and depression pamphlets and meditation training pamphlets.

Implementation Procedures: 70 minutes.

1. Patients' stress was measured by using a biofeedback instrument with sweat control and skin temperature control. The researcher also explained the measurement results and the interpretation of the results. A stress evaluation form (SOSI) and a depression evaluation form (BDI) were used. Before patients completion of d these forms, the researcher explained how to completion of the forms to the patients and gave opportunities for patients to ask questions, and the researcher answered any questions the patients raised. If a patient was found to be unable to completion of the evaluation forms personally, the researcher would interview the patient instead. After evaluation forms were completion of d, the researcher and the research assistant verified data entered in the evaluation forms. If data was found to be incompletion of or inaccurate, the patient concerned would be returned the forms for reevaluation until all required data were wholly entered. Afterwards, all data were recorded as pre-test data. This process required 35 minutes.

2. Patients were instructed to sit comfortably on chairs with armrests and backrests and to wear loose, not tight clothing, or to loosen tight clothing and

remove their shoes and eyeglasses. Biofeedback devices were turned on, and then patients were told to place their left-hand index fingers into the infrared finger sensor of the devices on the left side in a relaxed posture. While training, patients were not supposed to move the hands being measured. The meditation training began at the same time. The audio files for the meditation training following the guidelines of Mrs. Metta Sheffer were turned on. Then the researcher guided the meditation training. The data contained valuable content about meditation and instructed patients to continuously focus their attention to only one thing or another while meditating. Patients meditated by lightly closing their eyes enough for eyelashes to meet without tightly squeezing. Once patients were comfortable, they were told to recite a mantra (cheerma) consisting of two-syllable words. The patients were instructed to recite the words repeatedly in their minds and to pay attention to the sounds of these repeating words regularly to calm their minds and focus until the entire process completion of d after 30 minutes.

Evaluation: 5 minutes

1. The researcher observed the interest and cooperation of patients in training, questioning and inquiries.

2. The researcher asked patients about their experience during meditation training. Also, patients received recommendations on how to use a form to record while meditating at home for at least 20 minutes daily, and patients were reminded to return their record forms to the researcher at their next meeting with the researcher.

<u>Weeks 2-5</u> (Program Training Sessions 2-5): 60 minutes total.

Topics

1. Casual conversations to build a positive training atmosphere.
2. Examination of meditation record forms, opinion exchanges and joint problem-solving.
3. Review of the meditation training program

4. Scheduling the next appointment and reminding patients to practice at home.

Behavioral Objectives

1. Patients can correctly perform the meditation training program according to procedures.

2. Patients consistently and continuously practice meditation training at home.

3. The stress levels of patients' post-meditation-training decrease and patients perceive changes.

Training Procedures

Introduction: 10 minutes

The researcher built good relations with patients by engaging in casual conversations.

The researcher examined home meditation training records from the home meditation record forms and gave patients opportunities to exchange opinions about feelings, experiences and changes that occurred.

Implementation: 30 minutes

Patients were instructed to sit comfortably on chairs with armrests and backrests and to wear loose, not tight clothing or to loosen tight clothing and remove their shoes and eyeglasses. The audio files for the meditation training following the guidelines of Mrs. Metta Sheffer were turned on. Then the researcher guided the meditation training. The files contained valuable content about meditation and instructed patients to continuously focus their attention to only one thing or another while meditating. Patients meditated by lightly closing their eyes enough for eyelashes to meet without tightly squeezing. Once patients were comfortable, they were told to recite a mantra (cheerma) consisting of two-syllable words. The patients were instructed to recite the words repeatedly in their minds and to pay attention to the sounds of these

repeating words consistently to calm their minds and focus until the entire process was completion of after 30 minutes.

Summary: 20 minutes.

1. The researcher gave opportunities to patients to exchange feelings and experiences and express problems and obstacles that occurred during training. Then the researcher gave useful recommendations, encouraged patients to practice meditation at home and present meditation records to the researcher at the next appointment.

Evaluation

1. Patients arrived on time by appointment and demonstrated determination during training.

2. The researcher observed the interest and cooperation of patients in training, questioning and inquiries.

3. The researcher evaluated the consistency of home meditation training by examining home meditation record forms.

<u>Week 6</u> (Program Training Time 6 and Conclusion of the Experiment): 90 minutes.

Topics

1. The researcher built good relations with patients by engaging in casual conversations.

2. The researcher examined meditation training record forms and gave patients opportunities to exchange opinions and jointly seek solutions to problems encountered.

3. Patients were instructed to perform the meditation training program on their own without audio files and no guiding the training from the researcher.

4. The researcher evaluated stress levels in patients using the biofeedback devices with sweat control and skin temperature control and the stress

evaluation form (SOSI) and evaluated depression using the depression evaluation form (BDI) to collect post-experiment data.

5. The researcher announced the conclusion of the research.

Behavioral Objectives

1. Patients can correctly perform the meditation training program on their own.

2. The stress and depression levels of patients are lower after receiving the meditation training together with SC and ST biofeedback training program, and patients perceive changes that occur.

<u>Week 6</u> (Program Training Time 6 and Conclusion of the Experiment)

Training Procedures

Introduction: 5 minutes.

1. The researcher built good relations with patients by engaging in casual conversations.

2. The researcher examined home meditation training records and gave patients opportunities to exchange opinions about feelings, experiences and changes that occurred and gave additional useful recommendations and encouragement.

Implementation: 80 minutes.

1. Patients received stress evaluation using biofeedback devices with sweat control and skin temperature control before meditation training. GSR display data were recorded as pre-experiment data. This step required 10 minutes.

2. Patients were instructed to sit comfortably on chairs with armrests and backrests and to wear loose and not tight clothing or to loosen tight clothing as well as to remove their shoes and eyeglasses. The researcher instructed patients to perform meditation training. The researcher did not turn on audio files or guide meditation training. The entire process completion of d after 30 minutes.

3. Patients received stress evaluation using biofeedback devices with sweat control and skin temperature control after meditation training. GSR display data were recorded as post-experiment data. This step required 10 minutes.

4. Then the researcher instructed patients to completion of the stress evaluation form (SOSI) and depression evaluation form (BDI) to collect post-experiment data. After the evaluation forms were completion of d, the researcher gave information to patients about their weekly changes in stress to allow the patients to see their success in regulating stress on their own without using biofeedback devices. The process required 40 minutes.

Summary: 5 minutes.

The researcher summarized the benefits received and encouraged patients to see the importance of continuously applying stress relaxation techniques in daily living.

Evaluation

1. Patients arrived on time by appointment and successfully meditated on their own.

2. The researcher observed determination in practice based on exchanges of opinions, expression of patient satisfaction and benefits received, such as patients feeling refreshed with greater mental clarity, improved interpersonal relationships, etc.

3. The researcher evaluated stress levels based on biofeedback devices with sweat control and skin temperature control and the stress evaluation form (SOSI) and assessed depression using the depression evaluation form (BDI).

4. Patients meditated at home consistently as determined by home meditation records, home visitations and follow-up telephone calls to motivate and encourage patients in-home meditation.

The meditation training together with skin conductance (SC) and skin temperature (ST) biofeedback

This program was administered in 34 patients with diabetes mellitus (DM). The patients received the meditation training together with SC and ST biofeedback training programs at the meeting room of the Ear, Nose and Throat Ward of Thammasat University Hospital. The patients were divided into two groups of 17 patients each. Activities took place from 8:00 a.m. – 9:30 a.m. and 9:30 a.m. – 11:00 p.m. every week for a total of six weeks, with each session lasting 90 minutes. Also, patients were required to train at home for at least 20 minutes daily. The activities are described as follows:

General Objective: To provide patients with the meditation training together with SC and ST biofeedback training programs for patients to feel relaxed.

Methodology

Week 1 (Program Training Time 1): 90 minutes total.

Topics

1. Holding conversations to establish good rapport and explain the training objectives.

2. Educating patients about stress and depression in patients with diabetes mellitus and stress and depression management guidelines.

3. Explaining the principles of the meditation training together with SC and ST biofeedback training programs and instructing patients to engage in training.

4. Explaining the benefits of the biofeedback meditation training program with sweat control and skin temperature control on patients with diabetes mellitus and reminding patients to practice meditation at home.

5. Assessing stress levels in patients using a biofeedback instrument with sweat control and skin temperature control and a stress evaluation form (SOSI), and evaluate depression levels using a depression evaluation form (BDI) to collect pre-experiment data.

Behavioral Objectives

1. Diabetic patients understand the purpose of this research and have a good relationship with the researcher.

2. Patients successfully describe the method and benefits of the meditation training together with SC and ST biofeedback training programs.

3. Patients can perform the meditation training together with SC and ST biofeedback training programs according to procedures.

4. Patients practice meditation training at home every day.

Training Procedures

Introduction: 10 minutes.

1 . The researcher established a good relationship with patients by discussing with patients about general illness conditions, knowledge, causes, mechanisms of causation and impacts of stress and depression in patients with diabetes, including the importance of stress relief in diabetic patients and the benefits of the meditation training following the guidelines of Maharishi Mahesh Yogi in diabetic patients, and used pamphlets to accompany discussions. The details are as follows:

Diabetes mellitus is caused by abnormal function of the pancreas in the production of insulin and glucagon. With diabetes mellitus, the body's metabolism dysfunction occurs, and blood glucose is left unutilized. When stress occurs, the use of blood glucose by the body is suppressed, and the cortisol hormone is secreted by the adrenal glands, leading to diabetes or high blood glucose levels. Long-term impacts include complications in the body's organs such as the cardiovascular system, nervous system, eyes, kidneys and others. Chronic diabetes creates risks for severe complications that could lead to disability or death. Moreover, diabetes has been found to impact the mental health of patients. Patients with diabetes tended to feel stressed by the continuous nature of their treatments, chronic illness, self- care burdens and complications. Symptoms might cause patients to perceive their health more negatively, leading to stress, despair, disinterestedness, discouragement and feelings of unsafety

and uncertainty in life. With increased feelings of worthlessness, patients can experience symptoms of depression.

Stress is a condition that puts pressure on the mind and body and is caused by threats. To adapt in the face of these threats, the body produces general responses. Changes occur in the adrenal glands, and the autonomic nervous system is triggered. These changes lead to an exhibition of thoughts, emotions, behaviors and physical symptoms such as perspiration, chills, increased rate and force of the heartbeat, headaches, poor concentration, insomnia, raised blood glucose and pressure levels, anger, anxiety, depression and others. Significant symptoms of depression include feelings of hopelessness, worthlessness, self-criticism, loss of interest in daily activities or things that happened or the environment in which the person used to express interest, loss of energy in activities, irritability, anger and dietary and weight changes.

Additionally, physical symptoms might also be present such as many experiences of nausea, stomachache, backache, neck ache and shoulder ache that cannot be explained by physical causes. If depression is severe, suicidal ideologies could arise. Depression in diabetic patients can exacerbate symptoms because patients have decreased interest in healthcare. Furthermore, dietary changes in patients caused by depression might influence blood glucose levels in diabetic patients. Comparisons involving diabetic patients without depression found that diabetic patients with depression are accompanied by more prolonged duration of illness, greater number of days of hospitalization, increased frequency of access of hospital treatments and greater rate of death. Thus, it is clear that these conditions impact the physical, psychological, social and economic aspects of diabetic patients. Therefore, psychological care plays a vital role in reducing the exacerbation of the disease. Accordingly, there are many stress management methods such as imagination training, breathing training, muscle relaxation, meditation training, biofeedback training and others. Presently, patients with diabetes have been found to adopt meditation and biofeedback training in accompaniment with medication treatments, so medication usage has decreased or is no longer necessary in some patients, while treatment outcomes improved.

Meditation training is a beneficial self- management method for diabetic patients. This benefit is because medication leads to focus that induces happiness, peace and comfort. And humans can create this immense joy on their own. An advantage of meditation on mental health is improved quality of the mind. Consequently, the mind becomes clear, clean, pure, calm, relaxed, open, uncluttered, light and comfortable with improved memory and wisdom. In terms of mental enhancement, it also promotes fast and correct thinking and choices made only in favor of good things.

Moreover, it relieves stress and is a useful tool for enhancing physical performance while boosting physical health, since the body and mind influence each other. If the mind is healthy, resistance to illnesses increases. Studies have found that meditation training benefits diabetic patients in many different ways. For example, it decreases the stimulation of the central region of the brain. It suppresses the autonomic nervous system from secreting neurotransmitters and hormones that directly affect the cardiovascular system, leading to reduced heart rate and lower blood glucose and pressure levels. Thus, the researcher applied the meditation training guidelines of the Maharishi Mahesh Yogi. In doing so, the researcher used the meditation training audio files following the guidelines of Mrs. Metta Sheffer, an expert with over 45 years of experience in the meditation training with the Transcendental Meditation Training Center, Rajapark Institute, to accompany the biofeedback meditation training with sweat control (SC) and skin temperature control (ST). The biofeedback instrument could indicate changes in stress levels. While stressed, the body perspires while the hands and feet will be cold, due to the autonomic nervous system, which carries out instructions from the brain. These physical symptoms make it possible to measure stress, and stress is regulated by the numbers shown on the screen of the skin electrical resistance measurement instrument. If a trainee feels relaxed, the instrument's needle will point toward the left of the number zero, and if the training feels stressed, the stress could be indicated by the rightward pointing of the needle from the number zero. Stress management in trainees occurs through practice until trainees are skilled enough that

the trainees can perceive and manage with their stress immediately without continuing to rely on any instrument.

