THE EFFECTIVENESS OF TIBETAN YOGA TO REDUCE CLIMACTERIC SYMPTOMS AND ENHANCING QUALITY OF LIFE IN PERIMENOPAUSAL WOMEN: A COMMUNITY-BASED RANDOMIZED CONTROLLED TRIAL

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ประสิทธิผลของทิเบตโยคะเพื่อลดกลุ่มอาการวัยหมดระดูและเสริมสร้างคุณภาพชีวิตในสตรีวัยใกล้หมดระดู :การทดลองแบบสุ่มและมีกลุ่มควบคุมในชุมชน

น.ส.ณัฐสุภา อาจองค์

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ณัฐสุภา อาจองค์ : ประสิทธิผลของทิเบตโยคะเพื่อลดกลุ่มอาการวัยหมดระดูและเสริมสร้างคุณภาพชีวิตในสตรีวัยใกล้หมดระดู :การทดลองแบบสุ่มและมีกลุ่มควบคุมในชุมชน.

(THE EFFECTIVENESS OF TIBETAN YOGA TO REDUCE CLIMACTERIC SYMPTOMS AND ENHANCING QUALITY OF LIFE IN PERIMENOPAUSAL WOMEN: A COMMUNITY-BASED RANDOMIZED CONTROLLED TRIAL)

อ.ที่ปรึกษาหลัก : ศาสตราจารย์พิชาน นพ.สำลี เปลี่ยนบางช้าง

บทนำ: กลุ่มอาการวัยหมดหมดระดูเป็นปัญหาของสตรีวัยใกล้หมดระดูจนถึงปัจจุบัน การวิจัยนี้ทำการตรวจสอบผลของการใช้โยคะทิเบตในการลดกลุ่มอาการวัยหมดระดู และเพิ่มคุณภาพชีวิตของผู้หญิงวัยใกล้หมดระดู *วัตถุประสงค์ :* เพื่อศึกษาผลของการใช้โยคะแบบทิเบตในการลดกลุ่มอาการวัยหมดระดู และ การเพิ่มคุณภาพชีวิตของสตรีวัยใกล้หมดระดู ผู้เข้าร่วมการวิจัยคือสตรีวัยใกล้หมดประจำเดือนจำนวน 64 คนซึ่งพักอาศัยอยู่ที่หมู่ 9 ชุมชนละหาร เขตบางบัวทอง จังหวัดนนทบุรี โดยที่ 32 คนถูกสุ่มเลือกให้เข้าร่วมกลุ่มทดลอง และที่เหลือเข้าร่วมกลุ่มควบคุม เครื่องมือการวิจัยประกอบด้วย แบบประเมินอาการสภาวะหมดประจำเดือน แบบสอบถามลักษณะทางสังคมประชากร แบบบันทึกระดับฮอร์โมนเอสโตรเจน และ แบบสอบถามคุณภาพชีวิตขององค์การอนามัยโลกฉบับภาษาไทย โปรแกรมโยคะทิเบตได้ถูกนำมาใช้กับกลุ่มทดลองในฐานะการแทรกแซง การเก็บข้อมูลดำเนินการก่อนเริ่มการทดลอง เมื่อสิ้นสุดการทดลองในสัปดาห์ที่ 12 และ หลังจากการทดลองสิ้นสุดไปแล้ว 4 สัปดาห์ (สัปดาห์ที่ 16) ทำการวิเคราะห์ข้อมูลโดยใช้สถิติเชิงพรรณนาได้แก่ ค่าความถี่ ค่าร้อยละ ค่าเฉลี่ย และส่วนเบี่ยงเบนมาตรฐาน เพื่อบรรยายลักษณะทางสังคมประชากรของผู้เข้าร่วมการวิจัย สถิติอ้างอิงได้แก่ t-test และ repeated-measures ANOVA ถูกใช้ในการทดสอบสมมติฐานการวิจัย ผลการวิจัยชี้ให้เห็นความแตกต่างอย่างมีนัยสำคัญในคะแนนกลุ่มอาการวัยใกล้หมดระดูระหว่างผู้เข้าร่วมการวิจัยทั้งสองกลุ่มในสัปดาห์ที่ 12 และ สัปดาห์ที่ 16 (F= 531.4, P-value < 0.001) ในสัปดาห์ที่ 16 คุณภาพชีวิตทุกด้านของผู้เข้าร่วมการวิจัยทั้งกลุ่มทดลอง และกลุ่มควบคุมมีคะแนนคุณภาพชีวิตสูงกว่าคะแนนที่วัดก่อนเริ่มทดลองอย่างมีนัยสำคัญ (P-value < 0.001) มีความแตกต่างอย่างมีนัยสำคัญในระดับของเอสตราดิออลซีรั่ม ของผู้เข้าร่วมการวิจัยระหว่างกลุ่มควบคุม และ กลุ่มทดลองในสัปดาห์ที่ 12 และ สัปดาห์ที่ 16 (F= 37.55, P-value < 0.001) *สรุปผล*: โยคะแบบทิเบตสามารถใช้ในการลดกลุ่มอาการวัยหมดระดูและเพิ่มคุณภาพชีวิตในสตรีวัยใกล้หมดระดู

สาขาวิชา	สาธารณสุขศาสตร์	ลายมือชื่อนิสิต .....
ปีการศึกษา	2564	ลายมือชื่อ อ.ที่ปรึกษาหลัก .....

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Natsupa Archong : THE EFFECTIVENESS OF TIBETAN YOGA TO REDUCE CLIMACTERIC SYMPTOMS AND ENHANCING QUALITY OF LIFE IN PERIMENOPAUSAL WOMEN: A COMMUNITY-BASED RANDOMIZED CONTROLLED TRIAL. Advisor: Samlee Plianbangchang, M.D., Dr.P.H.

Introduction: The climacteric symptoms has been the problems of most perimenopause women so far. This research examined the effect of using Tibetan Yoga in reducing climacteric symptoms and enhance quality of life of the perimenopause women. *Objectives:* To study the effect of Tibetan Yoga in reducing climacteric symptoms and increasing the quality of life in perimenopausal women.

Method: This research is an experimental research. The research participants were sixty-four Thai perimenopausal women who lived in Moo 9, Lahan community, Bangbuatong District of Nonthaburi. Thirty-two of them were randomly selected to join the experimental group, the rest were in the controlled group. The research instruments contended the Climacteric symptom assessment form, Socio-demographic characteristics questionnaire, Estrogen hormone record form, and the WHO quality of life questionnaire in the Thai language. The Tibetan Yoga program was performed with the controlled group as an intervention. The data were collected from the participants at the based- line, at the end of the program on week 12^{th} and 4 weeks after the program finished. (week 16^{th}) The data were analyzed using descriptive statistics, such as frequency, percentage, mean, and standard deviation to describe socio-demographic characteristics of the participants. The inferential statistics such as t-test and repeated-measures ANOVA were used to test the research hypothesis. *Result:* There was a significant difference in the climacteric symptoms score of the participants between the two groups in week 12^{th} and week 16^{th} ($F= 531.4$, P-value < 0.001). All parts of the participants 'quality of life in both experimental and controlled group had the significant higher scores than at baseline (P-value < 0.001).There were significant differences in serum estradiol levels of the participants between the controlled group and experimental group during week 12^{th} and week 16^{th} ($F= 37.55$, P-value < 0.001) *Conclusion:* Tibetan Yoga can be used to reduce climacteric symptoms and increase quality of life of perimenopause women.

Field of Study:	Public Health	Student's Signature .....
Academic Year:	2021	Advisor's Signature .....

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Through this course, I would like to thank you for people living at Moo 9, Lahan community Bangbuatong District in Nonthaburi province as well as the health volunteer in the district for participating as the part of the thesis. Furthermore, thank you for the Yoga specialist who established a Yoga training course for me and the population in the research.

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Natsupa Archong

TABLE OF CONTENTS

Page

LIST OF TABLES

Page

LIST OF FIGURES

Page

LIST OF ACRONYMS AND ABBREVIATIONS

BMI – Body Mass Index

FMP - Final menopausal period

FSH - Follicle-stimulating Hormone

GnRH - Gonadotropin Releasing Hormone

IU - International Unit

LDL - Low Density Lipoprotein

LH - Luteinizing Hormone

MENQOL - Menopause-Specific Quality of Life

PI – Principle investigator

PFMT – Pelvic Floor Muscle Exercise

QOL - Quality of Life

SSRI - Selective Serotonin Reuptake Inhibitor

WHO – World Health Organization

WHOQOL-BREF - World Health Organization Quality of Life Instrument

CHAPTER 1
INTRODUCTION

The introductory chapter reviews the context, statement of the problem and objectives of the study regarding Tibetan Yoga in reducing climacteric symptoms score and increasing the quality of life in perimenopausal women.

1. Background and Rationale

There are many meanings on Quality of life (QoL) especially in the field of health and life statuses such as health, work, quality of the environment, emotional well-being and social relationships. The World Health Organization (WHO) has described it as people's insights into their life status within the value and cultural systems where they live and concerning their expectations. Figure 1 below shows the world quality of life index by country 2022 Mid-Year, starting from the United States of America, China, United Kingdom, Russia, Germany, France, Japan, Italy, and Canada. Therefore, the quality of life in Germany is the highest and China is the lowest (Figure 1).

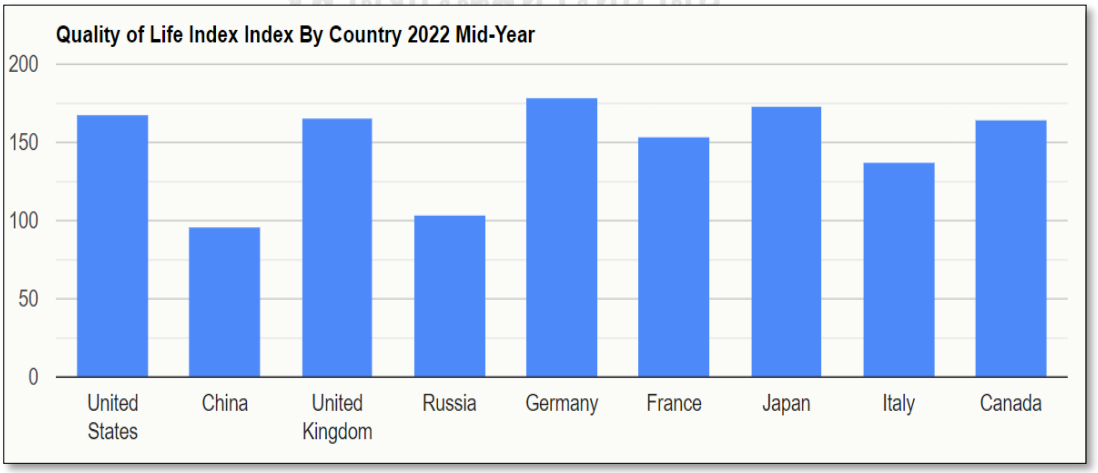


Figure 1.1 Quality of Life Index (Index by country 2022 Mid-Year) (numbeo, 2022)

This means that each woman spends at least one-third of her life during the menopausal period and is considered key to measuring QOL in relation to changes in health status. Regarding cultural and ethnic differences, the frequency of these symptoms varies in different countries. Statistics show an increasing number of postmenopausal women worldwide. In particular, more than 477 million women in 1998 were living in the postmenopausal period, and this rate will reach 1.1 billion people by 2025 (Barati et al., 2021).

1.1 Perimenopause

The term menopause has been derived from the World Health Organization (WHO) which means a critical final stage or the time in a woman's life when the reproductive capacity ends, that is, the ovaries stop functioning with important implications relating to fat mass and its distribution, dyslipidemia and neurodegeneration; this means the production of steroid and peptide hormones reduces. On the other hand, perimenopause is defined as the period of time between the transition from the reproductive years of a woman and the menopause (World Health Organization, 1996, Ambikairajah, Tabatabaei-Jafari, Hornberger & Cherbuin, 2021; Nanette, Cassandra, Brandilyn & Genevieve, 2020).

According to Dr Cristina Menni, from the School of Life Course & Population Sciences (King's College London, 2022) who stated that:

"Perimenopause is poorly diagnosed due to highly irregular hormonal cycles and symptoms that can last for as long as 15 years. Currently, there is no accurate diagnostic test for perimenopause. Adding that an easily quantifiable novel early biomarker of perimenopause could be a valuable improvement to current clinical practice."

Additionally, perimenopause is also one of many terms that refer to the transition from regular ovulatory menstrual cycles to irregular menstrual cycles that result from ovarian ageing and the accompanying decline in oocyte quantity and quality (See figure 1). Another common nomenclature is climacteric and the menopausal transition. Not surprisingly, perimenopause occurs when the ovaries gradually begin to develop reduced estrogen. It usually starts in women in their 40s, but it can also start in their 30s or even earlier (Verrilli & Berga, 2020). Menopause is retroactively determined permanent cessation of menstruation after twelve months of amenorrhea in midlife. Another definition states that during the menopausal transition and early post-menopause, some women show altered gonadal steroids, an increased risk of negative mood symptoms, changes in endocrine activity, and an increased risk of depression. However, there is a 2-to-5-fold increased risk of depressive disorder during perimenopause versus late premenopause (Bromberger & Epperson, 2018; (Adashi et al., 1995). Perimenopause is a transition period between perimenopause and postmenopause that is characterized by the emergence of physical and psychological changes that are influenced by environmental factors, and socioeconomic and nutritional status. Hong, Kim, Kim & Kim, (2019) also stated that perimenopause begins a few years before menopause and occurs when the ovaries gradually began to reduce estrogen. Menopausal symptoms begin 5-10 years before menopause and can last up to 7 years after menopause, depending on the individual

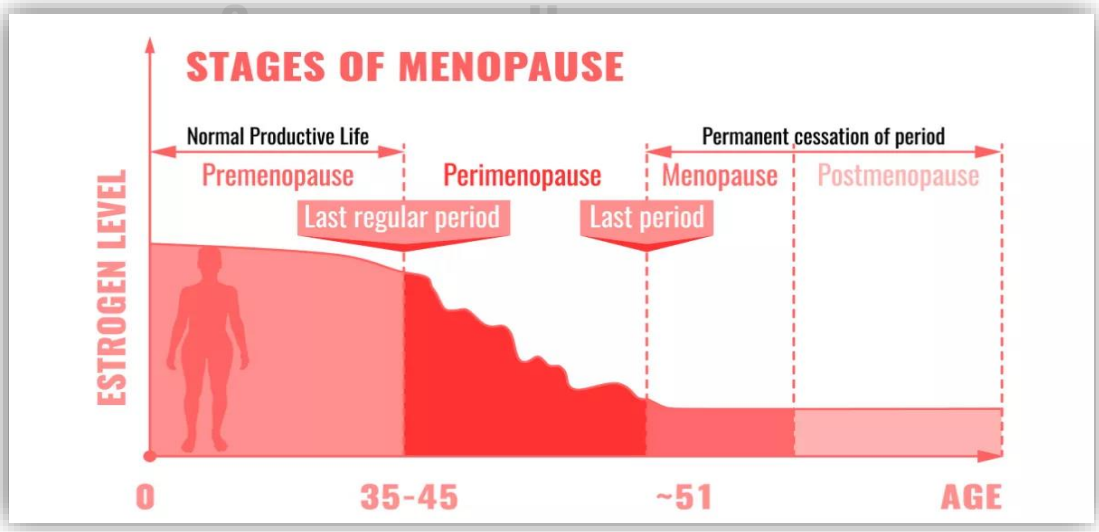


Figure 1.2 Stages of Menopause **(**Responsum Health Inc, 2022)

Perimenopause can happen in women whose ages are in the 40s or 50s almost at the time that gets close to the end of their menstrual cycles and is a natural biological process. Surprisingly, the highest percentage of women worldwide who were not aware of or felt unprepared for and didn't understand perimenopause with menopause in 2020 (Figure 1). More specially, Baber, Panay and Fenton (2016) stated that Demographic data has shown that every year, 25 million women worldwide experience the menopause. This will result in 1.2 billion postmenopausal women worldwide by 2030.

The National Institute on Aging (NIA) (2022) stated that more than one million women in the United States experience menopause each year, and few women know about the health effects of this natural biological occurrence.

Furthermore, the State of Menopause research showed that 1,039 women aged 40 to 65 in the United States never sought information about the menopause before they experienced it. Of this number of women in the United States, nearly half the women didn't know the difference between perimenopause, the transitional period leading up to the menopause and the menopause itself, the biological process that marks the end of a woman's menstrual cycles. Most women reported that they were not currently treating their menopause, which included hot flushes, weight gain, difficulties with sleep, and night sweats, among others. Moreover, women in sub-Saharan Africa stated that they reported considerable physical and psychological issues associated with the menopause, these include bone and joint pain, hot flushes, and forgetfulness among women in Eastern Nigeria and bodily pains, irritability, and sleeplessness in Ghana (Drew et al., 2022). Therefore, a new study has found that women 'age' significantly faster in the perimenopausal period.

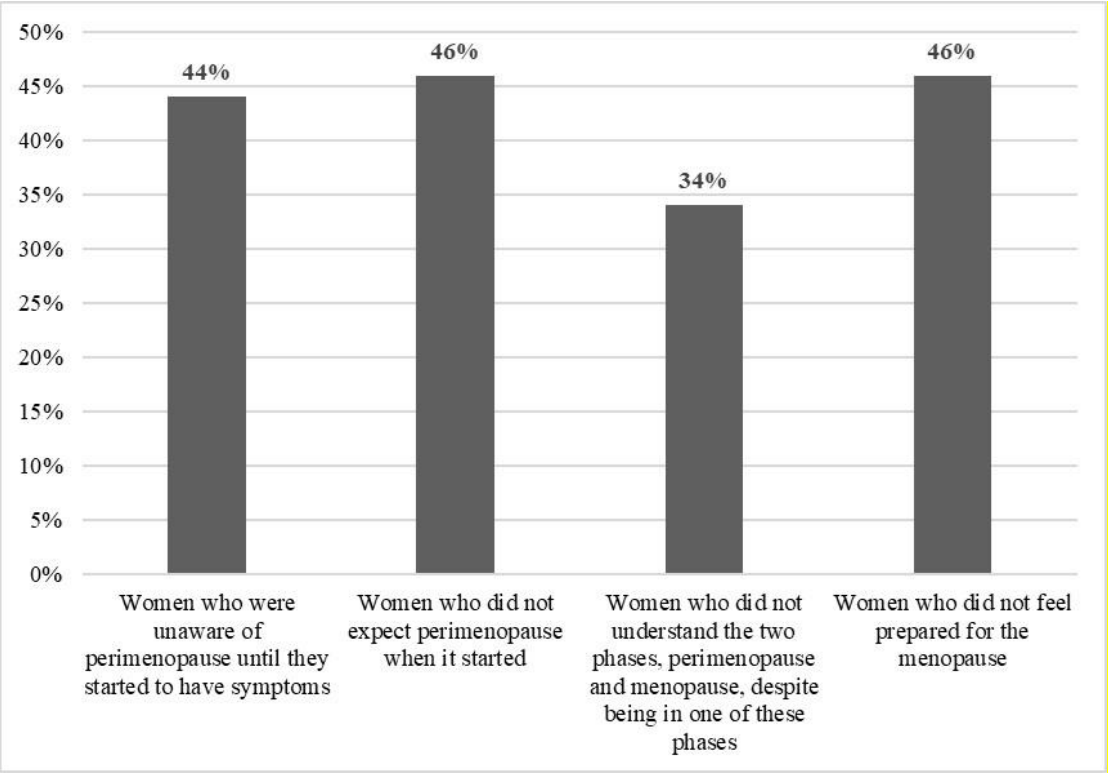


Figure 1.3 Percentage of women who were not aware of, felt unprepared for, or didn't understand perimenopause and menopause worldwide as of 2020 (Statista Research Department, 2021).

The study of perimenopause has been ignored for most of the time during a woman's life, the effects of estrogen deficiency are most pronounced, including vasomotor symptoms, metabolic syndrome, mood changes in symptomatic urogenital disorders vaginal atrophy and weight loss, hormonal imbalance, and the occurrence of osteopenia or osteoporosis (Szuscik-Niewiadomy, Plinta, Niewiadomy & Knapik, 2021). Namazi, Sadeghi & Moghadam (2019) stated that the menopause is the complete cessation of menstruation due to a lack of estrogen production by the ovaries and is considered a natural phenomenon in a woman's life between the ages of 45 and 54, with an average age of menopause at 51. The research shows that Iran has the same results, and the researchers estimate that by 2030, 1.2 billion people will be of menopause and postmenopausal age. In 2022 there will be around 5 million women

in Iran of menopausal age. Due to increased life expectancy, women are expected to spend an average of one-third of their lives in menopause.

1.2 Climacteric Symptom

The majority of changes in menstrual pattern and the most common symptoms of the menopause transition are vasomotor symptoms, or hot flushes and night sweats. Vasomotor symptoms are reported by over 70% of midlife women at some point during the menopause transition and for a third of women vasomotor symptoms were very frequent or severe and long thought to last the few years around the final menstrual period. On average vasomotor symptoms last for 7–10 years for frequent or moderate to severe symptoms and longer for less frequent or severe Vasomotor symptoms 3–5 (Thurston, 2018). Especially in the late perimenopause and early postmenopausal period, it affects 60-80% of women during the menopausal transition. Perimenopause is a period of a high incidence of negative mood symptoms: 46.9% and 56.3% of perimenopausal Brazilian women reported symptoms of depression and anxiety, respectively (Jaeger, 2021). Although, vasomotor symptoms are a common problem women experience during early and postmenopausal the duration differs from person to person. This is because some people have serious problems that affect their personal and social functioning as well as their quality of life (Giri, Tripathy & Nayak 2020). Hot flushes are experienced by 55 to 85% of perimenopausal women, peaking in the later perimenopausal stages, and can be experienced for months to years ((Maleki, Cheng, Tu & Locascio, 2019).

It has been reported that in the case of Asian, including Thai, women the mean age of menopause is between 49.4 years and 51.1 years, with an average mean of 50.7 years (Alwi, Brohi & Awi, 2021). Also, climacteric symptoms are disruptive factors to quality of life (QoL) among Thai women during the menopausal transition period(Khunasap, Khuakoonratt, Prommas,Smanchat,BhamarapravatanaSuwannarurk , 2022). Perimenopausal women have an increased risk of developing new-onset and recurrent mental health conditions such as anxiety, low mood, and depressive

symptoms (Leonhardt, 2019). However, the quality-of-life outcomes depend on several factors and not just one particular phenomenon. It has also been reported by some studies that perimenopausal women experience more negative life events such as the loss of a family member, compared to younger women, however, it was noted by Leonhardt (2019) that negative life events were associated with perimenopausal mood and behavioural symptoms. Many women report that they generally feel less confident and less resistant to stress and that they have become indecisive and insecure for no apparent reason. They feel more anxious, irritable, and insecure, they are easily irritable, angry and sometimes they feel like they are losing control of their life.

Another important symptom of perimenopause having a marked impact on the quality of life of women is psychological disturbances, in particular depressive symptoms (Bromberger & Epperson, 2018). Epidemiologic research indicates that roughly 1 in 5 women will experience an episode of major depressive disorder at some point in their lifetime. Importantly, for some women, depression can present or worsen during periods of dynamic hormonal flux, such as prementum, peripartum, and perimenopause. According to Khunasap, Khuakoonratt, Prommas, Smanchat, and Bhamarapravatana Suwannarurk, (2022), whose study was conducted in Thailand with healthy women visiting gynecologic outpatient clinics aged 45 to 55 years old, who still menstruated, both regular and irregular, were categorized into the control group. They also presented natural amenorrhea within two years, as the absence of menstruation for 12 to 24 months, and were enrolled in the study group. The results showed that the mean age and standard deviation of the participants in the control and the study groups were 48.0±2.8 and 52.3±2.8 years, respectively. Another study conducted in Cambodia with 180 Cambodian women aged 40–60 who lived in a community setting were recruited from four regions of Cambodia via convenience sampling. This study revealed that the most burdensome menopause symptom among Cambodian women was heart discomfort while vaginal dryness was the least burdensome.

1.3 Menopausal Transition

Menopausal transition refers to the period from the moment of increased variation in the menstrual cycle until the moment immediately before the last day of menstruation. It varies among individuals and is a period that often includes vasomotor symptoms such as hot flushes alongside frequent or excessive menstruation. Hot flushes differ among individuals but may appear from 1 year to 3 years before the last day of menstruation and are especially severe around the last day of menstruation, but they may last for several years. The study by Bromberger & Epperson (2018) showed that approximately 75% of women aged between 45 years and 55 years suffer from the symptoms of the menopause that may lead to low self-esteem, sleep disorder, and feelings of decreased energy. To evaluate the ovarian reserve during the menopausal transition, measuring the serum level of anti-mullerian hormone (AMH), day 3 follicle-stimulating hormone (FSH), estradiol (E2), and ovarian antral follicle count (AFC) using pelvic ultrasonography is possible, but they are not used as indicators for predicting menopause. Additionally, because the function of the ovaries changes during this period, it is advised not to conduct a hormone test for menopause diagnosis.

Also, the study by Maki et al. (2019) showed depression risk rises significantly in 5-6 years after menstruation stops which is known as the menopausal transition. However, exposure to extreme estradiol levels may help explain this increase, but few studies have examined individuals' estradiol levels to predict perimenopausal depression. Multiple studies have identified this transition period as a time of increased susceptibility to depressive moods, longitudinal studies note a 1.3-2.9-fold increased risk. The current study enrolled 101 perimenopausal women. They used 12 weekly measures of estrone 3 measurements to quantify each woman's sensitivity to changes in estradiol. Glucuronide, a urinary metabolite of estradiol, is associated with depressive symptoms. Cortisol wakefulness responses were measured weekly to examine hypothalamic-pituitary-adrenal axis-mediated emotional sensitivity to estradiol. Depressive symptoms and major depressive diagnoses were assessed monthly for 9 months. The association between stage 1 Glucuronide sensitivity and stage 2 depressive symptoms and major depressive disorder episodes

were checked. Several baseline characteristics were examined as potential moderators of this relationship. Emotional sensitivity to estradiol predicts the risk of perimenopausal depression, especially in women who are otherwise at low risk and in women who gave birth prematurely in transition (Gordon, Sander, Eisenlohr-Moul & Tottenham, 2020).

Furthermore, the above studies suggest that women with a history of major depressive disorders have an increased risk level of relapse during menopausal transition compared to premenopausal. So, it is unclear whether the risk of major depression is also increased in women with no history of depression. The menstrual cycle is characterized by luteal estradiol levels as high as 2-3 times higher than typically seen in women of childbearing age, starting early in the menopausal transition and continuing into the later transition. At the same time, perimenopausal estradiol levels may also be due to a low number of antral follicles. The display occasionally drops to postmenopausal levels. In addition, the low estradiol early follicular phase is prolonged due to delay. Increased sensitivity to this changing hormonal milieu has long been suspected as a key aetiology for the development of perimenopausal depressive symptoms; however, perimenopausal depression is associated with hypo-v. Hype estrogen sensitivity remains unclear. Another pioneering study finds that experimentally induced estradiol withdrawal triggers depressive symptoms. Women selected, based on their personal history of depression, respond to hormone therapy; by contrast, no effect was observed in women with no medical history of depression (perimenopausal onset or otherwise). Although this study shows that some women are emotionally sensitive to perimenopausal estradiol withdrawal, not ruling out increased sensitivity to estradiol surges, some women experience symptoms of perimenopausal depression. Furthermore, in a small study comparing the effect of salivary estradiol on the human body. In a 4-week mood measurement, we found that women with current perimenopausal depression were more sensitive to weekly increases in estradiol than non-depressed. Thus, there is reason to believe that although estradiol withdrawal is a trigger for some perimenopausal depressive moods in women, others may experience depressive symptoms for other reasons including increased sensitivity to elevated estradiol and may be sensitive to changes in estradiol in both directions. However, this hypothesis

remains to be tested. Vasomotor symptoms have long been understood to be important to women's mental health, sleep, and quality of life, but only recently have they been understood to have implications for women's cardiovascular health. Early observations came from hormone therapy trials, including the Women's Health Initiative and Heart and Estrogen Replacement. The study, both of which showed in post hoc analyses that the relation between hormone therapy trials and cardiovascular disease risk was modified not only by age (in the case of the Women's Health Initiative) but also by vasomotor symptoms. These initial findings suggested a difference in the underlying vasculature of women with vasomotor symptoms relative to their counterparts without them. We examined the associations between vasomotor symptoms and women's vascular health in Women's Health Across the Nation Heart, a sub-study of 600 from Women's Health Across the Nation that focused on cardiovascular health. Women's Health Across the Nation participants without clinical cardiovascular disease underwent multiple measures of subclinical cardiovascular disease, including measures of endothelial function, coronary and aortic calcification, and carotid intima-media thickness. As clinical cardiovascular disease typically begins to manifest itself beginning in women's sixth decade of life, subclinical cardiovascular disease measures, which involve imaging the vasculature to assess cardiovascular disease risk before the clinical disease is present, are useful in assessing vascular risk in midlife women.

In Women's Health Across the Nation Heart, we found that women reporting hot flushes in the prior 2 weeks had poorer endothelial function as well as greater aortic calcification relative to women without vasomotor symptoms, associations that persisted with adjustment for multiple cardiovascular disease risk factors as well as endogenous E2 and follicle-stimulating hormone. Later, we examined the associations between vasomotor symptoms and intima-media thickness, another commonly used and well-validated subclinical cardiovascular disease measure. In this analysis, we found that women reporting vasomotor symptoms in the prior 2 weeks had a higher intima-media thickness than women without vasomotor symptoms, controlling for standard cardiovascular disease risk factors or sex hormones. We further found that associations were most pronounced among women who were overweight or obese (the majority of this US sample). (Thurston, R. C. 2018).

Most women do not understand the changes that occur during the transition phase and therefore suffer various problems and diseases associated with perimenopause which necessitates the need for treatment plans and approaches to limit and control the severity of perimenopausal symptoms and improve their quality of life (Nayak et al., 2014). Hormonal therapies have been used extensively in controlling the symptoms of perimenopause, however, in 2018, hormone therapy is only recommended in postmenopausal women with climacteric symptoms. This raises questions about the safety of this association particularly for perimenopausal women. First, several studies have shown an increased risk of breast cancer dependent on the duration of hormone therapy users. Hormone therapy initiated from the perimenopausal period would increase the duration of treatment by several years. Moreover, the occurrence of breast tenderness is an adverse event that affects 30% to 35% of hormone therapy users and doubles the risk of invasive breast cancer. (Hugon-Rodin, J., Amand, G., & Plu-Bureau, G. 2018)

Climacteric Symptoms

Committee opinions from the American College of Obstetricians and Gynecologists published in 2013 also reported that hormonal therapy cannot be used for primary or secondary prevention of cardiovascular disease and women who are 65 years and older or start hormonal therapy after 10 years of menopause have higher incidences of stroke, coronary heart disease and deep vein thrombosis (American College of Obstetricians and Gynecologists, 2013a, 2013b; Nayak et al., 2014). As a result, various studies have been focused on alternative approaches such as traditional Indiana yoga, physical exercises, meditation, Tai Chi, and Qigong, among others, to control perimenopausal symptoms and improve quality of life. Yoga has proved to be effective in various health-related disorders such as cardiovascular, neuroendocrine, gastrointestinal, and musculoskeletal systems (McCaffrey & Park, 2012; Sengupta, 2012; Woodyard, 2011). Therefore, various studies have focused on yoga, meditation and different types of relaxation techniques, biofeedback, guided images and breathing exercises to help women adjust and manage stress, issues related to menopause and the ageing process in their lives. Yoga is an original, integrative art of

living that can help people overcome some health problems including the menopause, cardiovascular disease and depression. (Aust Prescr. 2018; Sakuntala Giri1 , PravatiTripathy2 , Debajani Nayak, 2020). An experimental study conducted in South India among 216 perimenopausal women aged 40-60 years concluded that yoga resulted in a significant improvement in symptoms in vasomotor, psychosocial, physical and sexual domains, thereby improving the overall quality of life (Nayak et al., 2014). In India, most women do not know what changes take place in their bodies mostly after the age of 45 years and they spend their life fighting the problems associated with perimenopause. Therefore, it is necessary to develop a different integrated comprehensive approach to control perimenopausal problems to improve their quality of life. One of the experimental studies of 120 perimenopausal women aged 40-60 in India concluded that yoga therapy is effective in improving the quality of life of people for perimenopausal women. (Sakuntala Giri1, PravatiTripathy2, Debajani Nayak, 2020).

Similarly, a quasi-experimental study with a pretest & post-test control group design was adopted for a study of women aged between 40-50 years who were considered a sample. A survey was conducted through a self-structured checklist on symptoms of perimenopause to identify the numbers of women available with perimenopausal symptoms. Premenopause and perimenopause are sometimes used interchangeably. A total of 120 women were identified based on the presence of at least 60% of the symptoms. Those who were able to follow and perform the yoga programs were identified and 60 were selected for the control and experimental group. The demographic section addressed the background data of women including age, parity, level of education, occupation, menstrual history, and duration of perimenopausal symptoms. The second section was the self-structured perimenopausal QOL interview schedule. The study was approved by the Hospital Research Ethics Committee. The researcher got training in yoga which included yoga asana, pranayama, breathing exercises and meditation. Pranayama and breathing exercises consisted of Nadhisodhana Pranayama and Sitali Pranayama, anulomvilum, kapalbhati for 10-15 minutes. Yogasana consisted of Tadasana, ardhakatichakrasana, Bhadrasana, Paschimothasana, Bhujangasana, Ardhasalabhasana and Shavasana. Each asana was for one minute except savasana, which was of 5 minutes, with a total

duration of 10-12 minutes. For meditation, they were asked to chant “Om” for 3-5 minutes. For the three sessions (meditation, pranayam & breathing exercise, and yogasanas) the total time required was 30- 40 minutes per day. The women in the study group were taught yoga by video and asked to practice for 30-45 minutes per day for 30 consecutive days under the supervision of the researcher and at the same time, the control group listened to some spiritual music. This study shows that before intervention the quality of life of perimenopausal women was low but after the intervention, the quality of life was improved to a moderate and high quality of life. The perimenopausal women who were not taking any intervention, gradually noticed their quality of life was worsening in comparison with the experimental group. Many studies reported that after yoga therapy there was an increased quality of life and decreased perimenopausal symptoms among the women. (Giri1, Tripathy & Nayak, 2020）

1.4 Statement of the Problem

It has been estimated that there are over 6.6 million women between the ages of 45 and 59 years in Thailand and therefore are at the risk of physical and mental health problems and other health-related problems associated with the menopause resulting in a poor quality of life. Various forms of mind and body exercises as well as complementary and alternative medicines have been studied in Thailand regarding their prevalence and effectiveness in improving the quality of life among Thai women entering menopause. A cross-sectional study conducted in July and October 2013 on 200 postmenopausal women attending the outpatient department of Obstetrics and Gynecology, Srinagarind Hospital, a tertiary care hospital, in Northeastern Thailand found that 65% of the participants used complementary and alternative medicine (Booning et al., 2015).

