

## **Preliminary Outcomes and Safety of Menopausal Symptoms Treatment using Cannabis-containing Suksaiyat Formulation based on Thai Traditional Medicine Wisdom**

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### **ABSTRACT**

The objectives of this study were to study the cannabis-containing Suksaiyat formulation based on Thai traditional medicine wisdom and to study the preliminary outcomes and safety of menopausal symptoms treatment using cannabis-containing Suksaiyat formulation. This study was a qualitative research. The data were collected using in-depth interview, observation and focus group discussion from Thai Traditional Medical Cannabis Clinic, Phanatnikhom Hospital, ChonBuri Province, where Special Access Scheme (SAS) have been used as individual patient treatment. Data triangulation was conducted and the results were presented using descriptive statistics.

The results showed that Suksaiyat formulation listed in Vishnu's Medicine Scripture. This formulation contains 12 active ingredients with a total weight of 78 parts. The main ingredient with highest proportion is cannabis leaves, accounting for 12 parts. There were 2 groups of menopausal symptoms reported by the subjects: 1) pain in the muscles, tendons and bones. In this study, the symptoms showed improvement after 2 months of treatment. 2) neurological and circulatory symptoms included insomnia, hot flash, hot flash, loss of appetite (patients reported that these symptoms were improved within 1-2 weeks), dyspnea, weakness, irritable and vaginal dryness and atrophy. Treatment outcomes: 1) Suksaiyat is a thermal formulation with hypnotic, appetite stimulating, analgesic and anti-stress effects. Instructions: dissolve 0.5 g of this formulation in water and drink with 1 g of "Thepjit cordial". In this study, the treatment follow-up period was 1-3 months. 2) Thepjit cordial was used as a supplementary or aqueous adjuvant. Thepjit cordial consists of 48 active ingredients and is suitable for fainting and dizziness. 3) Acupressure point massage was performed at 4-5 points and the patients were asked to refrain from injurious foods such as sticky rice, bamboo shoot, offal, liquor and beer. For the safety of menopausal symptoms treatment using Suksaiyat formulation in a period of 1-3 months, it was found that the use of Suksaiyat formulation in combination with Thepjit cordial was safe without any adverse effects.

### **Keywords:**

treatment outcomes, safety, menopause, Suksaiyat formulation, cannabis

### **Introduction**

Local wisdom of health, traditional medicine and Thai traditional medicine are traditional health wisdoms and are considered the social capital and also a part of Thai community culture. The direction of health development must therefore comply with the community, culture, customs, beliefs and religions in order to lead to health self-reliance of the community and the country. Therefore, health can be considered as a human value and dignity and the promotion of all medicinal systems must be based on the basic principle that all levels of medicine have its value, dignity and equality. Each medical system is an alternative and supplementary to each other, aiming at the well-being and promotion of the self-reliance of people. In other words, the ultimate goal of all medical systems is to promote human health (PrasertAttohi, 2020: 1-2).

At present, “Thai society is an aging society”. According to the Strategic Plan for the Development of Health and Environmental Health Promotion System (2017-2021), people in the middle age (40-59 years), the driving force of the country's economy, are golden agers with health problems related to internal systems such as dental health, cardiovascular, and diabetes (Department of Health, 2016). According to the Postmenopausal Women's Health Center, Samitivej Hospital, the estimated average age of women in their menopause is 40 to 75 years. Nowadays, the number of elderly people is increasing, indicating that there will also be an increase in golden agers. It is also expected that in 2050, an average life expectancy for women and men will increase to 81 and 78 years, respectively. As a result, the population of postmenopausal women will increase from 27% to 45% (Samitivej Hospital, 2015). It can be seen that the changes and problems encountered in menopause are becoming increasingly common in all regions of the world. (Yang, 2016: 770-781).