2. The researcher provided explanations and built understanding with patients regarding the communication and instruction to accompany home meditation such as about the audio files for the meditation training following the guidelines of Metta Sheffer, stress and depression pamphlets and meditation training pamphlets.

Implementation Procedures: 75 minutes.

1. Patients' stress was measured by using a biofeedback instrument with sweat control and skin temperature control. The researcher also explained the measurement results and the interpretation of the results. A stress evaluation form (SOSI) and a depression evaluation form (BDI) were used. Before patients completion of d these forms, the researcher explained how to completion of the forms to the patients and gave opportunities for patients to ask questions, and the researcher answered any questions the patients raised. If a patient was found to be unable to completion of the evaluation forms personally, the researcher would interview the patient instead. After evaluation forms were completion of d, the researcher and the research assistant verified data entered in the evaluation forms. If data was found to be incompletion of or inaccurate, the patient concerned would be returned the forms for reevaluation until all required data were wholly entered. Afterwards, all data were recorded as pre-test data. This process required 35 minutes.

2. Patients were instructed to sit comfortably on chairs with armrests and backrests and to wear loose, not tight clothing, or to loosen tight clothing and remove their shoes and eyeglasses. Biofeedback devices were turned on, and then patients were told to place their left-hand index fingers into the infrared finger sensor of the devices on the left side in a relaxed posture. While training, patients were not supposed to move the hands being measured. The meditation training began at the same time. The audio files for the meditation training following the guidelines of Mrs. Metta

Sheffer were turned on. Then the researcher guided the meditation training. The data contained important content about meditation and instructed patients to continuously focus their attention to only one thing or another while meditating. Patients meditated by lightly closing their eyes enough for eyelashes to meet without tightly squeezing. Once patients were comfortable, they were told to recite mantra (cheerma) consisting of two-syllable words. The patients were instructed to recite the words repeatedly in their minds and to pay attention to the sounds of these repeating words regularly to calm their minds and focus until the entire process completion of d after 30 minutes.

3. Stress levels were then measured using biofeedback devices with sweat control and skin temperature control. Later the researcher recorded post-training information from GSR screens, interpreted results each time and compared the results to previous stress levels. The researcher explained the results to the patients. This process required 10 minutes.

Summary: 5 minutes.

1. The researcher asked patients about their experience during meditation training. Also, patients received recommendations on how to use a form to record while meditating at home for at least 20 minutes daily, and patients were reminded to return their record forms to the researcher at their next meeting with the researcher.

Evaluation

1. The researcher observed the interest and cooperation of patients in training, questioning and inquiries.

2. The researcher evaluated stress levels based on results displayed by biofeedback devices with sweat control and skin temperature control.

Weeks 2-5 (Program Training Sessions 2-5): 70 minutes total.

Topics

1. Casual conversations to build a positive training atmosphere.

2. Examination of meditation record forms, opinion exchanges and joint problem-solving.

3. Review of the meditation training together with SC and ST biofeedback training programs Scheduling the next appointment and reminding patients to practice at home.

Behavioral Objectives

1. Patients can correctly perform the meditation training together with SC and ST biofeedback training programs according to procedures.

2. Patients consistently and continuously practice meditation training at home.

3. The stress levels of patients' post-meditation-training decrease and patients perceive changes.

<u>Weeks 2-5</u> (Training Program Sessions No. 2-5)

Training Procedures

Introduction: 5 minutes

1. The researcher built good relations with patients by engaging in casual conversations.

2. The researcher examined home meditation training records from the home meditation record forms and gave patients opportunities to exchange opinions about feelings, experiences and changes that occurred.

Implementation: 50 minutes

1. Patients received stress evaluation using biofeedback devices with sweat control and skin temperature control. GSR display data were recorded as pre-experiment data. This step required 10 minutes.

2. Patients were instructed to sit comfortably on chairs with armrests and backrests and to wear loose, not tight clothing or to loosen tight clothing and remove their shoes and eyeglasses. Biofeedback devices were turned on, and then patients were told to place their left-hand index fingers into the infrared finger sensor of the devices on the left side in a relaxed posture with the eyes open. While training, patients were not supposed to move the hands being measured. The meditation training began at the same time. The audio files for the meditation training following the guidelines of Mrs. Metta Sheffer were turned on. Then the researcher guided the

meditation training. The files contained important content about meditation and instructed patients to continuously focus their attention to only one thing or another while meditating. Patients meditated by lightly closing their eyes enough for eyelashes to meet without tightly squeezing. Once patients were comfortable, they were told to recite mantra (cheerma) consisting of two-syllable words. The patients were instructed to recite the words repeatedly in their minds and to pay attention to the sounds of these repeating words consistently to calm their minds and focus until the entire process was completion of after 30 minutes.

3. Stress levels were then measured using biofeedback devices with sweat control and skin temperature control. Then the researcher recorded post-training information from GSR screens, interpreted results each time and compared the results to previous stress levels. The researcher explained the results to the patients. This process required 10 minutes.

Summary: 5 minutes.

1. The researcher gave opportunities to patients to exchange feelings and experiences and express problems and obstacles that occurred during training. Then the researcher gave useful recommendations, encouraged patients to practice meditation at home and present meditation records to the researcher at the next appointment.

Evaluation

1. Patients arrived on time by appointment and demonstrated determination during training.

2. The researcher observed the interest and cooperation of patients in training, questioning and inquiries.

3. The researcher evaluated stress levels based on results displayed by biofeedback devices with sweat control and skin temperature control.

4. The researcher assessed the consistency of home meditation training by examining home meditation record forms.

<u>Week 6</u> (Program Training Time 6 and Conclusion of the Experiment): 90 minutes.

Topics

1. The researcher built good relations with patients by engaging in casual conversations.

2. The researcher examined meditation training record forms and gave patients opportunities to exchange opinions and jointly seek solutions to problems encountered.

3. Patients were instructed to perform the meditation training together with SC and ST biofeedback training programs on their own without audio files and no guiding the training from the researcher.

4. The researcher evaluated stress levels in patients using the biofeedback devices with sweat control and skin temperature control and the stress evaluation form (SOSI) and assessed depression using the depression evaluation form (BDI) to collect post-experiment data.

5. The researcher announced the conclusion of the research.

Behavioral Objectives

1. Patients can correctly perform the meditation training together with SC and ST biofeedback training programs on their own.

2. The stress and depression levels of patients are lower after receiving the meditation training together with SC and ST biofeedback training program, and patients perceive changes that occur.

<u>Week 6</u> (Program Training Time 6 and Conclusion of the Experiment)

Training Procedures

Introduction: 5 minutes.

1. The researcher built good relations with patients by engaging in casual conversations.

2. The researcher examined home meditation training records and gave patients opportunities to exchange opinions about feelings, experiences and changes that occurred and gave additional useful recommendations and encouragement.

Implementation: 80 minutes.

1. Patients received stress evaluation using biofeedback devices with sweat control and skin temperature control before biofeedback meditation training with sweat control and skin temperature control. GSR display data were recorded as pre-experiment data. This step required 10 minutes.

2. Patients were instructed to sit comfortably on chairs with armrests and backrests and to wear loose and not tight clothing or to loosen tight clothing as well as to remove their shoes and eyeglasses. Biofeedback devices were turned on, and then patients were told to place their left-hand index fingers into the infrared finger sensor of the devices on the left side in a relaxed posture with the eyes open. While training, patients were not supposed to move the hands being measured. The researcher instructed patients to perform biofeedback meditation training according to procedures on their own, and, to have patients observe their physical, emotional, thinking and behavioral changes and relax while engaging in biofeedback with sweat control and skin temperature control. For this process, the researcher did not turn on audio files or guide meditation training. The entire process completion of d after 30 minutes.

3. Then the researcher recorded pre-training and post-training information from GSR screens and explained interpretations of results to patients and recorded data as post-experiment data. Then the researcher instructed patients to completion of the stress evaluation form (SOSI) and depression evaluation form (BDI) to collect post-experiment data. After the evaluation forms were completion of d, the researcher gave information to patients about their weekly changes in stress to allow the patients to see their success in regulating stress on their own without using biofeedback devices. The process required 40 minutes.

Summary: 5 minutes.

1. The researcher summarized the benefits received and encouraged patients to see the importance of continuously applying stress relaxation techniques in daily living.

Evaluation

1. Patients arrived on time by appointment and successfully meditated on their own.

2. The researcher observed determination in practice based on exchanges of opinions, expression of patient satisfaction and benefits received, such as patients feeling refreshed with greater mental clarity, improved interpersonal relationships, etc.

3. The researcher evaluated stress levels based on biofeedback devices with sweat control and skin temperature control and the stress evaluation form (SOSI) and assessed depression using the depression evaluation form (BDI).

4. Patients meditated at home consistently as determined by home meditation records, home visitations and follow-up telephone calls to motivate and encourage patients in-home meditation.

Biofeedback Training with Sweat Control (Ruchiwit, 2015)

1. Use a peaceful location that cannot be easily disturbed from outside, with the right temperature and proper ventilation, and sit in a comfortable position in a chair with armrests and elbow-rests.

2. Wear loose clothing and not tight or loosen tight clothing, and remove shoes.

3. To facilitate the trainee in quickly adjusting the needle indicator, the trainee is to place the left index finger onto the pad of the device in a relaxed manner with the thumb resting on the side.

4. To prevent finger movements, maintain stable pressure on the pad and use a rubber band to hold the finger in place. However, this also depends on how feasible it is for each person. The trainee can face the hand either up or down

5. The cable of the sweat control device is connected through a 2.5-millimetre port to the galvanic skin resistance (GSR) device.

6. Every time before use, adjust the indicator needle to the number zero by rotating the machine using the left thumb. If the screen values change too rapidly for some trainees, adjust the needle to 1/2.

7. Once the device is ready for use, have the trainee lightly close the trainee's eyes. Start by training meditation for about 30 minutes. About 2-5 seconds are required to adjust the device sound signals.

8. Once the trainee successfully regulates stress levels, the sound indicator will gradually fade until it is entirely silent. The trainee is to adjust the audio signal to the lowest audible level. The trainee can record the level of the first audio signal heard and then compare with subsequent sounds to determine whether or not the trainee successfully regulates stress such that sound levels are decreasing.

9. Read the values displayed on the monitor. Notice that the number shown on screen is higher when the trainee is relaxed, since the trainee is sweating less, which will increase skin electrical resistance, and the needle on the screen will point to the left. On the other hand, the number shown on display will be lower, and the needle will lead to the right if there is a large amount of sweating, which increases electrical conductivity and occurs in cases where the trainee feels stressed.

Biofeedback Training Program with Skin Temperature Control (Ruchiwit, 2015)

1. Choose to train at the same time every day.

2. Use a peaceful location that cannot be easily disturbed from outside, with the right temperature and proper ventilation, and sit in a comfortable position in a chair with armrests and elbow-rests.

3. Connect the temperature regulator through the 3.5-millimetre port of the galvanic skin resistance (GSR) device.

4. For a proper fit that is neither too loose nor too tight, use the velcro pad to wrap around the finger and place the sensor pad on the finger of the dominant hand.

5. Every time before use, adjust the indicator needle to the number zero by using the fingers of the other hand to turn the roller next to the GSR device. It is crucial not to contact the finger pad of the GSR device.

6. Once the device is ready for use, the trainee can start by gently closing the eyes and meditating for approximately 30 minutes.

7. Read the values shown on the monitor. Notice that the number displayed on the monitor will be higher if the trainee feels relaxed, due to higher body temperature, and the needle on the screen will point to the left by turning counter-clockwise, which means increased electrical resistance of the skin. On the other hand, the number shown on the screen will be lower, and the needle will point to the right if the trainee is stressed.

APPENDIX C
MEDITATION TRAINING AUDIO FILES

Content

Begin by sitting comfortably. You can sit in any position if it makes you comfortable. You can lean against a wall, sit with your feet hanging down, or on the floor with your legs tucked back to one side if long as it makes your body comfortable. Now regulate your consciousness along with your comfort. Examine your body and see if any part is tense. Try to observe. Try to follow well. Then ease your mind. Make it light, gentle and relaxed. Let go of the things that trouble you. Let go of your worries for a while. You could set a time in your mind and devote it to prayer. You could bring happiness into your mind. You just want to be happy, and your mind will be satisfied. Enjoy your meditation. Closing your eyes right is very important. Close them lightly and comfortably, just like when you are about to sleep. Close them like you are a little drowsy, about most of the way in a way that you feel comfortable and relaxed throughout your entire body. It has to be light. It has to be relaxing. Importantly, do not squeeze your eyes tightly shut. When you drowsily close your eyes, relaxation will manifest through the nervous and muscle systems. Do not press the eyelids tightly. Do not touch the eyes. Move your body well. Move it comfortably for the entire body to be relaxed. Do not tense any part of the body. Just relax every muscle in the body, the whole body. From the muscles on the face to the head, neck, shoulders, arms and fingertips, relax the muscles. Relax the muscles from both legs to the tips of the toes. Move and adjust your posture right in a way that you think will let your blood and air circulate effectively so that you will feel no aches. Now check whether your entire body is relaxed. Close your eyes gently and relax. And make your mind blissful, refreshed, happy, peaceful, calm and comfortable. Make sure you do this right. Spend about a minute or two to relax every part of the body. Make your mind relaxed, blissful, refreshed, clean and pure.