A further study that focused on Rusie Dutton, a traditional Thai exercise, examined the effects of exercise on the health and quality of life on 50 perimenopausal women aged between 45-59 years. The participants were divided into two groups – intervention (n = 24) and control (n = 26) After 13 weeks the post-test results showed a marked improvement in all menopause quality of life domains –

vasomotor, physical, psychosocial and sexual in the intervention group while no significant change was noted in the control group. Furthermore, a significant difference was also observed in all the domains between the two groups (Kanit Ngowsiri et al., 2014). A qualitative ethnographic study was conducted among nine Thai women yogi masters aged between 48 to 61 years exploring how the study participants managed their menopausal transition through yoga. Three women reported having symptoms associated with the menopause and perceived the symptoms to be mild and not bothersome. The women also reported having a positive attitude towards their experience with the menopause and a smooth menopausal transition leading to an improved quality of life (Rakpanusit et al., 2013). differences between groups in terms of anxiety, depression and fatigue were observed.

Tibetan Yoga

Many researchers have found that yoga helps alleviate or cure symptoms of various diseases, such as asthma, high blood pressure, hypertension, and obesity. Additionally, yoga practice has been found to help control hormones in menopausal women. Numerous studies reveal the effects of yoga practice on estrogen. In a community-based randomized controlled trial, two groups of pre-test and post-test designs were organized in Thai perimenopausal women living in Moo 9, Lahan community in Bangbuatong District of Nonthaburi Province between 1st August 2020 and 30th November 2020 to assess the effect of Tibetan Yoga on their levels of Estrogen. The population of this study was three hundred thirty-two Thai perimenopausal women aged between 45 and 55 years. The t-test statistic was employed to determine the mean difference between the two groups. The analysis results yielded the number of participants per group was 26 and 52 as a whole. However, the number of participants was increased to 64 to prevent dropout during the experiment. The 64 participants were randomly placed into two groups, namely the intervention group and the control group. With 32 participants for each group. The inclusion criteria of this study designated that: 1) Research participants had climacteric symptoms score greater than 15. The assessment was executed through the Climacteric Symptoms Assessment Form for screening. 2) They must not have amenorrhea in the last consecutive 12 months. 3) They must have no history of

diabetes, high blood pressure or heart disease, and 4) They must haven't been in a systemic exercise program or been in a yoga program in the past 6 months. 5) The participants in the intervention group must be able to attend the intervention program for at least 10 weeks accounting for 80% of the total intervention period. This experiment excluded perimenopausal women with a history of knee or spine surgery, hysterectomy or endometrial ablation, any type or form of hormone replacement therapy, or currently taking any type of supplements (vitamins, phytoestrogens and many more). The results showed that after four months of yoga practice, participants showed a significant increase in estrogen levels (Giri1, Tripathy, Nayak, 2020).

Although various approaches have been studied in controlling the symptoms of perimenopause and menopause and improving the quality of life of Thai women, there have been no studies on the effectiveness of Tibetan Yoga in improving the climacteric symptoms and its effect on the quality of life of perimenopausal women. Tibetan yoga is a form of mind and body techniques and dates back to the ancient times of a Buddhist monk named Gampopa Sönam Rinchen (1079-1153) from where the technique is believed to have originated (Kragh, 2015). Nevertheless, Tibetan yoga is a type of yoga practice based on the Buddhist religion. Unlike other yoga practices, it encourages the union of body, mind, and spirit. This yoga practice comprises of 5 simple poses called the "5 Rites" which can be performed easily. Tibetan yoga has been reported by practitioners, medical professionals, and yoga instructors to help relieve joint pain and stiffness, improve strength and coordination, improve blood circulation, reduced anxiety, have better sleep, and enhance a youthful appearance. Despite its benefits, the researchers that studied the effect of Tibetan yoga on the estrogen levels in perimenopause women are scared (Giri1, Tripathy, Nayak, 2020).

2. Research Gap

2.1 Thailand still does not have the knowledge to use Tibetan Yoga to change climacteric symptoms in perimenopausal women.

2.2 Thailand lacks the information on using Tibetan Yoga to improve Estrogen Hormone in perimenopausal women.

2.3 Thailand still lacks information on the use of Tibetan Yoga to help relax, reduce stress, reduce depression and improve the quality of life in perimenopausal women.

3. Research Objective

3.1 General Objective

To assess the effectiveness of Tibetan Yoga in reducing climacteric symptom scores and increasing the quality of life in perimenopausal women.

3.2 Specific Objectives

1. To compare general characteristics of the intervention and control groups.

2. To find climacteric symptoms, Estrogen Hormone Levels and determine the quality-of-life scores at baseline and follow-up among intervention and control groups.

3. To assess the change of climacteric symptoms, Estrogen Hormone Levels, and quality of life scores before and after the program among both groups.

4. To compare changes in climacteric symptom scores and quality of life scores among the intervention and control groups after receiving the program.

5. To compare climacteric symptoms scores and quality of life scores before and after receiving the program within the intervention and control groups.

6. To compare the change in Estrogen Hormone levels between the intervention and control groups after receiving the program.

4. Research Questions

4.1 Does Tibetan Yoga affect the climacteric symptoms score and quality of life score in perimenopausal women?

4.2 Is there a difference in the climacteric symptoms scores and quality of life scores between the intervention and control groups after receiving the program?

4.3 Is there a difference in climacteric symptoms scores and quality of life scores at the baseline and after receiving the program within the intervention and control groups?

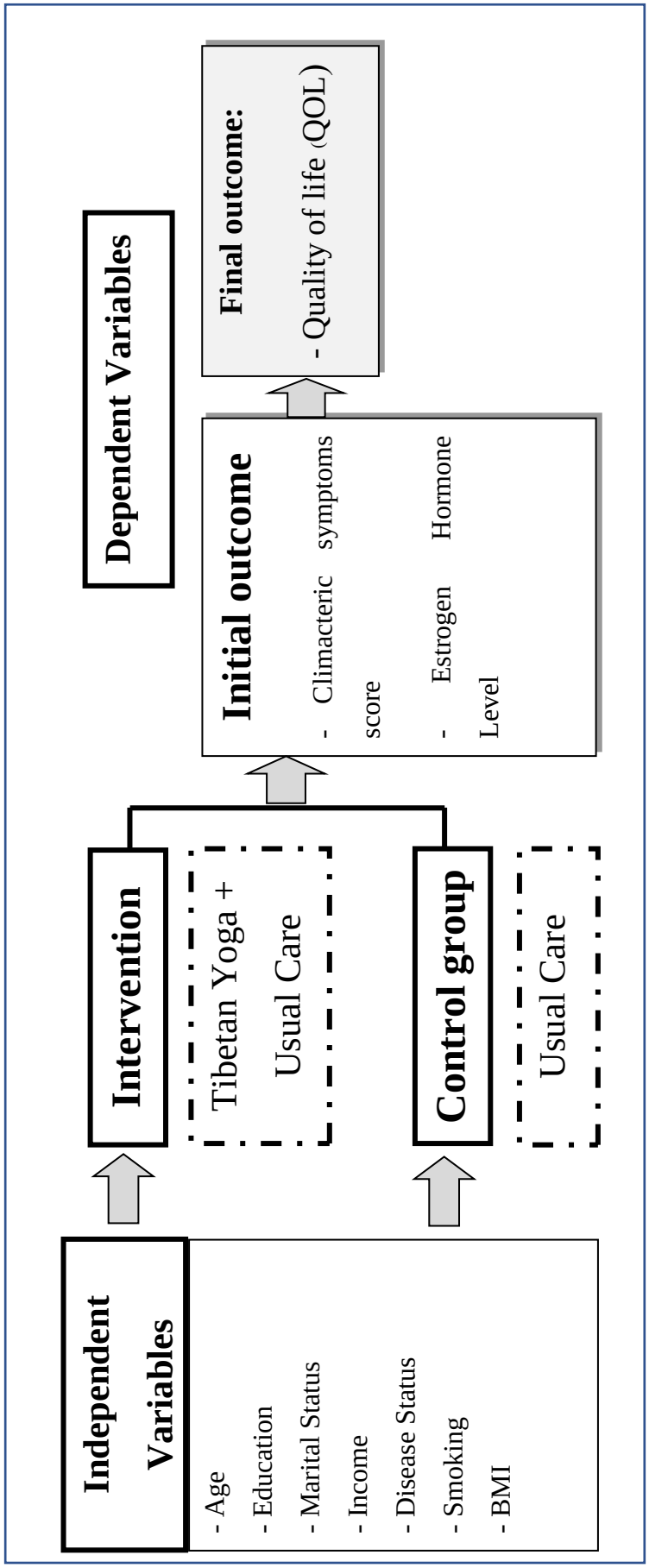
4.4 Is there a difference in Estrogen Hormone levels between the intervention and control groups after receiving the program?

5. Research Hypothesis

5.1 Tibetan Yoga affects the climacteric symptoms scores and quality of life scores in perimenopausal women.

5.2 Tibetan Yoga affects Estrogen Hormone levels in perimenopausal women

6. Conceptual Framework



7. Operational Definitions

Table 1.1 Operational Definitions

Term	Operational Definitions
Age	The length of time the study participant has been perimenopausal.
Education	The total number of years of the highest formal education reached by the study participant. The duration of formal education is calculated by adding the number of years of formal education from elementary education until the highest education reached (Benjamas Sukatit, 2004).
Marital Status	Indicates whether the person is single, married or divorced.
Income	Income is the revenue a business earns from selling its goods and services or the money an individual receives in compensation for his or her labour, services, or investments such as less than 10,000 THB or 10,001-20,000 THB or 20,001-30,000 THB more than 30,000 THB per month.
Disease Status	Questions are about health problems that the study participants might have had at any time in their lives. This includes the following: Chronic back or neck pain, headaches, and chronic pain.
Smoking	Substance abuse is when illegal drugs are taken by a person. It's also when alcohol, prescription medicine, and other legal substances are used excessively or in the wrong manner. This includes– "Current" smoker, "Ex"- smoker and "Never" smoked
Perimenopausal women	Thai women 45-55 years of age also known as menopause transition or climacteric (critical period) which takes place over several years in advance of the menopause
Tibetan Yoga	Tibetan Yoga is defined here as a form of mind-body exercise that comprises of five Tibetan rites (five simple *kriyas*-movements through two or more poses) that can be completed in less than 20 minutes and will help people live long, healthy, and vigorous life. Such as Rite 1 Tibetan Spin, Rite 2 Prone To Upward Staff Pose, Rite 3 Rabbit To Camel Pose, Rite 4 Staff To Upward Plank Pose and Rite 5 Upward Dog To Downward Dog

Table 1.1 (Continued)

Term	Operational Definitions
Effectiveness	It refers to determining the extent to which Tibetan Yoga has achieved the desired effect on the level of estrogen, physical and psychological symptoms, and vasomotor symptoms as well as improvement in the quality of life of perimenopausal women which are measured on a 5-point rating scale.
Climacteric symptoms	Are a group of symptoms that are reported in perimenopausal women and are categorized as vasomotor symptoms, psychological symptoms, and physical symptoms. Symptoms reported are - hot flushes, vaginal dryness, sleep disturbances, mood changes, urinary tract symptoms, sexual problems (loss of libido, dyspareunia, other) and other bodily symptoms

CHAPTER 2
LITERATURE REVIEW

This study was conducted based upon the review of concepts, theories, and related researches in respect to the following subjects;

1. Menopause and Perimenopause
    1.1 Defining of menopause
    1.2 Definition of perimenopause
    1.3 Perimenopausal in Thai context
2. Diagnosis of perimenopausal ICD-10 (WHO, 2019)
3. Perimenopausal symptoms
    3.1 Short-term symptoms
        3.1.1 Period Changes
        3.1.2 Hot Flashes and/or Night Sweats
        3.1.3 Mood changes
        3.1.4 Vaginal dryness
        3.1.5 Trouble sleeping
        3.1.6 An Increase in fat around the waist.
        3.1.7 Pounding Heart (Palpitations)
        3.1.8 Dry Skin and Hair Loss
    3.2 Long-term symptoms
        3.2.1 Cardiovascular system

3.2.2 Osteoporosis

3.2.3 Urinary tract problems

3.2.4 Weight gain and getting fat

3.3. Psychiatric Disorders in Perimenopause and Menopause

3.4. Metabolic change and care during perimenopausal.

3.5 Treatments for perimenopause symptoms

3.5.1 Hot flashes

3.5.2 Vaginal dryness

3.5.3 Insomnia and mood swings

3.5.4 Osteoporosis

3.5.5 Hair loss

4. Climacteric Symptoms

5. Tibetan Yoga

5.1 History of Tibetan Yoga

5.2 The Five Tibetan Yoga Rites.

5.3 Benefits of the Five Tibetan Rites

5.4 The Five Rites Exercise Program

6. Estrogen and Perimenopausal Women

7. Yoga as a treatment for Perimenopausal and Menopausal symptoms

8. Yoga and the quality of life of the Perimenopausal and Menopausal women

1. Definition of Perimenopause

1.1 Defining Menopause

The word “Menopause” is a medical term that refers to the time that women do not have menstruation for 12 consecutive months. When entering the menopausal stage, the hormone level decreases which results in night sweats, hot flushes, weight loss, mood changes, vaginal dryness, vaginal pain, and pain when having sex (Wayne Blocker, 2019).

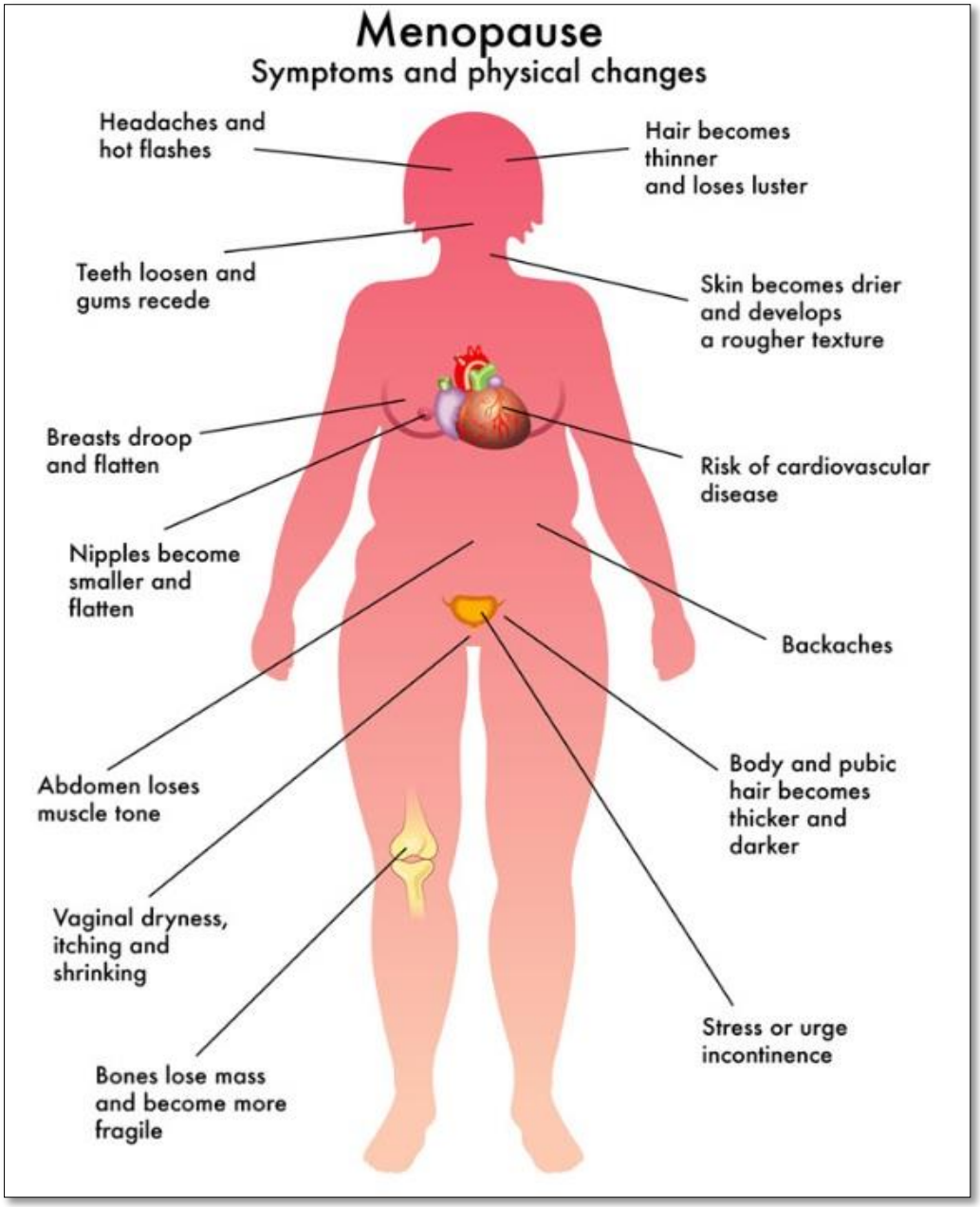


Figure 2.1 Menopause Symptoms and physical changes

(Thailand Medical News, 2019)

1.2 Definition of Perimenopause

Perimenopause means the period when the ovaries begin to decline and continue until menopause. The perimenopause period is called the "change of life" or "change period." It usually begins in the 40s, but may begin in the late 30s. During this period, women may show several symptoms that are mostly due to fluctuations in the hormone cover (Stöppler, 2019).

According to Gorrindo et al. (2007) perimenopause refers to the change in the life span before the final menstrual period (FMP). The average duration of perimenopause is 5 years, but the symptoms may start 8 years or more before FMP. While the mean age of onset of irregular menstruation is approximately 47.5 years (Santoro N, Brockwell S, Johnston J, et al.,2007) Perimenopause has become a difficult time in a woman's life as her ovary decreases its production of eggs and hormones. Hence, each woman must understand the changes in her body and try to adapt to her physiological changes (Blocker, 2019)

1.3 Perimenopause in the Thai context

In Thailand, menopausal women are confined to women with an average age of 50 years (45-55 years). However, currently, this average period has been expanded from 55 to 75 years old which is approximately 25 years or one-thirds of a woman's life. Therefore, understanding perimenopause and menopause symptoms will help prepare women when they enter the aforesaid period and enable them to enjoy their good health throughout the menopause duration. (Drewes & Vonne, 2014; Galantino, 2012).

2. Diagnosis of perimenopausal ICD-10 (WHO, 2019)

N 95 Menopausal and other perimenopausal

Excl: excessive bleeding in the premenopausal period (N92.4) *postmenopausal:*

- osteoporosis (M81.0)
- with pathological fracture (M80.0)
- urethritis (N43.2)

- premature menopause NOS (E28.3)

N 95.1 Menopausal and female climacteric states

***Symptoms*:** such as flushing, sleeplessness, headache, lack of concentration, associated with menopause

Excl: that associated with artificial menopause (N92.4)

Use Additional Code

Code for associated symptoms

Not Coded Here

- asymptomatic menopausal state (Z78.0)
- symptoms associated with artificial menopause (E89.41)
- symptoms associated with a premature menopause (E28.310)

3. Symptoms of Perimenopause

3.1 Short-term symptoms

In perimenopause women, several short-term symptoms are observed. These include irregular menstruation and abnormal bleeding, hot flush or night sweat, irritable mood with easy anxiety, depressive symptoms, dry vagina, vagina inflammation, vaginal laxity, etc. The details of which are as follows;

3.1.1 Period Changes

Menstrual cycle changes are normal during perimenopause. The periods may be shorter, or longer. Heavy bleeding, less bleeding, or even missing period can be experienced. However, abnormal bleeding can be a sign of other medical problems. Therefore, the doctor's advice is suggested3.1.2 Hot flushes and/or Night Sweats.

A hot flush is a sudden feeling of heat in the chest area and face. Hot flushes are very common in perimenopause but are quite variable in how often they occur and their severity. For instance, some women experience a hot flush here and there whereas other women experience several a day. Likewise, for some women, having a hot flush is a minor interruption in their day whereas, for other women, it can be more debilitating. While night sweat refers to a hot flush that occurs during sleep.

Night sweats can interrupt a woman's sleep cycle which may lead to daytime fatigue. (Megan McNamara, Pelin Batur, Kristi Tough DeSapri, 2015).

3.1.3 Mood changes

Mood changes and swings are common during perimenopause and may include symptoms of depression and anxiety. Also, while it's normal to be a bit more irritable than usual, a doctor or other mental health professional's advice is required in cases where these mood changes are persistent and affect the quality of life.

3.1.4 Vaginal dryness

Vaginal dryness (called vaginal atrophy) is a common symptom during perimenopause and is due to the body producing less of the hormone estrogen. Vaginal dryness is one symptom that may worsen as a woman gets older and can make sex uncomfortable. To relieve this symptom, the doctor's advice is required. Since there are several options to help women with this symptom, including an over-the-counter vaginal lubricant or moisturizer or even prescription vaginal medication. (Megan McNamara, Pelin Batur, Kristi Tough DeSapri, 2015)

3.1.5 Trouble sleeping

The women who are entering the perimenopause period may find it difficult to fall asleep (called insomnia) or stay asleep. Particularly if they’re bothered by night sweats or hormonal fluctuations.

3.1.6 An Increase in fat around the waist.

The expanding waistline may be noticed in perimenopausal women which may partly be due to estrogen loss which the experts believe causes fat redistribution in women. To prevent waistline expansion, perimenopausal women should take a low-carbohydrate diet and do regular exercise (at least 30 minutes, three times a week, walking or doing another type of aerobic exercise).

3.1.7 Pounding Heart (Palpitations)

Heart palpitations are due to hormone fluctuations but can also be signs of anaemia or thyroid disease. Therefore, seeing a doctor is recommended for any heart disturbances.

3.1.8 Dry Skin and Hair Loss

Skin and hair changes are also common, and they may begin in perimenopause as estrogen levels begin to decline. For skin changes, women often notice less firmness and drier skin, which is due to a decrease in collagen and a decreased water-holding capacity.

3.2 Long-term symptoms

The age when the symptoms of perimenopause occur varies, but in general, most women begin noticing perimenopausal symptoms in their 40s, with an average age of 47 years. While the average age at which a woman reaches menopause is 51 years old. This list of the common climacteric symptoms of perimenopausal is long, but remember, each woman experiences a personal “mix” that usually (and thankfully) doesn’t include all of them. (Megan McNamara, Pelin Batur, Kristi Tough DeSapri, 2015). The major long-term symptoms are:

3.2.1 Cardiovascular system

After the menopause, the body has a greater risk of developing coronary artery disease due to a lack of estrogen. Because, the estrogen hormone acts as an important role in reducing bad cholesterol, LDL.

3.2.2 Osteoporosis

The lack of estrogen causes more bone destruction by up to 5% per year, resulting in subsequent osteoporosis, especially in the spine, wrist bones, and hip bones.

3.2.3 Urinary tract problems

The effect of the lower spine level causes the lining of the urethra to become thinner and a flabby bladder stomach causing a burning sensation while urinating and there was no urinary incontinence.

3.2.4 Weight gain and getting fat

The effect of reducing estrogen levels can affect the metabolism causing higher fat accumulation in the abdomen.

3.3 Psychiatric Disorders in Perimenopause and Menopause.

Psychotic symptoms that are common in pre-menopausal women are confirmed to be related to the reduction of estrogen and other factors, such as the original physical and mental health problems, perception of menopause, family, and social environmental expectations, etc.

The psychiatric disorders in perimenopause and menopause can be diagnosed in the forms of mood swings, irritability, anxiety, depression, shock, fatigue, weakness, sleepiness, lack of concentration, and loss of memory which decreases self-confidence.

3.4 Metabolic change and care during perimenopausal.

Menstruation is caused by the brain. The hypothalamus secretes gonadotropin-releasing hormone (GnRH) that stimulates the anterior pituitary gland to secrete FSH (Follicle Stimulating Hormone) hormones to stimulate the eggs in the ovaries to grow. When one egg grows more than the others it leaves, it is called a dominant follicle. The ovaries secrete estrogen hormones to inhibit the activity of the FSH hormone, not to release the secretion of other eggs. In addition, the hormone estrogen causes the follicle to accumulate fluid during which the cells and the central cavity (astral follicle) surround the egg or oocyte. While the follicle grows, more estrogen secretion is released, resulting in the receptor of the hormone LH (Luteinizing Hormone). The ovarian theca layer has increasingly higher levels of FSH and LH to stimulate estrogen and progesterone, increasing secretion until the LH hormone is rapidly elevated (LH Surge). Alternatively, the hormone LH encourages granulosa cells to produce plasminogen activators. Increasingly, when the hormone LH stimulates the plasminogen it is transformed into plasmin to decompose collagen in a soft egg bag, causing the wall to weaken when the pressure of the fluid in the antrum leads to ovulation. The follicle in the ovary that is removed is called the corpus luteum, which acts primarily to produce the hormone progesterone and create

estrogen so that the uterine lining grows to prepare, embedding the embryo and starting the function of the immune system to prevent the embedding of embryos that have been fertilized after ovulation. The corpus luteum will produce hormones until the placenta is replaced. But without fertilization, the corpus luteum will drop the hormone and turn white, called corpus albican, and decays about 12 days after the eggs fall. If there is no fertilization, the estrogen and progesterone levels will drop rapidly and stimulate the FSH to work again, causing the lining of the uterus to become menstrual. (Soules MR, Sherman S, Parrott E, et al., 2001 & McKinlay SM., 1996 & Gindoff PR, Jewelewicz R., 1986).

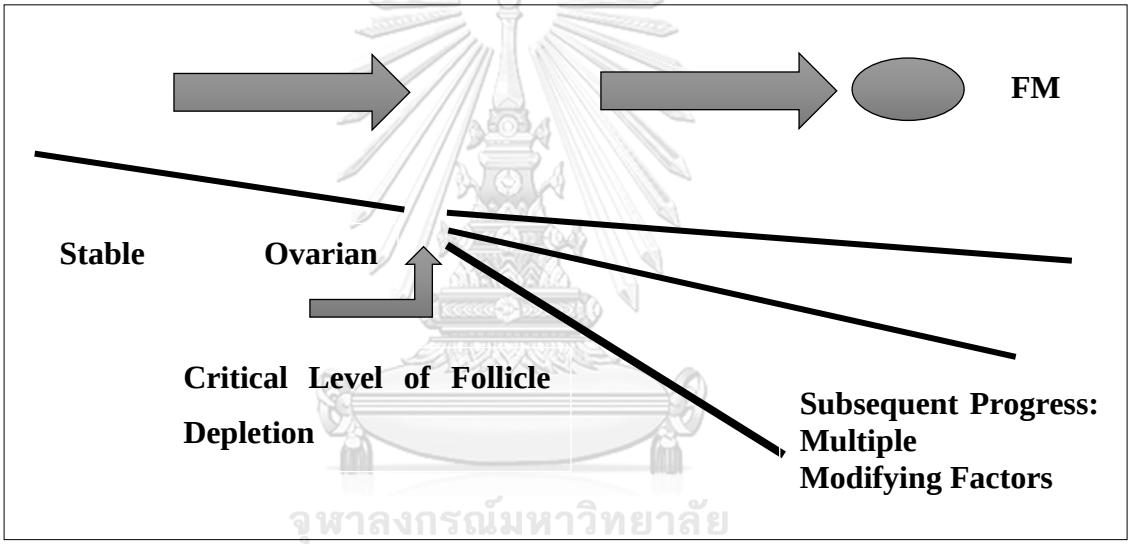


Figure 2.2 Ovarian aging model works across the menopausal transition.

Figure 2.2 Ovarian ageing model works across the menopausal transition. Ovarian reserve shrinking life and reaching the critical threshold at the start of menopause at this point, the woman recorded her first period was over. The routine subsequent loss of ovarian reserve can be made many times.

3.5 Treatment of the Perimenopause symptoms

3.5.1 Hot Flushes

To lessen the hot flush, perimenopause women should avoid exposure to extremely hot air, spicy foods, hot foods, drinks with arterial stimulants such as caffeine and alcohol, and smoking. Moreover, they should take foods that contain vitamin E and B complex as well as supplements of these substances. Additionally, they should be relaxed and avoid stress which is a cause of an increase in body temperature.

3.5.2 Vaginal dryness

Vaginal dryness can be relieved by using lubricants such as K-Y Jelly or by using estrogen cream to stimulate the blood to nourish the vagina more. Additionally, making it natural and easy while having sex will help stimulate good blood circulation in the vagina and make the vagina more flexible.

3.5.3 Insomnia and mood swings

For an easier and deeper sleep, antidepressants such as Selective Serotonin Reuptake Inhibitor (SSRI) drugs can be taken. Moreover, recreational activities can help relieve stress and make the mind clearer.

3.5.4 Osteoporosis

To avoid Osteoporosis, foods that contain calcium and high vitamin D should be consumed. Moreover, supplemental hormones can be taken on the advice of a doctor. Additionally, exercise and hard work should be avoided.

3.5.5 Hair loss

To lessen the hair loss in perimenopause, estrogen hormone can be taken to inhibit the creation of dihydrotestosterone which causes weak hair roots. Regular hair washing should be done to eliminate and prevent bacteria that may cause damage to the hair roots and scalp. Additionally, a shampoo that contains stimulants to regenerate or nourish the hair is recommended.

4. Climacteric Symptoms

Climacteric is a period of change from fertility (reproductive period) to infertility (non-reproductive period) which starts from perimenopause onwards. Climacteric syndrome generally occurs at an average age of 45-55 years up to 60 years and sometimes longer. (Norozi E, Mostafavi F, Hasanzadeh A, Moodi M, Sharifirad G., 2013).

Kurugodiyavar, et.al. (2017) conducted a study on an assessment of perimenopause' symptom prevalence of perimenopause women. The study revealed 75% of the participants. had muscle and joint pain, 60% complained of headache, 60% had lower backache and 40% complained of constant weakness or lack of energy. Moreover, a study conducted by Singh A, Pradhan SK. (2014) showed that 89.3% of the participants experienced at least one or more menopausal symptoms. The most common complaints of postmenopausal women were sleep disturbances, accounting for 62.7%, muscle or joint pain, accounting for 59.1%, hot flushes, accounting for 46.4% and 45.6% of the participants experienced night sweats. A total of 32.1% of participants suffered from depression and 21.0% from anxiety. Additionally, a study by Nayak, on peri-menopausal women in coastal areas of Karnataka, suggested several other factors that seem to influence the physical and psychosocial development of symptoms such as progressive ageing, growing family responsibilities, and possible mid-life crisis, and other non-menopausal factors during this phase of their lives. (Nayak G, Kamath A, Kumar P, Rao A., 2012). Moreover, understanding, beliefs, values, attitudes, education, and cultural factors seem to indirectly influence the symptom profile.

5. Tibetan Yoga

5.1 History of Tibetan Yoga

Tibetan yoga is a union of body, mind, and spirit which is based on Buddhism. It is a set of simple yoga exercises which comprises of 5 yogics called 'ritual'. This type of yoga has developed over the centuries in 5 temples of Tibet. (Unraveling the Mystery of Tibetan Yoga Practices., 2019).

Tibetan yoga was brought to the west by a retired British Army officer Col. Bradford who had spent time with Lama in Tibet and had 3 years of experience in Tibetan training. After he came back, his friend Peter K. Elder recorded his experience in a book called "The Ancient Secret of the Fountain of Youth," Currently millions of people do these 5 ritual exercises and gain amazing experience of regaining youth, vitality, and treatment of depression, rheumatoid inflammation, pain, diabetes and digestive, respiratory and heart problems. Additionally, Chris Kilham, a yoga teacher who wrote The Five Tibetans (Healing Arts Press, 1994) stated that perhaps this type of practice originated by lamas in Tibet and was later introduced to Nepal and India.

5.2 The Five Tibetan Yoga Rites.

The five ritual Tibetan also called “the fountain of youth and fitness” is the easy movement through two or more poses that can be completed in less than 20 minutes. Practising these rituals help the practitioners to live a long and healthy life like the Tibetan monks. (Unraveling the Mystery of Tibetan Yoga Practices., 2019).

5.3 Benefits of the Five Tibetan Rites

Regular practice of the five Tibetan rites will provide the following benefits: improved strength and coordination, reverse the ageing process, detoxification, sleep soundly, balance of the chakras, emotional and mental health, enhanced memory and relief from joint pain and arthritis.

5.4 The Five Rites Exercise Program

Tibetan Yoga contains 5 postures (The Five Tibetan Rites) (sometimes called "The Five Rites" or "The Five Tibetans" or "The Five. Rites of Rejuvenation. "But nowadays it is referred to as " T5T" for short). (Kelder, P., & Watt, J. W.,1939) the details of which are as follows:

Rite 1: Tibetan Spin

The first rite aims to speed up the chakras. It begins with standing up straight, arms outstretched parallel to the floor with the palms facing down. Then slowly spin clockwise from left to right without bending the knees forward. Keep the

eyes open and cast toward the ground. Rotate your body as many times as you like but stop when you feel slightly dizzy. Excessive spinning which is said to overstimulate the chakras should be avoided.

Figure 2.3 Rite 1: Tibetan Spin (Kelder & Watt,1939)

Rite 2: Prone to Upward Staff Pose

The second rite aims to tune the seven chakras. It starts by lying flat with your back against the floor. Placing your arms at your sides, palms on the floor. Lift your head off the floor, and hold the chest attachment storage. Lift both legs perpendicular to the ground until both the legs get straight. Then place the head and feet back onto the ground. Repeat this action. The rhythm of breathing should be deep and consistent.

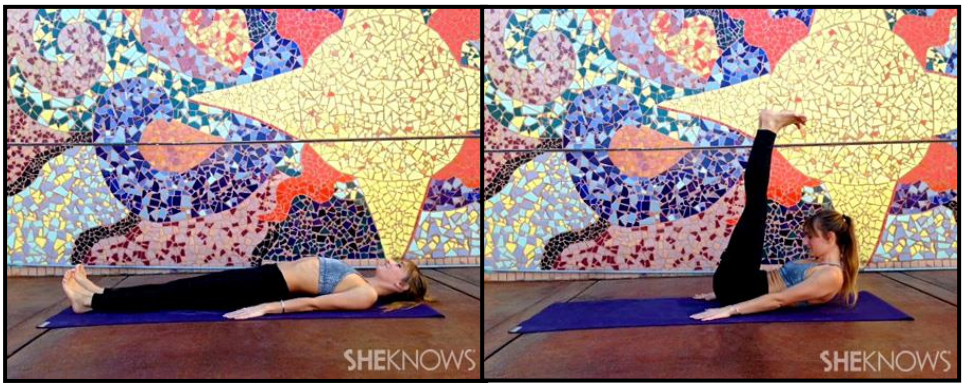


Figure 2.4 Rite 2: Prone to Upward Staff Pose (Kelder & Watt,1939)

Rite 3: Rabbit to Camel Pose

This process should be continued immediately after the second procedure. It starts by kneeling on the floor shoulder-width apart and hips aligned over the knees. Straighten your trunk and place your palms on the back of your thighs, below your buttocks. Inhale and drop your head and neck to the back gently as much as you can, arching your spine to open your chest. Exhale and drop your head forward moving your chin toward your chest.