Golden age is the inevitable stage of life and is commonly seen in women. In women of reproductive age, the body generally produces a sex hormone called estrogen, which is responsible for the development of sexual characteristics from girl to woman and plays a role in regulating the menstrual cycle and pregnancy. However, as a woman reaches the golden age, the functions of endocrine glands of the reproductive system rapidly deteriorates, resulting in structural and functional changes in the body and symptoms that affect emotional health as a result of decreased sex hormones. Such adverse reactions may lead to discomfort and affect the quality of life of postmenopausal women and the elderly. (SuratsawadeeSinwat, 2019: 37-49). The health problems caused by the effects of menopause depend on the women's health condition, including preparing for changes, figuring out how to manage the potential adverse reactions as well as self-care such as dietary supervision, regular exercise, vaginal muscle exercise, mental health promotion activities, family and social support. The management of these menopausal symptoms is aimed at alleviating the discomfort affecting the lifestyle of women in her golden age, a period when most women achieve family and professional success (PraweedaKhamdeang, 2020: 478).

Over the past three decades to the present, the general public, including in Thailand, has increasingly chosen various alternative medicines and there is a tremendous increase in the development of knowledge in this area. The use of medical cannabis is a form of alternative medicine which increasing application. Alternative medicine systems are one of the most important challenges, especially at the present where health problems are becoming more severe and linked to more psychological, socio-economic factors. At the same time, medical technology has evolved considerably at molecular and genetic levels. However, it has been found that there are a number of health problems that the use of modern medicine alone is still a stalemate and unable to cure and continually support the quality of life of patients. This has led many people to seek alternative health care to heal and promote their physical and mental health simultaneously (SupattraSriwanitchakorn, 2020: 4-6).

Menopausal symptoms can be treated by both modern medicine and Thai traditional medicine. As for Thai traditional medicine, there are several formulations and one of them is Suksaiyat formulation. Suksaiyat is one of 16 Thai traditional medicine formulations containing cannabis listed in Vishnu's Medicine Scripture, a Thai traditional medicine pharmacopoeia which mentioned that “Cure for all diseases, increase vitality and appetite and for better sleep”. The Department of Thai Traditional and Alternative Medicine has specified that this formulation can be used for better sleep, appetite stimulation and restoration of the patient's strength (Department of Thai Traditional and Alternative Medicine, 2019: 15-17). This formulation consists of **1-12** parts of herbs, the ingredient with lowest amount is camphor (1 part) and the highest was

cannabis leaves (12 parts). Cannabis is therefore important in this formulation, which has been commonly used in Thai traditional medicine, but there are no researches and trials on postmenopausal patients in public hospitals. Nowadays, the use of cannabis is of an interest of both public and private sectors as a component in the production of medicines for the treatment of many important diseases. Therefore, there is a need to study the preliminary outcomes and safety of menopausal symptoms treatment using cannabis-containing Suksaiyat formulation based on Thai traditional medicine wisdom. This is in order to build confidence and verify the treatment outcomes, as well as for drug formulation development and improvement to lead to a more widespread use of this formulation for menopausal symptoms treatment.

### **Objectives**

1. To study cannabis-containing Suksaiyat formulation based on Thai traditional medicine wisdom
2. To study the preliminary outcomes and safety of menopausal symptoms treatment using cannabis-containing Suksaiyat formulation

### **Methodology**

In this study, the qualitative research approach was used. The sample were 27 key informants selected by using purposive sampling method. The results were presented by descriptive analysis and the data were collected using in-depth interview, observation and focus group discussion (SongkoonChantachon, 2020: 118-150).

### **Key informants consisted of**

- 1) 2 applied Thai traditional doctors who have experience in preliminary treatment of menopausal symptoms using the Sukayasai formulation and have the Healing Arts Practices License and a certificate for the training courses on the use of Thai traditional medical cannabis
- 2) 25 patients, aged 40-75 years who had been diagnosed with menopausal symptoms by a modern physician or applied Thai traditional doctor and treated with Sukayasai formulation

### **Data collection**

The data was collected from Thai Traditional Medical Cannabis Clinic, Phanatnikhom Hospital, ChonBuri Province, where Special Access Scheme (SAS) have been used as individual patient treatment. Data triangulation was conducted and the results were presented by descriptive statistics. The data collection procedure was as follows: study of related documents and researches on the treatment of menopausal symptoms, integration of knowledge of patient care using applied Thai traditional medicine by studying documents related to the study area and studying the diagnosis and treatment using secondary data sources and hospital documents such as medical record; field studies, complete data collection was carefully performed in a timely manner.