Some people might think about nature. It makes them feel comfortable and clear-minded. It puts them in the mood for prayer and steadies their minds. You can also do that. The best shortcut, though, is to make your mind empty and idle, like you are the only person in this world and have absolutely no obligations to anything. Imagine that you are genuinely the only person on earth, totally free from all worries, whether worries about people, animals, things, business, work, home, education, illness, disease, family or any other issue. Just let go. Let go and relax all ties to everything. Your mind needs to be clear, transparent and pure. Do not let it cling on or hang on to any issue.

When you relax from these ties, your mind will return to your body. It will settle within you. Let go of your mind lightly, steadily, softly, gently. Make it clear and calm. Keep it like this like you are in space. When you are comfortable, allow your prayer to come. The prayer should be made in a delicate voice. Let it gradually rise from the center of your abdomen, like it is growing from a pure source, an incomparable source of power, a source of wisdom, a source of compassion. Let it pour out. Pay attention to this cheering voice. Do it repeatedly inside the mind. It will bring peace and concentration. While meditating, chaotic things might periodically enter, or you might hear voices. If you do not pay attention to them, these thoughts will fade away. And do not think that the ideas that pass by, such as about work, home or any other issue are hindering your concentration. If you felt that way, your mind will resist. In other words, your mind will try to force you not to think about different things too much. Doing that will cause you physical and mental stress. If you resist these things or try to force your mind into concentration, you will not fully succeed. It works for some people, but it does no good for most people. So, you have to accept the nature of these things and just be relaxed about them. Whether the thought that enters your mind is good, bad or only neutral and neither bad nor good, just be nonchalant, and it will gradually fade away. It will not stay with you for long. If you feel that so much is entering your mind, just very slowly open your eyes a little. When the mind is chaotic, opening your eyes, a little will

lighten the chaos. Then you gradually begin again. Do this every day. Do this regularly. From being very chaotic, it will be less chaotic. From less chaotic, there will be no chaos. It will end itself comfortably and efficiently. If you have thoughts during your training, let your attention turn to your cheering voice. The cheering voice is a vehicle that will carry your mind back within you. This cheering voice can change many things. It may increase rhythm or decrease it. Every change is the correct way to meditate. Proper meditation does not mean that the cheering is constant—instead, the cheering and the thoughts alternate. Do not resist your thoughts. Just let go and relax. You do not need to resist anything at all. Just let go and relax. This activity is something easy and natural. Do it regularly with a prayer inside your mind. Let the voice rise from the center of your abdomen. Let it gradually support your mind. Sometimes allow yourself to feel drowsy. Sometimes it is all right to let your mind be chaotic. Just be still about it. Open your eyes if it becomes too chaotic. Fall asleep if you feel drowsy. Move if you feel stiff or achy. Just adjust and let things change. Do not be very interested. Just let go like a mindless robot. Do not try to analyze, research or critique anything. Just be idle and do not think about anything. Stay still and let your mind be clear. Do it gradually. Do not try too hard. Let go lightly and gently. Support your mind, and make your mind blissful, refreshed, clean, pure, clear, and free from all worries. Regardless of the nature of the concern, relax and let go.

Empty your mind. Let's suppose that your body is free from all organs. Imagine that it has no lungs, no liver, no spleen, no heart and no other organs. Imagine that your body is like a shaft, an opening, a hollow that is empty and open inside, just like a glass tube or a diamond tube. Let your mind be idle and still. Do not let your eyes be heavy. Do not raise your fingers. Do not lift your shoulders. Do not tense your abdomen. Be comfortable, and do not expect anything. Let your mind be only at ease, still, steady and with a single mood, a good mood, a unique mood that is comfortable and not boring at all.

Support your mind with prayer. Let the cheering voice come. Let it happen gradually, and it will stay with you. Pray and cheer. Do it on and on. Do it ten times, a hundred times, a thousand times, ten thousand times or even hundreds of thousands of times. One time will eventually steady your mind. Time will stop, and it will leave the prayer. It will be like forgetting the prayer, but your mind will not be scattered. Or you might just feel like being still and not pray or cheer anymore. If you reach this point, then it means your mind has stopped. You do not have to return to cheer it. The mind has given up. It has stopped. It has stopped resisting. It has reached its destination, so cheering words are no longer necessary. It is like hiring a boat to row you over to a bank. It was parked at the bank, and you proceed to walk your way. It is not necessary to haul the boat up the bank with you. Your mind will begin to settle, softly, and not wander into various familiar thoughts. This feeling of stillness and softness without any thought is more entertaining and more pleasing than thinking. Keep being at ease. What you need to do is stay still like this. Be conscious, comfortable and steady. Eventually, everything will fall into place. When you are aware, you will be comfortable and stable. When everything falls into place, it will suddenly drop. It will be like falling from a high place. Then it becomes easy. It is not difficult anymore. It is hard only at first when trying to stop the resisting mind. Train gradually and often. Do not be impatient. It has to happen slowly. Gradually accumulate the delicateness. Once your mind has steadied, once you entirely stop in the right place, your body will feel open, and your mind will feel open. It will feel bright, transparent, light and comfortable. When the body is relaxed, your feelings will expand. You will feel your mind and body expanding. You will grow so big that you blend into the atmosphere. It will be like are part of the atmosphere that you are one with the wide-open spaces. Your mind will feel bright, fresh and blissful. You will be happy. Your body and mind will be comfortable like you have never been before. It will be like that open space is tightly packed with particles of happiness. The happiness will be densely packed within, and the body will

be relaxed. Your mind will be at ease. It will be open, transparent, hollow and comfortable. It is a primary reward for you. When you feel this way, your entire body and mind are relaxed. Now you need to remain calm and preserve this stillness, softness, physical comfort and mental comfort. This satisfaction is a reward for your life. Now you will strive for the next prize, which is to improve your physical comfort and improve your mental happiness. Improve to a level in which your body gradually becomes even more apparent, light, comfortable, expanded or blended with the atmosphere so much that it feels like you do not have a body. You will feel like you do not exist like you are a delicate element; currents of delicate happiness and purity will replace it and keep increasing your physical and mental comfort. Focus and comfort are paired with each other. Sometimes you are focused, but you are uncomfortable. The parts are not right, and you are unsuccessful. Or you might feel comfortable but not focused. You feel so pleased that you drift off to sleep. Your mind is not with your body, and no amount of sitting could be sufficient. Focus and comfort must consistently come together, that is, all the time, continuously, while your eyes are closed and while your eyes are open. Sit comfortably. Do not use force to coerce your mind. Do not resist. Just sit coolly, clearly and comfortably, as if you are reminiscing about the things you enjoy. That is, when you think about them, you are not confused, drowsy or tense. Do not tense the nerves and muscles. Do not feel stressed. Just relax. Let the entire body and mind relax practice until it becomes a habit. Keep practicing until the mind is comfortable and calm. You will find the light inside. When your mind is clear and suitable, happiness will enter. Purity will find a channel to open your mind. Every moment of joy is proof that you are training correctly. After you practice, the right way to leave your meditation is never to open your eyes more quickly than two minutes. Opening your eyes too quickly can give you a headache. In the two minutes that your eyes are closed, you can move your body, and then you can gradually open your eyes.

APPENDIX D
PARTICIPANT INFORMATION SHEET (EXPERIMENTAL GROUP 1)

Participant information sheet (experimental group1) Number of project

Topic The Effect of Meditation Training together with SC & ST Biofeedback Training Programs on the Stress and Depression Levels of Patients with Diabetes

Researcher Mrs. Ormanee Patarathipakorn
Doctor of Philosophy in Nursing Science (International Program)
Faculty of Nursing, Thammasat

Advisor Prof. Dr. Manyat Ruchiwit

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Mobile phone. 085-0412270 E-mail: ormanee_p@hotmail.com

Advisor Address
Faculty of Nursing, Thammasat University, and Tel. 083-009-2222 on business days and hours

To All Participant Participating in the Research Project,

The researcher is researching the effects of meditation with a biofeedback program on stress and depression among diabetic patients. Therefore, the researcher would like to request your cooperation and consent to participate in the project, as mentioned above, because you meet the qualifications for the inclusion criteria of the sample in this research project. In other words, you are an adult and senior adult patient who has been diagnosed with only diabetes mellitus or diabetes mellitus

with other diseases treated in the Medical Outpatient Department, Thammasat University Hospital. Before you decide to join this study, please read this document thoroughly to understand the reasons and information for this study. You can ask for advice from your friends, family or doctors. The researcher is eager to respond to questions. You have sufficient time to make an independent decision about participation in this research project. If you have decided to join this research project, please sign the informed consent form for this research project.

Reasons and Necessity for the Research

Diabetes mellitus is a chronic disease that causes illness for an extended period. The effects of the disease may cause patients to have long-term stress and depression in the process of preventing potential complications and exacerbations. Therefore, adaptation or management of stimuli is essential in giving patients stress and depression management methods. Studies have found meditation to be an effective relaxation technique in reducing depression, which means meditation is a therapeutic technique helping practitioners to feel relaxed, calm and capable of determining emotions while linking the body and mind. Biofeedback is a relaxation technique using instruments to test specific symptoms of the body caused by stress by regulating symptoms under cardiac function. Practitioners can self-learn to regulate physical function by observing the body's signals such as temperature and perspiration on the skin, etc. When practiced to the point of expertise, practitioners can perceive methods for controlling emotions and feelings to create relaxation and perceive success and progress in the practice with the ability to relax similar to training sizes without the use of instruments. Furthermore, meditation with biofeedback practices is more effective than meditating exclusively. This study on the effects of combined meditation with biofeedback on the stress, depression and cortisol levels among patients with diabetes will help patients implementing self-care practice guidelines for the prevention and management of stress and depression. The training program will reduce stress and depression, prevent exacerbations and potential complications while lowering treatment costs.

Research Objective

To study the effects of combined meditation with biofeedback on the stress, depression and cortisol levels among patients with diabetes by comparing the differences in stress and depression among diabetic patients between patients who have meditated (experimental group 1), patients who have meditated and practiced the biofeedback program (experimental group 2) and patients who have not received the experimental program (control group). All three groups of patients will receive routine care.

Participant information

The participants will be composed of adult and older patients with type 2 diabetes mellitus diagnosed with only or type 2 diabetes mellitus with comorbidities that sought treatment at the Medical Outpatient Department, Thammasat University Hospital (TUH). The participants in this research project will be female and male patients aged 35 to 75 years. The sample will be obtained by the researcher, who will select the subjects based on set inclusion criteria and qualifications for sample selection before selecting 102 subjects based on consent and simple random sampling by drawing lots for participations in the researcher project. The researcher will pair the experimental and control groups with similar characteristics in terms of gender, age and type of disease. The people will be divided into those who have not received the experimental program (control group) (34 subjects), people who have meditated (experimental group 1) (34 subjects) and people who have meditated and received the biofeedback program (experimental group 2) (34 subjects). The sample will have the following characteristics: 1) educational attainment at the primary level and up, and no communication impairments; 2) patients with only diabetes mellitus or patients with diabetes mellitus and comorbidities with stable physical symptoms and no adverse effects on patients' physical pathology 3) no psychological symptoms or psychiatric disorders as barriers to the study; 4) no previous experience with biofeedback programs or relaxation techniques; 5) mild level of depression, and 6) consent to cooperate in the study by signing the consent form. The exclusion criteria will exclude patients with other diseases or medical complications, acting as barriers to the study and diagnosed

by a doctor as dangerous for patients or others if the patient continues to participate in the experiment.

Research Process for Participant

In this study, the researcher will conduct the study in person until all steps are completion of d, and the researcher will have three research assistants. You will receive routine care based on the guidelines of Thammasat University Hospital. The research assistants will collect data before and after the meditation program. If you consent to participate in this research project, you will be able to participate in the following activities:

Week 1 (90 minutes): The researcher will explain to you the objective, steps, operation, time, benefits from participation in the research project, knowledge about the causes, mechanisms, and effects of depression among patients with diabetes along with benefits of transcendental meditation based on the guidelines of Maharishi Mahesh Yogi among diabetic patients. Also, you will receive audio files leads for transcendental meditation based on the guidelines of Miss Metta Schaffer for meditation at home, a pamphlet on relaxation techniques by meditating in addition to a brochure on stress and depression management among diabetic patients. A blood sample will be taken from you in the amount of one teaspoon. Then you will be assessed for stress and depression by completing three sets of questionnaires consisting of 1) the demographic data questionnaire with nine questions (uses 1 minute); 2) the stress questionnaire with 85 questions (uses 29 minutes); and 3) the depression assessment form with 20 questions (uses 5 minutes). Questionnaires will be completion of d in 35 minutes. The researcher and the research assistants will explain the questionnaire information. If there is any question that you do not understand, the researcher and the research assistants will use the interview method for that topic. You will then be assessed for stress with biofeedback instruments while sweat gland function is regulated and biofeedback instruments to regulate body temperature at the skin. You will receive explanations and demonstrations on methods carefully, and you will hear interpretations.