Figure 2.5 Rite 3: Rabbit to Camel Pose (Kelder & Watt,1939)

Rite 4: Staff to Upward Plank Pose

The fourth rite is sometimes called the “moving tabletop”. It begins by sitting down on the floor with both legs straight forward. The front end of both legs are about a foot apart and the body is erect. Place the palms on the floor beside the hips. Keep holding the chest tight. Then inhale and bend your head back towards the back as much as possible. Meanwhile, lift the body parallel to the floor, knees bent perpendicular to the ground. Both arms are straight, perpendicular to the ground as well. Contracting muscle in the body and hold your breath, then exhale, relax your muscles and return to the starting position.

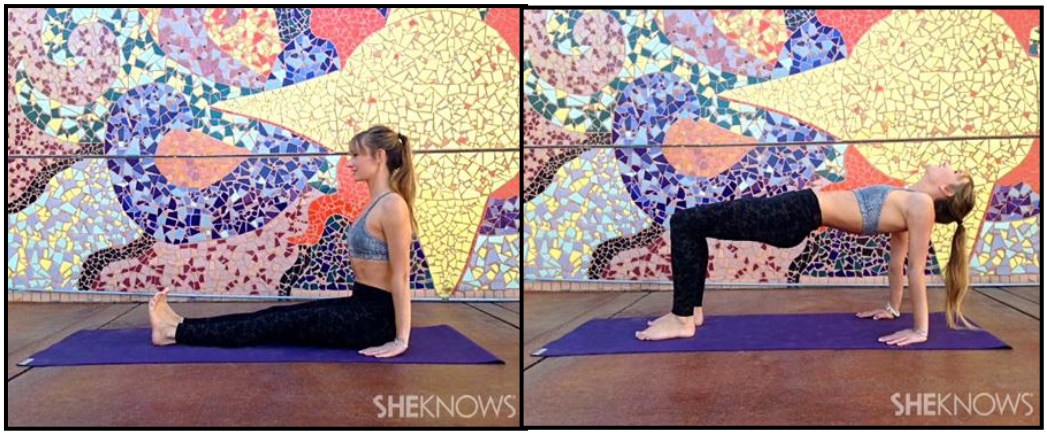


Figure 2.6 Rite 4: Staff to Upward Plank Pose (Kelder & Watt,1939)

Rite 5: Upward Dog to Downward Dog

This pose is often called “Two dogs” since it involves two poses that are, the Downward-Facing Dog and Upward-Facing Dog pose. This pose begins with sitting on the floor with your legs crossed and putting your hand on the floor. Use your arms, hands, and palms to support your body. Extend your feet behind you, toes curled and shoulder-width apart. Straighten your arms and arch your spine while keeping the tops of your legs on the ground. Drop your head back into Upward-Facing Dog. Then, inhale and lift your hips, moving your body into an upside-down “V” shape. Move your chin toward your chest and straighten your back into Downward-Facing Dog. Then exhale and move back into Upward-Facing Dog before returning to the starting position. Stay relaxed for a while and start doing this procedure again. The postures and breathing are like the previous ones. A deep breath while picking up a chevron and exhaling when dropped down.

Figure 2.7 Rite 5: Upward Dog to Downward Dog (Kelder & Watt,1939)

6. Estrogen in Perimenopause and Menopause women

Estrogen is a female hormone that is produced naturally. It controls the female reproductive system. Estrogen hormone and estradiol in females are created from the ovaries and are involved in controlling the expression of sexual characteristics. However, the level of Estrogen hormone will decrease when the woman enters the perimenopause and menopause periods. Once women get older, the hormone is produced less. In menopause insufficient levels of estrogen affect women, causing many short-term menopausal symptoms such as hot flushes, excessive sweating, a terrible cold, fainting, or dizziness. Therefore, physicians may recommend those who experience such symptoms take synthetic estrogen to increase their hormone levels as required by the body.

As for the long-term symptoms, the perimenopause/menopause may experience the wall of the uterus is thinner, dry, and less flexible and may cause pain when having sex. The decreasing hormones also affect bone density. As it was found that two years after menopause, bone mass density would rapidly decrease at the rate of 1% to 2% per year. This change in bone is associated with osteoporosis. (Metcalf, 1988 & Hee *et al.,* 1993). The reduction of the Estrogen hormone also results in higher levels of Low-Density Lipoprotein (LDL) which is a cause of the hardening of the arteries (atherosclerosis) and cardiovascular disease. In addition, hormonal changes in the premenopausal period also affect the mood and quality of life of family and society.

Estrogen also plays a vital role in controlling weight and body fat. During menopause, the estrogen level is low, and this causes weight gain. A decrease in estrogen will bring about dry skin, less flexible skin, fatigue, easy tiredness, thinner bones, etc.

7. Yoga as a treatment for Perimenopausal and Menopausal symptoms

Yoga is the science of self-practice and self-development which can be traced back over 5,000 years. It is an old Indian philosophy that was discovered to be an alternative, aiming to improve body, mind, and spirit to keep the balance of body and mind so that people who practice yoga will be happy and have a better quality of life. (ABC of YOGA, 2019)

Yoga has been brought to be a treatment tool for better health. Many researchers studied outcomes of yoga that can help cure various disease symptoms to be better such as asthma, high blood pressure (hypertension), and obesity. It is found that with yoga practice, the blood glucose level decreases. There is also a presumption that practising yoga can help control hormones in menopausal women. (Sahay BK, 1995 &Chatha R, Nagarathna R, Padmalatha V, Nagendra HR, 2008)

Yoga is beneficial for the body and mind, in particular, the body will receive stretching that will help muscles and ligaments gain more flexibility and the working system of other organs is improved. Concerning the benefit to the mind, practising yoga can help people feel more relaxed and know themselves better (Force BL, Thurston C., 2007). They will gain more concentration and consciousness, are not easily moody, and have more self-confidence. Yoga also helps promote the respiratory system to work more efficiently while the body can receive a sufficient amount of oxygen, causing better movement of the spine. Besides, yoga promotes hormone and endocrine systems in menopausal women, enabling the working mechanism of the endocrine system to be normal and reproductive organ becomes healthier. Physical changes in menopause relate to a decrease in body temperature. Once yoga is practised, it can respond to and stimulate the nervous system and reduce hot flushes by 66%. Yoga can also lessen insomnia with statistical significance. (Chattha R, Raghuram N, 2008)

Research has indicated the benefits of yoga practice as an optional treatment for perimenopausal/menopausal symptoms in women such as Daley, Strkes-Lampard AJ, MacArthur C (2009) who stated that yoga can relieve menopausal symptoms such as hot flushes, night sweats, sudden waves of heat coming from the skin, head, face and neck, nausea, and dizziness, headache, palpitations, anxiety, excessive sweating (diaphoresis), sleep problems and promote better memory. Permatasari (2017**)** studied the effectiveness of yoga as a treatment for menopausal symptoms. The findings revealed that yoga was effective as an additional treatment for menopausal symptoms, regarding psychological, vasomotor, and somatic. Afonso, Kozasa, Rodrigues, Leite, Tufik, and Hachul (2016) evaluated the level of estradiol and quality of life (QOL) of two postmenopausal women after yoga practice. The results showed that the participants exhibited an abnormal estrogen-level increase after 4 months of yoga

practice and showed QOL improvements. Further, Crowe, Puymbroeck, Linder, Mcguire, and Watt (2015) studied the effects of yoga participation on women's quality of life and symptom management during the menopausal transition. The results showed that yoga training helped decrease the physiological menopausal symptoms of the participants. Moreover, they experienced enhanced QOL as a result of their participation in yoga. Additionally, Nirmala Vaze, Sulabha Joshi (2010) explored new options for the management of menopausal symptoms in the form of non-hormonal drug therapy and non-pharmacological measures. The findings indicated that Yoga was effective and was strongly recommended to all women of menopausal age.

Concerning the aforementioned studies, it can be concluded that yoga does have the potential to provide physical, mental, and emotional health benefits as well as to decrease the climacteric symptoms of women during the menopausal transition.

8. Yoga and the quality of life of Perimenopausal and Menopausal women

Quality of life means good life and well-being which refers to having a good quality of life for such a long time. For centuries based on the background of philosophical fields, quality of life plays an important role in people's well-being which relates to human welfare and happiness. (WHO, 1994)

As soon as women enter menopause, they have health problems from estrogen hormone deficiency which affects their quality of life. Research studies conducted in many countries found that the estrogen hormone of women in perimenopause affects their quality of life (Clarke, Marshall, Ryff, & Rosenthal, 2000; Farquhar, 1995).
However, the mentioned symptoms can be relieved when the women took hormone replacement. As studies revealed that the group of women taking hormone replacement had a better quality of life-related to mental health and depression with a statistical significance. In contrast, the group of women who did not receive hormone replacement had poorer quality of life-related to physical functions and energy/fatigue than those who received the hormone replacement.

As for the non-hormonal treatment, yoga was found to be one of the effective treatments which increased the quality of life of menopausal women. For instance; Jayabharathi and Judie (2014) studied the use of yoga and meditation in improving

the quality of life in menopausal women. The results revealed that in the experimental group, the physical, psychological, social, and environmental domains of quality of life were greatly improved by practising for 18 weeks. Afonso, Kozasa, Rodrigues, Leite, Tufik, and Hachul (2016) evaluated the level of quality of life (QOL) and estradiol levels of two postmenopausal women after yoga practice. The result showed that the participants exhibited an abnormal estrogen-level increase after 4 months of yoga practice and showed QOL improvements. Gayathry Nayak, Asha Kamath, Pratap N. Kumar, Anjali Rao. (2014) studied the effect of yoga training on menopausal women's quality of life. The findings indicated that the participants experienced fewer menopausal' symptoms which resulted in a better quality of life.

The aforementioned studies are pieces of evidence to conclude that yoga can be an alternative tool in decreasing perimenopause/menopausal symptoms which helped increase the quality of life of women in the menopausal transition period. Therefore, this study explores the use of Tibetan yoga in reducing the symptoms of women in perimenopause to enable them to have a better quality of life.

CHAPTER 3

RESEARCH METHODOLOGY

1. Research Design

A community-based **r**andomized controlled trial, RCT, two group pre-test post-test design was conducted between 1st August 2020 and 30th November 2020 to assess the effect of Tibetan Yoga in reducing climacteric symptoms and improving quality of life in perimenopausal women. The study design and participant sampling are described in the following sections.

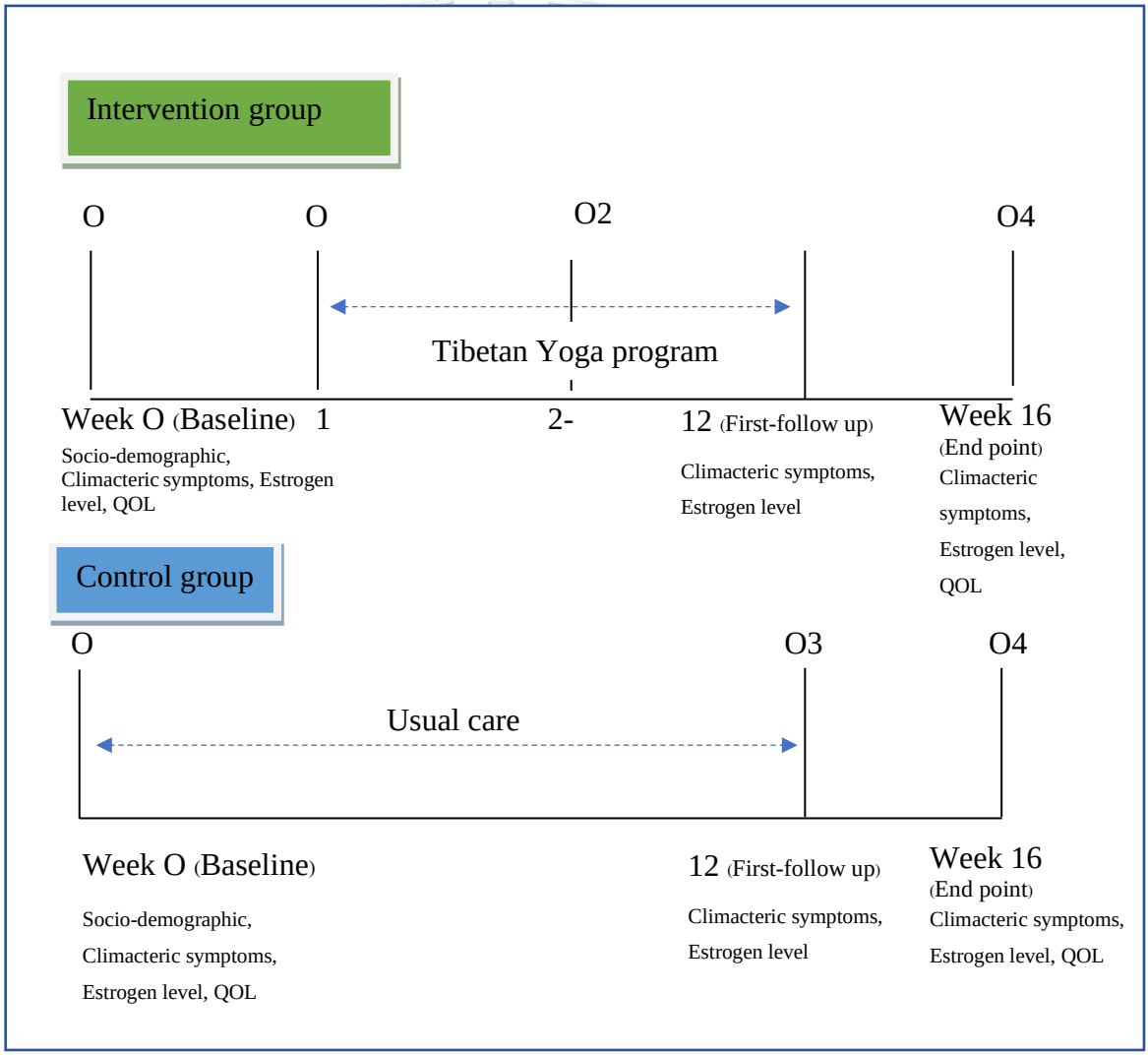


Figure 3.1 Research design

O = Baseline Measurement

O1 = Begin Tibetan Yoga Program

O2 = Week 2^n to 12 Tibetan Yoga Program

O3 = Week 12 - First-follow up

O4 = Week 16 End point (outcome measures)

2. Study Site

The study was conducted on Thai perimenopausal women living in Moo 9, Lahan community in Bangbuatong District of Nonthaburi Province.

3. Study Period

The study was conducted between 1st August 2020 and 30th September 2020. The study was divided into 4 phases:

Phase 1: Blood was collected from participants in both the experimental and the control groups to measure estrogen levels. Socio-demographic information was also collected from the participants and were screened for climacteric symptoms using the Climacteric Symptoms Assessment Form of the Bureau of Reproductive Health, Department of Health, Ministry of Public Health Thailand (Baseline measurement – Week 0). In addition, the QOL of participants were assessed at baseline before giving the intervention - Tibetan Yoga Program.

Phase 2: This phase involved initiating the intervention of Tibetan Yoga in Thai perimenopausal women in the study area. This phase started at week 1 and continued until week 12 of the intervention program.

Phase 3: The participants in the experimental and control group received a climacteric symptoms assessment using the Climacteric Symptoms Assessment Form of the Bureau of Reproductive Health, Department of Health under the Ministry of Public Health Thailand. This was conducted in week 12 as the first follow-up. In this phase, blood samples were also collected to measure the estrogen level in the participants in both groups.

Phase 4: The endpoint (outcome measurement) was done in week 16. Climacteric symptoms were assessed, and blood samples collected to determine the estrogen level and QOL of the participants was assessed.

Table 3.1 Detailed breakdown of study period into 4 phases.

Timeline	Activity	Study group		Tools
		Intervention group	Control group	
0 week (Baseline)	- Screen Estrogen hormone - Assess climacteric symptoms -Assess Quality of Life (QOL)	✓	✓	- Case record form of estrogen hormone - Climacteric Symptoms Assessment Form of the Bureau of Reproductive Health, Department of Health, Ministry of Public Health - WHOQOL – BREF – THAI
Week 1 -12	- Tibetan Yoga intervention	✓		- Yoga expert providing instructions on performing yoga rites
Week 12 (First follow- up)	- Screen estrogen hormone - Assess climacteric symptoms	✓	✓	- Climacteric Symptoms Assessment Form of the Bureau of Reproductive Health, Department of Health, Ministry of Public Health

Table 3.1 Detailed breakdown of study period into 4 phases (continue)

Timeline	Activity	Study group		Tools
		Intervention group	Control group	
Week 16 (end point)	- Estrogen hormone - Climacteric symptoms - QOL	✓	✓	- Case record form of estrogen hormone - Climacteric Symptoms Assessment Form of the Bureau of Reproductive Health, Department of Health, Ministry of Public Health - WHOQOL – BREF – THAI

4. Study Population

Participants in this study were Thai perimenopausal women who lived in Moo 9, Lahan community in Bangbuatong District of Nonthaburi Province, aged between 45 and 55 years. The total number of women aged 45-55 years in the study was 332.

5. Sample size and sampling technique

5.1 Sample size calculation

The sample size calculated for study participants was based on the *G*Power* program, using the t-test for the mean difference between two independent means (two groups), configuring the effect size at 0.80 and type I error at 0.05 (Kaewpitool, 2012). The number of study participants per group was 26 for the experimental group and 26 for the control group, including volunteers in this research. (Figure 3.2).

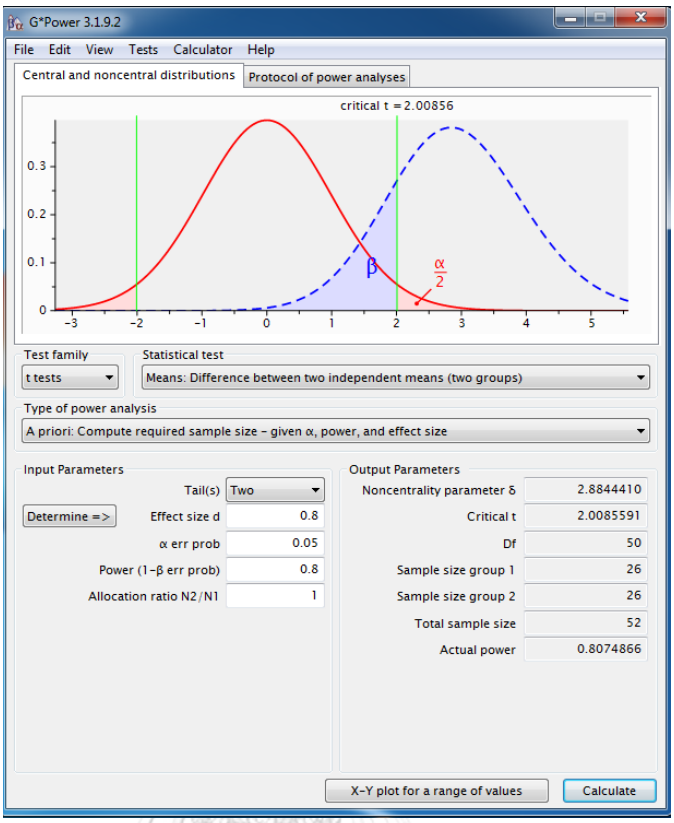


Figure 3.2 Sample size calculation using G*Power program

To prevent drop out the sample size was increased by 20% of the sample group the total sample was 64, divided into intervention and control groups with 32 study participants in each.

5.2 Sampling technique

Computer-generated random numbers were used in randomizing the study participants into intervention and control groups.

6. Inclusion and Exclusion Criteria

6.1 Inclusion Criteria

1. Thai perimenopausal women aged between 45-55 years old who have been living in Moo 9, Lahan community in Bangbuatong District Nontaburi Province for at least 6 months.

2. Thai perimenopausal women with climacteric symptoms whose score was greater than 15 were assessed using Climacteric Symptoms Assessment Form for screening and did not have amenorrhea in the last consecutive 12 months.

3. Thai perimenopausal women with no history of diabetes, high blood pressure or heart disease.

4. Thai perimenopausal women who are not participating in any systemic exercise program or been in any yoga programs in the past 6 months

5. Thai perimenopausal women provide written consent to participate in the research study by signing a letter of consent to participate voluntarily. For those participants who were not able to read and write, thumb impressions were taken after clearly making them understand the study, its purpose and protocol in presence of a witness (village head).

6.2 Exclusion Criteria

1. Thai perimenopausal women with a history of knee or spine surgery.

2. Thai perimenopausal women with a history of hysterectomy or endometrial ablation.

3. Thai perimenopausal women with a history of any type/form of hormone replacement therapy.

4. Thai perimenopausal women who are currently taking any type of supplements (vitamins, phytoestrogen, etc.)

5. Participants in the intervention group who cannot attend the Tibetan Yoga intervention program for a minimum of 80% of the total intervention period, that is, at least 10 weeks.

6.3 Termination criteria

Safety protocols were developed by the PI in consultation with experts and a licensed yoga expert to conduct the intervention – the Tibetan Yoga program, with care for the study participants. If any complications such as numbness of limbs, muscle spasms, suffocation or irregular heartbeats were reported in the participants in the intervention group, they will be taken to the nearest public health facility for immediate assistance and support from health personnel. In addition, if participants reported difficulty or uneasiness in practising the rites of Tibetan Yoga and therefore

are unable to continue the program, the PI will terminate the enrollment of the study participant.

7. Recruitment and Data Collection Procedures

7.1 Recruitment Studies Setting and Participant

The principal investigator (PI) visited the study site - Moo 9, Lahan community in Bangbuatong District in Nonthaburi Province, and contacted the village head to request permission to conduct the study in their village. This involved permitting the PI and the research assistants to search and identify a sample population for recruitment in the study. This was done by obtaining a list of women in the age group of 45-55 years from the village head, screening for eligibility based on the inclusion and exclusion criteria. After screening, they were offered participation in the study and finally, from the population who agreed to participate, women were enrolled into the intervention and control groups randomly and therefore enrolled 32 participants in each group. Written consent was obtained from recruited participants.

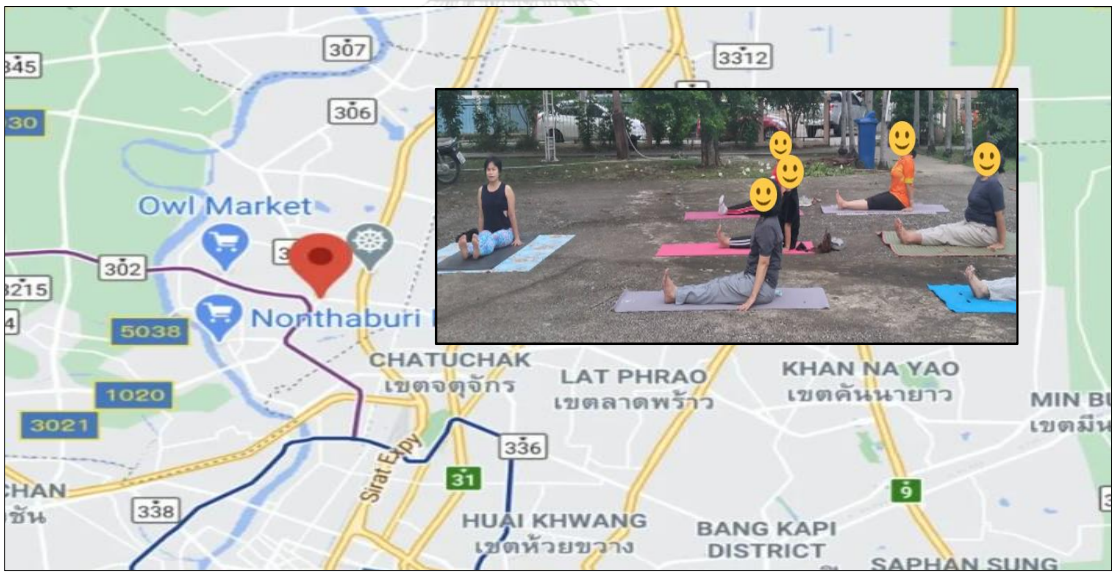


Figure 3.3 The location of Bangbuatong District in Nonthaburi Province. (Google Map, 2021)

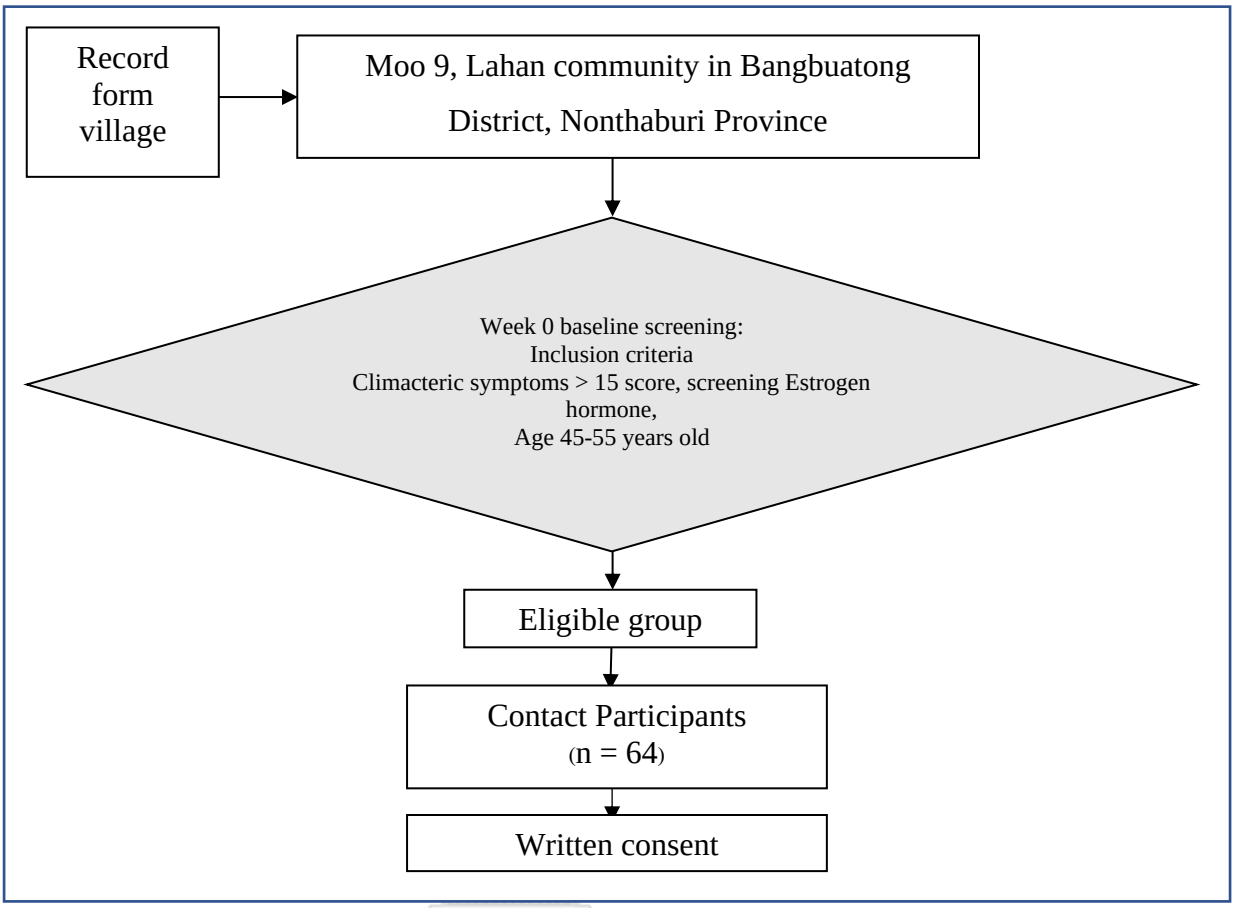


Figure 3.4 Flow chart of Enrollment participants

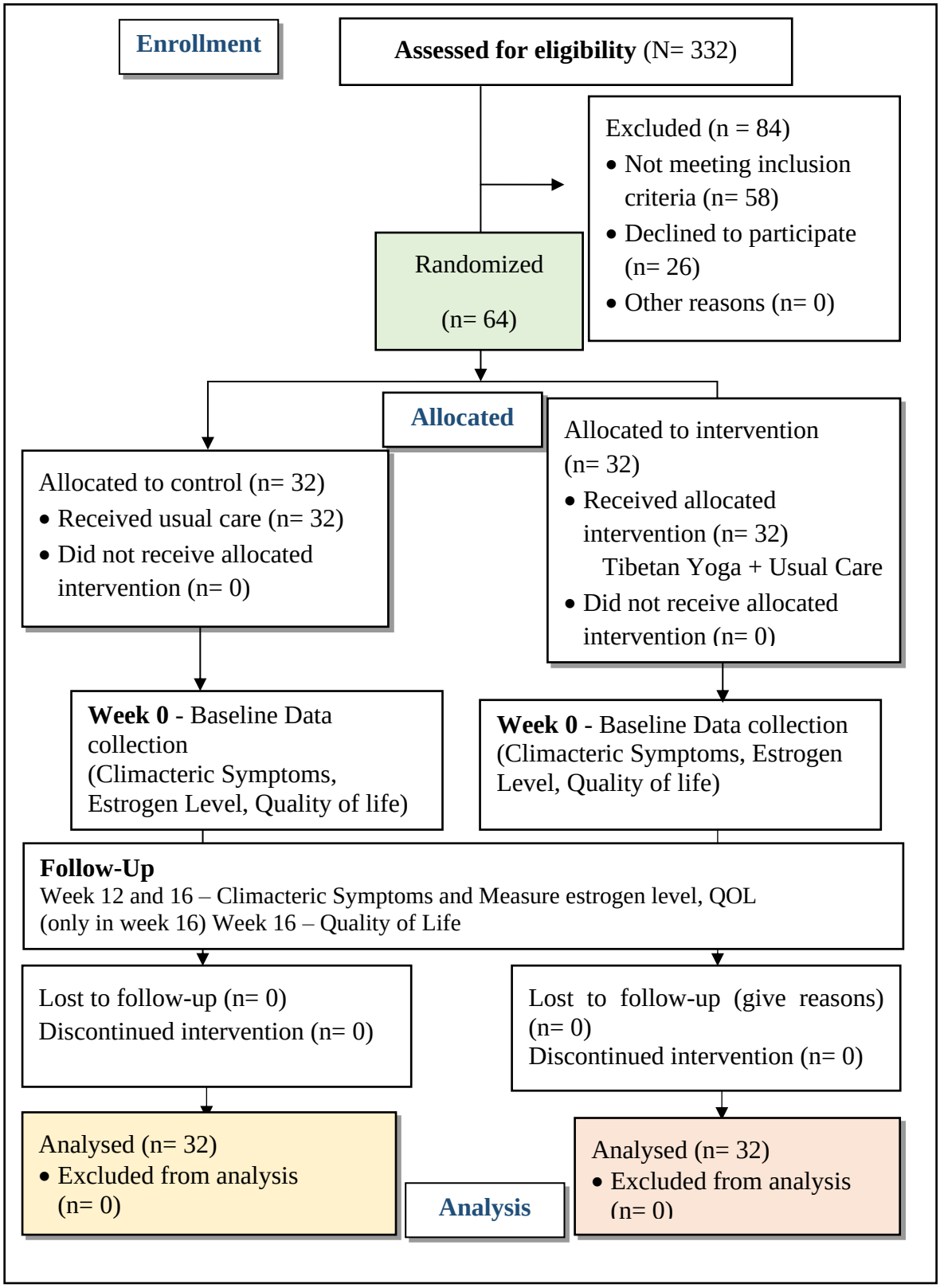


Figure 3.5 Consort Flow Chart

8. Data Collection

8.1 Preparation and Database collection

Data was collected between 1st August and 30th November 2020. The details of data collection are as follows:

a. The PI had help from three research assistants in collecting data in the study as well as assisting during the intervention. The PI and all research assistants received training on practising Tibetan Yoga from a yoga expert before the scheduled date of commencement of the study intervention. The purpose of this training was to support the yoga expert during the intervention.

b. The PI applied for ethical approval at the office of the Research Ethics Review Committee for Research Involving Human Research Subjects, Group I, Chulalongkorn University. Ethical approval was granted on 7th February 2020 with approval number 173.1/62.

c. After obtaining ethical approval, the PI submitted a letter of request to conduct the research to the village leader in Moo 9, Lahan community and explained the purpose, research outcome and benefits of the study.

d. After approval from the village leader, the PI contacted potential study participants aged 45-55 years to establish a relationship and explain the objectives, purpose, and benefits of the study. The PI then scheduled an appointment with all the women aged 45-55 years to carry out the recruitment and enrollment phase of the study.

e. Out of the 332 women aged 45-55 years in the study site, 26 declined to participate while 58 did not meet the inclusion criteria. Of the remaining 248 women, 32 were randomly selected (computer generated numbers) and enrolled on the intervention group and another 32 were randomly selected (computer generated numbers) and enrolled on the control group. The participants in both groups were detailed and informed about the purpose, objectives and procedures of collecting data, the right to decide to not participate in the research at any given time during the study and the anonymity of the collected data.

f. Once all the participants were clear about the study procedures, they were asked to sign a written consent of their participation in the study. In cases where

the participants could not read or write, thumb impressions were taken on the consent form in the presence of a witness (village head) after clearly explaining the details of the research.

g. Information on socio-demographic characteristics was only collected once, at baseline measurement, from the participants in both the experimental and control groups.

h. The intervention (Tibetan Yoga) was delivered by a licensed yoga expert and various measures were taken as previously mentioned to ensure the safety of the participants in the intervention group.

i. The intervention group. The participants were advised to attend the intervention at least 1 hour before eating or at least 2 hours post-meal. Tibetan yoga should not be practised immediately after eating meals. The participants were also advised to wear comfortable clothes that facilitate easy movements and flexibility while practising yoga.

j. On the days of practising Tibetan yoga, study participants were highly encouraged by the researcher through explanations of the advantages and benefits of Tibetan Yoga on perimenopause and its positive impact on their lives. They were motivated and made to believe in themselves by the PI to succeed in practising yoga and continue it as a lifestyle before each session of Tibetan Yoga.

8.2 Implementation of the intervention program

Intervention Group

A total of 32 participants enrolled in the intervention group practised yoga together as demonstrated and advised by the licensed yoga expert and was performed three times a week (Monday, Wednesday and Friday) at 17:30 hours for 45 minutes to 1 hour per session in a public park located in the study site. Data was collected individually from the participants in the intervention group at various points during the intervention. At baseline, socio-demographic characteristics, climacteric symptoms, estrogen level through a blood test and QOL of the study participants were measured. The intervention was carried out until week 12 at which time the first follow-up was performed. Climacteric symptoms were assessed, and estrogen level was measured at the first follow-up (Anna K. Koch, 2017). At week 16, a second

follow-up was performed where characteristics, climacteric symptoms, estrogen level and QOL were measured (Anna K. Koch, 2017) . This marked the endpoint of the study.