### **Treatment and data analysis**

Treatment and data analysis of preliminary data review were performed simultaneously throughout the study period and upon completion of the field data collection. The data obtained from the recordings, interview transcripts and photographs were categorized and data triangulation was performed in terms of location, time and data.

## Data presentation

The data were presented using descriptive analysis according to the research purpose.

## Results

The results of this study consisted of 2 parts: cannabis-containing Suksaiyat formulation based on Thai traditional medicine wisdom and preliminary outcomes and safety of menopausal symptoms treatment.

### 1. Cannabis-containing Suksaiyat formulation based on Thai traditional medicine wisdom

Suksaiyat is one of 16 Thai traditional medicine formulations containing cannabis listed in Vishnu's Medicine Scripture, a Thai traditional medicine pharmacopoeia which mentioned that "Cure for all diseases, increase vitality and appetite and for better sleep". Traditionally, Indian Ayurvedic medicine recognized the sleep-inducing properties of cannabis and it was described as Nidrajanan or sleep induction. This ancient tradition was reflected in a survey of Indian cannabis users in Varanasi in 1991, where 90% of the participants found that cannabis was beneficial for sleep and also reduced stress. In the past, the use of cannabis to treat sleep disorders was closely related to its medicinal properties for pain and discomfort (Michael Backes, 2020: 365). In Thailand, cannabis has been used in Thai traditional medicine for a long time. This indicates that Suksaiyat formulation can reduce the time spent to fall asleep. It also results in deep sleep, changes the brainwave pattern into negative mode, relaxes and improves mood, and improves neurotransmitter function. It has been shown to be particularly effective in treating insomnia caused by pain or tension or age-related hormonal disorders.

The Department of Thai Traditional and Alternative Medicine has specified that this formulation can be used for better sleep, appetite stimulation and restoration of the patient's strength. Cannabis has been used in three groups of patients with insomnia who do not get good results from modern medicine. Suksaiyat is a powder formulation packed in seal sachet with the properties to induce sleep, relieve pain, increase appetite, which can be used as a replacement for sleeping pills and antidepressants.



Picture 1: Sachet of Suksaiyat formulation, 2 g

Suksaiyat formulation is listed in Vishnu's Medicine Scripture. This formulation contains 12 active ingredients with a total of 78 parts including camphor (1 part), neem leaves (2 parts),

*Micromelum minutum* (Forst.f.) Wright & Arn. (3 parts), *Cinnamomum bejolghota* (4 parts), *Nigella sativa* L. (5 parts), *Saussurea lappa* (Decne.) C.B. Clarke (6 parts), nutmeg (7 parts), iron wood flowers (8 parts), pepper (9 parts), dried ginger (10 parts), long pepper (11 parts), and cannabis leaves (12 parts). This formulation is made into powder and dissolved in honey. Before drinking, give a prayer with Sapphitiyopsalm for 3 rounds. This formulation is a “Cure for all diseases, increase vitality and appetite and for better sleep”.

No.	Herb	Weight
1	camphor	1 part
2	neem leaves	2 parts
3	<i>Micromelum minutum</i> (Forst.f.) Wright & Arn.	3 parts
4	<i>Cinnamomum bejolghota</i>	4 parts
5	<i>Nigella sativa</i> L.	5 parts
6	<i>Saussurea lappa</i> (Decne.) C.B. Clarke	6 parts
7	nutmeg	7 parts
8	iron wood flowers	8 parts
9	pepper	9 parts
10	dried ginger	10 parts
11	long pepper	11 parts
12	cannabis leaves	12 parts

Indications: induce sleep, increase appetite

Dosage form: powder, capsule dosage and instructions: for insomnia 0.5-2 g, once a day, before bedtime for loss of appetite: 0.5-2 g, 1-2 times a day, before bed meals aqueous adjuvant

- 1 teaspoon of honey (5 cc)

- If you can't find honey, use half a cup (125 cc) of boiled water.

Contraindication: Do not use in pregnant women, lactating women, people with fever and people under 18 years old.

Cautions: 1. Caution should be taken with anticoagulants and antiplatelets.

2. Caution should be taken with continued use, especially in patients with hepatic and renal impairment, as camphor buildup and toxic effects may occur.