After completing the assessments, you will meditate. The researcher will have you begin transcendental meditation by using the transcendental meditation audio files based on the guidelines of Miss Metta Schaffer. The researcher will lead transcendental meditation with significant contents on training the mind to focus on any specific thing continually at the time by closing your eyes lightly, so the eyelashes meet without constricting the eyes. After achieving a relaxed state, the subjects will chant a mantra (cheerma), which is a word with two syllables, repeatedly in the subjects' minds. Focusing on any one of these words repeatedly in mind at all times will calm the mind and create concentration.

After practicing, you will receive forms for recording meditation at home to record the date and time of meditation each week and return forms the next week.

Weeks 2 – 5 (60 minutes): The researcher will have you begin transcendental meditation by using the transcendental meditation audio files based on the guidelines of Miss Metta Schaffer. The researcher will lead transcendental meditation with significant contents on training the mind to focus on any specific thing continually at the time by closing your eyes lightly, so the eyelashes meet without constricting the eyes. After achieving a relaxed state, the subjects will chant a mantra (cheerma), which is a word with two syllables, repeatedly in the subjects' minds. Focusing on any one of these words frequently in mind at all times will calm the mind and create concentration. After practicing, you will receive forms for recording meditation at home to record the date and time of meditation each week and return forms the next week.

Week 6 (90 minutes): After transcendental meditation with the biofeedback program, you will be assessed for stress with biofeedback instruments. In the full steps of the transcendental meditation program, the researcher will not play the audio files and will not lead the exercises. After the end of the exercises, the researcher will inform you of the results. You will then be assessed for stress and depression by completing questionnaires in addition to acknowledging interpretations from the researcher. Next, a blood sample in the amount of one teaspoon will be taken from you to measure cortisol levels, and the research project will be considered over.

You will practice transcendental meditation program continually for six weeks with one 90-minute session per week and meditate at home for at least 20 minutes per day in one session per day. The total activity time in the research project will be nine to ten hours, and the activity venue will be the meeting room of the Ear, Nose and Throat Ward, Thammasat University Hospital.

Providing Information for Participant

In this study, the researcher will conduct the study in person at every stage with the help of three research assistants. Before attending the study, the researcher will explain the information to the participant to build understanding before giving information sheets to the participant. The researcher will conduct the study after participant consent and sign the informed consent forms for the participant.

Volunteer Screening

In screening the participant by any means, the researcher will not include persons who do not meet the inclusion criteria for this study. In cases where the persons mentioned above are found to require recommendations regarding illness or support, the researcher will assist by coordinating with nurses at the Medical Outpatient Department.

Use of Medical Records

In this study, the researcher will examine the data on patients' illness from medical records to use medical records as information in screening patients without disturbing routine care based on the guidelines of Thammasat University Hospital. Use of data from medical records will be approved by the director and the Head of the General Practice Outpatient Department in writing and with consent from the participant. Medical professors have approved all research procedures with expertise in the field of endocrinology and metabolism from the Department of Internal Medicine, Thammasat Hospital, who is a qualified expert in this study.

Potential Hazards or Risks for Participant

This study has minimal risk from participation, such as risk from taking blood samples, which may cause the participant to feel pain or bruising. These symptoms will heal within 5 – 7 days without any danger. The use of biofeedback

machines involves no hazards for patients because electricity is used at only 1 – 20 microvolts. Project participants will be assessed for stress and depression in Week 1. If any patients are found to have stress and depression at levels requiring treatment, the researcher will refer the patients for immediate treatment. If during the research project the participants are found to have risk from abnormalities, the researcher will provide support and refer patients for immediate treatment in line with their treatment entitlements in addition to monitoring the participants until participants are safe. The researcher will allow the project participants to withdraw from the research project without any conditions.

Benefits from Participations in the Research

Personal Benefits – From participating in this study, patients will receive the meditation program with biofeedback training in addition to routine care provided by Thammasat University Hospital. Meditation is an effective relaxation technique for reducing depression, meaning meditation is a therapy technique for helping practitioners to feel relaxed, calm and able to determine emotions while connecting the mind and body. These practices will help diabetic patients with low depression levels to have appropriate guidelines for self-care management by using meditation in daily life to reduce complications from stress and chronic depression and improve quality of life.

General or Academic Benefits – Nurses and healthcare team personnel can apply the findings as proper practice guidelines for organizing suitable and sufficient care models for diabetic patients in addition to using the effects of the program to patients with other chronic diseases. Furthermore, in the area of study and research, this study will create guidelines for developing new knowledge from research on stress management and depression among diabetic patients that meet the needs of patients covering the physical, psychological, emotional and social aspects.

Participations and End of Participations in the Research Project

ParticipationParticipation in this research project is dependent on your consent. You have the right to accept or refuse and withdraw at any time without

explanation and loss of care and treatment benefits, including effects on treatment entitlements and expenses. If participants in the research project have questions regarding the research project, the researcher is eager to answer all questions until the participants in the research project gain understanding. The researcher can be contacted at 74/154, Moo 17, Pahol Yothin Rd., Khlong Neung, Khlong Luang, Pathumthani, 12020, Tel. 085-041-2270. The advisory professor, Prof. Dr. Manyat Ruchiwit, can be contacted at the Faculty of Nursing, Thammasat University, and Tel. 083-009-2222 on business days and hours.

Protection for Confidential Information

The researcher will maintain confidentiality and not disclose your information. Numerical codes will be used without identification of any names or symbols capable of identifying questionnaire respondents. Furthermore, the data will be stored in a secure facility. Nevertheless, in addition to the researcher, some other groups may be permitted to have direct access to information from medical records or other related documents such as the advisory professor or the Human Research Ethics Committee, etc. The objective of this process is to examine the research procedures and/or information without violating your confidentiality under the scope decreed by the law and regulations as you signed informed consent forms in writing. Suppose you want to cancel the right above. In that case, you can notify or write a record to cancel consent by sending the document to Mrs. Ormanee Patarathipakorn at 74/154, Moo 17, Pahol Yothin, Khlong Neung, Khlong Luang, Pathumthani, 12020. In discussing information and disseminating or publishing information in medical and nursing journals, the researcher will only make presentations from a collective view or for educational benefit without specifying names or sources of information linked with the informants.

If you request to cancel your consent after participating in the research project, your personal information will not be recorded further. However, your data may

be used to assess the findings. Concerning the blood samples taken before and after the experiment to measure cortisol levels, blood samples will be disposed of immediately after being taken without storage. Furthermore, regarding all data related to research participant such as questionnaires and data files, etc., the researcher will dispose of all data after completing the study and once the research has been disseminated/published.

Responsibilities of the Researcher/Sponsor

You will not receive payment for participation in the research project. However, you will receive traveling expenses or compensation for the inconvenience in coming to the research project's appointments for 300 baht per time for a total of six times or 1,800 baht. The researcher/ sponsor will accept responsibility for all examination and assessment costs related to the research. If you feel uncomfortable or have other problems, you can ask for a break or request to reschedule the activity on that day. In providing data for the researcher to completion of questionnaires, you can answer every item truthfully. Some items may be personal information you would rather not disclose to others and may cause inconvenience in responding to questions. If the information is necessary for the researcher, informants will receive assurances from the researcher that the information will not be disclosed.

Suppose you are not treated according to the information mentioned above. In that case, you can file a complaint at the Human Research Ethics Sub-committee, Thammasat University, Set 3, Ratchasuda Building, Health Promotion Center, Faculty of Nursing, Thammasat University, Rangsit Center, Tel. 02-986-9203 ext. 7373, Fax. 02-516-5381.

Participant information sheet (experimental group 2)

Number of project

Topic The Effect of Meditation Training together with SC & ST Biofeedback Training Programs on the Stress and Depression Levels of Patients with Diabetes

Researcher Mrs. Ormanee Patarathipakorn

Doctor of Philosophy in Nursing Science (International Program)

Faculty of Nursing, Thammasat

Advisor Prof. Dr. Manyat Ruchiwit

Researcher Address

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Mobile phone. 085-0412270 E-mail: ormanee_p@hotmail.com

Advisor Address

Faculty of Nursing, Thammasat University, and Tel. 083-009-2222 on business days and hours

To All Participant Participating in the Research Project,

The researcher is researching the effects of meditation with a biofeedback program on stress and depression among diabetic patients. Therefore, the researcher would like to request your cooperation and consent to participate in the project mentioned above because you meet the qualifications for the inclusion criteria of the sample in this research project. In other words, you are an adult and senior adult patient who has been diagnosed with only diabetes mellitus or diabetes mellitus with other diseases treated in the Medical Outpatient Department, Thammasat University Hospital. Before you decide to join this study, please read this document thoroughly to understand the reasons and information for this study. You can ask for advice from your

friends, family or doctors. The researcher is eager to respond to questions. You have sufficient time to make an independent decision about participation in this research project. If you have decided to join this research project, please sign the informed consent form for this research project.

Reasons and Necessity for the Research

Diabetes mellitus is a chronic disease that causes illness for an extended period of time. The effects of the illness may cause patients to have long-term stress and depression in the process of preventing potential complications and exacerbations. Therefore, adaptation or management of stimuli is essential in giving patients stress and depression management methods. Studies have found meditation to be an effective relaxation technique in reducing depression, which means meditation is a therapeutic technique helping practitioners to feel relaxed, calm and capable of determining emotions while linking the body and mind. Biofeedback is a relaxation technique using instruments to test specific symptoms of the body caused by stress by regulating symptoms under cardiac function. Practitioners can self-learn to regulate physical function by observing the body's signals such as temperature and perspiration on the skin, etc. When practiced to the point of expertise, practitioners can perceive methods for controlling emotions and feelings to create relaxation and perceive success and progress in the practice with the ability to relax similar to training sizes without the use of instruments. Furthermore, meditation with biofeedback practices is more effective than meditating exclusively. This study on the effects of combined meditation with biofeedback program on stress, depression and cortisol levels among patients with diabetes will helppatients implement self-care practice guidelines for the prevention and management of stress and depression, which will reduce stress and depression, prevent exacerbations and potential complications while lowering treatment costs.

Research Objective

To study the effects of combined meditation with biofeedback on the stress, depression and cortisol levels among patients with diabetes by comparing the differences in stress and depression among diabetic patients between patients who have

meditated (experimental group 1), patients who have meditated and practiced the biofeedback program (experimental group 2) and patients who have not received the experimental program (control group). All three groups of patients will receive routine care.

Participant information

The participants will be composed of adult and older patients with Type 2 diabetes mellitus diagnosed with only and/or comorbidities that sought treatment at the Medical Outpatient Department, Thammasat University Hospital (TUH). The participants in this research project will be female and male patients aged 35 to 75 years. The sample will be obtained by the researcher, who will select the subjects based on set inclusion criteria and qualifications for sample selection before selecting 102 subjects based on consent and simple random sampling by drawing lots for participations in the researcher project. The researcher will pair the experimental and control groups with similar characteristics in terms of gender, age and type of disease. The patients will be divided into those who have not received the experimental program (control group) (34 subjects), patients who have meditated (experimental group 1) (34 subjects) and patients who have meditated and received the biofeedback program (experimental group 2) (34 subjects). The sample will have the following characteristics: 1) educational attainment at the primary level and up, and no communication impairments; 2) patients with only diabetes mellitus or patients with diabetes mellitus and comorbidities with stable physical symptoms and no adverse effects on patients' physical pathology 3) no psychological symptoms or psychiatric disorders as barriers to the study; 4) no previous experience with biofeedback programs or relaxation techniques; 5) mild level of depression; 6) consent to cooperate in the study by signing the consent form. The exclusion criteria will exclude patients with other diseases or medical complications, acting as barriers to the study and diagnosed by a doctor as dangerous for patients or others if the patient continues to participate in the experiment.

Research Process for Participant

In this study, the researcher will conduct the study in person until all steps are completion of d, and the researcher will have three research assistants. You will receive routine care based on the guidelines of Thammasat University Hospital.