Each time Tibetan yoga was performed, it was divided into 3 phases –

Phase 1: Warm-up was done for 5 minutes to allow stretching and activate the muscles

Phase 2: Practicing Tibetan yoga, which included its 5 rites, each rite required 5 minutes

Phase 3: Cool down was done for 5 minutes

Warm-up and cool-down poses

Pose 1: Jogging: was performed by keeping the body in an upright position and preparing to run. Start with jogging in place and do not move forward for 1 minute.

Figure 3.6 Pose 1: Jogging (Koch, 2017).

Pose 2: Front Kicking: In this, the participant stood in an upright position, and folded the arms with a high guard position at chest level. Then they lifted a leg and kicked in the front. The participants did not bend the knee and performed it alternatively - left and right leg.

Figure 3.7 Pose 2: Front Kicking (Koch, 2017).

Pose 3: Knee Bending: The participant stood straight with feet slightly apart and hands were put to the front parallel to the floor at chest level. Then the knees were bent the same as in “squat posture”, while the arms were kept in the same position.

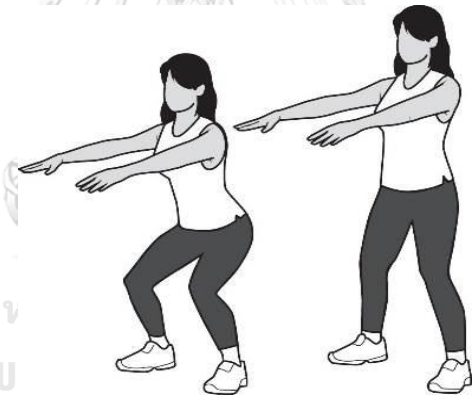


Figure 3.8 Pose 3: Knee Bending (Koch, 2017).

Pose 4: Arm stretch and Full: The participants stood straight with the feet slightly apart and put their right arm on the left arm and then pulled the arm to stretch muscles. This was performed alternately, left – right side.

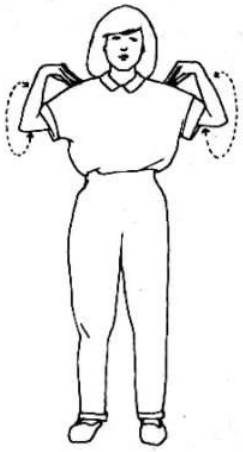


Figure 3.9 Pose 4: Arm stretch and Full (Koch, 2017).

Pose 5: Shoulder Rotating: Stand in an upright position. Move the shoulder forward and backwards.

Figure 3.10 Pose 5: Shoulder Rotating (Koch, 2017).

Pose 6: Foot Touching: The participants stood straight with feet slightly apart. Then they bent down and put their right hand to touch the right foot.

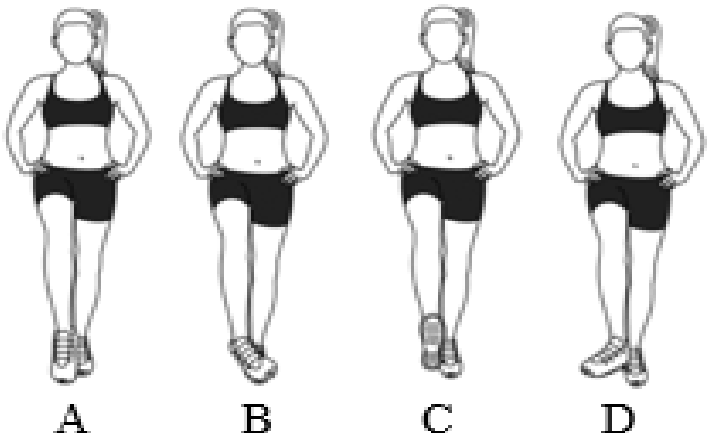


Figure 3.11 Pose 6: Foot Touching (Koch, 2017).

Pose 7: Neck Rotation Stretch: The participants sat straight and turned their faces to the left side as far as they could. Then they used their right hand to hold the face and pull it to become tight. It was performed in alternate successions, left-right.

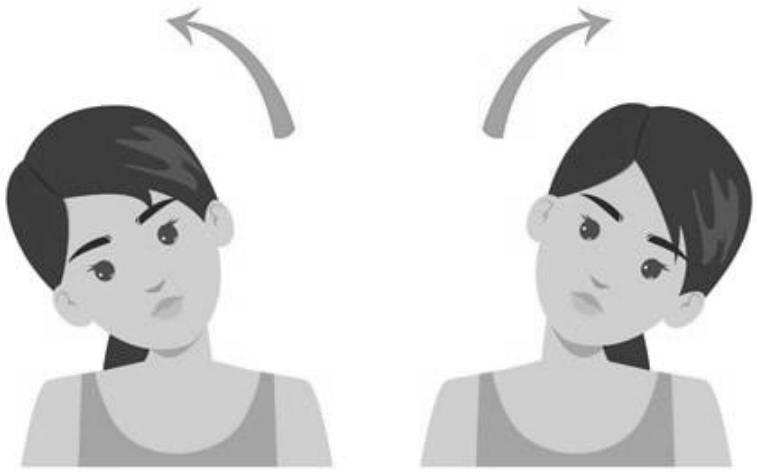


Figure 3.12 Pose 7: Neck Rotation Stretch (Koch, 2017).

Pose 8: Ankle Circles: The participants stood straight and lifted up the tip of their feet slightly over the floor and then rolled the ankles back and forth.

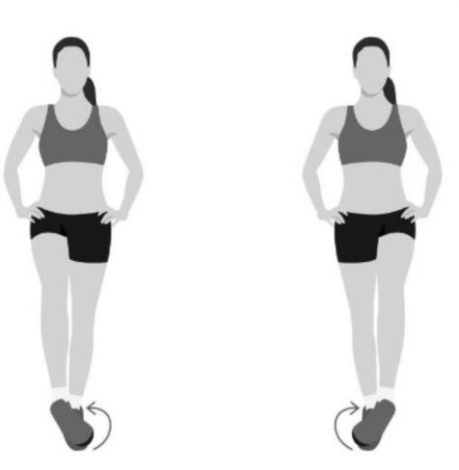


Figure 3.13 Pose 8: Ankle Circles (Koch, 2017).

Pose 9: Dynamic Chest: The participants stood straight with feet slightly apart. They then stretched their arms as far as they could to the side of the body and finally dropped down the arms to the body.

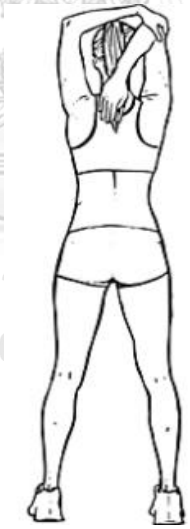


Figure 3.14 Pose 8: Ankle Circles (Koch, 2017).

Pose 10: Triceps: The participants stood straight with feet slightly apart. Then they bent their left or right arm backwards and used the hand on the opposite side to push the elbow. This was performed in alternate successions, left–right side.

Figure 3.15 Pose 10: Triceps (Koch, 2017).

Pose 11: Groin and back: The participants sat on an exercise mat or yoga mat. The soles of the feet were brought together such that the legs are at a 45-degree angle to the floor (the legs were not allowed to touch the floor). Then both hands touched the tip of the feet and the body was bent forward.

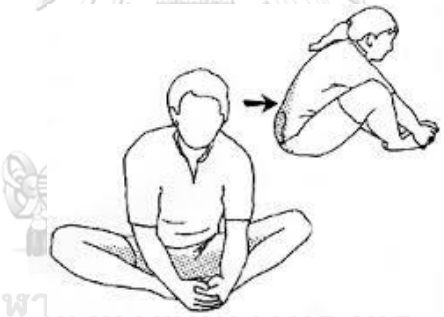


Figure 3.16 Pose 11: Groin and back (Koch, 2017).

Practising Tibetan yoga, 5 rites, each rite requires 5 minutes

Tibetan Yoga consists of 5 postures called the Five Tibetan Rites (sometimes also called "The Five Rites" or "The Five Tibetans" or "The Five Rites of Rejuvenation" or "T5T", in short.

Rite 1: The Spin

To perform this rite, stand up straight, arms stretched outwards parallel to the floor. Then rotate clockwise from left to right and continue it until you start

feeling a slight dizzy. Repeat the process gradually in increments from 3 to 21 repetitions. If you feel dizzy, stop the practice, sit or lie down still (Figure 3.17).

Figure 3.17 Rite 1: The Spin (Koch, 2017).

Rite 2: Leg Raise

This process tunes the seven chakras of the human body and is aimed at stimulating the chakra. To perform this rite, lay down on your back facing upwards. Extend your arms fully along your sides and place the palms of your hands on the floor with fingers kept close together. Raise the head up off the floor and hold the chin against the chest (inhale during this step). While doing this lift both legs, with knees stretched straight perpendicular to the ground. Try to extend the legs backwards over the body if possible without bending the knees. Finally, slowly lower both your head and legs to the floor, keeping the knees straight (exhale during this step). Perform 21 repetitions.

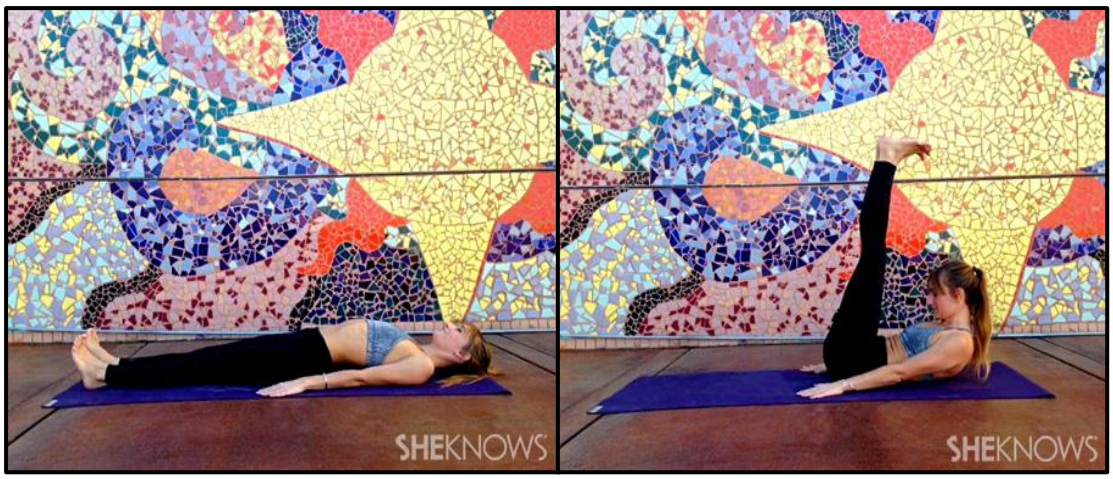


Figure 3.18 Rite 2: Leg Raise (Koch, 2017).

Rite 3: Kneeling Backbend

This process should follow after the second rite. Firstly, position your body in a kneeling posture on the flat floor with your body erect. Place two hands on the side of the legs (on thigh muscles) and bring the head and neck forward. Keep and hold the chest tight, lifting the top of the rib cage then bend your head and neck to the back as much as you can. At the same time bend the spine to bend down. Then, throw the head and neck backwards, arching the spine. As you arch backwards, place your hands against the thighs for support. Finally, return to the initial position and start the process again. Perform the rite for 21 repetitions. Breathe in deeply while you arch your spine and exhale during returning to the erect position.

Figure 3.19 Rite 3: Kneeling Backbend (Koch, 2017).

Rite 4: Tabletop

First, sit down on the floor and stretch both legs out straight. Position the front end of both legs about a foot apart and keep the body erect. Place the palms of your hand on the floor beside the hips. Then bring forward your head towards your chest and tuck it in and then drop the head backwards as far as it can go. Meanwhile, lift the body parallel to the floor with knees bent perpendicular to the ground. Keep both arms straight, perpendicular to the ground as well. Contract the muscles in the body while lifting and relaxing the muscles while you return to your original position and rest before starting to process again. Take a deep breath as you tense the muscles while lifting the body parallel to the ground. Then hold your breath while flexing muscles, and slowly breathe out as you return to the original position. Perform 21 repetitions.

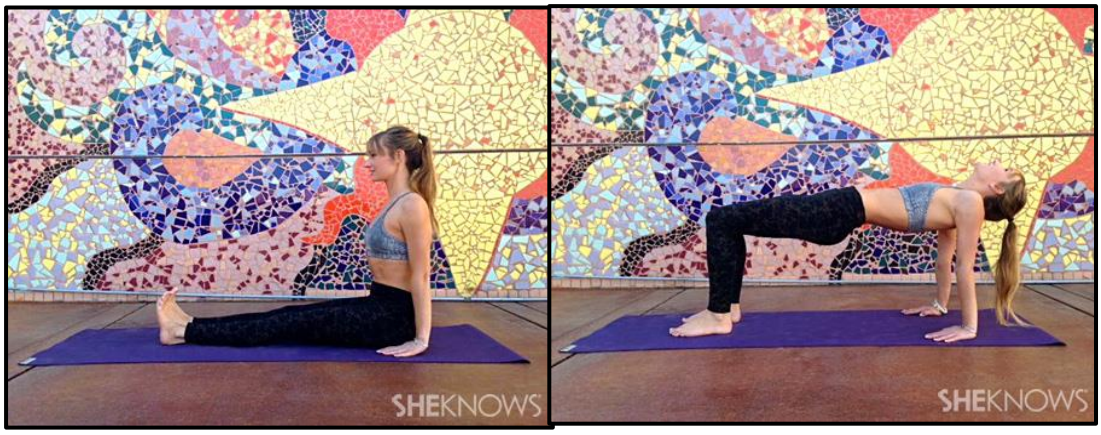


Figure 3.20 Rite 4: Table top (Koch, 2017).

Rite 5: Pendulum

While performing this rite the body will be face-down to the floor. Place the palm of your hands against the floor to support the body. Also, stretch the legs and support your body with your toes in a flexed position. The hands and feet should be kept straight throughout this rite. Then start by keeping the arms perpendicular to the floor and arch the spine such that the body is in a sagging position. Throw the head back as far as possible, then bend at the hip bringing the body upwards in an inverted V shape. Simultaneously, bring the chin forward and tuck it against the chest. Take deep breaths while raising the body and exhale completely when you lower it.

Figure 3.21 Rite 5: Pendulum (Koch, 2017).

Control Group

The assessment of climacteric symptoms was evaluated at weeks 0, 12 and 16. In addition, the level of estrogen hormone was also measured at weeks 0, 12 and 16 while QOL was evaluated at weeks 0 and 16.

8.3 Assigned responsibilities and duties

a. The PI

The preparation and organization of the Tibetan Yoga intervention was achieved by the PI with the support of research assistants and a licensed yoga expert.

i. The PI practised Tibetan yoga by studying, learning, and practising from the licensed yoga expert who provided the intervention in the study.

ii. The PI practised Tibetan yoga for a month before the commencement of the intervention to enhance her skills before performing actual Tibetan yoga activity. This also helped the PI to assist the licensed yoga expert in monitoring the intervention groups while Tibetan Yoga was delivered to the intervention group.

b. Licensed yoga expert

i. The yoga expert prepared the methods of delivering the intervention, Tibetan Yoga, including teaching all postures of Tibetan Yoga to the participants in the intervention group as well as explaining the safe approach to practising Tibetan Yoga.

ii. Instructional media and information were prepared including Tibetan Yoga presentation slides, training videos and a five-posture Tibetan Yoga poster.

iii. Tibetan Yoga was taught to the participants in the intervention group for 12 weeks and coordinated with the PI to assure the accuracy of five-posture Tibetan Yoga during each session.

c. Research assistants

Three community volunteers were recruited to screen the participants based on climacteric symptom scores. This was done first, to recruit the participants into the study and after enrollment to assist in collecting data and support for the study.

Also, two medical technicians from a medical technology clinic were recruited and were responsible for blood collection from the study participants to

measure estrogen levels and submitting the blood samples for examination, result generation and interpretation at ProLab Co., Ltd., Thailand.

8.4 Laboratory examination

8.4.1 Specimen and Collection medium

Six millilitres of blood was collected from the study participants in both the intervention and control group using a SYRINGE 21 G x1 "1/2 in blood collection tubes without anticoagulant (red stopper).

8.4.2 Handling

The blood samples were sent to the laboratory within 2 hours after collection and inspection.

8.4.3 Methodology

Electrochemiluminescence Immunoassay (ECLIA), the competition principle was employed for determining estrogen levels.

8.4.4 Results

pg/mL, Reference range

Follicular phase	12.4 – 233 pg/mL
Ovulation phase	41.0 – 398 pg/mL
Luteal phase	22.3 – 341 pg/mL
Post menopause	< 5 – 138 pg/mL

9. Research Instruments

The tools used in the study were divided into 2 categories –

a. Tools used for screening study volunteers into the experimental and control groups

b. Tools used for data collection included questions on socio-demographic characteristics, climacteric symptoms assessment, measurement of estrogen hormone and QOL using WHOQOL-BREF-THAI

Part 1: Tools used for screening the study population and enrollment in the experimental and control groups.

The Climacteric Symptom Assessment Form from the Bureau of Reproductive Health, Department of Health under the Ministry of Public Health Thailand was used for screening and recruitment of participants in the study. This was carried out by the PI with the help of the research assistants. The climacteric symptoms assessment tool was used for evaluating menopausal symptoms in perimenopausal women in the past 1 month. The evaluation form comprised 20 items that assesses menopausal symptoms in 3 domains – psychosocial, somatic, and vasomotor which were adapted and modified from Green J (reference). Each symptom is rated from 0 to 3 in terms of the extent to which the participants are bothered by the climacteric symptoms. In this, 0 indicates 'not at all' 1 indicates 'a little', 2 indicates 'quite a bit' and 3 indicates "extreme" (Greene, 2002; Burbos & Morris, 2011)

The scale is translated into the Thai language using back translation. The questions in the scale were modified and adapted to meet the context of Thailand. During data collection, an "X" mark was recorded in the box in the questionnaire to record the answers of the respondents.

Scoring criteria

Symptoms	Score	Interpretation
Not at all	0	A score of more than 15 points indicates a high risk of estrogen deficiency
A little	1	
Quite a lot	2	
Extremely	3	

Part 2: Tools used for data collection included

Part 2.1: Socio-demographics of participants

The socio-demographic characteristics included age, marital status, highest attained education, income, tobacco use, health problems or pain, height, weight and BMI.

Part 2.2: Record form for changes in estrogen hormone levels

Changes in estrogen hormone levels were assessed by collecting blood samples at weeks 0, 12 and 16 in the intervention and control groups. Changes in estrogen hormone level were recorded first by measuring the level of hormone at week 0, before the intervention program of Tibetan Yoga. At week 12 the level of hormone is measured again and finally at week 16. The blood samples collected during each period were sent for analysis at ProLab Co., Ltd., Thailand.

Part 2.3: WHOQOL – BREF –THAI

The Quality of Life Instrument used in this study was the 26-item version of the WHO Quality of Life (WHOQOL–BREF–THAI), Mental Health Indicators of the Department of Mental Health, Ministry of Public Health Thailand. The questionnaire consisted of 2 types of questions – Perceived Objective and Self-Reported Subjective questions. Furthermore, the instruments include items on the 4 domains of quality of life – Physical, Psychological, Social relationships and the Environment, which are measured on a 5-point Likert scale categorized as “Not at all”, “A little”, “A moderate amount”, “Very much”, and “Extremely” (Mahatnirunkul, et al., 1997; Mahatnirun et al., 1998; World Health Organization, 1996).

Rating

The WHOQOL-BREF-THAI consists of 26 questions, 23 are positive while the remaining 3 are negative questions.

Group 1 Positive 23 items

Group 2 Negative 3 items

Positive questions -

Group 1	Questions										
	1	3	4	5	6	7	8	10	12	13	14
	15	16	17	18	19	20	21	22	23	24	25
	26										

Scoring was done as follows:

Choice	*Score*
Not at all	1
A little	2
A moderate amount	3
Very much	4
Extremely	5

Negative questions -

Reverse scoring was performed for negative questions.

Group 2	2	9	11

Scoring was done as follows:

Choice	*Score*
Not at all	5
A little	4
A moderate amount	3
Very much	2
Extremely	1

The total score of QOL ranged from 26 to 130 points and QOL scores were categorized into three levels as follows:

Score	*QOL*
26-60	Poor
61-95	Fair
96-130	Good

Based on the 4 domains of QOL, the QOL scores can be categorized into -

		Scores		
	Domain	**Poor**	**Fair**	**Good**
1.	Physical	7-16	17-26	27-35
2.	Psychological	6-14	15-22	23-30
3.	Social relationships	3-7	8-11	12-15
4.	Environment.	8-18	19-29	30-40
	Total	**26-60**	**61-95**	**96-130**

Domains	*Item No.*
Physical	2, 3,4,10,11,12,24
Psychological	5,6,7,8,9,23
Social relationships	13, 14, 25
Environment	15, 16,17,18,19,20,21,22

10. Validity and Reliability

10.1 Content Validity

Various literature reviews were carried out to determine suitable instruments for assessing climacteric symptoms in perimenopausal women. In addition, three experts in women's health and 1 yoga expert were consulted for determining the measurement tools to be used in the study.

Content validity for Climacteric Symptom Assessment Form was performed to ensure clarity, accuracy and appropriateness of the instrument. A group of 3 experts (Professor Surasak Taneepanichskul, Associate Professor Ratana Somrongthong and Dr Nattawut Weschasat were consulted to evaluate the content of the questionnaire by the Item-Objective Congruence (IOC) Index. The IOC was assessed based on a scale: +1 indicated the agreement between the item and the study

variable, 0 indicated undecided and -1 indicated disagreement between the item and the study variable. The IOC was found to be 0.886.

10.2 Reliability

The reliability of the instrument, the Climacteric Symptoms Assessment Form of the Bureau of Reproductive Health under the Ministry of Public Health Thailand was ensured by conducting a pilot study. The pilot test was conducted by the PI among 30 participants in another district having similar characteristics to the participants in the study site. The internal consistency was assessed through Cronbach's Alpha coefficient. To ensure that the study participants in the pilot study clearly understood the questions without losing their actual content, the interview was closely monitored by the PI and adjustments to the instrument were made accordingly. The alpha value for the scale was found to be 0.93.

WHOQOL – BREF –THAI scale with 26 items measured on a 5-point Likert scale was used to obtain responses from the study participants on the quality of life. The internal consistency of the instrument was determined to be 0.8406 as compared to the WHOQOL-100 version.

11. Data Analysis

After completion of data collection, the data was cleansed, coded, and entered and analyzed using Statistical Package for the Social Science (SPSS) version 21.

11.1 Descriptive statistics

The general characteristics of the study participants which are nominal or ordinal (age, marital status, education, occupation, income) were presented as frequency and percentage, and continuous variables were represented as mean ± standard deviation.

Table 3.2 Data Analysis

Variable	Measurement Scale	Descriptive Statistics	Inferential Statistics
Independent Variable			
-Age	Ratio Scale	Mean, S.D	T- Test
-Education Level	Ordinal Scale	Frequency, Percentage	Chi-square
-Marital Status	Nominal Scale	Frequency, Percentage	Chi-square
-Income	Nominal Scale	Frequency, Percentage	Chi-square
-Disease Status	Nominal Scale	Frequency, Percentage	Chi-square
-Smoking, Substance abuse, Alcohol	Nominal Scale	Frequency, Percentage	Chi-square
-BMI	Nominal Scale	Frequency, Percentage	Chi-square
-Climacteric symptoms score at baseline (week 0), week 12 and week 16	Interval Scale	Mean, S.D	Repeated ANOVA
-Estrogen Hormone Level at baseline (week 0), week 12 and week 16	Interval Scale	Mean, S.D	Repeated ANOVA
-Quality of life at week 0 week and week 16	Ratio Scale	Mean, S.D	Paired T-Test

11.2 Analytical statistics

T-test will be performed to compare the means difference between 2 groups (intervention and control) to determine significant differences between the groups.

A Chi-square test was used to determine the association between categorical variables in the 2 groups. The significance of the test was determined at a p-value < 0.05, a 95% significance level. Repeated measures ANOVA were performed to test the overall change in climacteric symptoms and estrogen hormone levels.

11.3 Summarize Statistical analysis

Statistical analysis will be done as follows:

11.4 Assumption of statistic

11.4.1 Pair T-test

Paired T-Test Assumptions:

1. The data is continuous (not discrete).

2. The data, i.e., the differences for the matched pairs, follow a normal probability distribution.

The sample of pairs is a simple random sample from the population. Each individual in the population has an equal probability of being selected in the sample.

11.4.2 Wilcoxon Signed-Rank Test

The assumptions of the Wilcoxon signed-rank test are as follows (note that the difference is between the two data values of a pair):

1. The differences are continuous (not discrete).

2. The distribution of these differences is symmetric.

3. The differences are mutually independent.

4. The differences all have the same median.

5. The measurement scale is at least interval.

11.4.3 Chi-square test

The chi-square test can be used to determine differences in proportions using a two-by-two contingency table. It is however important to understand that the chi-square test yields only an approximate p-value, on which a correction factor is then applied. This only works well when your datasets are large enough. When sample sizes are small, as indicated by more than 20% of the contingency cells having expected values < 5 a Fisher's maybe more appropriate. This test is one of a class of "exact tests", because the significance of the deviation from a "null hypothesis" can be calculated exactly, rather than relying on an approximation.

11.4.4. Repeated ANOVA

To use the ANOVA test the following assumptions were made:

1. Each group sample is drawn from a normally distributed population

2. All populations have a common variance

3. All samples are drawn independently of each other

4. Within each sample, the observations are sampled randomly and independently of each other

5. Factor effects are additive

12. Intention to treat (ITT)

ITT analysis reflects a practical clinical scenario because it recognizes violations and protocol deviations. ITT analysis maintains the prognostic balance resulting from the random allocation of the original treatment. This provides an estimate containing the effects of treatment. If subjects who did not comply and dropped out were excluded from the final analysis, it might make important

prognostic differences between the treatment groups (Armijo-Olivo, Warren, & Magee, 2009).

ITT analysis maintains sample size because if subjects who do not comply and drop out are excluded from the final analysis, it might significantly reduce sample size, leading to reduced statistical power (Armijo-Olivo et al., 2009).

13. Ethical Consideration

Before participant recruitment, enrollment and data collection, ethical approval was taken from the Research Ethics Review Committee for Research Involving Human Research Participants, Group I, Chulalongkorn University with approval number - 173.1/62. Additionally, the study was also approved by the Thai Clinical Trails Registry (TCTR) with identification number TCTR20210201008. Participation in the study was voluntary and written consent was obtained from the participants in both the intervention and control groups. Furthermore, the participants were also detailed on the purpose and benefit of the study and were informed about the anonymity and confidentiality of the data including freedom of withdrawal from the study at any given point, refusal to answer any questions and use of the data collected orally as well as through the consent form.

CHAPTER 4

RESULT

The study assessed the effectiveness of Tibetan Yoga in reducing climacteric symptom scores, changing estrogen hormone levels, and increasing quality of life among perimenopausal women. A total of 64 perimenopausal women were enrolled, 32 in the intervention and 32 in the control group. The general characteristics such as age, marital status, education, occupation, income, disease Status, smoking, substance abuse, alcohol drinking, and BMI which were independent variables were collected. It was presented as frequency and percentage, and continuous variables were represented as mean ± standard deviation. Moreover, the dependent variables such as climacteric symptoms scores and estrogen hormone levels were collected at baseline (week 0), 12-week, and 16-week follow-up. In addition, the quality of life was collected only 2 times (baseline (week 0) and 16-week follow-up).

This chapter presents the findings of the study, guided by the research hypothesis. There are two sections in this chapter. The first section describes the sample characteristics and the baseline demographic characteristics. The second section focuses on hypothesis testing, considering the effect of the intervention on climacteric symptoms scores, estrogen hormone level, and quality of life.

4.1 Baseline Characteristics of Sample

4.1.1 General characteristics of perimenopausal patients

The results found that the participants in the intervention group had an average of 48.81 ± 3.66 whereas the control group had 48.22 ± 3.02. The age was almost between 45-50 years 68.8% in the intervention group and 75% in the control group. In terms of status, married status was most in both intervention and control groups (68.8% and 59.4%). The education levels among the intervention group had about half (50%) of secondary education in the same as the control group (53.1%). Considering income, 40.6% and 43.8% of the intervention and control groups had income between 10,001 to 20,000 baht. Among participants who had tobacco use only

25% were in the intervention group and 15.6% in the control group. Most of the participants had no health problems or pain which was 75% in the intervention group and 87.5% in the control group. About height, it was shown that the intervention group had an average height of 166.98 ± 2.93 centimeters and the control group were 166.87 ± 2.57 centimeters. In terms of weight, the intervention group had an average weight of 58.85 ± 3.39 kilograms, and the control group were 59.38 ± 2.5 kilograms. The average BMI was 21.04 ± 1.03 kg/m^2 in the intervention group and 21.27 ± 0.7 kg/m^2 in the control group. Finally, serum estradiol of the intervention group had an average of 46.08 ± 8.7 nearly identical to the control group with an average of 48.07 ± 7.61. The statistical analysis between the intervention and control group revealed that all of the baseline characteristics had not significantly differed in both groups, details as Table 4.1

Table 4.1 Number and percentage of 64 perimenopausal women classify by group

Baseline Characteristics	**Intervention group (n=32)**	**Control group (n=32)**	**P-value**
	N (%)	**N (%)**	
Age (year)			0.578[a]
45-50 year	22 (68.8%)	24 (75%)	
51-55 year	10 (31.3%)	8 (25%)	
Mean ± SD	48.81 ± 3.66	48.22 ± 3.02	0.482[b]
Status			0.496[a]
single	4 (12.5%)	2 (6.3%)	
marries	22 (68.8%)	19 (59.4%)	
Divorced/Separate	3 (9.4%)	5 (15.6%)	
Widow	3 (9.4%)	6 (18.8%)	
Education			0.559[a]
Primary	3 (9.4%)	4 (12.5%)	
secondary	16 (50%)	17 (53.1%)	
Diploma/Certificate	8 (25%)	4 (12.5%)	
Bachelor	2 (6.3%)	5 (15.6%)	
Higher than bachelor	3 (9.4%)	2 (6.3%)	

Table 4.1 (continue)

Baseline Characteristics	Intervention group (n=32)	Control group (n=32)	P-value
	N (%)	N (%)	
Income			0.825[a]
Less than 10,000 bath	13 (40.6%)	13 (40.6%)	
10,001-20,000 bath	13 (40.6%)	14 (43.8%)	
20,001-30,000 bath	4 (12.5%)	2 (6.3%)	
More than 30,000 bath	2 (6.3%)	3 (9.4%)	
tobacco use			0.351[a]
Yes	8 (25%)	5 (15.6%)	
No	24 (75%)	27 (84.4%)	
Health problems or pain			0.2[a]
Yes	8 (25%)	4 (12.5%)	
No	24 (75%)	28 (87.5%)	
Height (CM) Mean ± SD.	166.98 ± 2.93	166.87 ± 2.57	0.874[b]
Weigh (KG) Mean ± SD.	58.85 ± 3.39	59.38 ± 2.5	0.484[b]
BMI Mean ± SD.	21.04 ± 1.03	21.27 ± 0.7	0.319[b]
Serum estradiol Mean ± SD.	46.08 ± 8.7	48.07 ± 7.61	0.335[b]

[a] = chi-square test, [b] = independent t-test

4.1.2 Time Point of Serum Estradiol

Change in estrogen hormone levels was assessed by collecting blood samples at weeks 0, 12, and 16 in the intervention and control groups. The results show that both the intervention group and control group were increasing the mean of serum estradiol during each time point as shown in Table 4.2

Table 4.2 Mean of serum estradiol among 64 perimenopausal women classify by group

Serum estradiol	Intervention group (n=32) Mean ± SD.	Control group (n =32) Mean ± SD.
Baseline	46.08 ± 8.7	48.07 ± 7.61
12-week follow-up	57.73 ± 9.11	49.88 ± 8.78
16-week follow-up	57.78 ± 9.04	50.09 ± 8.72

4.1.3 Descriptive statistic of climacteric symptoms score

The climacteric symptoms score was categorized into 4 levels, not at all, a little, quite a lot, and extremely. It was interpreted that a total score of more than 15 points indicated a high risk of estrogen deficiency. The result revealed that at baseline the participants in the intervention group selected "not at all" most symptoms "hot flushes" about 78.1% followed by "urinary frequency" and "dysuria" about 71.9% and 62.5%, respectively. Only 3.1% selected "extremely" in symptoms of "difficulty in sleeping" and "back pains". Among the control group it was found that the participants selected "not at all" most symptoms "hot flushes" about 81.3% followed by "sweating at night", "urinary frequency" and "urinary incontinence" about 62.5%, and 59.4%, respectively whereas they selected "extremely" in only symptoms "feeling abandoned" 3.1% as shown in Table 4.3.

Table 4.3 Percentage of screening Climacteric symptoms at baseline between intervention and control group

Symptoms	Intervention group (%)				Control group (%)			
	Not at all	A little	Quite a lot	Extremely	Not at all	A little	Quite a lot	Extremely
1. Hot flushes	78.1	21.9	0.0	0.0	81.3	15.6	3.1	0.0
2. Sweating at night	31.3	56.3	12.5	0.0	62.5	31.3	6.3	0.0
3. Headaches	9.4	62.5	28.1	0.0	31.3	40.6	28.1	0.0

Table 4.3 (continue)

Symptoms	Intervention group (%)				Control group (%)			
	Not at all	A little	Quite a lot	Extremely	Not at all	A little	Quite a lot	Extremely
4. Attacks of anxiety, panic	0.0	78.1	21.9	0.0	15.6	53.1	31.3	0.0
5. Irritability	9.4	65.6	25.0	0.0	6.3	71.9	21.9	0.0
6. Feeling abandoned	21.9	68.8	9.4	0.0	0.0	75.0	21.9	3.1
7. Feeling tense or nervous	6.3	78.1	15.6	0.0	9.4	71.9	18.8	0.0
8. Difficulty in Sleeping	9.4	78.1	9.4	3.1	6.2	56.3	37.5	0.0
9. Feeling tired or lacking in energy	6.3	71.9	21.9	0.0	6.3	71.9	21.9	0.0
10. Back Pains	0.0	68.8	28.1	3.1	9.4	71.9	18.8	0.0
11. Joint pains	6.3	78.1	15.6	0.0	3.1	62.5	34.4	0.0
12. Muscle pains	9.4	65.6	25.0	0.0	12.5	65.6	21.9	0.0
13. Dry skin	12.5	75.0	12.5	0.0	15.6	71.9	12.5	0.0
14. Dry Vagina	25.0	62.5	12.5	0.0	6.3	68.8	25.0	0.0
15. Dyspareunia	18.8	62.5	18.8	0.0	15.6	75.0	9.4	0.0
16. Reduced sex drive	31.3	62.5	6.3	0.0	15.6	75.0	9.4	0.0
17. Loss of interest in sex	40.6	56.3	3.1	0.0	34.4	59.4	6.3	0.0
18. Dysuria	62.5	37.5	0.0	0.0	40.6	59.4	0.0	0.0
19. Urinary frequency	71.9	28.1	0.0	0.0	59.4	40.6	0.0	0.0
20.Urinary incontinence	59.4	40.6	0.0	0.0	59.4	40.6	0.0	0.0

At the 12-week follow-up evaluation, all of the participants in the intervention group selected “not at all” in symptoms “back pains” (100%) followed by “difficulty in sleeping”, “irritability” and “feeling tired or lacking in energy” about 93.8% and 87.5%, respectively whereas not all of the symptoms were selected “extremely”. In the same control group, all of the participants selected “not at all” in symptoms “back pains” (100%) followed by “attacks of anxiety, panic”, “irritability” and “joint pains” about 93.8% whereas not all of the symptoms were selected “extremely” as shown in Table 4.4.