3. Caution should be taken when used in combination with phenytoin, propranolol, theophylline and rifampicin because this formulation contains pepper.

4. Caution should be taken for patients with hypertension (in case of unable to control blood pressure), heart arrhythmia (if symptoms cannot be controlled), patients with eczema, peptic ulcer and acid reflux because it is a hot formulation.

5. Caution should be taken when used in combination with central nervous system depressants such as sedatives and anti-seizure, including alcohol or alcohol mixture.

6. This formulation may cause drowsiness. Avoid driving vehicles or working with machinery after using this formulation.

7. For diabetics, boiled water should be used as a aqueous adjuvant.

Additional information: This formulation may results in dry mouth, dry throat, flushing. (Department of Thai Traditional and Alternative Medicine, 2019: 15-17)

## 2. Preliminary outcomes and safety of menopausal symptoms treatment using Suksaiyat formulation

### 2.1 Preliminary outcomes

#### 2.1.1 General characteristics of patients with menopausal symptoms

Menopause is an inevitable stage of life and is commonly seen in women. The estimated average age of women in their menopause is 40 to 75 years. There were 2 groups of menopausal symptoms reported by the subjects: 1) pain in the muscles, tendons and bones. The reported symptoms included shoulder pain, neck stiffness, pain in both legs, calf pain, numbness in hands and feet, tension around the shoulder muscles, shoulder blades and hips, shoulder muscle stiffness, can't lift arms straight overhead, discomfort while bending over and looking up, difficulty walking, leg weakness, back pain, pain under the knee joint, calf cramp, back stiffness, trouble standing up after bending down, hip stiffness, sciatica, bone-thinning, osteopenia, leg weakness while walking. The symptoms of individual patient can be severe or mild.

#### 2) Neurological and circulatory symptoms

The reported symptoms include insomnia, dyspnea, weakness, hot flash, loss of appetite, waking up at night, headache or lightheadedness, dizziness, bleary-eyed, stress, anxiety, or loss of appetite, allergic reactions, asthma, irritable and vaginal dryness and atrophy, atherosclerosis, hyperlipidemia. The doctor did a complete test before the treatment by asking patients to lift **10-kg** luggage. It was found that two cases experienced pain or lightheadedness and weakness.

#### 2.1.2 Treatment outcomes

1) Suksaiyat administration: Suksaiyat were prescribed according to its effects. Suksaiyat is a thermal formulation with hypnotic, appetite stimulating, analgesic and anti-stress effects.



Picture 2: Suksaiyat dosage: divided into portions 0.5 g per sachet, 4 sachets

Instructions: Suksaiyat is a power formulation packed in sachet. Before use, dissolve 2 g of this formulation in water and divided into 4 portions, 0.5 g each. Drink with 1 g of “Thepjit cordial”.

The follow-up period started 1 day after treatment by making follow-up call. After 1 week, a follow-up call was made and patients were appointed for follow-up at the hospital after another 1 month to make an adjustment. The treatment period was 1 - 3 months and the doctors would arrange for a basic blood test. A blood test was not required the first time a patient attended the

study. This is because the patients were local resident, their medical record could be obtained from the hospital system.

## 2) Supplementary or aqueous adjuvant: Thepjit cordial

Thepjit cordial consists of 48 ingredients. The main active ingredient is jasmine, which is half of the total weight of the formulation. Thepjit cordial also contains **8** kinds of orange peels for **56** parts of a total of **368** parts of the whole formulation. It is suitable for fainting and dizziness due to the thermal effects of all 8 kinds of orange peels. According to Thai traditional medicine principles, orange peel has properties to relieve fainting and dizziness, lightheadedness, feeling of faintness and is also a heart tonic for nourishing and clearing the mind. Thepjit cordial is suitable for people who are depressed or have a melancholy mood that often occurs from time to time and are one of the most common symptoms in menopausal or elderly people who feel lonely and sad. Jasmine, the main ingredient, has properties to nourish the mind. However, cordial can only be used for the initial symptoms and not for patients with psychiatric disorders who need consultation with a modern physician.