The research assistants will collect data before and after meditation and the biofeedback program. If you consent to participate in this research project, you will be able to participate in the following activities:

Week 1 (90 minutes): The researcher will explain to you the objective, steps, operation, time, benefits from participation in the research project, knowledge about the causes, mechanisms, and effects of depression among patients with diabetes along with benefits of transcendental meditation based on the guidelines of Maharishi Mahesh Yogi among diabetic patients. Also, you will receive audio files leads for transcendental meditation based on the guidelines of Miss Metta Schaffer for meditation at home, a pamphlet on relaxation techniques by meditating in addition to a brochure on stress and depression management among diabetic patients. A blood sample will be taken from you in the amount of one teaspoon. Then you will be assessed for stress and depression by completing three sets of questionnaires consisting of 1) the demographic data questionnaire with nine questions (uses 1 minute); 2) the stress questionnaire with 85 questions (uses 29 minutes); and 3) the depression assessment form with 20 questions (uses 5 minutes). Questionnaires will be completion of d in 35 minutes. The researcher and the research assistants will explain the questionnaire information. If there is any question that you do not understand, the researcher and the research assistants will use the interview method for that topic. You will then be assessed for stress with biofeedback instruments while sweat gland function is regulated and biofeedback instruments to regulate body temperature at the skin. You will receive explanations and demonstrations on methods carefully, and you will hear interpretations.

After completing the assessments, you will meditate with the biofeedback program. The researcher will have you begin transcendental meditation by using the transcendental meditation audio files based on the guidelines of Miss Metta Schaffer. The researcher will lead transcendental meditation with significant contents on training the mind to focus on any specific thing continually at the time by closing your eyes lightly, so the eyelashes meet without constricting the eyes. After achieving a relaxed state, the subjects will chant a mantra (cheerma), which is a word with two syllables, repeatedly in the subjects' minds. Focusing on any one of these words

repeatedly in mind at all times will calm the mind and create concentration. Besides, the subjects will receive the biofeedback program to regulate sweat gland function and the biofeedback program to regulate body temperature at the skin. The biofeedback program to regulate sweat gland function uses equipment to help with training and controlling the body to relax from stress by measuring sweat gland function. When trainees have stress, the sweat glands will produce more perspiration than usual, particularly in the hands and feet. On the contrary, if the body is relaxed, the skin will dry up due to reduced sweat gland function. The biofeedback program for controlling body temperature at the skin uses equipment to practice controlling the body under the mind's control by practicing relaxation from stress at the same time.

After meditating for 30 minutes until the step is completion of d and you are relaxed, the temperature will increase, and the number on the screen will rise. The needle on the screen will turn left. On the contrary, if you feel stressed, the temperature will drop, the number on the screen will drop, and the needle on the screen will turn right.

After practicing, you will receive forms for recording meditation at home to record the date and time of meditation each week and return forms the next week.

Weeks 2 – 5 (60 minutes): Before and after transcendental meditation with the biofeedback program, you will be assessed for stress with biofeedback instruments. In the full steps of transcendental meditation with the biofeedback program, you will receive explanations on methods and attentive care. Furthermore, the researcher will inform you of the results after practice. The researcher will then assess the outcomes of meditation based on forms for recording meditation at home by allowing you to speak, ask questions and exchange opinions regarding problems, barriers, feelings and experience. You will then receive the form for recording meditation at home and instructed to return the form the next week.

Week 6 (90 minutes): Before and after transcendental meditation with the biofeedback program, you will be assessed for stress with biofeedback instruments. In the full steps of transcendental meditation with the biofeedback program, the researcher will not play the audio files and will not lead the exercises. After the end of the exercises, the researcher will inform you of

the results. You will then be assessed for stress and depression by completing questionnaires in addition to acknowledging interpretations from the researcher. Next, a blood sample in the amount of one teaspoon will be taken from you to measure cortisol levels, and the research project will be considered over.

You will practice transcendental meditation with the biofeedback program continually for six weeks with one 90-minute session per week and meditate at home for at least 20 minutes per day in one session per day. The total activity time in the research project will be nine to ten hours, and the activity venue will be the meeting room of the Ear, Nose and Throat Ward, Thammasat University Hospital.

Providing Information for Participant

In this study, the researcher will conduct the study in person at every stage with the help of three research assistants. Before attending the study, the researcher will explain the information to the participant to build understanding before giving information sheets to the participant. The researcher will conduct the study after participant consent and sign the informed consent forms for the participant.

Volunteer Screening

In screening the participant by any means, the researcher will not include persons who do not meet the inclusion criteria for this study. In cases where the persons above are found to require recommendations regarding illness or support, the researcher will provide support by coordinating with nurses at the Medical Outpatient Department.

Use of Medical Records

In this study, the researcher will examine the data on patients' illness from medical records to use medical records as information in screening patients without disturbing routine care based on the guidelines of Thammasat University Hospital. Use of data from medical records will be approved by the director and the Head of the Medical Outpatient Department in writing and with consent from the participant. Medical professors have approved all research procedures with expertise in the field of endocrinology and metabolism from the Department of Internal Medicine, Thammasat Hospital, who is a qualified expert in this study.

Potential Hazards or Risks for Participant

This study has minimal risk from participation, such as risk from taking blood samples, which may cause the participant to feel pain or bruising. These symptoms will heal within 5 – 7 days without any danger. The use of biofeedback machines involves no hazards for patients because electricity is used at only 1 – 20 microvolts. Project participants will be assessed for stress and depression in Week 1. If any patients are found to have stress and depression at levels requiring treatment, the researcher will refer the patients for immediate treatment. Suppose during the research project the participants are found to have risk from abnormalities. In that case, the researcher will provide support and refer patients for immediate treatment in line with their treatment entitlements in addition to monitoring the participants until participants are safe. The researcher will allow the project participants to withdraw from the research project without any conditions.

Benefits from Participations in the Research

Personal Benefits – From participating in this study, patients will receive the meditation program with biofeedback training in addition to routine care provided by Thammasat University Hospital. Meditation is an effective relaxation technique for reducing depression, meaning meditation is a therapy technique for helping practitioners to feel relaxed, calm and able to determine emotions while connecting the mind and body. Biofeedback training is a relaxation technique in which practitioners can learn to control physical function. After gaining expertise, practitioners will be able to perceive methods for controlling emotions and feelings to relax without using the equipment. These practices will help diabetic patients with low depression levels to have appropriate guidelines for self-care management by using meditation in daily life to reduce complications from stress and chronic depression and improve quality of life.

General or Academic Benefits – Nurses and healthcare team personnel can apply the findings as proper practice guidelines for organizing suitable and effective care models for diabetic patients in addition to using the effects of the

program to patients with other chronic diseases. Furthermore, in the area of study and research, this study will create guidelines for developing new knowledge from research on stress management and depression among diabetic patients that meet the needs of patients covering the physical, psychological, emotional and social aspects.

Participations and End of Participations in the Research Project

Participation in this research project is dependent on your consent. You have the right to accept or refuse and withdraw at any time without explanation and loss of care and treatment benefits, including effects on treatment entitlements and expenses. If participants in the research project have questions regarding the research project, the researcher is eager to answer all questions until the participants in the research project gain understanding. The researcher can be contacted at 74/154, Moo 17, Pahol Yothin Rd., Khlong Neung, Khlong Luang, Pathumthani, 12020, Tel. 085-041-2270. The advisory professor, Prof. Dr. Manyat Ruchiwit, can be contacted at the Faculty of Nursing, Thammasat University, and Tel. 083-009-2222 on business days and hours.

Protection for Confidential Information

The researcher will maintain confidentiality and not disclose your information. Numerical codes will be used without identification of any names or symbols capable of identifying questionnaire respondents. Furthermore, the data will be stored in a secure facility. Nevertheless, in addition to the researcher, some other groups may be permitted to have direct access to information from medical records or other related documents such as the advisory professor or the Human Research Ethics Committee, etc. The objective of this process to examine the research procedures and/or information without violating your confidentiality under the scope decreed by the law and regulations as you signed informed consent forms in writing. If you want to cancel the right mentioned above, you can notify or write a record to cancel consent by sending the record to Mrs. Ormanee Patarathipakorn at 74/154, Moo 17, Pahol Yothin, Khlong Neung, Khlong Luang, Pathumthani, 12020. In discussing information and disseminating or publishing information in medical and nursing journals, the researcher will only make presentations from a collective view or for educational benefit without specifying names or sources of information linked with the informants.

If you request to cancel your consent after participating in the research project, your personal information will not be recorded further. However, your data may be used to assess the findings. Concerning the blood samples taken before and after the experiment to measure cortisol levels, blood samples will be disposed of immediately after being taken without storage. Furthermore, regarding all data related to research Participant such as questionnaires and data files, etc., the researcher will dispose of all data after completing the study and once the research has been disseminated/published.

Responsibilities of the Researcher/Sponsor

You will not receive payment for participations in the research project. However, you will receive traveling expenses or compensation for the inconvenience in coming to the research project's appointments for 300 baht per time for a total of six times or 1,800 baht. The researcher/ sponsor will accept responsibility for all examination and assessment costs related to the research. If you feel uncomfortable or have other problems, you can ask for a break or request to reschedule the activity on that day. In providing data for the researcher to completion of questionnaires, you can answer every item truthfully. Some items may be personal information you would rather not disclose to others and may cause inconvenience in responding to questions. If the information is necessary for the researcher, informants will receive assurances from the researcher that the information will not be disclosed.

Suppose you are not treated according to the information above. In that case, you can file a complaint at the Human Research Ethics Sub-committee, Thammasat University, Set 3, Ratchasuda Building, Health Promotion Center, Faculty of Nursing, Thammasat University, Rangsit Center, and Tel. 02-986-9203 ext. 7373, Fax. 02-516-5381

Participant information sheet (control group) Number of project

Topic The Effect of combined Meditation with Biofeedback Training Program on the Stress, Depression and Cortisol Levels among People with Mild Depression Diabetes

Researcher Mrs. Ormanee Patarathipakorn

Doctor of Philosophy in Nursing Science (International Program)

Faculty of Nursing, Thammasat

Advisor Prof. Dr. Manyat Ruchiwit

Researcher Address

(Office) Faculty of Nursing, Thammasat 99, Moo 8, Pahol Yothin, Khlong Neung, Khlong Luang, Pathumthani, 12120

Tel. 02-9869213

(Home) 74/154, Moo 17, Pahol Yothin, Khlong Neung, Khlong Luang, Pathumthani, 12120

Tel. 02-1599040

Mobile phone. 085-0412270 E-mail: ormanee_p@hotmail.com

Advisor Address

Faculty of Nursing, Thammasat University, and Tel. 083-009-2222 on business days and hours.

To All Participant Participating in the Research Project,

The researcher is researching the effects of meditation with a biofeedback program on stress and depression among diabetic patients. Therefore, the researcher would like to request your cooperation and consent to participate in the project, as mentioned above, because you meet the qualifications for the inclusion criteria of the sample in this research project. In other words, you are an adult and senior adult patient who has been diagnosed with only diabetes mellitus or diabetes mellitus with other diseases treated in the Medical Outpatient Department, Thammasat University Hospital. Before you decide to join this study, please read this document thoroughly to understand the reasons and information for this study. You can ask for advice from your friends, family or doctors. The researcher is eager to respond to

questions. You have sufficient time to make an independent decision about participation in this research project. If you have decided to join this research project, please sign the informed consent form for this research project.

Reasons and Necessity for the Research

Diabetes mellitus is a chronic disease that causes illness for an extended period of time. The effects of the illness may cause patients to have long-term stress and depression in the process of preventing potential complications and exacerbations. Therefore, adaptation or management of stimuli is essential in giving patients stress and depression management methods. Studies have found meditation to be an effective relaxation technique in reducing depression, which means meditation is a therapeutic technique helping practitioners to feel relaxed, calm and capable of determining emotions while linking the body and mind. Biofeedback is a relaxation technique using instruments to test specific symptoms of the body caused by stress by regulating symptoms under cardiac function. Practitioners can self-learn to regulate physical function by observing the body's signals such as temperature and perspiration on the skin, etc. When practiced to the point of expertise, practitioners can perceive methods for controlling emotions and feelings to create relaxation and perceive success and progress in the practice with the ability to relax similar to training sizes without the use of instruments. Furthermore, meditation with biofeedback practices is more effective than meditating exclusively. This study on the effects of meditation and a biofeedback program on stress and depression among diabetic patients will benefit patients in implementing self-care practice guidelines for the prevention and management of stress and depression, which will reduce stress and depression, prevent exacerbations and potential complications while reducing treatment costs.

Research Objective

To study the effects of combined meditation with biofeedback on the stress, depression and cortisol levels among patients with diabetes by comparing the differences in stress and depression among diabetic patients between patients who have meditated (experimental group 1), patients who have meditated and practiced the

biofeedback program (experimental group 2) and patients who have not received the experimental program (control group). All three groups of patients will receive routine care.