Table 4.4 Percentage of screening Climacteric symptoms at 12-week follow-up between intervention and control group

Symptoms	Intervention group (%)				Control group (%)			
	Not at all	A little	Quite a lot	Extremely	Not at all	A little	Quite a lot	Extremely
1. Hot flushes	75.0	25.0	0.0	0.0	46.9	53.1	0.0	0.0
2.Sweating at night	68.8	28.1	3.1	0.0	71.9	28.1	0.0	0.0
3. Headaches	12.5	31.3	56.3	0.0	34.4	65.6	0.0	0.0
4. Attacks of anxiety, panic	65.6	34.4	0.0	0.0	93.8	6.3	0.0	0.0
5. Irritability	87.5	12.5	0.0	0.0	93.8	6.3	0.0	0.0
6. Feeling abandoned	43.8	46.9	9.4	0.0	18.8	71.9	9.4	0.0
7. Feeling tense or nervous	3.1	43.8	53.1	0.0	3.1	9.4	87.5	0.0
8. Difficulty in Sleeping	93.8	6.3	0.0	0.0	62.5	37.5	0.0	0.0
9. Feeling tired or lacking in energy	87.5	12.5	0.0	0.0	87.5	12.5	0.0	0.0
10. Back Pains	100.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0
11. Joint pains	68.8	31.3	0.0	0.0	93.8	3.1	3.1	0.0

Table 4.4 (continue)

Symptoms	Intervention group (%)				Control group (%)			
	Not at all	A little	Quite a lot	Extremely	Not at all	A little	Quite a lot	Extremely
12. Muscle pains	3.1	68.8	28.1	0.0	53.1	46.9	0.0	0.0
13. Dry skin	28.1	46.9	25.0	0.0	62.5	31.3	6.3	0.0
14. Dry Vagina	50.0	40.6	9.4	0.0	46.9	50.0	3.1	0.0
15. Dyspareunia	21.9	53.1	25.0	0.0	62.5	28.1	9.4	0.0
16. Reduced sex drive	40.6	37.5	21.9	0.0	81.3	18.8	0.0	0.0
17. Loss of interest in sex	84.4	15.6	0.0	0.0	34.4	65.6	0.0	0.0
18. Dysuria	65.6	31.3	3.1	0.0	25.0	65.6	9.4	0.0
19. Urinary frequency	34.4	46.9	18.8	0.0	65.6	15.6	18.8	0.0
20.Urinary incontinence	68.8	21.9	9.4	0.0	71.9	21.9	6.3	0.0

At the 16-week follow-up evaluation, all of the participants in the intervention group selected “not at all” in symptoms “back pains” (100%) followed by “difficulty in sleeping” and “joint pains” about 96.9% whereas not all of the symptoms were selected “quite a lot” and “extremely”. In the same control group, all of the participants selected “not at all” in symptoms “irritability” and “back pains” (100%) followed by “joint pains”, “attacks of anxiety, panic”, “sweating at night” and “irritability” about 96.9% and 93.8%, respectively whereas not all of the symptoms were selected “extremely” as shown in Table 4.5.

Table 4.5 Percentage of screening Climacteric symptoms at 16-week follow-up between intervention and control group

Symptoms	Intervention group (%)				Control group (%)			
	Not at all	**A little**	**Quite a lot**	**Extremely**	**Not at all**	**A little**	**Quite a lot**	**Extremely**
1. Hot flushes	93.8	6.3	0.0	0.0	53.1	46.9	0.0	0.0
2. Sweating at night	81.3	18.8	0.0	0.0	93.8	6.3	0.0	0.0
3. Headaches	40.6	59.4	0.0	0.0	18.8	81.3	0.0	0.0
4. Attacks of anxiety, panic	93.8	6.3	0.0	0.0	93.8	6.3	0.0	0.0
5. Irritability	90.6	9.4	0.0	0.0	100.0	0.0	0.0	0.0
6. Feeling abandoned	71.9	28.1	0.0	0.0	18.8	71.9	9.4	0.0
7. Feeling tense or nervous	28.1	71.9	0.0	0.0	3.1	12.5	84.4	0.0
8. Difficulty in Sleeping	96.9	3.1	0.0	0.0	62.5	37.5	0.0	0.0
9. Feeling tired or lacking in energy	84.4	15.6	0.0	0.0	87.5	12.5	0.0	0.0
10. Back Pains	100.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0
11. Joint pains	96.9	3.1	0.0	0.0	96.9	3.1	0.0	0.0

Table 4.5 (continue)

Symptoms	Intervention group (%)				Control group (%)			
	Not at all	A little	Quite a lot	Extremely	Not at all	A little	Quite a lot	Extremely
12. Muscle pains	54.8	45.2	0.0	0.0	6.3	53.1	40.6	0.0
13. Dry skin	59.4	40.6	0.0	0.0	65.6	31.3	3.1	0.0
14. Dry Vagina	71.9	28.1	0.0	0.0	46.9	46.9	6.3	0.0
15. Dyspareunia	62.5	37.5	0.0	0.0	62.5	25.0	12.5	0.0
16. Reduced sex drive	71.9	28.1	0.0	0.0	87.5	12.5	0.0	0.0
17. Loss of interest in sex	90.6	9.4	0.0	0.0	37.5	56.3	6.3	0.0
18. Dysuria	90.6	9.4	0.0	0.0	65.6	25.0	9.4	0.0
19.Urinary frequency	62.5	37.5	0.0	0.0	68.8	18.8	12.5	0.0
20.Urinary incontinence	81.3	18.8	0.0	0.0	71.9	25.0	3.1	0.0

An average score of the climacteric symptoms at each time point was shown in Table 4.6. It was found that both the intervention and control groups were reducing their scores during follow-up. However, the control group seemed to be more of the climacteric symptoms score than the intervention group.

Table 4.6 Mean of Climacteric symptoms score among 64 perimenopausal women classify by group

Climacteric symptoms score	Intervention group (n=32)	Control group (n =32)
	Mean ± SD.	Mean ± SD.
Baseline	17.69 ± 1.42	18.44 ± 1.87
12-week follow-up	11.59 ± 2.87	11.44 ± 1.95
16-week follow-up	4.75 ± 1.65	10.5 ± 2.65

The interpretation of the climacteric symptoms score was found that the intervention group at baseline had a proportion of high-risk estrogen deficiency less than the control group. At the 12-week follow-up, the control group seemed to be of a lesser proportion of higher risk than the intervention group. Finally, the intervention group didn't have a proportion of high risk whereas the control group had a 3.1% of high risk as shown in Table 4.7.

Table 4.7 The Climacteric symptoms score interpretation classify by group

Climacteric symptoms score	Intervention group (%)			Control group (%)		
	Baseline	12-week	16-week	Baseline	12-week	16-week
Low risk (0-15 score)	3.1	87.5	100	0	100	96.9
High risk (> 15 score)	96.9	12.5	0	100	0	3.1

4.1.4 Descriptive statistic of quality of life

The WHO Quality of Life (WHOQOL–BREF–THAI) included items on the 4 domains of quality of life – Physical, Psychological, Social relationships, and the Environment, which are measured on a 5-point Likert scale categorized as "Not at all", "A little", "A moderate amount", "Very much", and "Extremely". Among the intervention group, the participants have selected "not at all" most questions were "Have you enough money to meet your needs?" about 78.1% followed by "How satisfied are you with the support you get from your friends?", "To what extent do you feel your life to be meaningful?" and "How satisfied are you with your sex life?" about 56.3% and 53.1%, respectively. For "extremely" choice, it was found that the intervention group was most in question "How much do you need any medical treatment to function in your daily life?" about 28.1% followed by "To what extent do you feel that physical pain prevents you from doing what you need to do?", "How satisfied are you with your health?" and "How well are you able to get around?" about 18.8% and 15.6%, respectively. Considering the control group, the participants were selected "not at all" most in question "How well are you able to get around?" about

59.4% followed by “How satisfied are you with the support you get from your friends?” and “How safe do you feel in your daily life?” about 53.1% and 50.0%, respectively as shown in Table 4.8.

Table 4.8 Percentage of quality of Life at baseline between intervention and control group

Questions	Intervention group (%)					Control group (%)				
	Not at all	A little	A moderate amount	Very much	Extremely	Not at all	A little	A moderate amount	Very much	Extremely
1. How satisfied are you with your health?	21.9	25.0	18.8	18.8	15.6	31.3	28.1	15.6	18.8	6.3
2. To what extent do you feel that physical pain prevents you from doing what you need to do?	9.4	28.1	9.4	34.4	18.8	3.1	43.8	12.5	40.6	0.0
3. Do you have enough energy for everyday life?	0.0	53.1	21.9	25.0	0.0	46.9	37.5	12.5	3.1	0.0
4. How satisfied are you with your sleep?	0.0	50.0	34.4	3.1	12.5	46.9	12.5	18.8	18.8	3.1
5. How satisfied are you with your capacity for work?	12.5	50.0	37.5	0.0	0.0	37.5	43.8	6.3	9.4	3.1
6. How well are you able to concentrate?	40.6	28.1	6.3	21.9	3.1	25.0	37.5	18.8	9.4	9.4

Table 4.8 (continue)

Questions	Intervention group (%)					Control group (%)				
	Not at all	**A little**	**A moderate amount**	**Very much**	**Extremely**	**Not at all**	**A little**	**A moderate amount**	**Very much**	**Extremely**
7. How much do you enjoy life?	37.5	34.4	12.5	9.4	6.3	15.6	43.8	9.4	28.1	3.1
8. Are you able to accept your bodily appearance?	9.4	46.9	21.9	12.5	9.4	28.1	43.8	9.4	12.5	6.3
9. How often do you have negative feelings such as blue mood, despair, anxiety, depression?	15.6	25.0	9.4	50.0	0.0	0.0	0.0	9.4	31.3	59.4
10. To what extent do you feel your life to be meaningful?	53.1	18.8	0.0	15.6	12.5	12.5	46.9	18.8	12.5	9.4
11. How much do you need any medical treatment to function in your daily life?	3.1	15.6	12.5	40.6	28.1	3.1	12.5	43.8	25.0	15.6

Table 4.8 (continue)

Questions	Intervention group (%)					Control group (%)				
	Not at all	A little	A moderate amount	Very much	Extremely	Not at all	A little	A moderate amount	Very much	Extremely
12. How satisfied are you with your ability to perform your daily living activities?	31.3	18.8	15.6	18.8	15.6	28.1	53.1	0.0	9.4	9.4
13. How satisfied are you with your personal relationships?	28.1	31.3	3.1	28.1	9.4	31.3	34.4	0.0	9.4	25.0
14. How satisfied are you with the support you get from your friends?	56.3	31.3	3.1	9.4	0.0	53.1	18.8	0.0	28.1	0.0
15. How safe do you feel in your daily life?	40.6	28.1	21.9	9.4	0.0	50.0	40.6	6.3	3.1	0.0
16. How satisfied are you with the conditions of your living place?	31.3	34.4	3.1	18.8	12.5	31.3	43.8	0.0	6.3	18.8

Table 4.8 (continue)

Questions	Intervention group (%)					Control group (%)				
	Not at all	**A little**	**A moderate amount**	**Very much**	**Extremely**	**Not at all**	**A little**	**A moderate amount**	**Very much**	**Extremely**
17. Have you enough money to meet your needs?	78.1	9.4	0.0	12.5	0.0	21.9	59.4	15.6	3.1	0.0
18. How satisfied are you with your access to health services?	0.0	50.0	50.0	0.0	0.0	31.3	56.3	12.5	0.0	0.0
19. How available to you is the information that you need in your day-to-day life?	28.1	37.5	31.3	3.1	0.0	18.8	46.9	25.0	9.4	0.0
20. To what extent do you have the opportunity for leisure activities?	43.8	25.0	12.5	15.6	3.1	46.9	43.8	6.3	3.1	0.0
21. How healthy is your physical environment?	28.1	46.9	15.6	9.4	0.0	25.0	65.6	6.3	3.1	0.0
22. How satisfied are you with your transport?	34.4	37.5	12.5	9.4	6.3	15.6	43.8	9.4	28.1	3.1

Table 4.8 (continue)

Questions	Intervention group (%)					Control group (%)				
	Not at all	**A little**	**A moderate amount**	**Very much**	**Extremely**	**Not at all**	**A little**	**A moderate amount**	**Very much**	**Extremely**
23. How satisfied are you with yourself?	9.4	46.9	21.9	12.5	9.4	28.1	43.8	9.4	12.5	6.3
24. How well are you able to get around?	0.0	50.0	9.4	25.0	15.6	59.4	31.3	9.4	0.0	0.0
25. How satisfied are you with your sex life?	53.1	18.8	0.0	15.6	12.5	12.5	46.9	18.8	12.5	9.4
26. How would you rate your quality of life?	28.1	40.6	12.5	15.6	3.1	15.6	25.0	43.8	12.5	3.1

At the 16-week follow-up evaluation, all of the samples of the intervention group were not selected “not at all” (0%) in the same participants among the control group. For the “extremely” choice in the intervention group, the question was most chosen “To what extent do you feel that physical pain prevents you from doing what you need to do?” and “How much do you need any medical treatment to function in your daily life?” about 46.9% followed by “How well are you able to get around?” and “How satisfied are you with your personal relationships?” about 40.6% and 37.5%, respectively. Considering the control group, the question was selected “extremely” most in “How often do you have negative feelings such as blue moods, despair, anxiety, depression?” about 71.9% followed by “How much do you need any medical treatment to function in your daily life?” and “To what extent do you feel that physical pain prevents you from doing what you need to do?” about 50% and 34.4%, respectively. The details were shown in Table 4.9

Table 4.9 Percentage of quality of Life at 16-week follow-up between intervention and control group

Questions	Intervention group (%)					Control group (%)				
	Not at all	**A little**	**A moderate amount**	**Very much**	**Extremely**	**Not at all**	**A little**	**A moderate amount**	**Very much**	**Extremely**
1. How satisfied are you with your health?	0.0	25.0	28.1	15.6	31.3	0.0	31.3	28.1	15.6	25.0
2. To what extent do you feel that physical pain prevents you from doing what you need to do?	0.0	0.0	9.4	43.8	46.9	0.0	12.5	21.9	31.3	34.4
3. Do you have enough energy for everyday life?	0.0	0.0	53.1	21.9	25.0	0.0	46.9	37.5	12.5	3.1
4. How satisfied are you with your sleep?	0.0	0.0	50.0	34.4	15.6	0.0	46.9	12.5	18.8	21.9
5. How satisfied are you with your capacity for work?	0.0	15.6	50.0	34.4	0.0	0.0	37.5	43.8	6.3	12.5
6. How well are you able to concentrate?	0.0	40.6	28.1	6.3	25.0	0.0	25.0	37.5	18.8	18.8

Table 4.9 (continue)

Questions	Intervention group (%)					Control group (%)				
	Not at all	**A little**	**A moderate amount**	**Very much**	**Extremely**	**Not at all**	**A little**	**A moderate amount**	**Very much**	**Extremely**
7. How much do you enjoy life?	0.0	34.4	34.4	12.5	18.8	0.0	15.6	43.8	9.4	31.3
8. Are you able to accept your bodily appearance?	0.0	9.4	46.9	21.9	21.9	0.0	28.1	43.8	9.4	18.8
9. How often do you have negative feelings such as blue mood, despair, anxiety, depression?	0.0	3.1	12.5	56.3	28.1	0.0	0.0	6.3	21.9	71.9
10. To what extent do you feel your life to be meaningful?	0.0	53.1	18.8	0.0	28.1	0.0	15.6	46.9	15.6	21.9
11. How much do you need any medical treatment to function in your daily life?	0.0	3.1	3.1	46.9	46.9	0.0	0.0	18.8	31.3	50.0
12. How satisfied are you with your ability to perform your daily living activities?	0.0	31.3	18.8	15.6	34.4	0.0	28.1	53.1	0.0	18.8

Table 4.9 (continue)

Questions	Intervention group (%)					Control group (%)				
	Not at all	**A little**	**A moderate amount**	**Very much**	**Extremely**	**Not at all**	**A little**	**A moderate amount**	**Very much**	**Extremely**
13. How satisfied are you with your personal relationships?	0.0	28.1	31.3	3.1	37.5	0.0	31.3	34.4	0.0	34.4
14. How satisfied are you with the support you get from your friends?	0.0	56.3	31.3	3.1	9.4	0.0	53.1	18.8	0.0	28.1
15. How safe do you feel in your daily life?	0.0	40.6	28.1	21.9	9.4	0.0	46.9	43.8	6.3	3.1
16. How satisfied are you with the conditions of your living place?	0.0	34.4	34.4	3.1	28.1	0.0	31.3	43.8	0.0	25.0
17. Have you enough money to meet your needs?	0.0	78.1	9.4	0.0	12.5	0.0	21.9	59.4	15.6	3.1
18. How satisfied are you with your access to health services?	0.0	0.0	50.0	50.0	0.0	0.0	31.3	56.3	12.5	0.0

Table 4.9 (continue)

Questions	Intervention group (%)					Control group (%)				
	Not at all	**A little**	**A moderate amount**	**Very much**	**Extremely**	**Not at all**	**A little**	**A moderate amount**	**Very much**	**Extremely**
19. How available to you is the information that you need in your day-to-day life?	0.0	28.1	37.5	31.3	3.1	0.0	21.9	46.9	21.9	9.4
20. To what extent do you have the opportunity for leisure activities?	0.0	43.8	25.0	12.5	18.8	0.0	46.9	43.8	6.3	3.1
21. How healthy is your physical environment?	0.0	28.1	46.9	15.6	9.4	0.0	21.9	78.1	0.0	0.0
22. How satisfied are you with your transport?	0.0	34.4	37.5	12.5	15.6	0.0	15.6	43.8	9.4	31.3
23. How satisfied are you with yourself?	0.0	9.4	46.9	21.9	21.9	0.0	28.1	43.8	9.4	18.8
24. How well are you able to get around?	0.0	0.0	50.0	9.4	40.6	0.0	59.4	31.3	9.4	0.0

Table 4.9 (continue)

Questions	Intervention group (%)					Control group (%)				
	Not at all	**A little**	**A moderate amount**	**Very much**	**Extremely**	**Not at all**	**A little**	**A moderate amount**	**Very much**	**Extremely**
25. How satisfied are you with your sex life?	0.0	53.1	18.8	0.0	28.1	0.0	12.5	46.9	18.8	21.9
26. How would you rate your quality of life?	0.0	28.1	40.6	12.5	18.8	0.0	15.6	25.0	43.8	15.6

Mean of Quality of Life among perimenopausal women included items on the 4 domains of quality of life – Physical, Psychological, Social relationships, and the Environment. An average of all parts of quality of life among the intervention group was higher than the control group in all time points except in social relationships at baseline which the intervention group seemed to be lesser than control group as shown in Table 4.10

Table 4.10 Mean of Quality of Life among 64 perimenopausal women classify by group

Quality of Life	**Intervention group (n=32)**	**Control group (n =32)**
	Mean ± SD.	**Mean ± SD.**
Total Quality of Life		
Baseline	61.66 ± 6.63	57.59 ± 7.5
16-week follow-up	80.09 ± 6.40	76.94 ± 6.35
Physical		
Baseline	18.41 ± 3.07	15.91 ± 2.32
16-week follow-up	21.09 ± 2.82	18.72 ± 2.28
Psychological		
Baseline	14.94 ± 2.69	12.97 ± 3.72
16-week follow-up	18.53 ± 2.42	17.53 ± 3.15
Social relationship		
Baseline	6.41 ± 2.26	7.25 ± 2.83
16-week follow-up	9.19 ± 2.10	9.91 ± 2.47
Environment		
Baseline	16.84 ± 3.24	16.44 ± 2.56
16-week follow-up	24.53 ± 2.96	23.84 ± 1.78

The interpretation of total quality of life was classified in 3 levels; poor (score=26-60), fair (score=61-95), good (score=96-130).

Considering the total quality of life at the baseline, more than half of participants in the intervention group had poor quality of life (53.1%). All of the

participants in the intervention group had a fair quality of life after finishing the program (16-week follow-up). In the control group, about 68.8% had poor quality of life at baseline whereas all of the participants changed to fair quality of life after finishing the program (16-week follow-up).

In terms of the physical part, most of the participants among the intervention group had a fair quality of life (68.8%) at the baseline. At 16-week follow-up, it increased to 93.8%the of fair quality of life and 6.3% of good quality of life. Among the control group, more than half of the participants had poor physical quality of life at the baseline whereas they were increased to fair quality of life by about 81.3% at the end of follow-up.

The psychological part revealed that 53.1% of the intervention group had a fair quality of life whereas 75% of the control group had a poor quality of life at the the baseline. However, both groups of participants had an increasing proportion of good quality of life after a 16-week follow-up (intervention group: 6.3%, control group: 9.4%).

Quality of life regarding social relationships found that 62.5% of the intervention group had a poor quality of life and in the control group had 56.3% poor quality of life. At the 16-week follow-up, the result was changed to fair quality of life in both groups (intervention group: 59.4%, control group: 65.6%).

Finally, the environment part of the quality of life showed that at the baseline intervention and control group had a poor quality of life (68.8% and 84.4%, respectively) whereas after finishing the program, it had changed to a fair quality of life in both groups (intervention group: 90.6%, control group: 100%). The detail was shown in Table 4.11.

Table 4.11 Quality of Life interpretation classify by group

Quality of Life	Intervention group (%)		Control group (%)	
	Baseline	**16-week**	**Baseline**	**16-week**
Total Quality of Life				
Poor Quality of Life	53.1	0.0	68.8	0.0
Fair Quality of Life	46.9	100.0	31.3	100.0
Good Quality of Life	0.0	0.0	0.0	0.0
Physical				
Poor Quality of Life	31.3	0.0	59.4	18.8
Fair Quality of Life	68.8	93.8	40.6	81.3
Good Quality of Life	0.0	6.3	0.0	0.0
Psychological				
Poor Quality of Life	46.9	3.1	75.0	12.5
Fair Quality of Life	53.1	90.6	21.9	78.1
Good Quality of Life	0.0	6.3	3.1	9.4
Social relationship				
Poor Quality of Life	62.5	25.0	56.3	12.5
Fair Quality of Life	37.5	59.4	34.4	65.6
Good Quality of Life	0.0	15.6	9.4	21.9
Environment				
Poor Quality of Life	68.8	0.0	84.4	0.0
Fair Quality of Life	31.3	90.6	15.6	100.0
Good Quality of Life	0.0	9.4	0.0	0.0

4.2 Testing the Effect of the Program on serum estradiol

4.2.1 Comparison of the trend of serum estradiol between groups

Considering between the two groups, we compared the mean of serum estradiol in both control and intervention groups by an independent t-test. The results found that the mean of serum estradiol was not significantly different at baseline (P-value = 0.335). However, both the 12-week and 16-week follow-ups had significantly different P-values < 0.001 detailed in Table 4.12.

Table 4.12 Comparison of serum estradiol among intervention and control groups by independent t-test

Serum estradiol	Mean difference	95% CI of difference		P-value
		lower	upper	
Baseline	-1.99	-6.07	2.10	0.335
12-week follow-up	7.84	3.37	12.31	0.001
16-week follow-up	7.69	3.25	12.13	0.001

4.2.2 Differences in serum estradiol between the intervention and the control groups at baseline, 12-week, and 16-week follow-up by repeated measures ANOVA

For comparative analysis of the differences mean, repeated ANOVA statistics were used. The assumptions of these statistics were analyzed. First, we could test the normal distribution for serum estradiol by the Kolmogorov-Smirnov test. The results found that serum estradiol normality was (P-value = 0.20) as shown in graph 4.1.

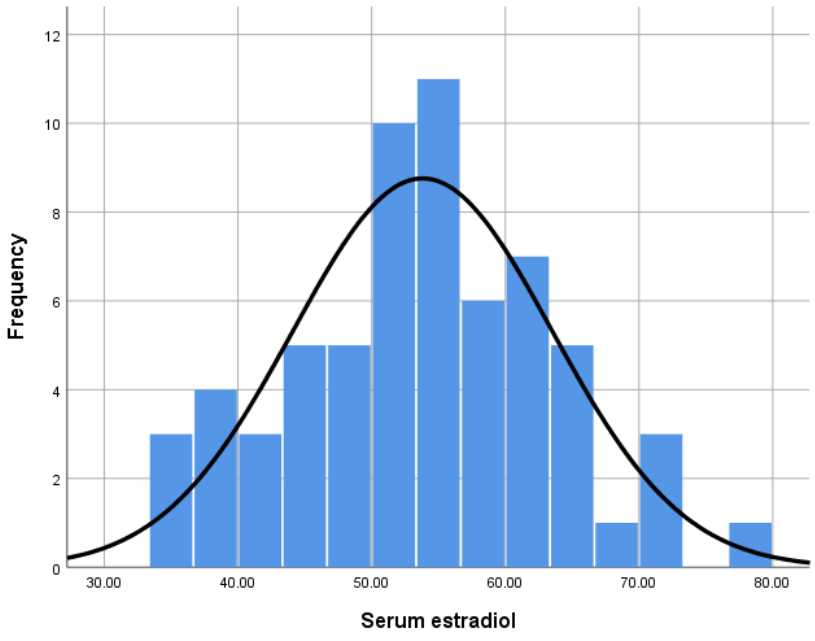


Figure 4.1 Graph the normal distribution for serum estradiol

Secondly, we require equal variances which are described as homogeneity of variance by using Levene's test. The results found that serum estradiol was no different among variances of each week (P-value =0.686, 0.953, and 0.961 on the baseline, 12-week, and 16-week follow-up, respectively). The test of compound symmetry for serum estradiol was exceeded, thus we analyzed mean differences by the Greenhouse-Geisser adjustment with the univariate test. Then, we computed the comparative analysis of the differences in means of serum estradiol among control and intervention groups in the baseline, 12-week, and 16-week follow-up by repeated ANOVA. It was the differences significantly of serum estradiol of the samples in each week (F= 37.55, P-value < 0.001) as shown in Table 4.13 and Graph 4.2-4.3

Table 4.13 Comparison of serum estradiol among intervention and control groups at baseline, 12-week and 16-week follow-up by repeated ANOVA

Source of variance	SS	df	MS	F	P-value
Time (Week)	1968.74	1.004	1960.32	72.83*	< 0.001
Time*Type[a]	1014.93	1.004	1010.59	37.55*	< 0.001
Error	1676.00	62.27	26.92		

SS = Sum Square; df = degree of freedom; MS = Mean square
*= Greenhouse-Geisser correction was used to reduce type I error
[a]Type = Intervention Group and Control Group

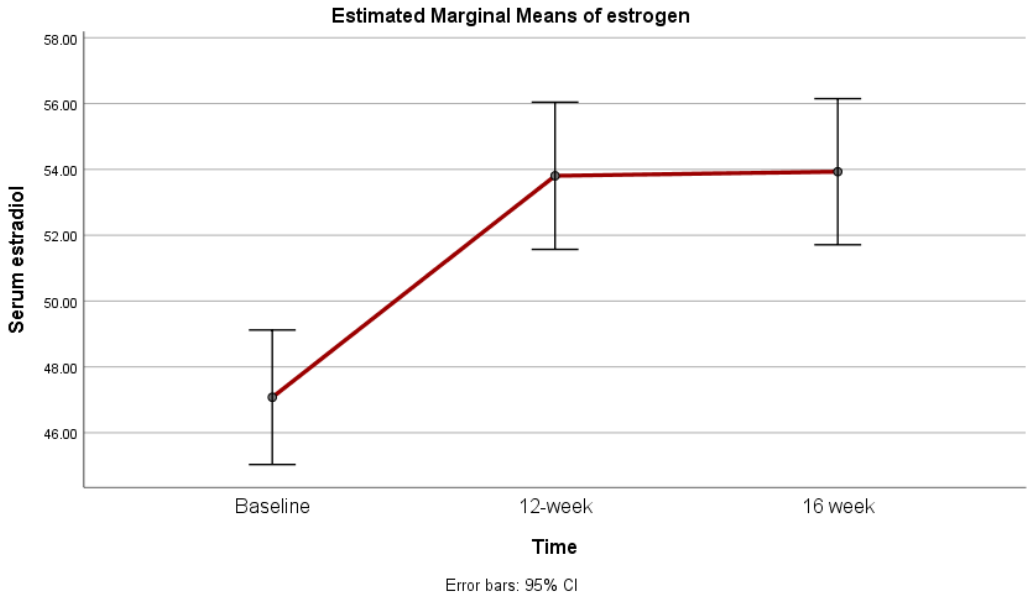


Figure 4.2 Graph Comparison of serum estradiol at baseline, 12-week and 16-week follow-up

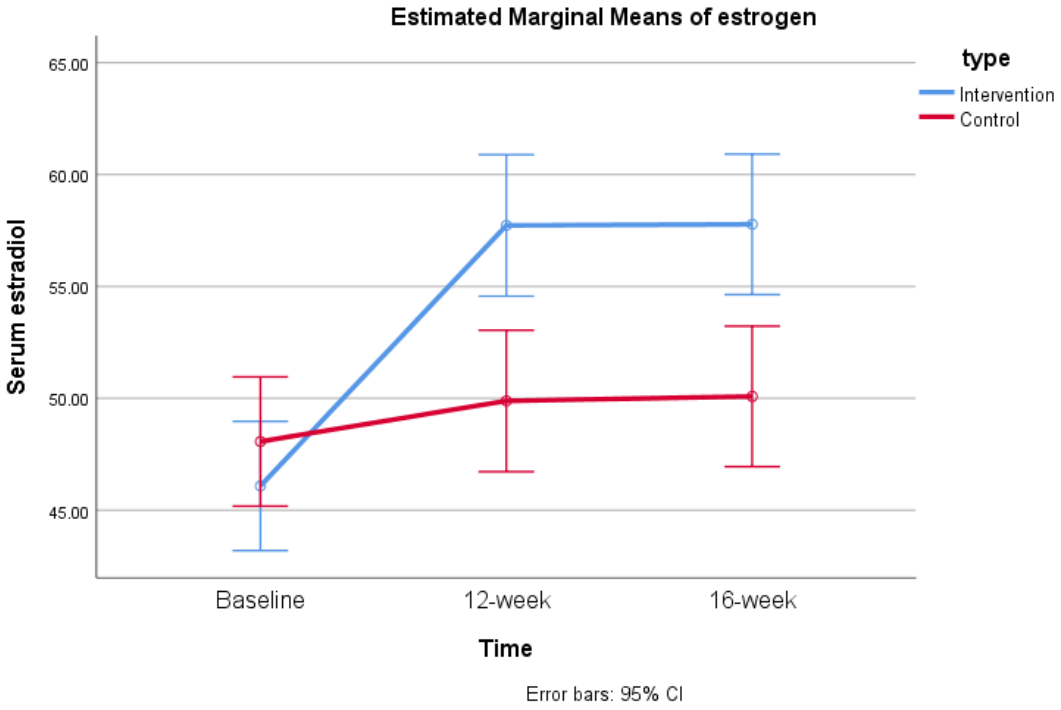


Figure 4.3 Graph Comparison of serum estradiol among intervention and control groups at baseline, 12-week and 16-week follow-up

4.2.3 Pairwise comparisons of serum estradiol

These are pairwise comparisons of the average serum estradiol for each week. Pairwise differences were significant at the baseline, 12-week, and 16-week follow-up among the intervention group. These are Bonferroni adjusted pairwise comparisons as shown in Table 4.14-4.15 and graph 4.5-4.6.