Picture 3 :Thepjit cordial used as supplementary or aqueous adjuvant

Aqueous adjuvant for Suksaiyat formulation is honey or water. However, the doctors chose to use Thepjit cordial as aqueous adjuvant. This is because the doctors were not sure whether the patients can find honey or not. When honey was available, the doctors were not sure if it was real honey or artificial honey used in cooking. Thepjit cordial was chosen because it has a more cooling effect compared to other cordials.

## 3) Massage: Massage method according to Thai traditional procedure was used.

Massage was performed to alleviate the adverse effects caused by the symptoms and to reduce the discomfort. Myofascial pain syndrome on 4-5 points is common in the office syndrome. The symptoms found are such as pain and stiffness at shoulder, neck and shoulder blades. There may be numbness to the shoulder, down to the outside and inside of arms and to the fingertips. Patients may experience numbness, dizziness, headache, eye socket pain and nape pain. For patients with severe pain, a light touch and oil massage on the limbs may be used to stimulate and relieve the pain together with herbal compress to increase blood flow. In addition, the patient should be encouraged in conjunction with the therapy. The current treatment for muscle pain depends on the treatment approach used by the doctor or the person delivering treatment. In this study, the treatment methods were basic massage for the affected shoulder, acupressure point



massage at 4-5 points focusing on point 4 and 5 and shoulder massage on 4 acupressure points. If necessary, compress massage will be used as additional treatment method. Hot pressing was used in the morning and evening for 10-15 minutes. Compress massage is another traditional Thai medical procedure used for the comorbidity of the patient, which is used in combination with Thai massage. Herbal compress is often used after the massage. Most of the herbs used for compresses contain active ingredients effective in treating sprains and bruises, and loosening tendons. When used in combination with heat from the compress, it is a synergistic effect for each other. Fresh herbs are used in compress as they have the better properties compared to dried herbs. In this study, the herbs in the compress included Bengal root, zedoary, turmeric, lemongrass, bergamot peel with essential oils as active ingredients. If dry herbs are used, more essential oils will be evaporated and results in less therapeutic effect.



Picture 4: Massage was performed to alleviate the adverse effects caused by the symptoms and to reduce the discomfort of patients with myofascial pain syndrome on 4-5 points

In addition, some patients may use physical exercises. The exercises used are 3-step armrest movement, 3-step arm pull and raise, and other exercise as appropriate. Contraindications: avoid movements that cause pain such as intense twisting, bending, violent shaking of the neck and arms. Injurious foods: sticky rice, bamboo shoot, offal, liquor and beer, painkiller, seafood, including food with cooling effect (watermelon, squash, ice, ice cream, cool water), etc.

## **2.2 Safety for menopausal symptoms treatment**

The treatment follow-up period was 1-3 months. The sample were 25 patients, aged 40-75 years. Most patients were diagnosed with congenital diseases such as hypertension, hyperlipidemia, cancer of the organs, diabetes, migraine, gastritis, allergy, palpitation. As for menopause, it was found that most of the symptoms of the sample in this study were insomnia, waking up in the



middle of the night, hot flashes. The dosage ranges between 0.5 – 4 g. This formulation was dissolved in half a cup of warm water and drank before bedtime. The treatment for insomnia and waking up at night showed that the earliest period the patients showed improvement was 2 weeks, but most patients showed improvement within 1 month.



Picture 5: Patient appointment for physical examination and follow-up

Adverse effects: Most patients experienced burning in their mouth, throat and stomach, and dry throat. These symptoms were mild and disappeared within 6 hours. It was found that when this formulation was used in combination with 1 teaspoon of Homthepjit cordial dissolved in warm water, no adverse effects were found. In addition, other symptoms were also observed, such as body burning and sweating. These symptoms appeared occasionally and then disappeared. Tachycardia was also found on the first day, which disappeared within 1-2 minutes. It can be concluded that the use of the Sukasayasai formulation in combination with Homthepjit cordial was safe and did not result in any adverse effects.