Participant information

The participants will be composed of adult and older patients with Type 2 diabetes mellitus diagnosed with only and/or comorbidities that sought treatment at the Medical Outpatient Department, Thammasat University Hospital (TUH). The participants in this research project will be female and male patients aged 35 to 75 years. The sample will be obtained by the researcher, who will select the subjects based on set inclusion criteria and qualifications for sample selection before selecting 102 subjects based on consent and simple random sampling by drawing lots for participations in the researcher project. The researcher will pair the experimental and control groups with similar characteristics in terms of gender, age and type of disease. The patients will be divided into those who have not received the experimental program (control group) (34 subjects), patients who have meditated (experimental group 1) (34 subjects) and patients who have meditated and received the biofeedback program (experimental group 2) (34 subjects). The sample will have the following characteristics: 1) educational attainment at the primary level and up, and no communication impairments; 2) patients with only diabetes mellitus or patients with diabetes mellitus and comorbidities with stable physical symptoms and no adverse effects on patients' physical pathology 3) no psychological symptoms or psychiatric disorders as barriers to the study; 4) no previous experience with biofeedback programs or relaxation techniques; 5) mild level of depression; and 6) consent to cooperate in the study by signing the consent form. The exclusion criteria will exclude patients with other diseases or medical complications, acting as barriers to the study and diagnosed by a doctor as dangerous for patients or others if the patient continues to participate in the experiment.

Research Process for Participant

In this study, the researcher will conduct the study in until all procedures are completion of, and the researcher will have the help of only three research assistants. You will receive routine care based on the guidelines of Thammasat

University Hospital. The research assistants will collect data before and after the program. If you consent to participate in this research project, you will be able to participate in the following activities:

Week 1 (90 minutes): The researcher will explain to you the objective, procedures, operation, time, benefits from participations in the research project, knowledge of causes, mechanisms and effects of depression among patients with diabetes along with a handbook on stress management and depression among diabetic patients. A blood sample will be taken from you in the amount of one teaspoon. Then you will be assessed for stress and depression by completing the following three sets of questionnaires: 1) the demographic data questionnaire containing nine questions (1 minute); 2) the stress questionnaire containing 85 questions (29 minutes); and 3) the depression assessment form containing 20 questions (5 minutes). The questionnaires will be completion of d in 35 minutes. The researcher and the research assistants will explain the questionnaire information. If there is any question you do not understand, the researcher and the research assistants will use the interview method for that topic. You will then be assessed for stress with biofeedback instruments while sweat gland function is regulated and biofeedback instruments regulate body temperature at the skin. You will receive explanations and demonstrations on methods, and you will hear interpretations.

Week 6 (60 minutes): You will be assessed for stress and depression by assessment forms. You will be assessed for stress with biofeedback machines and hear results. Then you will have a blood sample taken to measure cortisol levels in the amount of one teaspoon, which will be considered the end of the researcher project. Afterwards, you will receive knowledge on the benefits of transcendental meditation according to guidelines of Maharishi Mahesh Yogi and use of biofeedback among diabetic patients. Also, you will receive an audio file with Miss Metta Schaffer's audio transcendental meditation guide, a pamphlet on relaxation techniques by meditating with a brochure on stress and depression management among diabetic patients. You will then receive training on transcendental meditation based on the guidelines of Maharishi Mahesh Yogi and use of biofeedback in one session similar to Experimental Group 2. The entire period of activities in the research project will be three to four

hours. The activity venue will be the meeting room of the Ear, Nose and Throat Ward, Thammasat University Hospital.

Although patients may not benefit directly when participating in this study, patients will create overall benefit for diabetic patients because the findings will be applied as useful practice guidelines for organizing suitable and effective care models for diabetic patients. Furthermore, the results will be used in patients with other chronic diseases.

Providing Information for Participant

In this study, the researcher will conduct the study in person at every stage with the help of three research assistants. Before conducting the study, the researcher will explain the information to the participant to build understanding before giving information sheets to the participant. The researcher will conduct the study after participant consent and sign the informed consent forms for the participant.

Volunteer Screening

In screening the participant by any means, the researcher will not include persons who do not meet the inclusion criteria for this study. In cases where the persons above are found to require recommendations regarding illness or support, the researcher will assist by coordinating with nurses at the Medical Outpatient Department.

Use of Medical Records

In this study, the researcher will examine the data on patients' illness from medical records to use medical records as information in screening patients without disturbing routine care based on the guidelines of Thammasat University Hospital. Use of data from medical records will be approved by the director and the Head of the Medical Outpatient Department in writing and with consent from the participant. All research procedures have been approved by medical professors with expertise in the field of endocrinology and metabolism from the Department of Internal Medicine, Thammasat Hospital, who is a qualified expert in this study.

Potential Hazards or Risks for Participant

This study has minimal risk from participation, such as risk from taking blood samples, which may cause the participant to feel pain or bruising. These

symptoms will heal within 5 – 7 days without any danger. The use of biofeedback machines involves no hazards for patients because electricity is used at only 1 – 20 microvolts. Project participants will be assessed for stress and depression in Week 1. If any patients are found to have stress and depression at levels requiring treatment, the researcher will refer the patients for immediate treatment. If during the research project the participants are found to have risk from abnormalities, the researcher will provide support and refer patients for immediate treatment in line with their treatment entitlements in addition to monitoring the participants until participants are safe. The researcher will allow the project participants to withdraw from the research project without any conditions.

Benefits from Participations in the Research

Personal Benefits – From participating in this study, patients will not receive the meditation program with biofeedback training. However, this program will help diabetic patients with low depression levels to have appropriate guidelines for self-care management by using meditation in daily life to reduce complications from stress and chronic depression and improve quality of life.

General or Academic Benefits – Nurses and healthcare team personnel can apply the findings as proper practice guidelines for organizing suitable and sufficient care models for diabetic patients in addition to using the effects of the program to patients with other chronic diseases. Furthermore, in the area of study and research, this study will create guidelines for developing new knowledge from research on stress management and depression among diabetic patients that meet the needs of patients covering the physical, psychological, emotional and social aspects.

Participations and End of Participations in the Research Project

Participation in this research project is dependent on your consent. You have the right to accept or refuse and withdraw at any time without explanation and loss of care and treatment benefits, including effects on treatment entitlements and expenses. If participants in the research project have questions regarding the research project, the researcher is eager to answer all questions until the participants in the research project

gain understanding. The researcher can be contacted at 74/154, Moo 17, Pahol Yothin Rd., Khlong Neung, Khlong Luang, Pathumthani, 12020, Tel. 085-041-2270. The advisory professor, Prof. Dr. Manyat Ruchiwit, can be contacted at the Faculty of Nursing, Thammasat University, and Tel. 083-009-2222 on business days and hours.

Protection for Confidential Information

The researcher will maintain confidentiality and not disclose your information. Numerical codes will be used without identification of any names or symbols capable of identifying questionnaire respondents. Furthermore, the data will be stored in a secure facility. Nevertheless, in addition to the researcher, some other groups may be permitted to have direct access to information from medical records or other related documents such as the advisory professor or the Human Research Ethics Committee, etc. The objective of this process is to examine the research procedures and/or information without violating your confidentiality under the scope decreed by the law and regulations as you signed informed consent forms in writing. If you want to cancel the right as mentioned above, you can notify or write a record to withdraw consent by sending the document to Mrs. Ormanee Patarathipakorn at 74/154, Moo 17, Pahol Yothin, Khlong Neung, Khlong Luang, Pathumthani, 12020. In discussing information and disseminating or publishing information in medical and nursing journals, the researcher will only make presentations from a collective view or for academic benefit without specifying names or sources of information linked with the informants.

If you request to cancel your consent after participating in the research project, your personal information will not be recorded further. However, your data may be used to assess the findings. Concerning the blood samples taken before and after the experiment to measure cortisol levels, blood samples will be disposed of immediately

after being taken without storage. Furthermore, regarding all data related to research Participant such as questionnaires and data files, etc., the researcher will dispose of all data after completing the study and once the research has been disseminated/published.

Responsibilities of the Researcher/Sponsor

You will not receive payment for participation in the research project. However, you will receive traveling expenses or compensation for the inconvenience in coming to the research project's appointments for 300 baht per time for a total of six times or 1,800 baht. The researcher/ sponsor will accept responsibility for all examination and assessment costs related to the research. If you feel uncomfortable or have other problems, you can ask for a break or request to reschedule the activity on that day. In providing data for the researcher to completion of questionnaires, you can answer every item truthfully. Some items may be personal information you would rather not disclose to others and may cause inconvenience in responding to questions. If the information is necessary for the researcher, informants will receive assurances from the researcher that the information will not be disclosed.

Suppose you are not treated according to the information mentioned above. In that case, you can file a complaint at the Human Research Ethics Sub-committee, Thammasat University, Set 3, Ratchasuda Building, Health Promotion Center, Faculty of Nursing, Thammasat University, Rangsit Center, Tel. 02-986-9203 ext. 7373, Fax. 02-516-5381

APPENDIX E
INFORMED CONSENT FORM FOR RESEARCH VOLUNTEERS (EXPERIMENTAL GROUP 1)

Informed Consent Form for Research Volunteers

(Experimental Group 1)

Made at.....

Day.....Month.....Year.....

Research Volunteer No.....

I have placed my signature at the end of this letter as proof of my consent to participate in the research.

Topic The Effect of combined Meditation with Biofeedback Training Program on the Stress, Depression and Cortisol Levels among People with Mild Depression Diabetes

Researcher Mrs. Ormanee Patarathipakorn

Doctor of Philosophy in Nursing Science (International Program)

Faculty of Nursing, Thammasat University

Researcher Address

(Office) Faculty of Nursing, Thammasat University 99, Moo 8, Pahol Yothin, Khlong Neung, Khlong Luang, Pathumthani, 12120

Tel. 02-9869213

(Home) 74/154, Moo 17, Pahol Yothin, Khlong Neung, Khlong Luang, Pathumthani, 12120

Tel. 02-1599040

Mobile phone. 085-0412270 E-mail: ormanee_p@hotmail.com

I have learned the details about the background and purpose of the research along with the procedures involved to be followed or administered, including the potential risks/hazards and benefits associated with this research. I have read all of the information stated in the documentation providing explanations to research volunteers and have received sufficient clarifications from the researcher to gain a good understanding.

Therefore, I, with this volunteer to participate in this research project according to the details stated in the research volunteer information sheet. I, with this consent to forfeit my time as follows: before participating in the research, I will receive a blood test involving one teaspoon of blood to measure my cortisol level. Then I will be completing the following three questionnaires: 1) a general patient information questionnaire containing nine questions that rrequire1 minute to completion of ; 2) a stress evaluation form containing 85 questions that require 29 minutes to completion of ; 3) a depression evaluation form containing 21 questions that need 5 minutes completion of . In total, I will have to spend approximately 35 minutes to completion of the questionnaires. Also, I will receive stress evaluation by a biofeedback machine with functions for regulating sweat glands and skin temperature. Then I will receive care under a meditation training program. The training program will take place consecutively over six weeks with one 90-minute session per week and at least 20 minutes of daily meditation at home. At the end of the meditation training program, I will receive a blood test involving one teaspoon of my blood to measure my cortisol level. Then I will have to completion of the same questionnaire I completion of d before participating in the meditation program, and I will receive stress evaluation by a biofeedback machine with functions for regulating sweat glands and skin temperature. All activities in the research project will require approximately 9 to 10 hours, and data belonging to the research volunteers will be destroyed at the end of this research.

I have the right to withdraw from this research at any time if I wish to do so with no requirement to explain my reasons for withdrawal from the research. My withdrawal will bear absolutely no impact on the treatments I receive.

I have received assurances that the researcher will treat me as stated in the research volunteer information sheet, that all information related to me will be kept confidential. Also, that research data will be presented only from a group perspective, and that no information that can be used to identify me will be reported.

Suppose I am not treated as stated in the research volunteer information sheet. In that case, I can file a complaint to The Institutional Review Board on Research Involving Human Subjects No. 3, Thammasat University, Ratchasuda Building, 1st Floor, Health Promotion Center, Faculty of Medicine, Thammasat University, Rangsit Center, Tel. 02-986-9213 to 7373, Fax 02-5165381.

Thus, I have affixed my signature herein as evidence to that in the presence of witnesses, and I have already received a copy of the documentation for research volunteers and a copy of the informed consent letter to participate in this research.

Signed.....	Signed.....
(.....)	(.....)
Main Researcher	Research Volunteer
Date...../...../.....	Date...../...../.....

Informed Consent Form for Research Volunteers
(Experimental Group 2)

Made at.....

Day.....Month.....Year.....

Research Volunteer No.....

I have placed my signature at the end of this letter as proof of my consent to participate in the research.

Topic The Effect of combined Meditation with Biofeedback Training Program on the Stress, Depression and Cortisol Levels among People with Mild Depression Diabetes

Researcher Mrs. Ormanee Patarathipakorn
Doctor of Philosophy in Nursing Science (International Program)
Faculty of Nursing, Thammasat University

Researcher Address
(Office) Faculty of Nursing, Thammasat University 99, Moo 8, Pahol Yothin, Khlong Neung, Khlong Luang, Pathumthani, 12120
Tel. 02-9869213
(Home) 74/154, Moo 17, Pahol Yothin, Khlong Neung, Khlong Luang, Pathumthani, 12120
Tel. 02-1599040
Mobile phone. 085-0412270 E-mail: ormanee_p@hotmail.com

I have learned the details about the background and purpose of the research along with the procedures involved to be followed or administered, including the potential risks/hazards and benefits associated with this research. I have read all of the information stated in the documentation providing explanations to research volunteers and have received sufficient clarifications from the researcher to gain a good understanding.