Table 4.14 Pairwise comparisons on the average serum estradiol for each week among intervention group

Comparative time	Mean difference	95% CI of difference mean		P-value
		Lower	Upper	
Baseline - Week 12	-11.64	-14.51	-8.78	< 0.001
Baseline - Week 16	-11.69	-14.52	-8.87	< 0.001
Week 12- Week 16	-0.05	-0.12	0.02	0.276

Table 4.15 Pairwise comparisons on the average serum estradiol for each week among control group

Comparative time	Mean difference	95% CI of difference mean		P-value
		Lower	Upper	
Baseline- Week 12	-1.81	-4.67	1.04	0.355
Baseline - Week 16	-2.02	-4.86	0.83	0.248
Week 12- Week 16	-0.20	-0.41	0.01	0.057

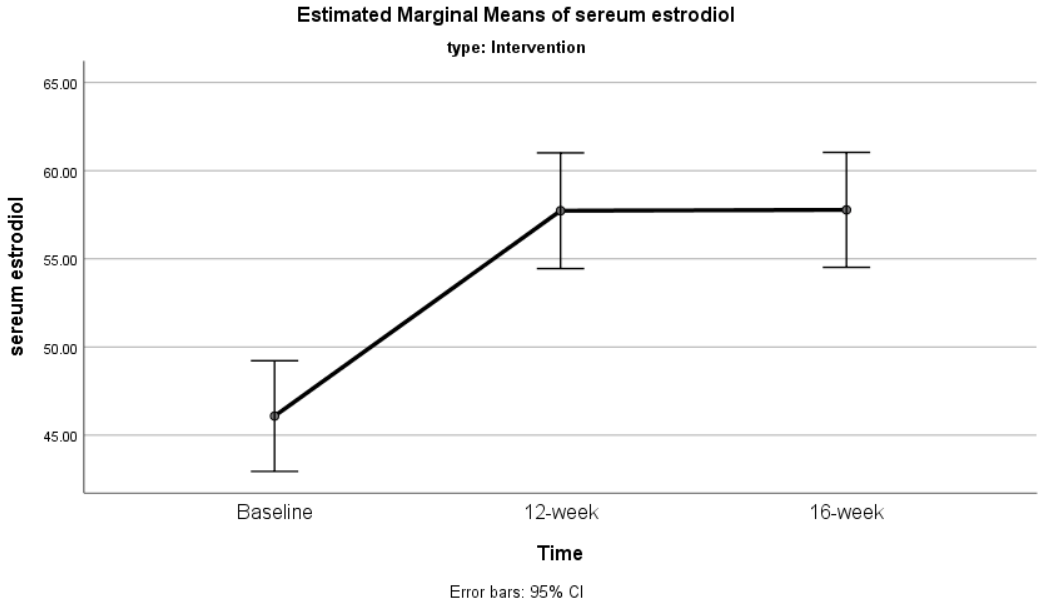


Figure 4.4 Graph comparisons on the average serum estradiol for each week among intervention group

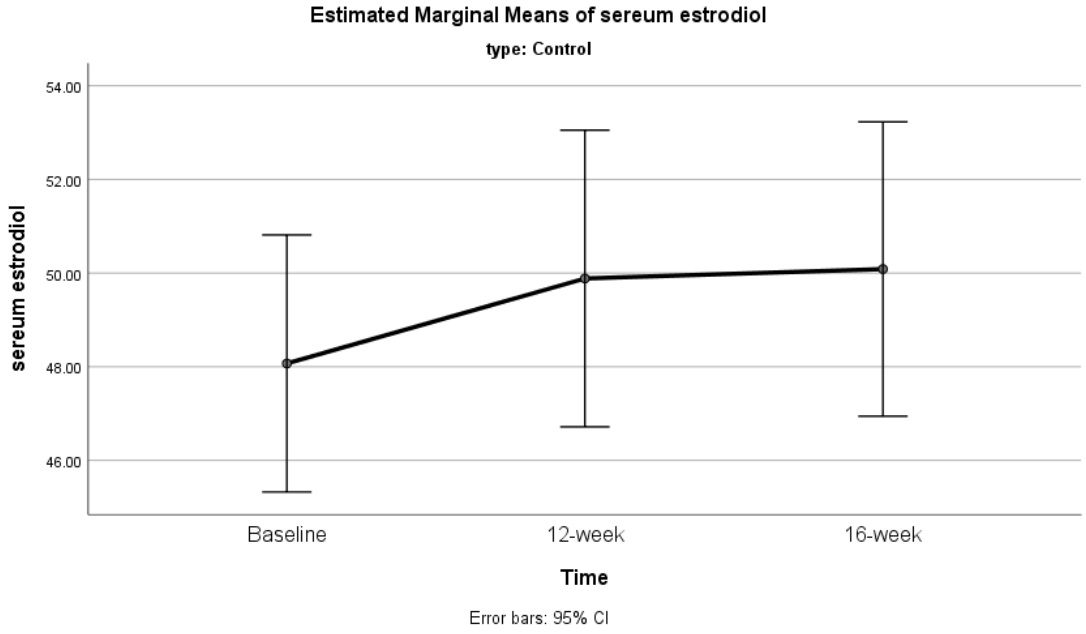


Figure 4.5 Graph comparisons on the average serum estradiol for each week among control group

4.3 Testing the Effect of the Program on Climacteric symptoms

4.3.1 Comparison of the trend of Climacteric symptoms between groups

In terms of comparisons between groups, we compared the mean climacteric symptoms scores for both control and intervention groups by an independent t-test. The results found that the mean of serum estradiol had non-significantly differed at both the baseline and 12-week follow-up (P-value = 0.075 and 0.80, respectively). However, a 16-week follow-up had a significantly different P-value < 0.001 detailed in Table 4.16.

Table 4.16 Comparison of Climacteric symptoms score among intervention and control groups by independent t-test

Climacteric symptoms score	Mean difference	95% CI of difference		P-value
		lower	upper	
Baseline	-0.75	-1.58	0.08	0.075
12-week follow-up	0.16	-1.07	1.39	0.800
16-week follow-up	-5.75	-6.85	-4.65	< 0.001

4.3.2 Differences in climacteric symptoms scores between the intervention and the control groups at the baseline, 12-week, and 16-week follow-up by repeated measures ANOVA

For comparative analysis of the differences mean, repeated ANOVA statistics were used. The assumptions of these statistics were analyzed. First, we could test the normal distribution for climacteric symptoms score by Kolmogorov-Smirnov test. The results found that climacteric symptoms scores were normally (P-value = 0.051) as shown in graph 4.6.

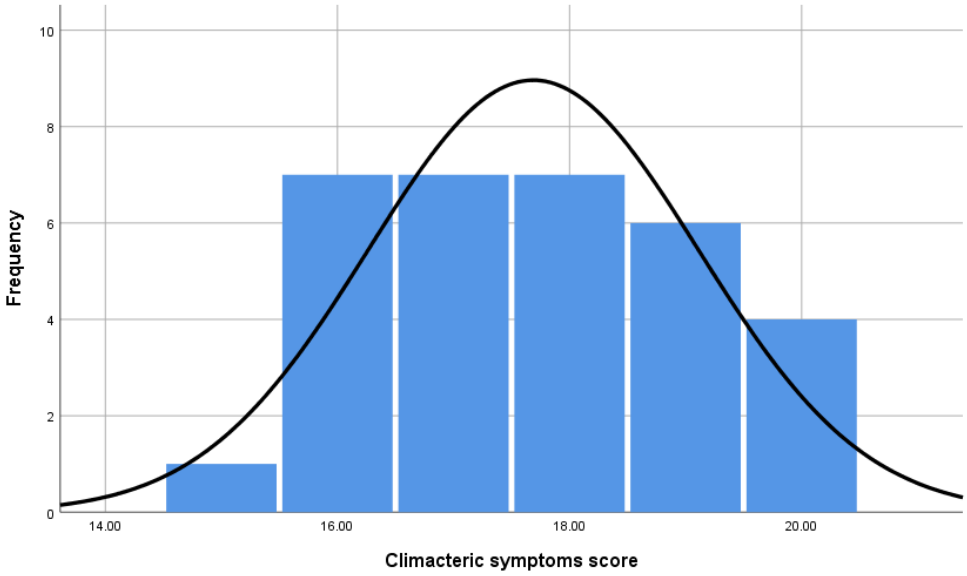


Figure 4.6 Graph the normal distribution for climacteric symptoms score

Secondly, we require equal variances which are described as homogeneity of variance by using Levene's test. The results found that climacteric symptoms scores were no different among variances of each week (P-value =0.206, 0.11, and 0.219 on the baseline, 12-week, and 16-week follow-up, respectively). The test of compound symmetry for serum estradiol was exceeded, thus we analyzed mean differences by Greenhouse-Geisser adjustment with the univariate test. Then, we computed the comparative analysis of the differences mean climacteric symptoms score among control and intervention groups in baseline, 12-week, and 16-week follow-up by repeated ANOVA. It was the differences significantly climacteric symptoms score of the samples in each week (F= 531.4, P-value < 0.001) as shown in Table 4.17 and Graph 4.7-4.8.

Table 4.17 Comparison of Climacteric symptoms score among intervention and control groups at baseline, 12-week and 16-week follow-up by repeated ANOVA

Source of variance	SS	df	MS	F	P-value
Time (Week)	3561.39	1.87	1909.33	531.40*	< 0.001
Time*Type	323.76	1.87	173.57	48.31*	< 0.001
error	415.52	115.65	3.59		

SS = Sum Square; df = degree of freedom; MS = Mean square

*= Greenhouse-Geisser correction was used to reduce type I error

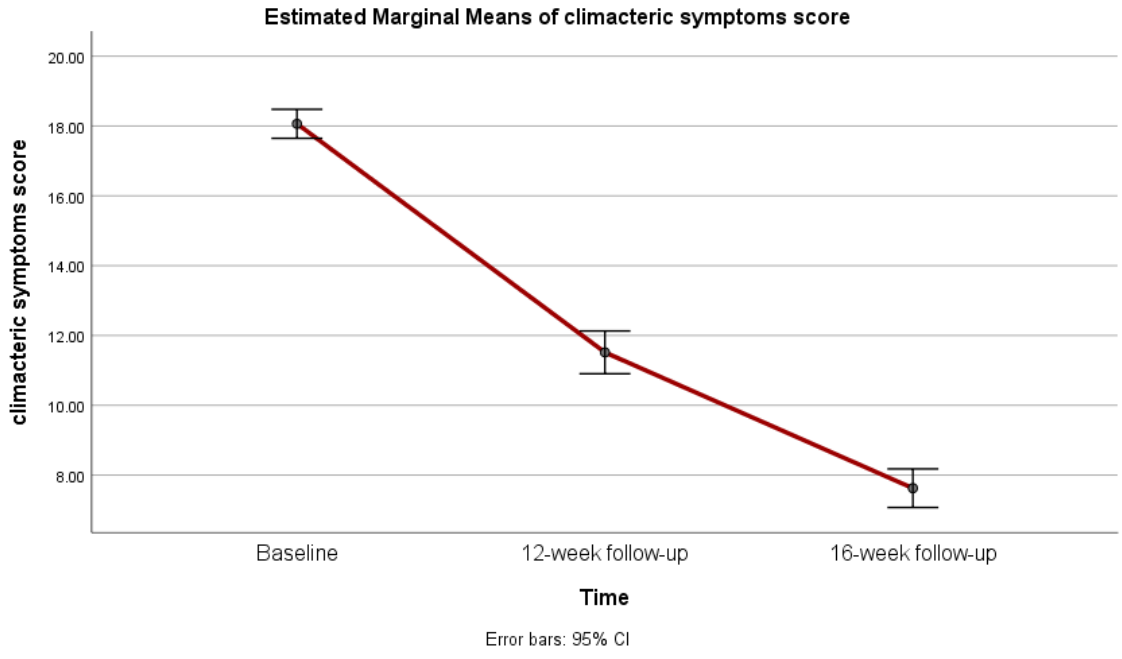


Figure 4.7 Graph Comparison of Climacteric symptoms score at baseline, 12-week and 16-week follow-up

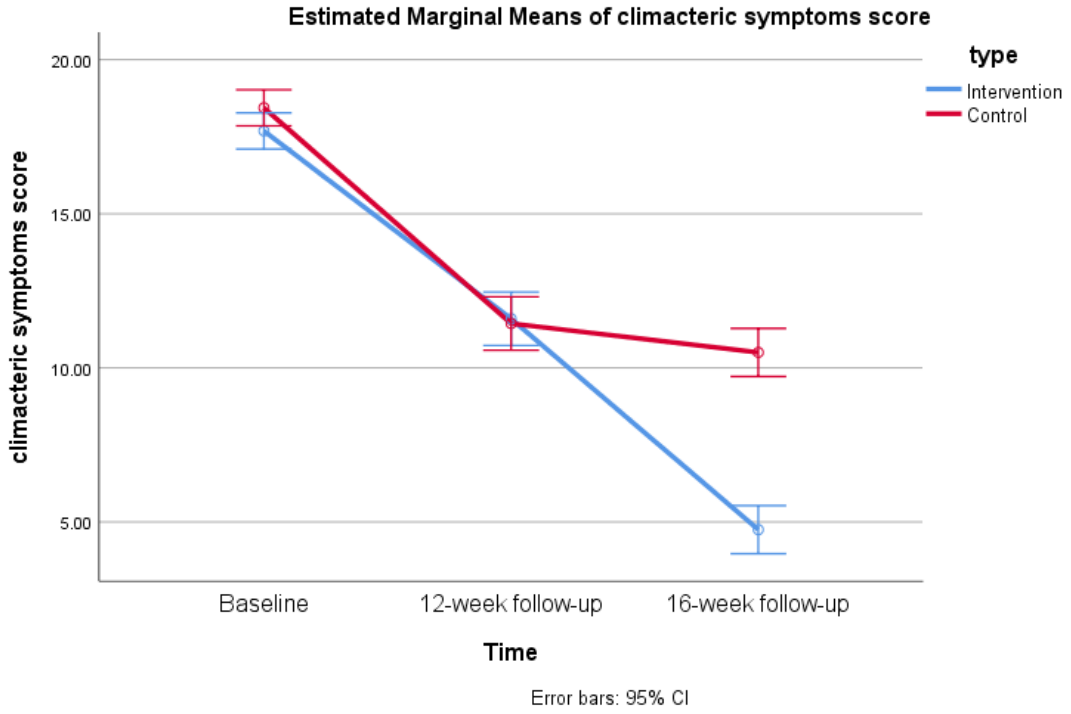


Figure 4.8 Graph Comparison of Climacteric symptoms score among intervention and control groups at baseline, 12-week and 16-week follow-up

4.3.3 Pairwise comparisons of Climacteric symptoms score

These are pairwise comparisons on the average climacteric symptoms score for each week. Pairwise differences were significant at the baseline, 12-week, and 16-week follow-up among intervention and control groups (P-value < 0.001) except at the 12-week and 16-week follow-up in the control group was not significantly different (P-value = 0.135). These are Bonferroni adjusted pairwise comparisons as shown in Table 4.18-4.19 and graph 4.9-4.10.

Table 4.18 Pairwise comparisons on the average Climacteric symptoms score for each week among intervention group

Comparative time	Mean difference	95% CI of difference mean		P-value
		Lower	Upper	
Baseline - Week 12	6.09	4.88	7.30	< 0.001
Baseline - Week 16	12.39	12.02	13.86	< 0.001
Week 12- Week 16	6.84	6.02	7.66	< 0.001

Table 4.19 Pairwise comparisons on the average Climacteric symptoms score for each week among control group

Comparative time	Mean difference	95% CI of difference mean		P-value
		Lower	Upper	
Baseline- Week 12	7.00	5.76	8.24	< 0.001
Baseline - Week 16	7.94	6.44	9.43	< 0.001
Week 12- Week 16	0.94	-0.20	2.07	0.135

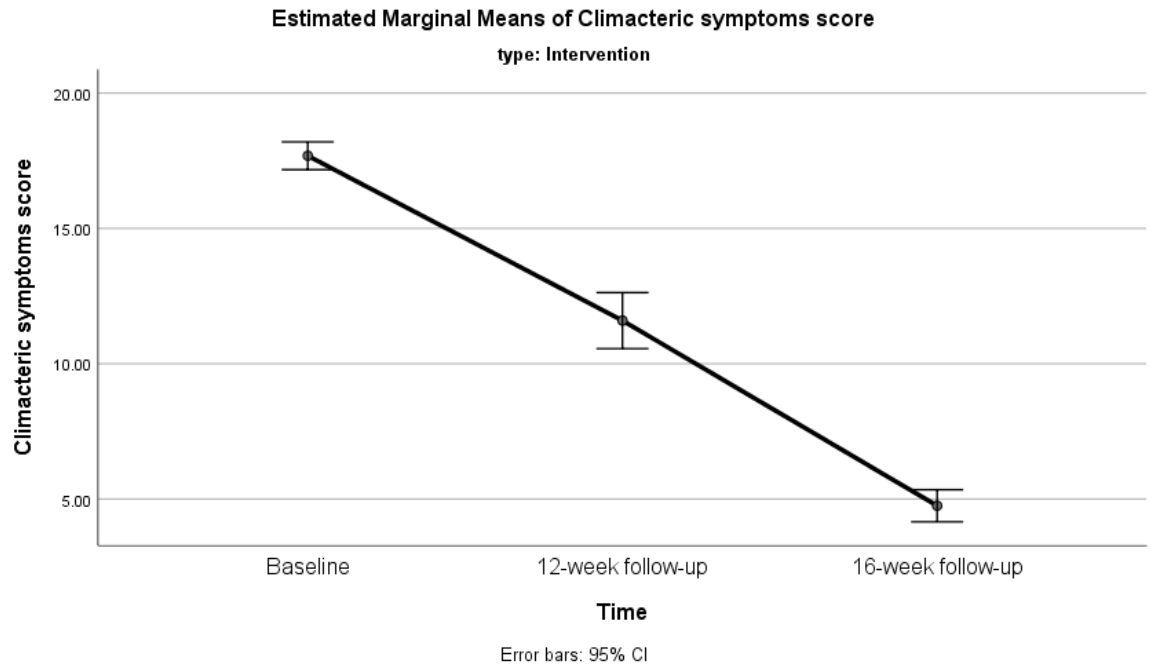


Figure 4.9 Graph Comparisons on the average Climacteric symptoms score for each week among intervention group

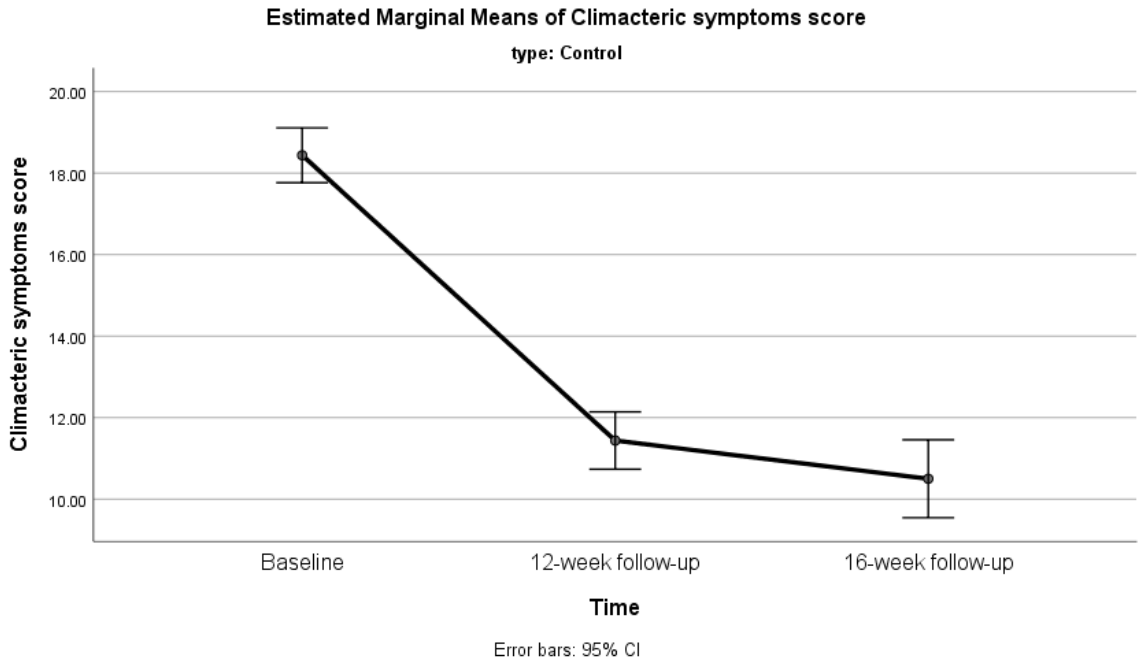


Figure 4.10 Graph Comparisons on the average Climacteric symptoms score for each week among control group

4.4 Testing the Effect of the Program on Quality of Life

4.4.1 Comparison of the trend of Quality of Life between groups

The quality of life between the intervention and control group was compared by an independent t-test. The result revealed that total quality of life at the baseline was significantly different among both groups (P-value= 0.025) whereas at the 16-week follow-up it was not significantly different (P-value= 0.052). Considering the physical part, it was found that quality of life at both baseline and 16-week follow-up was significantly different (P-value < 0.001). In term of psychology, between the two groups was significantly different at only the baseline (P-value=0.018). Neither social relationship nor environment factors of the quality of life was found to be significantly different between the intervention and control groups as shown in Table 4.20

Table 4.20 Comparison of Quality of Life among intervention and control groups by independent t-test

Quality of Life	Mean difference	95% CI of difference		P-value
		lower	upper	
Total Quality of Life				
Baseline	4.06	0.52	7.60	0.025
16-week follow-up	3.16	-0.03	6.34	0.052
Physical				
Baseline	2.50	1.14	3.86	<0.001
16-week follow-up	2.38	1.09	3.66	<0.001
Psychological				
Baseline	1.97	0.35	3.59	0.018
16-week follow-up	1.00	-0.40	2.40	0.16
Social relationship				
Baseline	-0.84	-2.12	0.43	0.192
16-week follow-up	-0.72	-1.86	0.43	0.214
Environment				
Baseline	0.41	-1.06	1.87	0.58
16-week follow-up	0.69	-0.54	1.91	0.266

4.4.2 Comparison of the trend of Quality of Life within groups

For comparison of quality of before and after receiving this program, a statistical method was used paired t-test analysis. At the 16-week follow-up, all parts of quality of life in both the intervention and control groups had significantly higher scores than at baseline (P-value < 0.001) as shown in Table 4.21-4.22

Table 4.21 Comparisons on the average quality of life for each week among intervention group by pair t-test

Comparative time	Mean difference	95% CI of difference mean		P-value
		Lower	Upper	
Total Quality of Life				
Baseline - Week 16	-18.44	-19.27	-17.61	< 0.001
Physical				
Baseline - Week 16	-2.69	-3.18	-2.20	< 0.001
Psychological				
Baseline - Week 16	-3.59	-3.98	-3.21	< 0.001
Social relationship				
Baseline - Week 16	-2.78	-2.93	-2.63	< 0.001
Environment				
Baseline - Week 16	-7.69	-7.98	-7.39	< 0.001

Table 4.22 Comparisons on the average quality of life for each week among control group by pair t-test

Comparative time	Mean difference	95% CI of difference mean		P-value
		Lower	Upper	
Total Quality of Life				
Baseline - Week 16	-19.34	-20.30	-18.38	< 0.001
Physical				
Baseline - Week 16	-2.81	-3.25	-2.38	< 0.001
Psychological				
Baseline - Week 16	-4.56	-4.88	-4.25	< 0.001
Social relationship				
Baseline - Week 16	-2.66	-2.83	-2.48	< 0.001
Environment				
Baseline - Week 16	-7.41	-8.07	-6.74	< 0.001

CHAPTER 5

DISCUSSION

This chapter includes the summary of findings and the discussion. The discussion of the study will describe the effectiveness of Tibetan Yoga in reducing climacteric symptom scores and increasing quality of life in perimenopausal women. The findings are also supported by comparing and contrasting with previous relevant studies. Finally, the recommendations for future research will be presented.

5.1 THE SUMMARY OF RESEARCH FINDING

This research aimed to assess the effectiveness of Tibetan Yoga in reducing climacteric symptom scores and increasing quality of life in perimenopausal women. especially to compare general characteristics of intervention with the control group, find climacteric symptoms, Estrogen Hormone Levels and determine the quality of life score at baseline level and follow-up among intervention in the control group and assess changes of climacteric symptoms, Estrogen Hormone Levels and quality of life scores before and after program among both groups. Also, to compare change of climacteric symptom score and the quality of life score among intervention and control group after receiving the program, compare climacteric symptoms scores and quality of life scores before and after receiving the program within intervention and the control group, and compare the changes in Estrogen Hormone Levels between intervention with the control group after receiving the program. There were a total of 332 women aged 45-55 years who met the criteria, and these were divided into intervention and control groups with 32 study participants in each. These studies were classified into 4 phases: Phase 1: Blood collected from both groups to measure estrogen levels and were assessed at the baseline level before intervention - Tibetan Yoga Program. Phase 2: Initiated the intervention of Tibetan Yoga. Phase 3: The participants received climacteric symptoms assessment using Climacteric Symptoms Assessment Form of the Bureau of Reproductive Health, Department of Health under the Ministry of Public Health Thailand. Phase 4: End point Climacteric symptoms

were assessed, blood samples collected to determine estrogen level and QOL of the participants were assessed.

5.1.1 General Characteristics of Perimenopausal Patients

The results showed that the intervention group had an average of 48.81 ± 3.66 whereas the control group had 48.22 ± 3.02. The age was between 45-50 years and both groups were married. The educational levels among both groups were about half had secondary education and had income between 10,001 to 20,000 baht. However, the statistical analysis between the intervention and control group revealed that all of the baseline characteristics had not significantly differed in both groups.

5.1.2 Time point of serum estradiol

Both groups were increasing the mean of serum estradiol during each time point when changes in estrogen hormone levels was assessed by collecting blood samples at weeks 0, 12, and 16.

5.1.3 Descriptive statistic of climacteric symptoms score

The climacteric symptoms score was categorized into 4 levels, not at all, a little, quite a lot, and extremely. So, both groups had “not at all” most symptoms and followed by “hot flushes”. All the remaining symptoms, the intervention group had “urinary frequency”, “dysuria”, “extremely” in symptoms of “difficulty in sleeping” and “back pains”, respectively. On the other hand, the control group had “sweating at night”, “urinary frequency” and “urinary incontinence” but with less “extremely” in only symptoms “feeling abandoned” respectively. Concerning the 12-week follow-up evaluation, both groups had “not at all” in symptoms “back pains” but differed in “difficulty in sleeping”, “irritability” and “feeling tired or lacking in energy” respectively, whereas were they had “extremely” with no symptoms in the intervention group. In the control group had they had “attacks of anxiety, panic”, “irritability” and “joint pains” the most but not all of the symptoms had “extremely”. At the 16-week follow-up evaluation, both groups had “not at all” symptoms “back pains” and followed by “joint pains”. However, not all of the symptoms were selected “quite a lot” and “extremely” in the intervention group but “attacks of anxiety, panic”, “sweating at night” and

“irritability” respectively in the control group, whereas not all of the symptoms were selected “extremely”.

An average score of the climacteric symptoms at each time point was found that both groups were reducing their scores during follow-up but more of the climacteric symptoms were experienced in the control group. The interpretation of the climacteric symptoms score found that the intervention group at baseline level had a proportion of high-risk estrogen deficiency less than the control group. At the 12-week follow-up, the control group seemed to be of a lesser proportion of higher risk than the intervention group.

5.1.4 Descriptive statistic of quality of life

Among the intervention group regarding the results of “not at all” most questions were “Have you enough money to meet your needs?” followed by “How satisfied are you with the support you get from your friends?” respectively. Considering the control group, the participants selected “not at all” mostly in question “How well are you able to get around?” followed by “How satisfied are you with the support you get from your friends?” respectively. At the 16-week follow-up evaluation, both groups were not selecting “not at all” but the “extremely” choice in the intervention group, the question was most chosen “To what extent do you feel that physical pain prevents you from doing what you need to do?” and “How much do you need any medical treatment to function in your daily life?”. On the other hand, the question was selected “extremely” most in “How often do you have negative feelings such as blue moods, despair, anxiety, depression?” followed by “How much do you need any medical treatment to function in your daily life?” in the control group.

An average of all parts of quality of life among the intervention group was higher than the control group in all time points except in social relationships at the baseline. Considering the total quality of life at the baseline, more than half of participants in the intervention group had a poor quality of life with a fair quality of life after finishing the program (16-week follow-up). In the control group who had a poor quality of life at the baseline whereas all of the participants changed to fair quality of life after finishing the program (16-week follow-up). In terms of the

physical review, most of the participants among the intervention group had a fair quality of life at the baseline but increased to fair quality of life and good quality of life at the end of follow-up. The psychological review revealed that the intervention group had a fair quality of life but poor quality of life at the baseline of the control group. However, both groups of participants had an increasing proportion of good quality of life after the 16-week follow-up.

Quality of life regarding social relationships found that both groups had a poor quality of life but changed to fair quality of life after the 16-week follow-up. Concerning the environmenal item of the quality of life showed that at the baseline both groups had a poor quality of life but changed to a fair quality of life after a 16-week follow-up.

5.1.5 Testing the Effect of the Program on serum estradiol

The results showed that the mean of serum estradiol was not significantly different at baseline level (P-value = 0.335). However, both the 12-week and 16-week follow-ups had significantly different P-values < 0.001. The serum estradiol normality range was (P-value = 0.20) but didn't differ among variances each week (P-value =0.686, 0.953, and 0.961 on the baseline, 12-week, and 16-week follow-up, respectively). Also, it was the significant differences of serum estradiol of the samples of each week (F= 37.55, P-value < 0.001). Concerning pairwise comparisons, there were significant differences at the baseline, 12-week, and 16-week follow-up among the intervention group.

5.1.6 Testing the Effect of the Program on Climacteric symptoms

The mean level of serum estradiol had non-significantly differed at both the baseline and 12-week follow-up (P-value = 0.075 and 0.80, respectively). However, a 16-week follow-up had a significantly different P-value < 0.001. The climacteric symptoms scores were normally (P-value = 0.051). The climacteric symptoms scores were no different among variances of each week (P-value =0.206, 0.11, and 0.219 on the baseline, 12-week, and 16-week follow-up, respectively). There were differences significantly of climacteric symptoms scores in the samples of each week (F= 531.4, P-value < 0.001). Furthermore, pairwise differences were

significant at the baseline, 12-week, and 16-week follow-up among intervention and control groups (P-value < 0.001) except at the 12-week and 16-week follow-up in the control group which was not significantly different (P-value = 0.135).

5.1.7 Testing the Effect of the Program on Quality of Life

From the 16-week follow-up of both groups, total quality of life at the baseline was significantly different among both groups (P-value= 0.025). Considering the physical item, the quality of life at both baseline and 16-week follow-ups was significantly different (P-value < 0.001). In term of psychology, between the two groups it was significantly different at only the baseline (P-value=0.018). Neither social relationship nor environment factors of the quality of life was found to be significantly different between the intervention and control groups. All parts of quality of life in both groups had significantly higher scores than at baseline (P-value < 0.001).

5.2 Discussion on climacteric symptom scores, estrogen hormone levels, and quality of life score at baseline level and follow-up

5.2.1 The results of climacteric symptom scores, estrogen hormone levels, and quality of life scores

1. General Characteristics

1.1 Most perimenopausal women were aged 45-50 years. The experimental group and the control group had the similar characteristics with married status. Also, both groups had similar secondary education levesl with income between 10,001 to 20,000 baht. The results were similar to the previous study of Premenopausal women aged between 46.06-52.14 years, and had secondary education. (Hunter et al., 2011 & Beverley Ayers, 2012 & Sakuntala Giri., 2020). Study from India: Perimenopause women - 46-50 years; >80% housewives (Chattha, Raghuram, Venkatram & Hongasandra, 2008). Study by Reed, Guthrie, Newton, Anderson, Booth-LaForce, Caan & LaCroix (2014) had mean BMI of 27.1 ± 4.6 compared to 21.04±1.03 kg/m2 in this study.

2. Time point of serum estradiol, climacteric symptom scores, and quality of life score at baseline level and follow-up

2.1. At the 16-week follow-up evaluation, all the intervention group selected “not at all” in symptoms “Backaches”, followed by “Trouble Sleeping” with “Hot flashes” and may have other symptoms that are specific to any one specific organ system. There were increases in the mean serum estradiol levels during each time point in both groups. These results were similar to the results in the research of Suwan (2021), McNamara, Batur, Tough & DeSapri (2015) and Kaur, Kaur, Shanmugam & Kang (2014) that the signs and symptoms that were found in the order of least to greatest were backaches while moderate symptoms were trouble sleeping in their study. They also found statistically significant results on climacteric symptoms scores and yoga. Reason being yoga having the potential to reduce scores related to mental health and somatic symptoms.

2.2 Mean of serum estradiol in both the 12-week and 16-week follow-ups were statistically significant (P-value <0.001), increased estrogen levels**.** These results were similar to the research results of Ketki Vishvanath Pond., et al.(2020) and Nattapol Suwan, (2021) that after 8 weeks, exercise contributed to a statistically significant increase in estrogen levels, explaining that at the time of menopause, body and mood changes occur due to estrogen deficiency

2.3 Perimenopausal women at week 16 showed an improvement in quality of life by “How much do you need any medical treatment to function in your daily life?” about 46.9%. responded to the results of Giri, Tripathy & Nayak (2020) that Yoga therapy is effective in improving the quality of life in premenopausal women. Also, physical and mental symptoms in women were significantly reduced after yoga.

3. Change in the climacteric symptoms, Estrogen Hormone Levels, and quality of life scores before and after the program between groups

3.1 After the intervention group practiced yoga for 16 weeks, the QOL was moderate to good. While the control group before and after the program, no

difference in quality of life was shown which related to the study of Suwan (2021). His study showed signs and symptoms in the intervention group after exercise together with receiving phytoestrogens, it improved symptoms and signs. Also, the results were similar to Swain, Nanda & Das (2021) reported a significant decrease in symptoms between groups (pre and post)

3.2 It was the significant differences in serum estradiol levels in the samples of each week that similar results to the findings of Dharitri Swain, Pranati Nanda, Hrushikesh Das (2021) and Mangmee (2019) that Estrogen Hormone levels increased in the intervention group but in control groups were no different each week.

3.3 All of the participants changed to fair quality of life after finishing the program (16-week follow-up). Between groups no statistically significant difference was reported in this study in totals of QOL scores at 16 week follow up. On the other hand, Swain, D., Nanda, P., & Das, H. (2021) reported significant difference in means between intervention and control group in the overall QOL score. The study of women in the intervention group had significantly higher SF-36 scores in mental health than those in the control group. (Luoto, Moilanen, Heinonen, Mikkola, Raitanen, Tomas & Ojala, 2012).

4. Change in climacteric symptom scores and quality of life scores within intervention and control groups

The result showed Tibetan Yoga was the most common interventions for women with menopausal and climacteric symptoms. However, these results opposed the results of Ngowsiri et al (2014) and Luoto et al. (2012) that women who experienced inconvenience because of menopausal symptoms could reflect the actual effect of exercise on menopause-specific Quality of life.

5.2.2 What are the outcomes of climacteric symptom scores, estrogen hormone levels, and quality of life scores ?

1. General characteristics

The statistical analysis between the intervention and control group revealed that all of the baseline characteristics had not significantly differed in both groups. These results were similar to the result of Peteneinuo Rülu, et al. (2016) that the premenopausal women aged between 48.3-49 years. Also, signs of reproductive aging begin when a woman is about 35 years old and changes rapidly after 40 years. (Speroff L., 2002)

2. Climacteric symptom scores, time point of serum estradiol, and quality of life scores at baseline level and follow-up

2.1 At the 16-week follow-up evaluation, the intervention group had no back pains and had almost high scores with no difficulty in sleeping and joint pains, whereas not all of the symptoms were selected. This is consistent with the study of (Nattapol Suwan, 2021) . The results found that the sign and symptoms after receiving phytoestrogens from pomegranate seed oil and exercise (Stretching) for a period of 8 weeks found in the order of least to greatest were back pain, feeling tense or nervous, feeling more excited than usual and mood swings, such as irritability, anxiety, feeling unhappy, depressed, and hesitant, unsure of what to do. While moderate symptoms were insomnia, difficulty sleeping, feeling tired easily, different from the findings of (Speroff L, Glass RH, Kase NG., 1999) which were that hot flashes were most common during perimenopause.

2.2 Tibetan Yoga contributes to a statistically significant increase in estrogen levels, explaining that at the time of menopause, body and mood changes occur due to estrogen deficiency. The outcome associated with the estrogen and estradiol levels in females which are produced by the ovaries and involved in the control of the expression of sexual characteristics (Bedell, Nachtigal, Naftolin, 2014). The outcome also associated some premenopausal women may be asymptomatic or have mild symptoms while some have severe symptoms, for some, it can lead to years

of estrogen deficiency, which affects quality of life (Bedell, Nachtigal, Naftolin, (2014) the estrogen and estradiol in females is produced by the ovaries.

2.3 At week 16 it showed an improvement in quality of life in the intervention group which selected “How much do you need any medical treatment to function in your daily life?” below 50% but the control group still were above 50% on “How often do you have negative feelings such as blue moods, despair, anxiety, depression?”. These outcomes opposed Chandaragga (2000) who stated that the quality of life of premenopausal age in Thailand was at a good level. If classified by aspects such as life satisfaction and conceptual aspect health and body including premenopausal women with low quality of life will result in higher signs and symptoms of menopause (Peteneinuo Rülu, 2016).