### Conclusions

Suksaiyat is a cannabis-containing formulation based on Thai traditional medicine used as treatment for menopausal symptoms. It is one of 16 Thai traditional medicine formulations listed in Vishnu's Medicine Scripture. Cannabis has been used as treatment for sleep disorders, pain and discomfort since the past. This formulation contains 12 active ingredients with a total weight of 78 parts. The main ingredient with highest proportion is cannabis leaves, accounting for 12 parts. Golden age is an inevitable stage of life and is commonly seen in women in their menopause. The estimated average age of women in their menopause is 40 to 75 years. There were 2 groups of menopausal symptoms reported by the subjects: 1) pain in the muscles, tendons and bones such as shoulder pain, neck stiffness, pain in both legs, calf pain, numbness in hands and feet, tension around the shoulder muscles, shoulder blades and hips. 2) neurological and circulatory symptoms include insomnia, dyspnea, weakness, hot flash, waking up at night, headache or lightheadedness, dizziness, bleary-eyed, stress, anxiety, or loss of appetite, allergic reactions, asthma, irritable and vaginal dryness and atrophy, atherosclerosis, hyperlipidemia.

Treatment outcomes: 1) Suksaiyat were prescribed according to its effects. Suksaiyat is a thermal formulation with hypnotic, appetite stimulating, analgesic and anti-stress effects. Instructions:

dissolve 2 g of this formulation in water and divide into 4 portions, 0.5 g each. Drink with 1 g of Thepjit cordial. The treatment follow-up period was 1-3 months. 2) Thepjit cordial was used as a supplementary or aqueous adjuvant. This formulation consists of 48 ingredients. The main active ingredient is jasmine, which is half of the total weight of the formulation. It also contains 8 kinds of orange peels for 56 parts of a total of 368 parts of the whole formulation. It is suitable for fainting and dizziness. 3) Massage: Massage method based on Thai traditional procedure was used. Acupressure point massage was performed at 4-5 points for patients with symptoms such as pain and stiffness at shoulder, neck and shoulder blades. There may be numbness to the shoulder, down to the outside and inside of arms and to the fingertips. Injurious foods are such as sticky rice, bamboo shoot, offal, liquor, beer, painkiller, seafood, including foods with cooling effect (watermelon, squash, ice, ice cream, cool water). For the safety of menopausal symptoms treatment in a period of 1-3 months, it was found that the use of Suksaiyat formulation in combination with Thepjit cordial was safe without any adverse effects.

### **Discussion**

The results showed that Suksaiyat is a formulation with cannabis as its main active ingredient and can be used as treatment for menopausal symptoms. According to the findings, this formulation is an alternative treatment for menopausal patients that is increasing every year because Thailand has become the aging society. In addition, Suksaiyat formulation is a Thai traditional medicine that produced from herbs available in Thailand, thus reducing the cost of importing medicines and herbs from abroad. Furthermore, patients have easy access to treatment and it is desirable that the formulations based on Thai traditional medicine have been preserved and revived for use in the disease treatment.

For cannabis, which is the main active ingredient of Sukiyasai formulation, it has been clearly proven to be effective in insomnia, paranoia, anxiety, distress, body pain, loss of appetite, which are the symptoms suffered by people in menopause (Michael Backes, 2020: 286). This is consistent with studies which showed that cannabis could be successfully used as a treatment for many types of sleep disorders such as insomnia, sleep disruption and apnea. This is because cannabis has a mild sedative effect that can modulate sleep (Matthew J. Pava, Alexandros Makriyannis, and David M. Lovinger, 2016: e0152473). Cannabis has been used and considered the wisdom of traditional Thai medicine for a long time. However, the use of cannabis had to come to a halt after the law made it an illegal drug. Hence, it is desirable when Thailand has opened up such an opportunity for use of cannabis.

The results showed that cannabis is the main active ingredient in Sukiyasai formulation used as treatment for menopausal symptoms. Nowadays, Thai law has allowed the cultivation and propagation of cannabis for farmers and the private sector, thus it is a good opportunity to generate income for Thai farmers to improve their economic status. This opportunity has a wide impact for economic development across the country.

### **Recommendations for future research**

1. Clinical trials should be performed in order to determine the appropriate dosage for patients in each age range and patients with different congenital diseases, as well as the exact duration of treatment.
2. Researches should be conducted to compare this formulation with modern medicines used as treatment of menopause in order to determine efficacy and effectiveness of this formulation be acceptable for both medical and public health.

3. Clinical studies of other cannabis-containing formulations based on Thai traditional medicine should be conducted in order to determine the treatment outcome and safety.

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