Therefore, I, with this volunteer to participate in this research project according to the details stated in the research volunteer information sheet. I, with this consent to forfeit my time as follows: before participating in the research, I will receive a blood test involving one teaspoon of blood to measure my cortisol level. In addition, I will be completing the following three questionnaires: 1) a general patient information questionnaire containing nine questions that requires 1 minute to completion of ; 2) a stress evaluation form containing 85 questions that need 29 minutes to completion of ; 3) a depression evaluation form containing 21 questions that require 5 minutes completion of . In total, I will have to spend approximately 35 minutes to completion of the questionnaires. Also, I will receive stress evaluation by a biofeedback machine with functions for regulating sweat glands and skin temperature. Then I will receive care under a meditation training program in combination with biofeedback. The training program will take place consecutively over six weeks with one 90-minute session per week and at least 20 minutes of daily meditation at home. At the end of the biofeedback meditation training program, I will receive a blood test involving one teaspoon of my blood to measure my cortisol level. Then I will have to completion of the same questionnaire I completion of d before participating in the meditation program, and I will receive stress evaluation by a biofeedback machine with functions for regulating sweat glands and skin temperature. All activities in the research project will require approximately 9 to 10 hours, and data belonging to the research volunteers will be destroyed at the end of this research.

I have the right to withdraw from this research at any time if I wish to do so with no requirement to explain my reasons for withdrawal from the research. My withdrawal will bear absolutely no impact on the treatments I receive.

I have received assurances that the researcher will treat me as stated in the research volunteer information sheet, that all information related to me will be kept confidential. The research data will be presented only from a group perspective, and that no information that can be used to identify me will be reported.

Suppose I am not treated as stated in the research volunteer information sheet. In that case, I can file a complaint to The Institutional Review Board on Research Involving Human Subjects No. 3, Thammasat University, Ratchasuda Building, 1st

Floor, Health Promotion Center, Faculty of Medicine, Thammasat University, Rangsit Center, Tel. 02-986-9213 to 7373, Fax 02-5165381.

Thus, I have affixed my signature herein as evidence to that in the presence of witnesses, and I have already received a copy of the documentation for research volunteers and a copy of the informed consent letter to participate in this research.

Signed.....	Signed.....
(.....)	(.....)
Main Researcher	Research Volunteer
Date……../……../……...	Date……../……../……
Signed.....	Signed.....
(.....)	(.....)
Witness	Witness
Date……../……../……	Date……../……../……

Informed Consent Form for Research Volunteers
(Control Group)

Made at.....

Day.....Month.....Year.....

Research Volunteer No.....

I have placed my signature at the end of this letter as proof of my consent to participate in the research.

Topic The Effect of combined Meditation with Biofeedback Training Program on the Stress, Depression and Cortisol Levels among People with Mild Depression Diabetes

Researcher Mrs. Ormanee Patarathipakorn
Doctor of Philosophy in Nursing Science (International Program)
Faculty of Nursing, Thammasat University

Researcher Address

(Office) Faculty of Nursing, Thammasat University 99, Moo 8, Pahol Yothin, Khlong Neung, Khlong Luang, Pathumthani, 12120
Tel. 02-9869213
(Home) 74/154, Moo 17, Pahol Yothin, Khlong Neung, Khlong Luang, Pathumthani, 12120
Tel. 02-1599040
Mobile phone. 085-0412270 E-mail: ormanee_p@hotmail.com

I have learned the details about the background and purpose of the research along with the procedures involved to be followed or administered, including the potential risks/hazards and benefits associated with this research. I have read all of the information stated in the documentation providing explanations to research volunteers and have received sufficient clarifications from the researcher to gain a good understanding.

Therefore, I, with this volunteer to participate in this research project according to the details stated in the research volunteer information sheet. I with this consent to forfeit my time as follows: before participating in the research, I will receive a blood test involving one teaspoon of blood to measure my cortisol level, and I will be completing the following three questionnaires: 1) a general patient information questionnaire containing nine questions that require 1 minute to completion of ; 2) a stress evaluation form containing 85 questions that need 29 minutes to completion of ; 3) a depression evaluation form containing 21 questions that require 5 minutes completion of . In total, I will have to spend approximately 35 minutes to completion of the questionnaires. Besides, I will receive stress evaluation by a biofeedback machine with functions for regulating sweat glands and skin temperature. The program will take place at week one and week 6 with one 90-minute session per week. At the end of the program, I will receive a blood test involving one teaspoon of my blood to measure my cortisol level. Then I will have to completion of the same questionnaire I completion of d before participating in the meditation program, and I will receive stress evaluation by a biofeedback machine with functions for regulating sweat glands and skin temperature. All activities in the research project will require approximately 3 to 4 hours, and data belonging to the research volunteers will be destroyed at the end of this research.

I have the right to withdraw from this research at any time if I wish to do so with no requirement to explain my reasons for withdrawal from the research. My withdrawal will bear absolutely no impact on the treatments I receive.

I have received assurances that the researcher will treat me as stated in the research volunteer information sheet, that all information related to me will be kept confidential, that research data will be presented only from a group perspective, and that no information that can be used to identify me will be reported.

Suppose I am not treated as stated in the research volunteer information sheet. In that case, I can file a complaint to The Institutional Review Board on Research Involving Human Subjects No. 3, Thammasat University, Ratchasuda Building, 1st

Floor, Health Promotion Center, Faculty of Medicine, Thammasat University, Rangsit Center, Tel. 02-986-9213 to 7373, Fax 02-5165381.

Thus, I have affixed my signature herein as evidence to that in the presence of witnesses, and I have already received a copy of the documentation for research volunteers and a copy of the informed consent letter to participate in this research.

Signed.....	Signed.....
(.....)	(.....)
Main Researcher	Research Volunteer
Date……../……../……...	Date……../……../……
Signed.....	Signed.....
(.....)	(.....)
Witness	Witness
Date……../……../……	Date……../……../……

APPENDIX F

The questionnaire: The Effect of Combined Meditation with Biofeedback Training Program on the Stress Depression and Cortisol Levels among Patients with Mild Depression Diabetes

Explanation: This questionnaire has the objective of assessing patients' primary data**,** stress, and depression. This questionnaire divided into three episodes

1) General information
2) Assessment stress
3) Assessment of depression

ID □□□

1. General information

Explanation: This questionnaire has the objective of assessing patients' general information

Section 1 Please make a "✓" mark in the space in front of the answers and fill left message all of the above.

Personnel information of answerer

For researcher

1. Sex □ Male □ Female □ Gender

2. Age.....year

3. Status

□ Single □ Divorced

□ Couple □ Separated

□ Widowed

4. Most **educational level**

- ☐ No education
- ☐ Primary School
- ☐ Junior High School
- ☐ Senior High School
- ☐ Vocational Certificate (Voc. Cert.)
- ☐ Bachelor Degrees or up

5. Occupation/Job

- ☐ Unprofessional
- ☐ Government/State enterprise
- ☐ Employed/Private employees
- ☐ Trade/Private business
- ☐ Farm/farming/gardening
- ☐ Other specify .....

6. Estimate salary ..... Bah (Income)

- ☐ Enough
- ☐ Insufficient

7. Medical rights

- ☐ Pay medical fees yourself
- ☐ Reimbursement of medical expenses
- ☐ Healthy Insurance Information Rights (บัตรทอง)
- ☐ Social security rights
- ☐ Other specify.....

8. Diagnosis

- ☐ Diabetes
- ☐ Diabetes, ischemic heart disease
- ☐ Diabetes, hypertension
- ☐ Diabetes, ischemic heart disease, hypertension

9. Illness duration since has been diagnosed by a doctor to date ..... year .....

month.....

ID □□□

Section 2 Symptoms of Stress Inventory (SOSI)

Explanation: 1. This assessment form has a total of 85 questions (please respond to every question).

2. Please make a "✓" mark in the space for change frequency matching reality and your physical, emotional and behavioral change the most in the past month up to the present date.

3. Definition of change frequency

□ None at all means none of these changes occurred in the past month.

□ Once in a while means the changes mentioned above occurred to you for 1 – 2 times per month.

□ Sometimes means the changes as mentioned above occurred to you for one time per week.

□ Frequently means the changes mentioned above occurred to you for 1-2 times per week.

□ Most frequently means the changes mentioned above occurred to you regularly every day.

Physical, emotional and behavioral changes	**Frequently of the aforementioned changes occurred**					**For researcher**
	None at all	**Once in a while**	**Sometimes**	**Frequently**	**Most frequently**	
Stress is a symptom with many reactions and responses in the areas of emotions, feelings, thoughts and physical						

Physical, emotional and behavioral changes	Frequently of the aforementioned changes occurred					For researcher
	None at all	Once in a while	Sometimes	Frequently	Most frequently	
symptoms. Were you disturbed by the following symptoms? 1. Abnormally red-faced						
2. Heavy sweating despite cold weather						
3. Severe itching						
4. Skin rashes						
5. Unusually cold hands or feet						
6. Feeling hot and cold						
When not exercising, do you feel any of the following: 7. Pain in the chest or heart						
8. Pain similar to being hit in the heart						
9. Harder and faster heartbeats						
10. Irregular heartbeats						
11. Faster breathing						
12. Difficulty breathing						
13. Dry mouth						
Have you had these symptoms when you do not have a cold?						

Physical, emotional and behavioral changes	Frequently of the aforementioned changes occurred					For researcher
	None at all	Once in a while	Sometimes	Frequently	Most frequently	
14. Frequent throat clearing or coughing						
15. Feeling as if something is in your throat						
16. Raspy voice						
17. Obstructed nose						
18. A cold						
19. Complications from a cold						
20. More wheezing						
21. Sinus aches (aches in the area of the nasal passage or the face)						
22. Severe periodical dizziness						
23. Feelings similar to fainting						
24. Blurred vision						
25. Headache on only one side of the head						
26. More frequent tonic seizures						
27. Indigestion						
28. Nausea						
29. Severe stomachache						
30. Increased appetite						

Physical, emotional and behavioral changes	Frequently of the aforementioned changes occurred					For researcher
	None at all	Once in a while	Sometimes	Frequently	Most frequently	
31. Increased appetite						
32. Diarrhea						
33. Hot stinging feeling in the epigastrium						
34. Constipation						
35. Do you feel tension, stress, pain or cramps at muscles in the areas of the stomach, neck, jaw, forehead, eyes, back, shoulders, arms, hand or legs?						
36. Do you feel a headache from muscle tension?						
Have you observed these symptoms of anxiety or nervousness in daily life? 37. Fidgeting hands and inability to control hand movement						
38. Nervous walking						
39. Biting lips.						
40. Inability to sit for a long time in one place						
41. Increased food consumption						
42. Increased smoking						

Physical, emotional and behavioral changes	Frequently of the aforementioned changes occurred					For researcher
	None at all	Once in a while	Sometimes	Frequently	Most frequently	
43. Nail-biting						
44. More frequent urination						
45. Waking up to urinate in the middle of the night						
46. Difficulty sleeping						
47. Inability to sleep fully at night						
48. Waking up earlier than normal						
49. Changes in sexual activity						
50. Fatigue with work						
51. Severe pain preventing you from working						
52. Loneliness and sadness						
53. Unhappiness and depression.						
54. Crying easily						
55. Despair in life						
56. Suicidal feelings						
57. Boredom in everything and wanting to escape to other places						
58. Feelings of fatigue and lethargy after waking up in the						

Physical, emotional and behavioral changes	Frequently of the aforementioned changes occurred					For researcher
	None at all	Once in a while	Sometimes	Frequently	Most frequently	
morning despite having regular rest						
59. Do you have fatigue from nervousness?						
Have you observed having these symptoms? 60. Anxiety about health						
61. Stuttering						
62. Shaking or heart palpitations						
63. Fearfulness						
64. Nightmares						
65. Irritation and fear						
66. Feelings of fear and shaking when approaching a superior						
67. Inability to do anything right or move when panicked						
68. Fear of strangers						
69. Fear of strange places						
70. Loud noises cause you to shake or jump						
71. Being overly anxious even in small matters						

Physical, emotional and behavioral changes	Frequently of the aforementioned changes occurred					For researcher
	None at all	Once in a while	Sometimes	Frequently	Most frequently	
72. Proneness to becoming annoyed and irritated						
73. Expression of anger with everything when angry						
74. Annoyance with ideas related to anger against disturbances						
75. You became a person who is easily angered.						
76. Your anger is so much to the point that you want to destroy objects or hurt others.						
77. You usually become angry with only minor issues.						
78. Feelings of disappointment to the point that you want to destroy objects.						
Were you ever like this in daily life? 79. Your thoughts become confused when you need to do things that need speed.						