3. Change in the climacteric symptoms, Estrogen Hormone Levels, and quality of life scores before and after programs between groups

3.1 After receiving yoga for 16 weeks, quality of life was moderate to good in the intervention group and the mean scores for climacteric symptoms were different. While the control group before and after the trial experienced no difference in quality of life and the mean scores for climacteric symptoms were the same. This outcome indicated regarding the study of Suwan (2021) who found that signs and symptoms in the intervention group after exercise together with receiving phytoestrogens, it improved symptoms and signs. After exercise and received phytoestrogens, the signs and symptoms persisted and did not disappear after the end of the trial in the control group.

3.2 The outcome showed the significant differences in Estrogen Hormone levesl of the samples of each week. The comparative analysis of the differences in the mean serum estradiol among control and intervention groups at the baseline, 12-week, and 16-week. This outcome was different with the duration of time from the study of Dharitri Swain, Pranati Nanda, Hrushikesh Das (2021) showed that Estrogen Hormone levels were no different between the experimental and control groups after 1 year. However, changes in Estrogen Hormone levels compared before the experiment and after the experiment at weeks 4, 8 and 12 increased in the

intervention group but control groups were no different each week (Jinnapat Mangmee, 2019).

3.3 The intervention group a had fair quality of life after finishing the program (16-week follow-up). In the same item in the control group, about 68.8% had a poor quality of life at baseline level whereas all of participant changed to a fair quality of life after finishing the program (16-week follow-up). On the other hand, the outcome was different on women in the intervention group who had significantly higher SF-36 scores in mental health than those in the control group shown as a result of the research of Luoto, Moilanen, Heinonen, Mikkola, Raitanen, Tomas, Ojala (2012).

4. Change in climacteric symptom scores and quality of life scores within intervention and control groups

4.1 It was the significant differences of the climacteric symptoms score of the intervention group and the control group in each week but different at only the baseline. This outcome resulted in 6 weeks of yoga therapy and found that signs of menopause had decreased significantly by 27.83 to 6.6 by statistical significance (Afonso, Hachul, Kozasa et al., 2012). Similarly, QoL and sexual function of women with GSM improved after the intervention (Bertotto, Schvartzman, Uchoa, Wender, 2015).

4.2 Quality of life at both baseline and 16-week follow-up was significantly different in terms of psychological outcomes between the two groups. This outcome was different to a significant improvement in all MENQOL domains in the intervention group and between the two groups (Ngowsiri, Tanmahasamut, Sukontha., 2014). This was because there were no advantages of yoga over other types of exercise (Thi Mai Nguyen, Thi Thanh Toan Do, Tho Nhi Tran, and Jin Hee Kim, 2020).

Why are the results of climacteric symptom scores, estrogen hormone levels, and quality of life scores Significant ?

1. Quality of life between the intervention and control groups were compared by independent t-test was significantly different among both groups, whereas at the 16-week follow-up it was not significantly different. The results are consistent to Avis et al. (2014) which showed a non-significant negative association between yoga and general Quality of life, but they reported several limitations, including an underpowered sample size, a challenging participant recruitment process, and poor class attendance because of the inability to offer more flexible and varied intervention class days and times. Providing more options for classes, instead of only offering the class once per week, would improve both recruitment and class attendance. However, these results showed that Tibetan Yoga improved quality of life in the intervention group. This is because Tibetan Yoga significantly improved physical quality of life, its effects on general, psychological, sexual, and vasomotor symptoms quality of life scores. All these results associated to a recently published meta-analysis only identified an association between physical exercise and quality of life related to menopausal sexual symptoms (Carcelen-Fraile, M.D.Cet al.,2020).

2. Tibetan Yoga helped to improve menopausal symptoms and related Quality of life domains in the intervention group. This is consistent to the World Health Organization, (2020) which indicated the extent menopause affects a woman's life. Also, Cacciari et al. (2020); Carcelen-Fraile et al. (2020); Ketki Vishvanath Pond, et al. (2020) indicated that Yoga and PFMT can reduce the number of urinary leakage episodes and improve all types of urinary incontinence issues as well as Quality of life in women with urinary symptoms. Also, this is similar to the main findings of three included studies using PFMT, Cacciari et al. (2020) indicated that PFMT can reduce the number of urinary leakage episodes and improve all types of urinary incontinence issues as well as Quality of life in women with urinary symptoms.However, the results are non-consistent to Cramer, 2012) which indicated one cannot reduce menopause symptoms or climacteric symptoms in every aspect of statistical significance.

3. The results showed that health care and physical fitness including Tibetan Yoga professionals should encourage their patients or clients to engage in regular physical activity levels to reduce the risk of these important health outcomes. In the

meantime, the evidence is still accumulating regarding the role of physical activity for specific menopausal symptoms, health care professionals should periodically remind midlife women that they will experience a reduced lifetime risk of chronic disease and disability development if they remain physically active as they age. All these are consistent to Cramer et al. (2018) that, in comparison with no treatment, yoga reduced total menopausal, psychological, somatic, vasomotor, and urogenital symptoms. Dealing with potential methodological biases in the included studies, both reviews suggested that more well-designed studies are needed to confirm the effect of yoga on health status of women with menopausal symptoms.

5.3 Strength and Weakness

The challenges of implementing research outcomes such as those described here into community practice, state law, or public policy are formidable. Much groundwork has been laid—a process that has taken time, effort, and considerable resources. In our quest to disseminate research on older drivers and translate the results into policy-level changes with the potential to improve quality of life through sustained mobility, we have tried to establish as many collaborations as possible with industry, government, and older adult advocacy groups. We have recently sought funding in partnership with small business to develop educational videotapes for physicians and other health care providers in order to more directly inform this group of the older driver research and engage them in the practice of evaluating and intervening on behalf of high-risk patients.

5.4 Study Limitations

The study on Tibetan yoga and postmenopausal women should extend the duration of the study to more than twice weekly sessions over 16 weeks. It is recommended that interventions be provided to participants over a period of several months. There are 2-3 individual sessions per week. Additionally, future studies should include a larger sample size to ensure greater diversity among the participating populations and to ensure statistical analysis can occur. If the timeline allows for future studies, it should be organized into a single topic design where participants have a

formal structure to act as their own control group if not possible. The original control group should be included in the study and compared with the intervention group.

5.5 Recommendation

5.5.1 Healthcare professionals can use evidence-based research to identify and provide resources for women to improve their quality of life and promote overall health and well-being.

5.5.2 Community nurses play an important role in disseminating evidence-based complementary therapy. to help postmenopausal women alleviate their problems Evidence-based practice can facilitate quality improvements in women's health.

5.5.3 Tibetan Yoga can be initially recommended as an additional intervention for women experiencing physical and mental problems related to menopause.

5.5.4 Tibetan Yoga is popular as an adjuvant and alternative therapy. It can be added to the scientific evidence so gynecologists can recommend their patients instead of prescribing hormone therapy.

5.5.5 Tibetan Yoga can be recommended as a tool for promotion of mental and physical health leading to better performance of school children. Tibetan Yoga should be adapted to the curriculum of Physical Education subjects for school children.

5.5.6 Participating in Tibetan Yoga classes can be recommend to ease loneliness and provide an environment for group healing and support. Even during one-on-one sessions loneliness is reduced during participating in the creation of a personalized yoga plan.

5.6 Further Research

5.6.1 According to the result of the significant differences between the intervention and the control groups, to promote Tibetan Yoga for woman of other ages and from other areas in order to obtain more complied evidence.

5.6.2 Focus on the qualitative study for understanding the influential factors of exclusive and no exclusive in Tibetan Yoga.

5.6.3 Test the cost-effectiveness of Tibetan Yoga because of the required instructors and other materials which relate.

5.6.4. While there are many aspects of Tibetan Yoga, there is also a need to examine more of the styles and specific aspects of yoga on depression to get more and other results.

5.6.5 Examine the effect of yoga on depression among various groups, cultures, sexes, and occupations to obtain more complete evidence and results.

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APPENDIX

Appendix A/1: Ethical approval from Chulalongkorn University, Office of the Research Ethics Review Committee for Research Involving Human Subjects (Thai Version)

บันทึกข้อความ

ส่วนงาน คณะกรรมการพิจารณาจริยธรรมการวิจัยในคน กลุ่มสหสถาบัน ชุดที่ 1 โทร.0-2218-3049
ที่ จว 049 /2563 วันที่ 18 กุมภาพันธ์ 2563
เรื่อง แจ้งผลผ่านการพิจารณาจริยธรรมการวิจัย

เรียน คณบดีวิทยาลัยวิทยาศาสตร์สาธารณสุข

สิ่งที่ส่งมาด้วย เอกสารแจ้งผ่านการรับรองผลการพิจารณา

ตามที่นิสิต/บุคลากรในสังกัดของท่านได้เสนอโครงการวิจัยเพื่อขอรับการพิจารณาจริยธรรมการวิจัย จากคณะกรรมการพิจารณาจริยธรรมการวิจัยในคน กลุ่มสหสถาบัน ชุดที่ 1 จุฬาลงกรณ์มหาวิทยาลัย นั้น ในการนี้ กรรมการผู้ทบทวนหลักได้เห็นสมควรให้ผ่านการพิจารณาจริยธรรมการวิจัยได้ ดังนี้

โครงการวิจัยที่ 173.2/62 เรื่อง **ประสิทธิผลของทิเบตโยคะเพื่อลดกลุ่มอาการวัยหมดระดู และเสริมสร้างคุณภาพชีวิตในสตรีวัยใกล้หมดระดู : การทดลองแบบสุ่มและมีกลุ่มควบคุมในชุมชน** (THE EFFECTIVENESS OF TIBETAN YOGA TO REDUCE CLIMACTERRIC SYMPTOMS AND ENHANCING QUALITY OF LIFE IN PERIMENOPAUSAL WOMEN : A COMMUNITY-BASED RANDOMIZED CONTROLLED TRIAL) ของ นางสาวณัฐสุภา อาจองค์ นิสิตระดับดุษฎีบัณฑิต วิทยาลัยวิทยาศาสตร์สาธารณสุข จุฬาลงกรณ์มหาวิทยาลัย

จึงเรียนมาเพื่อโปรดทราบ

(รองศาสตราจารย์ ดร.นันทรี ชัยชนะวงศ์โรจน์)
กรรมการและเลขานุการ
คณะกรรมการพิจารณาจริยธรรมการวิจัยในคน
กลุ่มสหสถาบัน ชุดที่ 1 จุฬาลงกรณ์มหาวิทยาลัย

Appendix A/2: Ethical approval from Chulalongkorn University, Office of the Research Ethics Review Committee for Research Involving Human Subjects (English Version)

AF 02-12

The Research Ethics Review Committee for Research Involving Human Research Participants, Group I, Chulalongkorn University
Jamjuree 1 Building, 2nd Floor, Phyathai Rd., Patumwan district, Bangkok 10330, Thailand,
Tel: 0-2218-3202, 0-2218-3049 E-mail: eccu@chula.ac.th

COA No. 048/2020

Certificate of Approval

Study Title No. 173.2/62 : THE EFFECTIVENESS OF TIBETAN YOGA TO REDUCE CLIMACTERIC SYMPTOMS AND ENHANCING QUALITY OF LIFE IN PERIMENOPAUSAL WOMEN: A COMMUNITY-BASED RANDOMIZED CONTROLLED TRIAL

Principal Investigator : MISS NATSUPA ARCHONG

Place of Proposed Study/Institution : College of Public Health Sciences, Chulalongkorn University

The Research Ethics Review Committee for Research Involving Human Research Participants, Health Sciences Group, Chulalongkorn University, Thailand, has approved constituted in accordance with Belmont Report 1979, Declaration of Helsinki 2013, Council for International Organizations of Medical Sciences (CIOM) 2016, Standards of Research Ethics Committee (SREC) 2013, and National Policy and guidelines for Human Research 2015.

Signature: ..... Signature: .....
(Associate Prof. Prida Tasanapradit, M.D.) (Associate Prof. Nuntaree Chaichanawongsaroj, Ph.D.)
Chairman Secretary

Date of Approval : 7 February 2020 Approval Expire date : 6 February 2021

The approval documents including:

1) Research proposal
2) Participant Information Sheet and Consent Form
3) Researcher
4) Questionnaires

Protocol No. 173.2/62
Date of Approval - 7 FEB 2020
Approval Expire Date - 6 FEB 2021

The approved investigator must comply with the following conditions:

1. *The research/project activities must end on the approval expired date of the Research Ethics Review Committee for Research Involving Human Research Participants, Health Sciences Group, Chulalongkorn University (RECCU). In case the research/project is unable to complete within that date, the project extension can be applied one month prior to the RECCU approval expired date.*
2. *Strictly conduct the research/project activities as written in the proposal.*
3. *Using only the documents that bearing the RECCU's seal of approval with the subjects/volunteers (including subject information sheet, consent form, invitation letter for project/research participation (if available))*
4. *Report to the RECCU for any serious adverse events within 5 working days.*
5. *Report to the RECCU for any change of the research/project activities prior to conduct the activities.*
6. *Final report (AF 02-14) and abstract is required for a one year (or less) research/project and report within 30 days after the completion of the research/project. For thesis, abstract is required and report within 30 days after the completion of the research/project.*
7. *Annual progress report is needed for a two- year (or more) research/project and submit the progress report before the expire date of certificate. After the completion of the research/project processes as No. 6.*

Appendix A/3: Thai Clinical Trials Registry (TCTR) Approval E-mail

TCTR Approved [The effectiveness of Tibetan Yoga to reduce climacteric symptoms and enhancing quality of life in perimenopausal women] Inbox x

จาก: Thai Clinical Trials Registry <thaiclinicaltrials@gmail.com>
ส่ง: 1 กุมภาพันธ์ 2564 12:54
ถึง: natsupa_14@hotmail.com <natsupa_14@hotmail.com>
ชื่อเรื่อง: TCTR Approved [The effectiveness of Tibetan Yoga to reduce climacteric symptoms and enhancing quality of life in perimenopausal women]

Dear Natsupa Archong,

We are glad to inform you that the research titled "The effectiveness of Tibetan Yoga to reduce climacteric symptoms and enhancing quality of life in perimenopausal women" has been reviewed and approved by TCTR Committee on 01 February 2021. The TCTR identification number is TCTR20210201008.

If there are any changes in any of the information registered, please make sure you update them as soon as possible. We would greatly appreciate it if you may log in and review/update all the information at least within six months after the registered date, ie 01 August 2021 for the next update, and every six months thereafter.

Thank you for choosing TCTR for your research registration.

Best regards,

Thai Clinical Trials Registry (TCTR)

Medical Research Foundation of Thailand (MRF)

3rd Fl. National Research Council of Thailand (NRCT)
196 Phaholyothin Rd,Ladyao,Chatuchak,Bangkok 10900

Tel : +(66) 2940 5181-3 Ext.723
Fax : +(66) 2940 5184
Sponsored by Thailand Center of Excellence for Life Sciences (TCELS)

Appendix B/1: Participant information sheet for the intervention group

ข้อมูลสำหรับกลุ่มประชากรหรือผู้มีส่วนร่วมในการวิจัย

สำหรับกลุ่มออกกำลังกายทิเบตโยคะ

ชื่อโครงการวิจัย…ประสิทธิผลของทิเบตโยคะเพื่อลดกลุ่มอาการวัยหมดระดู และเสริมสร้างคุณภาพชีวิตในสตรีวัยใกล้หมดระดู: การทดลองแบบสุ่มและมีกลุ่มควบคุมในชุมชน

ชื่อผู้วิจัย…นางสาวณัฐสุภา อาจองค์….ตำแหน่ง…นิสิตปริญญาเอก ……..

สถานที่ติดต่อผู้วิจัย (ที่ทำงาน) …วิทยาลัยวิทยาศาสตร์สาธารณสุข จุฬาลงกรณ์มหาวิทยาลัย.....

(ที่บ้าน) ..102/58 หมู่ 8 ต.บางเลน อ.บางใหญ่ จ.นนทบุรี 11140.....

โทรศัพท์ (ที่ทำงาน) ….....……ต่อ …..…….. โทรศัพท์ที่บ้าน .....……

โทรศัพท์มือถือ ……087 782 6529…… E-mail : ……natsupa_14@hotmail.com…….

1. ท่านได้รับเกียรติให้เป็นตัวแทนของโครงการวิจัยนี้ ขอเรียนเชิญท่านเข้าร่วมในการวิจัย ก่อนที่ท่านจะตัดสินใจเข้าร่วมในการวิจัย มีความจำเป็นที่ท่านควรทำความเข้าใจว่างานวิจัยนี้ทำเพราะเหตุใด และเกี่ยวข้องกับอะไร กรุณาใช้เวลาในการอ่านข้อมูลต่อไปนี้อย่างละเอียดรอบคอบ และสอบถามข้อมูลเพิ่มเติมหรือข้อมูลที่ไม่ชัดเจนได้ตลอดเวลา

2. เนื่องจากแนวโน้มการเพิ่มจำนวนของประชากรสตรีไทยที่เข้าสู่วัยหมดประจำเดือนมีมากขึ้น และต้องประสบกับการเปลี่ยนแปลงทั้งร่างกาย และอารมณ์ แม้ว่าจะเป็นการเปลี่ยนแปลงตามธรรมชาติ เช่น ระบบกระดูก ระบบประสาท ส่งผลให้เกิดอาการร้อนวูบวาบ เหงื่อออกตอน

กลางคืน ช่องคลอดแห้ง อารมณ์หงุดหงิด นอนไม่หลับ ซึ่งอาการดังกล่าวส่งผลต่อคุณภาพชีวิต หากหญิงวัยหมดประจำเดือนมีความรู้ และมีการออกกำลังกายด้วยทิเบตโยคะที่ถูกวิธี จะสามารถช่วยลดอาการเหล่านี้ได้ โครงการนี้จึงได้ออกแบบโปรแกรมการออกกำลังกายด้วยทิเบตโยคะ เป็นท่าทางการออกกำลังกายที่ง่าย ใช้เวลาไม่นาน มีผู้เชี่ยวชาญด้านโยคะในการฝึกปฏิบัติและดูแลความปลอดภัย และสามารถฝึกปฏิบัติได้ด้วยตนเอง

โครงการนี้มีวัตถุประสงค์เพื่อศึกษาโปรแกรมการออกกำลังกายทิเบตโยคะเพื่อลดอาการวัยทองในหญิงไทยวัยก่อนหมดประจำเดือน เพื่อเป็นแนวทางในการวางแผนแก้ไข หรือลดปัญหาอาการวัยทอง รวมถึงส่งเสริมคุณภาพชีวิตของหญิงไทยวัยก่อนหมดประจำเดือน

3. รายละเอียดของกลุ่มประชากรหรือผู้มีส่วนร่วมในการวิจัย

ท่านได้รับเชิญให้เข้าร่วมโครงการนี้เนื่องจากท่านมีลักษณะตรงตามกลุ่มประชากรหรือผู้มีส่วนร่วมในการวิจัย ซึ่งมีเกณฑ์ดังนี้

- เกณฑ์คัดเข้า
  - หญิงไทยวัยก่อนหมดประจำเดือน อายุระหว่าง 45-55 ปี ที่อาศัยในชุมชนหมู่ 9 ต.ละหาร อ.บางบัวทอง จ.นนทบุรี ผ่านเกณฑ์การประเมินอาการวัยทอง โดยมีคะแนนมากกว่า 15 คะแนน
  - ไม่มีประวัติการป่วยด้วยโรคเบาหวาน โรคความดันโลหิตสูง และโรคหัวใจ
  - ไม่ได้รับการออกกำลังกายอย่างเป็นระบบ หรือได้รับการออกกำลังกายด้วยโปรแกรมโยคะในช่วง 6 เดือนที่ผ่านมา
  - ยินยอมเข้าร่วมโครงการวิจัย โดยการลงนามในเอกสารยินยอมเข้าร่วมโครงการวิจัย

- เกณฑ์การคัดออก
    - มีประวัติการผ่าตัดเข่า
    - มีประวัติการผ่าตัดมดลูก หรือเยื่อบุโพรงมดลูก
    - อยู่ในระหว่างการได้รับฮอร์โมนทุกชนิด
    - ไม่สามารถเข้าร่วมโครงการได้มากกว่าร้อยละ 80 หรือขาดเกิน 3 ครั้ง
- เกณฑ์การยกเลิก

ผู้วิจัยได้กำหนดมาตรการดูแลความปลอดภัยในขณะที่มีการฝึกโยคะสำหรับผู้เข้าร่วมวิจัย หากในระหว่างทำกิจกรรมผู้เข้าร่วมวิจัยมีภาวะแทรกซ้อนจากโยคะทิเบต เช่น อาการชาแขนขากระตุกชัก หัวใจเต้นผิดปกติ และอาจเกิดการเจ็บปวดบริเวณแขน ขา หรือส่วนอื่นใดที่ใช้ในการเล่นทิเบตโยคะ เป็นต้น หากท่านเกิดอาการดังกล่าว ผู้วิจัยจะยุติการรวบรวมข้อมูล และถูกส่งไปยังหน่วยบริการสาธารณสุขที่ใกล้ที่สุดเพื่อขอความช่วยเหลือจากเจ้าหน้าที่สาธารณสุข และรับผิดชอบค่าใช้จ่ายที่เกิดขึ้นจากการรักษาตามสิทธิการรักษาของท่าน

ในการศึกษานี้มีผู้เข้าร่วมโครงการนี้จำนวน 64 คน และจะแบ่งกลุ่มออกเป็น 2 กลุ่ม จำนวนกลุ่มละ 32 คน ทั้งนี้ได้กำหนดให้ผู้เข้าร่วมวิจัยที่อาศัยอยู่ในชุมน หมู่ 9 ต.ละหาร อ.บางบัวทอง จ.นนทบุรี จัดเป็น 2 กลุ่มโดยวิธีการสุ่มอย่างเป็นระบบ โดยเป็นกลุ่มที่ได้รับโปรแกรมการออกกำลังกายทิเบตโยคะ และกลุ่มที่ได้รับแผ่นพับความรู้เกี่ยวกับอาการวัยทองและการปฏิบัติตนในการดำเนินชีวิต

4. กระบวนการการวิจัยมีขั้นตอนดังนี้

4.1. ท่านจะได้รับการเชิญชวนโดยวาจาจากทีมนักวิจัย และจะได้รับข้อมูล รายละเอียดของโครงการ ประโยชน์ที่ได้รับและผลกระทบที่อาจจะเกิดขึ้นจากโครงการวิจัย เมื่อท่านรับทราบ

และยินยอมเข้าร่วมงานวิจัยจะขอให้ท่านลงชื่อในใบยินยอมของกลุ่มประชากรหรือผู้มีส่วนร่วมในการวิจัย

4.2. ในการประเมินอาการวัยทอง ท่านจะได้ถูกสอบถามเกี่ยวกับข้อมูลทั่วไป และแบบสอบถามอาการวัยทองของกรมอนามัย กระทรวงสาธารณสุข และตรวจประเมินน้ำหนัก ส่วนสูง และประเมินคุณภาพชีวิต ซึ่งจะทำที่นัดหมาย ณ บริเวณลานกิจกรรมของชุมชน ในช่วงเวลาหลังเลิกงาน โดยใช้เวลา 15-20 นาที

4.3. สำหรับกลุ่มศึกษาวิจัย

4.3.1. ท่านจะได้รับโปรแกรมออกกำลังกายทิเบตโยคะ ร่วมกับแผ่นพับความรู้อาการวัยทอง โดยในครั้งแรกท่านจะได้รับโปรแกรมออกกำลังกายจากผู้วิจัยและครูสอนโยคะ ณ ลานกิจกรรม

4.3.2. ในวันแรก (สัปดาห์ที่ 0) ของโครงการวิจัยนี้ ท่านจะได้รับการประเมินอาการวัยทอง ประเมินคุณภาพชีวิต สอบถามข้อมูลทั่วไป วัดส่วนสูง ชั่งน้ำหนัก และเจาะเลือดปริมาณ 6 มิลลิลิตร เพื่อตรวจหาฮอร์โมนเอสโตรเจน โดยผู้เชี่ยวชาญ โดยใช้เวลาประมาณ 30 นาที

4.3.3. การออกกำลังกายด้วยทิเบตโยคะทั้งหมด 11 สัปดาห์ โดยสัปดาห์ที่ 1 - สัปดาห์ที่ 11 ของโครงการวิจัยนี้ ท่านจะได้รับการออกกำลังกายด้วยทิเบตโยคะ 3 วันต่อสัปดาห์ ในวันจันทร์ วันพุธ และวันศุกร์ ครั้งละประมาณ 30 นาที เวลา 17.30-18.00 น. ณ ลานกิจกรรมชุมชนหมู่ 9 ต.ละหาร อ.บางบัวทอง จ.นนทบุรี

4.3.4. ในสัปดาห์ที่ 12 ของโครงการวิจัยนี้ ท่านจะได้รับการประเมินอาการวัยทอง โดยการประเมินนี้จะใช้เวลาประมาณ 10-15 นาที

4.3.5. ในสัปดาห์ที่ 16 ของโครงการวิจัยนี้ ท่านจะได้รับการประเมินอาการวัยทอง ประเมินคุณภาพชีวิต สอบถามข้อมูลทั่วไป วัดส่วนสูง ชั่งน้ำหนัก และเจาะเลือดปริมาณ 6 มิลลิลิตร เพื่อตรวจหาฮอร์โมนเอสโตรเจน โดยผู้เชี่ยวชาญใช้เวลาประมาณ 30 นาที

4.4. เมื่อเสร็จสิ้นการวิจัย และวิเคราะห์ผลการวิจัยเสร็จแล้ว ข้อมูลต่าง ๆ ที่เกี่ยวข้องกับท่าน ได้แก่ ข้อมูลส่วนตัว ผลการตรวจระดับฮอร์โมนในเลือด จะถูกทำลายทันที

5. กระบวนการให้ข้อมูลแก่กลุ่มประชากรหรือผู้มีส่วนร่วมในการวิจัยจะดำเนินการโดยทีมนักวิจัยที่ได้รับการฝึกฝน เพื่อให้เป็นรูปแบบ หรือแนวทางเดียวกัน และท่านสามารถสอบถามข้อมูลที่เกี่ยวข้องกับโครงการวิจัยจนเข้าใจ เพื่อใช้ประกอบการตัดสินใจในการยินยอมเข้าร่วมงานวิจัย

6. ในกรณี หากพบว่าท่านไม่อยู่ในเกณฑ์คัดเข้า และอยู่ในสภาวะที่สมควรได้รับความช่วยเหลือ/แนะนำ ผู้วิจัยจะแนะนำการดูแลตัวเองเบื้องต้น หรือส่งท่านต่อไปยัง แพทย์หรือผู้เชี่ยวชาญที่เกี่ยวข้องกับสภาวะของท่าน

7. อันตรายหรือความเสี่ยงที่อาจเกิดขึ้นในโครงการวิจัยนี้มีน้อย เนื่องจากโปรแกรมการออกกำลังกายทิเบตโยคะเป็นโปรแกรมที่ได้รับการฝึกฝน และดูแลความปลอดภัยโดยผู้เชี่ยวชาญ รวมถึงสถานที่ และอุปกรณ์ในการออกกำลังกายด้วยทิเบตโยคะเป็นอุปกรณ์ที่มีมาตรฐานจากครูโยคะ และผู้วิจัย ซึ่งจะสอนแสดง และอธิบายท่าทางการออกกำลังกายทิเบตโยคะนี้จนกว่าท่านจะเข้าใจ ร่วมถึงชี้แจงถึงข้อห้าม ข้อควรระวังในการออกกำลังกาย ข้อสังเกตอาการผิดปกติต่าง ๆ เช่น อาการล้า อาการเจ็บปวดกล้ามเนื้อและการปฐมพยาบาลเบื้องต้นหากมีอาการผิดปกติ อย่างไรก็ตามตลอดโครงการวิจัยท่านจะได้รับคำแนะนำและการปฏิบัติที่ถูกวิธีจากครูโยคะ อีกทั้งความเสี่ยงในการเจาะเลือดมีน้อยมาก

โดยท่านอาจจะมีอาการปวดเมื่อย หรือรอยช้ำบริเวณที่เจาะเลือด ซึ่งไม่มีผลต่อการรักษาของท่านและเกิดอันตรายใด ๆ ซึ่งผู้เชี่ยวชาญจะแนะนำการรักษารอยช้ำดังกล่าวโดยการเจาะเลือดดังกล่าวจะทำโดยผู้เชี่ยวชาญเฉพาะด้านเท่านั้น ท่านอาจจะรู้สึกไม่สะดวก หรือไม่สบายใจในการ

สอบถามข้อมูลหรือตรวจประเมินร่างกาย ทั้งนี้ผู้วิจัยจะดำเนินการสอบถามข้อมูลหรือตรวจประเมินร่างกายของท่านในช่วงเวลาที่ท่านสะดวกในเวลาหลังเลิกงานเท่านั้น โดยจะไม่รบกวนเวลาการปฏิบัติงานของท่าน

8. ประโยชน์ในการเข้าร่วมวิจัยครั้งนี้ ผลการศึกษาอาจจะสามารถนำไปเพื่อพัฒนารูปแบบการออกกำลังกายทิเบตโยคะที่เหมาะสมในกลุ่มคนที่มีรูปแบบลักษณะงานที่คล้ายคลึงกัน อีกทั้งท่านจะได้รับคำแนะนำในการปฏิบัติตัวที่เหมาะสมต่อไป

9. การเข้าร่วมในการวิจัยของท่านเป็นโดยสมัครใจ และสามารถปฏิเสธที่จะเข้าร่วมหรือถอนตัวจากการวิจัยได้ทุกขณะ โดยไม่ต้องให้เหตุผลและไม่สูญเสียประโยชน์ที่พึงได้รับ

10. หากท่านมีข้อสงสัยให้สอบถามเพิ่มเติมได้โดยสามารถติดต่อผู้วิจัยได้ตลอดเวลา และหากผู้วิจัยมีข้อมูลเพิ่มเติมที่เป็นประโยชน์หรือโทษเกี่ยวกับการวิจัย ผู้วิจัยจะแจ้งให้ท่านทราบอย่างรวดเร็วเพื่อให้ผู้มีส่วนร่วมในการวิจัยทบทวนว่ายังสมัครใจจะอยู่ในงานวิจัยต่อไปหรือไม่

11. ข้อมูลที่เกี่ยวข้องกับท่านจะเก็บเป็นความลับ หากมีการเสนอผลการวิจัยจะเสนอเป็นภาพรวม ข้อมูลใดที่สามารถระบุถึงตัวท่านได้จะไม่ปรากฏในรายงาน เมื่อสิ้นสุดโครงการวิจัยข้อมูลของท่านจะถูกทำลายทันทีด้วยเครื่องทำลายเอกสาร และตัวอย่างเลือดจะถูกทำลายตามวิธีปฏิบัติมาตรฐานของห้องปฏิบัติการ

12. หลังเสร็จสิ้นงานวิจัยนี้ท่านจะได้รับของที่ระลึกเป็นเสื่อโยคะและผ้าขนหนูซับเหงื่อเป็นที่ระลึก และในการวิจัยนี้ท่านไม่ต้องเสียค่าใช้จ่ายใด ๆ ทั้งสิ้น

13. หากท่านไม่ได้รับการปฏิบัติตามข้อมูลดังกล่าวสามารถร้องเรียนได้ที่ คณะกรรมการพิจารณาจริยธรรมการวิจัยในคน กลุ่มสหสถาบัน ชุดที่ 1 จุฬาลงกรณ์มหาวิทยาลัย 254 อาคารจามจุรี 1 ชั้น 2 ถนนพญาไท เขตปทุมวัน กรุงเทพฯ 10330 โทรศัพท์/โทรสาร 0-2218-3202 E-mail: eccu@chula.ac.th

Appendix B/2: Participant information sheet for the control group

ข้อมูลสำหรับกลุ่มประชากรหรือผู้มีส่วนร่วมในการวิจัย

สำหรับกลุ่มควบคุม

ชื่อโครงการวิจัย…ประสิทธิผลของทิเบตโยคะเพื่อลดกลุ่มอาการวัยหมดระดู และเสริมสร้างคุณภาพชีวิตในสตรีวัยใกล้หมดระดู: การทดลองแบบสุ่มและมีกลุ่มควบคุมในชุมชน

ชื่อผู้วิจัย…นางสาวณัฐสุภา อาจองค์….ตำแหน่ง…นิสิตปริญญาเอก ……..

สถานที่ติดต่อผู้วิจัย (ที่ทำงาน) …วิทยาลัยวิทยาศาสตร์สาธารณสุข จุฬาลงกรณ์มหาวิทยาลัย.....

(ที่บ้าน) ... 102/58 หมู่ 8 ต.บางเลน อ.บางใหญ่ จ.นนทบุรี 11140.....

โทรศัพท์ (ที่ทำงาน) ….....……ต่อ …..……. โทรศัพท์ที่บ้าน .....……

โทรศัพท์มือถือ ……087 782 6529…… E-mail : ……natsupa_14@hotmail.com…….