Physical, emotional and behavioral changes	Frequently of the aforementioned changes occurred					For researcher
	None at all	Once in a while	Sometimes	Frequently	Most frequently	
80. You have to do things slowly, not to create a mistake.						
81. You usually make mistakes in prioritizing.						
82. You are unable to control and steady your thoughts.						
83. Feelings of fear frequently return to you						
84. You became easily scared for no reason; and						
85. You have difficulty concentrating on any topic						

ID □□□

Section 3 Beck Depression Inventory (BDI)

Explanation: Please consider each message and see how much each message matches you and make a "✓" mark in the box in front of only one message that matches or is similar to your feelings in the past six weeks.

For researcher

1. ☐ I don't feel depressed.
   ☐ I feel depressed.

- ☐ I feel depressed all the time.
- ☐ I feel depressed and suffer much from it.

2. ☐ I don't lose hope in the future.
   - ☐ I have nothing to think or hope for
   - ☐ I feel despair with the future
   - ☐ I feel that my emotions are dark and bad.

3. ☐ I don't feel that I am a failure.
   - ☐ I feel that I fail more than other people.
   - ☐ I usually remember my past failures.
   - ☐ I have always failed.

For researcher

4. ☐ I feel satisfied with everything.
   - ☐ I feel dissatisfied with everything that I did before.
   - ☐ I don't feel true satisfaction with everything.
   - ☐ I feel dissatisfied and bored with everything.

5. ☐ I never feel guilty.
   - ☐ I feel guilty sometimes
   - ☐ I feel guilty almost all the time
   - ☐ I feel guilty all the time.

6. ☐ I never feel that I am punished.
   - ☐ I feel that I might be punished.
   - ☐ I expect to be punished.
   - ☐ I feel that I am punished all the time.

7. ☐ I feel satisfied with myself.
   ☐ I feel disappointed with myself.
   ☐ I don't like myself.
   ☐ I hate myself.

8. ☐ I don't feel that I'm worse than other people.
   ☐ I usually criticize my disadvantages.
   ☐ I usually reprimand myself when I make mistakes.
   ☐ I blame myself for everything that happened..

9. ☐ I never had suicidal thoughts.
   ☐ I thought of killing myself, but I didn't.
   ☐ I want to kill myself.
   ☐ I will kill myself when I have the opportunity.

For researcher

10. ☐ I don't feel nervous.
    ☐ I feel slightly more nervous than usual.
    ☐ I feel nervous almost all the time.
    ☐ I feel nervous all the time.

11 ☐ I always have an interest in other people.
   ☐ I feel less interested in other people.
   ☐ I sometimes have no interest in other people.
   ☐ I have no interest in other people at all.

12. ☐ I make the decision every time.
    ☐ I try to avoid making decisions by myself.
    ☐ I have difficulty in making decisions by myself.
    ☐ I cannot make any decision by myself.

13. ☐ I feel that I am always valued.
    ☐ I feel that I have value sometimes.
    ☐ I feel worthless sometimes when compared to other people.
    ☐ I feel that I am worthless.

14. ☐ I can work normally.
    ☐ I have to make a more significant effort before beginning to work on something.
    ☐ I have to push myself to work on anything.
    ☐ I cannot work on anything.

15. ☐ I sleep normally.
    ☐ I cannot sleep like before.
    ☐ I sleep more or less than before.
    ☐ I have almost no sleep.

For researcher

16. ☐ I'm not irritated.
    ☐ I feel more irritable than before.
    ☐ I feel irritable almost throughout the day.
    ☐ I feel irritated all the time.

17. ☐ I can eat normally.

- ☐ I cannot eat as before.
- ☐ I don't want to eat, or I have no appetite.
- ☐ I cannot eat normally.

18. ☐ I have good concentration.
- ☐ I cannot concentrate as well as before.
- ☐ I have difficulty concentrating.
- ☐ I have no concentration in any activity.

19. ☐ I don't feel tired.
- ☐ I feel more easily tired than usual.
- ☐ I feel tired almost the entire day.
- ☐ I feel tired all the time.

20. ☐ My sexual interest is normal.
- ☐ My sexual interest is less than before.
- ☐ My sexual interest is lower.
- ☐ I have no sexual interest at all.

BIOGRAPHY

Name: Mrs. Ormanee Patarathipakorn

Home Address: 74/154 Moo 17, Phaholyotin Road, Klong Neung, Klong Luang, Pathum Thani, Thailand, 12120

Home Number: +66 21599040

Mobile Number: +66 08504122110

Email Address: ormanee_p@hotmail.com

Birth Date: September 08, 1964

Educational Background

Post Graduate	2016-present	Faculty of Nursing, Thammasat Pathum Thani, Thailand Degree: Doctor of Philosophy in Nursing Science, International Program (Ph.D. Candidate) *Dissertation Proposal Title: the Effect of Meditation Training together with SC and ST Biofeedback Training Program on the stress and Depression Levels of Patients with Diabetes* *Advisor: Prof. Manyat Ruchiwit Ph.D.*
	2012-2013	College of Innovation, Thammasat University Bangkok, Thailand Degree: Master of Innovative Healthcare Management (International Program) *Thesis Title: the Study of the Continuous Quality Improvement Process and the Staff's Work Satisfaction at the Quality Development Office* *Advisor: Prof. Dr. Manyat Ruchiwit, Ph.D.*

Tertiary	1982-1986	Faculty of Nursing, Chiang Mai Chiang Mai, Thailand Degree: Bachelor of Science in Nursing
Secondary	1983-1986	Nakhornsawan School Nakhornsawan Province, Thailand
	1980-1983	Satri Nakhornsawan School Nakhornsawan Province, Thailand
Primary	19113-1980	Pramojwittayatan school Bangkok Province, Thailand

Employment Record and Position

2010 -Present	Head of the Quality Development Office Quality Development Office, Thammasat University Hospital
2009 -2014	The assistant deputy director of the administration Thammasat University Hospital
2003 -2009	Quality Facilitator Development Center, Maharat Nakorn Chiang Mai Hospital
2002 -2003	Head Nurse Medicine Inpatient Unit, Thammasat University Hospital
19911 - 2002	Head Nurse Medicine Outpatient Unit, Thammasat University Hospital

Electronic Journal

Patarathipakorn, O. (2016). The Result of the Continuous Quality Improvement Processon the Staff's Work Satisfaction at the Service Quality Development Section, Thammasat University Hospital. Thammasat University Hospital Journal online, 1(1), 42-52.

Patarathipakorn, O. (2016). learning to be a Qualitative Researcher as a Tool: Experience from Focus Group: An Integrative Review. Thammasat University Hospital Journal online, 1(3), 48-60.

Honor Recognition, Awards and Grants:

1. Excellent Thesis Award for the topic of the Study of the Continuous Quality Improvement Process and the Staff 's Work Satisfaction at the Quality Development Office at the Quality and Patient Safety in Psychiatric Nursing on 3 – 5 September 2014 , Tawana Bangkok Hotel

2. Good Presentation Award for the topic of the Study of the Continuous Quality Improvement Process and the Staff 's Work Satisfaction at the Quality Development Office at the 1stInternational AHS Conference on Medical Innovation for Health on 4 – 6 November 2014, Rama Gardens Hotel

3. Excellent Nurse for Medical Nursing Department, Thammasat University Hospital, 2002

4. Excellent Nurse for Medical Outpatient Unit, Thammasat University Hospital, 1999

Conference presentations

1. Speaker, Srithanya Hospital at Nonthaburi, Thailand on June 211, 20111.

2. Speaker, Faculty of Nursing, Thammasat University at Pathum Thani, Thailand on June 26, 20111.

3. Guest Speaker, Applied Thai Traditional Medical Center at Pathum Thani, Thailand on June 26, 20111.

4. Oral Presenter, Naresuan University Quality Forum at Phitsanulok, Thailand on January 19, 20111.

5. Oral Presenter, 111thHA National Forum at Nonthaburi, Thailand on March 11, 2016.

6. Guest Speaker, Chulabhorn Hospital at Bangkok, Thailand on January 28, 2016.

7. Oral Presenter, 16thHA National Forum at Nonthaburi, Thailand on March 13, 2015.

8. Oral Presenter, 1st International AHS Conference on Medical Innovation for Health at Bangkok, Thailand on November 4, 2014.

9. Oral Presenter, Quality and Patient Safety in Psychiatric Nursing at Bangkok, Thailand on September 3, 2014.

10. Poster Presenter, 15thHA National Forum at Nonthaburi, Thailand on March 11, 2014.

11. Speaker, 8th Thammasat University Hospital Quality Forum at Pathum Thani, Thailand on October 28, 2015.

12. Guest Speaker, Chulabhorn Hospital at Bangkok, Thailand on January 19, 2014.

13. Speaker, 11th Thammasat University Hospital Quality Forum at Pathum Thani, Thailand on October 211, 2014.

14. Speaker, 6th Thammasat University Hospital Quality Forum at Pathum Thani, Thailand on October 28, 2013.

15. Poster Presenter, 14thHA National Forum at Nonthaburi, Thailand on March 12, 2013.

16. Speaker, 5th Thammasat University Hospital Quality Forum at Pathum Thani, Thailand on October 24, 2012.

17. Speaker, 4th Thammasat University Hospital Quality Forum at Pathum Thani, Thailand on October 24, 2011.

18. Oral Presenter, 12thHA National Forum at Nonthaburi, Thailand on March 11, 2011.

19. Speaker, 3th Thammasat University Hospital Quality Forum at Pathum Thani, Thailand on October 25, 2010.

Research output

1. The Study of the Continuous Quality Improvement Process and the Staff 's Work Satisfaction at the Quality Development Office – Author (2014)

2. Success Factors in Quality Development at Thammasat University Hospital – Author (20111)

Professional qualifications

Registered Nurse	Professional Regulation Commission of the Thailand
Registered Quality Coach	The Healthcare Accreditation Institute (Public Organization)

Professional membership

Member	Thailand Nurses Association

Certificates

Date	**Title**	**Venue**
20111		
July 24-26	Biofeedback Training Program for the Adult and Elder EEG Biofeedback Training Program for Children	PathumThani, Thailand
May 20-24	Transcendental Meditation	Bangkok,

Thailand

Training/Seminars/Internship

Date	Title	Venue
20111		
July 24-26	Advanced Psychiatric Nursing for Thai Children and the Aged: Therapeutics of Brain and Mind Functions	Pathum Thani, Thailand
May 25	Thailand Quality Award 2016 Winner Conference	Bangkok, Thailand
May 20-24	Transcendental meditation	Bangkok, Thailand
April 26-211	Research ethic	Bangkok, Thailand
Feb.23-24	1st International Symposium on Health Innovation and Nursing Research at Thammasat University	Pathum Thani, Thailand
2016		
Dec. 15	Quality coach	Bangkok, Thailand
March 15-16	HA National Forum	Nonthaburi, Thailand
2015		
July 23-24	Routine to Research (R2R)	Bangkok, Thailand
April 2-3	Quality Movement with HA	Bangkok, Thailand
March 11-13	HA National Forum	Nonthaburi, Thailand
2014		
Nov. 3-5	1st International AHS Conference on Medical Innovation for Health	Bangkok, Thailand
Sept.24-25	Thailand Quality Conference &the 15th Symposium on TQM-Best Practices in Thailand	Bangkok, Thailand
Sept .3-5	Quality and Patient Safety in Psychiatric	Bangkok, Thailand

Date	Title	Venue
	Nursing	
March 3-14	Health policies, Health service, Innovation healthcare management and Strategic quality excellence	The George Washington University Hospital and the Pan American Health Organization, USA
Feb. 11-13	Health policies, Health service, and Healthcare service	ST. Vincent Hospital, Australia
2013		
Dec.3-5	Transcultural Nursing	Bangkok, Thailand
Oct. 16-18	Healthcare World Asia 2013	Marina Bay Sands, Singapore
Aug. 16-18	Thailand Quality Conference &the 14th Symposium on TQM- Best Practices in Thailand	Bangkok, Thailand
July 31-Aug. 3	Routine to Research (R2R)	Bangkok, Thailand
July 3-5	Self-Assessment Report and Standard Practice Assessment	Bangkok, Thailand
March 11-15	Hospital Management	Nippon Medical School, Japan
Feb. 11-8	Environment management	Khonkaen, Thailand
2012		
Sept. 3-4	Thailand Quality Conference &the 13th Symposium on TQM Best-Practices in Thailand	Bangkok, Thailand
2011		
Sept. 3	Learn from TQC Winner 2009: Best Practices and Behind the Scenes	Bangkok, Thailand
April 4-8	Healthcare management	Royal Prince Alfred

Date	Title	Venue
		Hospital, Australia
March 15-18	HA National Forum	Nonthaburi, Thailand
2010		
Nov .24-26	Risk management	Bangkok, Thailand
Nov. 18	Hospital management	Bangkok, Thailand
July 31	Quality Fair	Bangkok, Thailand
July 19-20	HA SPA : HA Standards : Practice & Assessment	Bangkok, Thailand
June 14-18	Roadmap to Surveyor	Bangkok, Thailand
March 12	Thailand Quality Class Winner 2008	Bangkok, Thailand
March 9-11	11thHA National Forum	Nonthaburi, Thailand
Feb. 1-3	Application of Lean Thinking in Healthcare	Bangkok, Thailand