1. ท่านได้รับเกียรติให้เป็นตัวแทนของโครงการวิจัยนี้ ขอเรียนเชิญท่านเข้าร่วมในการวิจัย ก่อนที่ท่านจะตัดสินใจเข้าร่วมในการวิจัย มีความจำเป็นที่ท่านควรทำความเข้าใจว่างานวิจัยนี้ทำเพราะเหตุใด และเกี่ยวข้องกับอะไร กรุณาใช้เวลาในการอ่านข้อมูลต่อไปนี้อย่างละเอียดรอบคอบ และสอบถามข้อมูลเพิ่มเติมหรือข้อมูลที่ไม่ชัดเจนได้ตลอดเวลา

2. เนื่องจากแนวโน้มการเพิ่มจำนวนของประชากรสตรีไทยที่เข้าสู่วัยหมดประจำเดือนมีมากขึ้น และต้องประสบกับการเปลี่ยนแปลงทั้งร่างกาย และอารมณ์ แม้ว่าจะเป็นการเปลี่ยนแปลงตามธรรมชาติ เช่น ระบบกระดูก ระบบประสาท ส่งผลให้เกิดอาการร้อนวูบวาบ เหงื่อออกตอน

กลางคืน ช่องคลอดแห้ง อารมณ์หงุดหงิด นอนไม่หลับ ซึ่งอาการดังกล่าวส่งผลต่อคุณภาพชีวิต หากหญิงวัยหมดประจำเดือนมีความรู้ และมีการออกกำลังกายด้วยทิเบตโยคะที่ถูกวิธี จะสามารถช่วยลดอาการเหล่านี้ได้ โครงการนี้จึงได้ออกแบบโปรแกรมการออกกำลังกายด้วยทิเบตโยคะ เป็นท่าทางการออกกำลังกายที่ง่าย ใช้เวลาไม่นาน มีผู้เชี่ยวชาญด้านโยคะในการฝึกปฏิบัติและดูแลความปลอดภัย และสามารถฝึกปฏิบัติได้ด้วยตนเอง

โครงการนี้มีวัตถุประสงค์เพื่อศึกษาโปรแกรมการออกกำลังกายทิเบตโยคะเพื่อลดอาการวัยทองในหญิงไทยวัยก่อนหมดประจำเดือน เพื่อเป็นแนวทางในการวางแผนแก้ไข หรือลดปัญหาอาการวัยทอง รวมถึงส่งเสริมคุณภาพชีวิตของหญิงไทยวัยก่อนหมดประจำเดือน

3. รายละเอียดของกลุ่มประชากรหรือผู้มีส่วนร่วมในการวิจัย

ท่านได้รับเชิญให้เข้าร่วมโครงการนี้เนื่องจากท่านมีลักษณะตรงตามกลุ่มประชากรหรือผู้มีส่วนร่วมในการวิจัย ซึ่งมีเกณฑ์ดังนี้

- เกณฑ์คัดเข้า
  - หญิงไทยวัยก่อนหมดประจำเดือน อายุระหว่าง 45-55 ปี ที่อาศัยในชุมชนหมู่ 9 ต.ละหาร อ.บางบัวทอง จ.นนทบุรี ผ่านเกณฑ์การประเมินอาการวัยทอง โดยมีคะแนนมากกว่า 15 คะแนน
  - ไม่มีประวัติการป่วยด้วยโรคเบาหวาน โรคความดันโลหิตสูง และโรคหัวใจ
  - ไม่ได้รับการออกกำลังกายอย่างเป็นระบบ หรือได้รับการออกกำลังกายด้วยโปรแกรมโยคะในช่วง 6 เดือนที่ผ่านมา

- ยินยอมเข้าร่วมโครงการวิจัย โดยการลงนามในเอกสารยินยอมเข้าร่วมโครงการวิจัย

● เกณฑ์การคัดออก

- มีประวัติการผ่าตัดเข่า
- มีประวัติการผ่าตัดมดลูก หรือเยื่อบุโพรงมดลูก
- อยู่ในระหว่างการได้รับฮอร์โมนทุกชนิด
- ไม่สามารถเข้าร่วมโครงการได้มากกว่าร้อยละ 80 หรือขาดเกิน 3 ครั้ง

ในการศึกษานี้มีผู้เข้าร่วมโครงการนี้จำนวน 64 คน และจะแบ่งกลุ่มออกเป็น 2 กลุ่ม จำนวนกลุ่มละ 32 คน ทั้งนี้ได้กำหนดให้ผู้เข้าร่วมวิจัยที่อาศัยในชุมชน หมู่ 9 ต.ละหาร อ.บางบัวทอง จ.นนทบุรี จัดเป็น 2 กลุ่มโดยวิธีการสุ่มอย่างเป็นระบบ โดยเป็นกลุ่มที่ได้รับโปรแกรมการออกกำลังกายทิเบตโยคะ และกลุ่มที่ได้รับแผ่นพับความรู้เกี่ยวกับอาการวัยทองและการปฏิบัติตนในการดำเนินชีวิต

4. กระบวนการการวิจัยมีขั้นตอนดังนี้

4.1. ท่านจะได้รับการเชิญชวนโดยวาจาจากทีมนักวิจัย และจะได้รับข้อมูล รายละเอียดของโครงการ ประโยชน์ที่ได้รับและผลกระทบที่อาจจะเกิดขึ้นจากโครงการวิจัย เมื่อท่านรับทราบและยินยอมเข้าร่วมงานวิจัยจะขอให้ท่านลงชื่อในใบยินยอมของกลุ่มประชากรหรือผู้มีส่วนร่วมในการวิจัย

4.2. ในการประเมินอาการวัยทอง ท่านจะได้ถูกสอบถามเกี่ยวกับข้อมูลทั่วไป และแบบสอบถามอาการวัยทองของกรมอนามัย กระทรวงสาธารณสุข และตรวจประเมินน้ำหนักส่วนสูง และประเมินคุณภาพชีวิต ซึ่งจะทำที่นัดหมาย ณ ลานกิจกรรม ชุมชนหมู่ 9 ต.ละหาร อ.บางบัวทอง จ.นนทบุรีในช่วงเวลาหลังเลิกงาน โดยใช้เวลา 15-20 นาที

4.3. สำหรับกลุ่มควบคุม

สำหรับกลุ่มควบคุม ท่านจะได้รับการให้ความรู้เกี่ยวกับอาการวัยทอง และแผ่นพับความรู้จากผู้วิจัยและได้รับคำแนะนำในการดูแลสุขภาพทั่วไปจากผู้วิจัยในวันแรกของการตรวจประเมินโดยใช้เวลา 10 -15 นาที

4.4. ในวันแรก (สัปดาห์ที่ 0) ของโครงการวิจัยนี้ ท่านจะได้รับการประเมินอาการวัยทอง ประเมินคุณภาพชีวิต สอบถามข้อมูลทั่วไป วัดส่วนสูง ชั่งน้ำหนัก และเจาะเลือดปริมาณ 6 มิลลิลิตร เพื่อตรวจหาฮอร์โมนเอสโตรเจน โดยผู้เชี่ยวชาญ ใช้เวลาประมาณ 30 นาที

4.5. ในสัปดาห์ที่ 12 ของโครงการวิจัยนี้ ท่านจะได้รับการประเมินอาการวัยทอง โดยการประเมินนี้จะใช้เวลาประมาณ 10-15 นาที

4.6. ในสัปดาห์ที่ 16 ของโครงการวิจัยนี้ ท่านจะได้รับการประเมินอาการวัยทอง ประเมินคุณภาพชีวิต สอบถามข้อมูลทั่วไป วัดส่วนสูง ชั่งน้ำหนัก และเจาะเลือดปริมาณ 6 มิลลิลิตร เพื่อตรวจหาฮอร์โมนเอสโตรเจน โดยผู้เชี่ยวชาญใช้เวลาประมาณ 30 นาที

4.7. เมื่อเสร็จสิ้นการวิจัยแล้วข้อมูลต่าง ๆ ที่เกี่ยวข้องกับท่าน ได้แก่ ข้อมูลส่วนตัว และผลการตรวจระดับฮอร์โมนในเลือด จะถูกทำลายทันที

5. กระบวนการให้ข้อมูลแก่กลุ่มประชากรหรือผู้มีส่วนร่วมในการวิจัยจะดำเนินการโดยทีมนักวิจัยที่ได้รับการฝึกฝน เพื่อให้เป็นรูปแบบ หรือแนวทางเดียวกัน และท่านสามารถสอบถามข้อมูลที่เกี่ยวข้องกับโครงการวิจัยจนเข้าใจ เพื่อใช้ประกอบการตัดสินใจในการยินยอมเข้าร่วมงานวิจัย

6. ในกรณี หากพบว่าท่านไม่อยู่ในเกณฑ์คัดเข้า และอยู่ในสภาวะที่สมควรได้รับความช่วยเหลือ/แนะนำ ผู้วิจัยจะแนะนำการดูแลตัวเองเบื้องต้น หรือส่งท่านต่อไปยัง แพทย์หรือผู้เชี่ยวชาญที่เกี่ยวข้องกับสภาวะของท่าน

7. **อันตราย**หรือ**ความเสี่ยง**ที่อาจเกิดขึ้นในโครงการวิจัยนี้มีน้อย เนื่องจากโปรแกรมการออกกำลังกายทิเบตโยคะเป็นโปรแกรมที่ได้รับการฝึกฝน และดูแลความปลอดภัยโดยผู้เชี่ยวชาญ รวมถึงสถานที่ และอุปกรณ์ในการออกกำลังกายด้วยทิเบตโยคะเป็นอุปกรณ์ที่มีมาตรฐานจากครู

โยคะ และผู้วิจัย ซึ่งจะสอนแสดง และอธิบายท่าทางการออกกำลังกายทิเบตโยคะนี้จนกว่าท่านจะเข้าใจ ร่วมถึงชี้แจงถึงข้อห้าม ข้อควรระวังในการออกกำลังกาย ข้อสังเกตอาการผิดปกติต่าง ๆ เช่น อาการล้า อาการเจ็บปวดกล้ามเนื้อและการปฐมพยาบาลเบื้องต้นหากมีอาการผิดปกติ อย่างไรก็ตามตลอดโครงการวิจัยท่านจะได้รับคำแนะนำและการปฏิบัติที่ถูกวิธีจากครูโยคะ อีกทั้งความเสี่ยงในการเจาะเลือดมีน้อยมาก โดยท่านอาจจะมีอาการปวดเมื่อย หรือรอยช้ำบริเวณที่เจาะเลือด ซึ่งไม่มีผลต่อการรักษาของท่านและเกิดอันตรายใด ๆ ซึ่งผู้เชี่ยวชาญจะแนะนำการรักษารอยช้ำดังกล่าวโดยการเจาะเลือดดังกล่าวจะทำโดยผู้เชี่ยวชาญเฉพาะด้านเท่านั้น

ท่านอาจจะรู้สึกไม่สะดวก หรือไม่สบายใจในการสอบถามข้อมูลหรือตรวจประเมินร่างกาย ทั้งนี้ผู้วิจัยจะดำเนินการสอบถามข้อมูลหรือตรวจประเมินร่างกายของท่านในช่วงเวลาที่ท่านสะดวกในเวลาหลังเลิกงานเท่านั้น โดยจะไม่รบกวนเวลาการปฏิบัติงานของท่าน

8. ประโยชน์ในการเข้าร่วมวิจัยครั้งนี้ ผลการศึกษาอาจจะสามารถนำไปเพื่อพัฒนารูปแบบการออกกำลังกายทิเบตโยคะที่เหมาะสมในกลุ่มคนที่มีรูปแบบลักษณะงานที่คล้ายคลึงกัน อีกทั้งท่านจะได้รับคำแนะนำในการปฏิบัติตัวที่เหมาะสมต่อไป

9. การเข้าร่วมในการวิจัยของท่านเป็นโดย**สมัครใจ** และสามารถ**ปฏิเสธ**ที่จะเข้าร่วมหรือ**ถอนตัว** จากการวิจัยได้ทุกขณะ โดยไม่ต้องให้เหตุผลและไม่สูญเสียประโยชน์ที่พึงได้รับ

10. หากท่านมีข้อสงสัยให้สอบถามเพิ่มเติมได้โดยสามารถติดต่อผู้วิจัยได้ตลอดเวลา และหากผู้วิจัยมีข้อมูลเพิ่มเติมที่เป็นประโยชน์หรือโทษเกี่ยวกับการวิจัย ผู้วิจัยจะแจ้งให้ท่านทราบอย่างรวดเร็วเพื่อให้ผู้มีส่วนร่วมในการวิจัยทบทวนว่ายังสมัครใจจะอยู่ในงานวิจัยต่อไปหรือไม่

11. ข้อมูลที่เกี่ยวข้องกับท่านจะเก็บเป็น**ความลับ** หากมีการเสนอผลการวิจัยจะเสนอเป็นภาพรวมข้อมูลใดที่สามารถระบุถึงตัวท่านได้จะไม่ปรากฏในรายงาน เมื่อสิ้นสุดโครงการวิจัยข้อมูลของท่านจะถูกทำลายทันทีด้วยเครื่องทำลายเอกสาร และตัวอย่างเลือดจะถูกทำลายตามวิธีปฏิบัติมาตรฐานของห้องปฏิบัติการ

12. หลังเสร็จสิ้นงานวิจัยนี้ท่านจะได้รับของที่ระลึกเป็นเสื่อโยคะและผ้าขนหนูซับเหงื่อเป็นที่ระลึก และในการวิจัยนี้ท่านไม่ต้องเสียค่าใช้จ่ายใด ๆ ทั้งสิ้น

13. หากท่านไม่ได้รับการปฏิบัติตามข้อมูลดังกล่าวสามารถร้องเรียนได้ที่ คณะกรรมการพิจารณาจริยธรรมการวิจัยในคน กลุ่มสหสถาบัน ชุดที่ 1 จุฬาลงกรณ์มหาวิทยาลัย 254 อาคาร

จามจุรี 1 ชั้น 2 ถนนพญาไท เขตปทุมวัน กรุงเทพฯ 10330 โทรศัพท์/โทรสาร 0-2218-3202 E-mail: eccu@chula.ac.th

Appendix C/1: Consent form for the intervention group

หนังสือแสดงความยินยอมเข้าร่วมการวิจัย

สำหรับกลุ่มออกกำลังกาย

ทำที่.....

วันที่.....เดือน.....พ.ศ. .....

เลขที่ ประชากรตัวอย่างหรือผู้มีส่วนร่วมในการวิจัย…..……

ข้าพเจ้า ซึ่งได้ลงนามท้ายหนังสือนี้ ขอแสดงความยินยอมเข้าร่วมโครงการวิจัย ชื่อโครงการวิจัย .....ประสิทธิผลของทิเบตโยคะเพื่อลดกลุ่มอาการวัยหมดระดู และเสริมสร้างคุณภาพชีวิตในสตรีวัยใกล้หมดระดู: การทดลองแบบสุ่มและมีกลุ่มควบคุมในชุมชน.....

ชื่อผู้วิจัย …นางสาวณัฐสุภา อาจองค์……..

ที่อยู่ที่ติดต่อ ..... 102/58 หมู่ 8 ต.บางเลน อ.บางใหญ่ จ.นนทบุรี 11140....โทรศัพท์ .... 087 782 6529.....

ข้าพเจ้า ได้รับทราบรายละเอียดเกี่ยวกับที่มาและวัตถุประสงค์ในการทำวิจัย รายละเอียดขั้นตอนต่าง ๆ ที่จะต้องปฏิบัติหรือได้รับการปฏิบัติ ความเสี่ยง/อันตราย และประโยชน์ซึ่งจะเกิดขึ้นจากการวิจัยเรื่องนี้ โดยได้อ่านรายละเอียดในเอกสารชี้แจงผู้เข้าร่วมการวิจัยโดยตลอด และได้รับคำอธิบายจากผู้วิจัย จนเข้าใจเป็นอย่างดีแล้ว

ข้าพเจ้าจึงสมัครใจเข้าร่วมในโครงการวิจัยนี้ ตามที่ระบุไว้ในเอกสารชี้แจงผู้เข้าร่วมการวิจัย ซึ่งโครงการนี้ใช้เวลาทั้งสิ้น 16 สัปดาห์ โดยข้าพเจ้ายินยอมเข้าร่วมการวิจัยโดยในวันแรก ของโครงการวิจัยนี้ ข้าพเจ้าจะได้รับโปรแกรมออกกำลังกายทิเบตโยคะ ร่วมกับแผ่นพับความรู้อาการวัยทอง โดยในครั้งแรกจะได้รับโปรแกรมออกกำลังกายจากผู้วิจัยและครูสอนโยคะ ณ ลานกิจกรรม และข้าพเจ้ายินยอมให้ผู้วิจัยประเมินอาการวัยทอง ประเมินคุณภาพชีวิต สอบถามข้อมูลทั่วไป วัดส่วนสูง ชั่งน้ำหนัก และเจาะเลือดปริมาณ 6 มิลลิลิตร เพื่อตรวจหาฮอร์โมนเอสโตรเจน โดยผู้เชี่ยวชาญ โดยใช้เวลาประมาณ 30 นาที โดยสัปดาห์ที่ 1 - สัปดาห์ที่ 11 ของโครงการวิจัยนี้ ข้าพเจ้าจะได้รับการออกกำลังกายด้วยทิเบตโยคะ 3 วันต่อสัปดาห์ ในวันจันทร์ วันพุธ และวันศุกร์ ครั้งละประมาณ 30 นาที เวลา 17.30-18.00 น. ณ ลานกิจกรรม ชุมชนหมู่ 9 ต.ละหาร อ.บางบัวทอง จ.นนทบุรี ในสัปดาห์ที่ 12 ของโครงการวิจัยนี้ ข้าพเจ้ายินยิมให้มีการประเมินอาการวัยทอง ใช้เวลาประมาณ 10-15 นาที และในวันสุดท้ายของโครงการวิจัย (สัปดาห์ที่ 16) ข้าพเจ้าจะได้รับการประเมินอาการวัยทอง ประเมินคุณภาพชีวิต สอบถามข้อมูลทั่วไป วัดส่วนสูง ชั่งน้ำหนัก และเจาะ

เลือดปริมาณ 6 มิลลิลิตร เพื่อตรวจหาฮอร์โมนเอสโตรเจน โดยผู้เชี่ยวชาญใช้เวลาประมาณ 30 นาที เมื่อเสร็จสิ้นการวิจัยแล้วข้อมูลที่เกี่ยวข้องกับผู้มีส่วนร่วมในการวิจัยจะถูกทำลาย

ข้าพเจ้ามีสิทธิถอนตัวออกจากการวิจัยเมื่อใดก็ได้ตามความประสงค์ โดยไม่ต้องแจ้งเหตุผล ซึ่งการถอนตัวออกจากการวิจัยนั้น จะไม่มีผลกระทบในทางใด ๆ ต่อข้าพเจ้าทั้งสิ้น

ข้าพเจ้าได้รับคำรับรองว่า ผู้วิจัยจะปฏิบัติต่อข้าพเจ้าตามข้อมูลที่ระบุไว้ในเอกสารชี้แจงผู้เข้าร่วมการวิจัย และข้อมูลใด ๆ ที่เกี่ยวข้องกับข้าพเจ้า ผู้วิจัยจะเก็บรักษาเป็นความลับ โดยจะนำเสนอข้อมูลการวิจัยเป็นภาพรวมเท่านั้น ไม่มีข้อมูลใดในการรายงานที่จะนำไปสู่การระบุตัวข้าพเจ้า

หากข้าพเจ้าไม่ได้รับการปฏิบัติตรงตามที่ได้ระบุไว้ในเอกสารชี้แจงผู้เข้าร่วมการวิจัย ข้าพเจ้าสามารถร้องเรียนได้ที่คณะกรรมการพิจารณาจริยธรรมการวิจัยในคน กลุ่มสหสถาบัน ชุดที่ 1 จุฬาลงกรณ์มหาวิทยาลัย 254 อาคารจามจุรี 1 ชั้น 2 ถนนพญาไท เขตปทุมวัน กรุงเทพฯ 10330 โทรศัพท์/โทรสาร 0-2218-3202

E-mail: eccu@chula.ac.th

ข้าพเจ้าได้ลงลายมือชื่อไว้เป็นสำคัญต่อหน้าพยาน ทั้งนี้ข้าพเจ้าได้รับสำเนาเอกสารชี้แจงผู้เข้าร่วมการวิจัย และสำเนาหนังสือแสดงความยินยอมไว้แล้ว

ลงชื่อ.....	ลงชื่อ.....
(นางสาวณัฐสุภา อาจองค์)	(.....)
ผู้วิจัยหลัก	ผู้มีส่วนร่วมในการวิจัย

ลงชื่อ.....

(.....)

พยาน

Appendix C/2: Consent form for the control group

หนังสือแสดงความยินยอมเข้าร่วมการวิจัย

สำหรับกลุ่มควบคุม

ทำที่.....

วันที่ .....เดือน .....พ.ศ. .....

เลขที่ ประชากรตัวอย่างหรือผู้มีส่วนร่วมในการวิจัย…..……

ข้าพเจ้า ซึ่งได้ลงนามท้ายหนังสือนี้ ขอแสดงความยินยอมเข้าร่วมโครงการวิจัย ชื่อโครงการวิจัย .....ประสิทธิผลของทิเบตโยคะเพื่อลดกลุ่มอาการวัยหมดระดู และเสริมสร้างคุณภาพชีวิตในสตรีวัยใกล้หมดระดู: การทดลองแบบสุ่มและมีกลุ่มควบคุมในชุมชน.....

ชื่อผู้วิจัย …นางสาวณัฐสุภา อาจองค์……..

ที่อยู่ที่ติดต่อ ... 102/58 หมู่ 8 ต.บางเลน อ.บางใหญ่ จ.นนทบุรี 11140.....โทรศัพท์ ... 087 782 6529.....

ข้าพเจ้า ได้รับทราบรายละเอียดเกี่ยวกับที่มาและวัตถุประสงค์ในการทำวิจัย รายละเอียดขั้นตอนต่าง ๆ ที่จะต้องปฏิบัติหรือได้รับการปฏิบัติ ความเสี่ยง/อันตราย และประโยชน์ซึ่งจะเกิดขึ้นจากการวิจัยเรื่องนี้ โดยได้อ่านรายละเอียดในเอกสารชี้แจงผู้เข้าร่วมการวิจัยโดยตลอด และได้รับคำอธิบายจากผู้วิจัย จนเข้าใจเป็นอย่างดีแล้ว

ข้าพเจ้าจึงสมัครใจเข้าร่วมในโครงการวิจัยนี้ ตามที่ระบุไว้ในเอกสารชี้แจงผู้เข้าร่วมการวิจัย ซึ่งโครงการนี้ใช้เวลาทั้งสิ้น 16 สัปดาห์ โดยข้าพเจ้ายินยอมเข้าร่วมการวิจัยโดยในวันแรก ของโครงการวิจัยนี้ ข้าพเจ้าจะได้รับการให้ความรู้เกี่ยวกับอาการวัยทอง และแผ่นพับความรู้จากผู้วิจัย และได้รับคำแนะนำในการดูแลสุขภาพทั่วไปจากผู้วิจัยในวันแรก และข้าพเจ้ายินยอมให้ผู้วิจัยประเมินอาการวัยทอง ประเมินคุณภาพชีวิต สอบถามข้อมูลทั่วไป วัดส่วนสูง ชั่งน้ำหนัก และเจาะเลือดปริมาณ 6 มิลลิลิตร เพื่อตรวจหาฮอร์โมนเอสโตรเจน โดยผู้เชี่ยวชาญ ในสัปดาห์ที่ 12 ของโครงการวิจัยนี้ ข้าพเจ้ายินยิมให้มีการประเมินอาการวัยทอง ใช้เวลาประมาณ 10-15 นาที และในวันสุดท้ายของโครงการวิจัย (สัปดาห์ที่ 16) ข้าพเจ้าจะได้รับการประเมินอาการวัยทอง ประเมินคุณภาพชีวิต สอบถามข้อมูลทั่วไป วัดส่วนสูง ชั่งน้ำหนัก และเจาะเลือดปริมาณ 6 มิลลิลิตร เพื่อตรวจหาฮอร์โมนเอสโตรเจน โดยผู้เชี่ยวชาญใช้เวลาประมาณ 30 นาที เมื่อเสร็จสิ้นการวิจัยแล้วข้อมูลที่เกี่ยวข้องกับผู้มีส่วนร่วมในการวิจัยจะถูกทำลาย

ข้าพเจ้ามีสิทธิถอนตัวออกจากการวิจัยเมื่อใดก็ได้ตามความประสงค์ โดยไม่ต้องแจ้งเหตุผล ซึ่งการถอนตัวออกจากการวิจัยนั้น จะไม่มีผลกระทบในทางใด ๆ ต่อข้าพเจ้าทั้งสิ้น

ข้าพเจ้าได้รับคำรับรองว่า ผู้วิจัยจะปฏิบัติต่อข้าพเจ้าตามข้อมูลที่ระบุไว้ในเอกสารชี้แจงผู้เข้าร่วมการวิจัย และข้อมูลใด ๆ ที่เกี่ยวข้องกับข้าพเจ้า ผู้วิจัยจะเก็บรักษาเป็นความลับ โดยจะนำเสนอข้อมูลการวิจัยเป็นภาพรวมเท่านั้น ไม่มีข้อมูลใดในการรายงานที่จะนำไปสู่การระบุตัวข้าพเจ้า

หากข้าพเจ้าไม่ได้รับการปฏิบัติตรงตามที่ได้ระบุไว้ในเอกสารชี้แจงผู้เข้าร่วมการวิจัย ข้าพเจ้าสามารถร้องเรียนได้ที่คณะกรรมการพิจารณาจริยธรรมการวิจัยในคน กลุ่มสหสถาบัน ชุดที่ 1 จุฬาลงกรณ์มหาวิทยาลัย 254 อาคารจามจุรี 1 ชั้น 2 ถนนพญาไท เขตปทุมวัน กรุงเทพฯ 10330 โทรศัพท์/โทรสาร 0-2218-3202

E-mail: eccu@chula.ac.th

ข้าพเจ้าได้ลงลายมือชื่อไว้เป็นสำคัญต่อหน้าพยาน ทั้งนี้ข้าพเจ้าได้รับสำเนาเอกสารชี้แจงผู้เข้าร่วมการวิจัย และสำเนาหนังสือแสดงความยินยอมไว้แล้ว

ลงชื่อ..... ลงชื่อ.....

(นางสาวณัฐสุภา อาจองค์) (.....)

ผู้วิจัยหลัก ผู้มีส่วนร่วมในการวิจัย

ลงชื่อ.....

(.....)

พยาน

Appendix D/1: Questionnaire on Screening Climacteric Symptoms (Thai version)

ID _____

DD/MM/YYYY of Interview ____/____/____

Screening Climacteric symptoms

คำชี้แจง: *ในระยะเวลา 1 เดือนที่ผ่านมา ท่านมีอาการต่อไปนี้มากน้อยเพียงใด โปรดทำเครื่องหมาย ☒ ลงในช่องแสดงระดับอาการที่เกิดขึ้นกับตัวท่านตามความเป็นจริงมากที่สุด*

อาการ	ไม่ มีอาการ (0)	มีอาการเล็กน้อย (1)	มีอาการปากลาง (2)	มีอาการมาก (3)
1.ร้อนวูบวาบตามตัวและหน้าอก				
2.เหงื่อออกมากช่วงกลางคืน				
3.ปวดศีรษะ				
4.อารมณ์แปรปรวน				
5.หงุดหงิด				
6.รู้สึกถูกทอดทิ้ง				
7.กระวนกระวายใจ				
8.นอนไม่หลับ				
9.รู้สึกเหนื่อยง่าย				
10.ปวดหลัง				
11.ปวดตามข้อต่าง ๆ				
12.ปวดกล้ามเนื้อ				
13.ผิวหนังแห้ง				
14.ช่องคลอดแห้ง				
15.เจ็บเวลาร่วมเพศ				
16.ไม่มีความสุขทางเพศ				
17.เบื่อและไม่สนใจทางเพศ				
18.ปัสสาวะแสบ				
19.ปัสสาวะบ่อย				
20.ปัสสาวะเล็ดหรือกลั้นปัสสาวะลำบาก				

รวมคะแนน

Appendix D/2: Socio-demographic characteristics (Thai version)

ID _____

DD/MM/YYYY of Interview ____/____/____

ส่วนที่ 1: ข้อมูลทั่วไป		
1. อายุ ณ วันที่สัมภาษณ์ ..... ปี		
2. สถานภาพสมรส	☐[1] โสด	☐[2] แต่งงาน
	☐[3] หย่าร้าง/แยกกันอยู่	☐[4] หม้าย
3. การศึกษา	☐[1] ประถมศึกษา ☐[3] อนุปริญญา/ประกาศนียบัตร ☐[5] สูงกว่าปริญญาตรี	☐[2] มัธยมศึกษา ☐[4] ปริญญาตรี
4. รายได้ (บาท/เดือน)		
	☐[1] น้อยกว่า 10,000	☐[2] 10,001-20,000
	☐[3] 20,001-30,000	☐[4] มากกว่า 30,000
5. สูงเท่าไหร่?		
	.....	(เซนติเมตร)
6. น้ำหนักเท่าไหร่?		
	.....	(กิโลกรัม)
7. คุณเคยสูบบุหรี่ หรือไม่?		
	☐[1] สูบ ..... (อายุ)	☐[2] ไม่สูบ
8. ภาวะเจ็บป่วย/ภาวะสุขภาพ (ปวดหลัง หรือปวดคอ, มีอาการปวดหัว และอาการปวดเรื้อรัง)		
คุณมีปัญหาสุขภาพ หรือมีอาการเจ็บป่วยหรือไม่.		
	☐[1] มี (ระบุ).....	☐[2] ไม่มี

Appendix D/3: Case Record Form – Laboratory

ID _____
DD/MM/YYYY of Interview ____/____/____

Part 3: Case Record Form (Laboratory)

	Week 0	**Week12**	**Week16**
Tall (CENTIMETERS)			
Weigh (KILOGRAMS)			
BMI			
ESTROGEN			

Appendix D/4: World Health Organization Quality of Life -BREF-THAI

ID _____

DD/MM/YYYY of Interview ____/____/____

แบบวัดคุณภาพชีวิตขององค์การอนามัยโลกชุดย่อ ฉบับภาษาไทย

(WHOQOL-BREF-THAI)

คำชี้แจง ข้อคำถามต่อไปนี้จะถามถึงประสบการณ์อย่างใดอย่างหนึ่งของท่าน ในช่วง 2 สัปดาห์ที่ผ่านมา ให้ท่านสำรวจตัวเอง และประเมินเหตุการณ์ หรือความรู้สึกของท่าน แล้วทำเครื่องหมาย ✓ ในช่องคำตอบที่เหมาะสม และเป็นจริงกับตัวท่านมากที่สุด

คำตอบมี 5 ตัวเลือก คือ

ไม่เลย หมายถึง ท่านไม่มีความรู้สึกเช่นนั้นเลย รู้สึกไม่พอใจมาก หรือรู้สึกแย่มาก

เล็กน้อย หมายถึง ท่านมีความรู้สึกเช่นนั้นนาน ๆ ครั้ง รู้สึกเช่นนั้นเล็กน้อย รู้สึกไม่พอใจ หรือรู้สึกแย่

ปานกลาง หมายถึง ท่านมีความรู้สึกเช่นปานกลาง รู้สึกพอใจระดับปานกลาง หรือรู้สึกระดับปานกลาง

มาก หมายถึง ท่านมีความรู้สึกเช่นนั้นบ่อย ๆ รู้สึกเช่นนั้นมาก รู้สึกพอใจ หรือรู้สึกดี

มากที่สุด หมายถึง ท่านมีความรู้สึกเช่นนั้นเสมอ รู้สึกเช่นนั้นมากที่สุด หรือรู้สึกว่าสมบูรณ์ รู้สึกพอใจมาก รู้สึกดีมาก

ข้อที่	ในช่วง 2 สัปดาห์ที่ผ่านมา	ไม่เลย	เล็กน้อย	ปานกลาง	มาก	มากที่สุด
1	ท่านพอใจกับสุขภาพของท่านในตอนนี้เพียงใด					
2	การเจ็บปวดตามร่างกาย เช่น ปวดหัว ปวดท้อง ปวดตามตัว ทำให้ท่านไม่สามารถทำในสิ่งที่ต้องการมากน้อยเพียงใด					
3	ท่านมีกำลังเพียงพอที่จะทำสิ่งต่าง ๆ ในแต่ละวันไหม (ทั้งเรื่องงาน หรือการดำเนินชีวิตประจำวัน)					
4	ท่านพอใจกับการนอนหลับของท่านมากน้อยเพียงใด					
5	ท่านรู้สึกพึงพอใจในชีวิต (เช่น มีความสุข ความสงบ มีความหวัง) มากน้อยเพียงใด					
6	ท่านมีสมาธิในการทำงานต่าง ๆ ดีเพียงใด					

ข้อที่	ในช่วง 2 สัปดาห์ที่ผ่านมา	ไม่เลย	เล็กน้อย	ปาน กลาง	มาก	มาก ที่สุด
7	ท่านรู้สึกพอใจในตนเองมากน้อยแค่ไหน					
8	ท่านยอมรับรูปร่างหน้าตาของตัวเองได้ไหม					
9	ท่านมีความรู้สึกไม่ดี เช่น รู้สึกเหงา เศร้า หดหู่ สิ้นหวัง วิตกกังวล บ่อยแค่ไหน					
10	ท่านรู้สึกพอใจมากน้อยแค่ไหนที่สามารถทำอะไรๆ นไปได้ในแต่ละวัน					
11	ท่านจำเป็นต้องไปรับการรักษาพยาบาลมากน้อยเพียงใด เพื่อที่จะทำงาน หรือมีชีวิตอยู่ไปได้ในแต่ละวัน					
12	ท่านพอใจกับความสามารถในการทำงานได้อย่างที่เคย					
	ทำมามากน้อยเพียงใด					
13	ท่านพอใจกับการผูกมิตร หรือเข้ากับคนอื่นอย่างที่ผ่านมาแค่ไหน					
14	ท่านพอใจกับการช่วยเหลือที่เคยได้รับจากเพื่อนๆ แค่ไหน					
15	ท่านรู้สึกว่าชีวิตมีความมั่นคงปลอดภัยดีไหมในแต่ละวัน					
16	ท่านพอใจกับสภาพบ้านเรือนที่อยู่ตอนนี้มากน้อยเพียงใด					
17	ท่านมีเงินพอใช้จ่ายตามความจำเป็นมากน้อยเพียงใด					
18	ท่านพอใจที่จะสามารถไปใช้บริการสาธารณสุขได้ตามความจำเป็นเพียงใด					
19	ท่านได้รู้เรื่องราวข่าวสารที่จำเป็นในชีวิตแต่ละวันมากน้อยเพียงใด					
20	ท่านมีโอกาสได้ผ่อนคลายความเครียดมากน้อยเพียงใด					
21	สภาพแวดล้อมดีต่อสุขภาพของท่านมากน้อยเพียงใด					
22	ท่านพอใจกับการเดินทางไปไหนมาไหนของท่าน (หมายถึงการคมนาคม) มากน้อยเพียงใด					

ข้อที่	ในช่วง 2 สัปดาห์ที่ผ่านมา	ไม่เลย	เล็กน้อย	ปาน กลาง	มาก	มาก ที่สุด
23	ท่านรู้สึกว่าชีวิตของท่านมีความหมายมาก น้อยแค่ไหน					
24	ท่านสามารถไปไหนมาไหนด้วยตนเองได้ดี เพียงใด					
25	ท่านพอใจในชีวิตทางเพศของท่านแค่ไหน (ชีวิตทางเพศ หมายถึง เมื่อเกิดความรู้สึกทาง เพศขึ้นแล้ว ท่านมีวิธีจัดการให้ผ่อนคลายลง ได้ รวมถึงการช่วยตนเอง หรือการมี เพศสัมพันธ์)					
26	ท่านคิดว่าท่านมีคุณภาพชีวิต (ชีวิตความ เป็นอยู่) อยู่ในระดับใด					

Appendix E: Budget

Activity	Estimated expenses (THB)
Transportation	25,000
Office Equipment	10,000
Measurement tool	40,000
Printing and Photo copy	40,000
Data Collection	40,000
Research Assistant	40,000
Compensation Tibetan YOGA expert	50,000
Laboratory Test	20,000
Souvenir for Participants	40,000
Total	305,000

Appendix F: Photos of research coordination, data collection and intervention

Picture 1: Research coordination and planning with village head for participant screening, recruitment enrollment, intervention and data collection

Picture 2: Tibetan Yoga Intervention

Picture 3: Blood sample collection

VITA

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AWARD RECEIVED	Short Course Scholarship: The 8th Harvard Special Session 2019 At Graduate School of Public Health, Teikyo University, Tokyo,Japan