SOUTH BAYLO UNIVERSITY

Effect of Individualized Acupuncture Treatment on Sleep Quality of Secondary Insomnia Patients Corresponding to Their Pain Status: Case Series

by

Byung Kyu Choi

A RESEARCH PROJECT SUBMITTED

IN PARTIAL FULFILLMENT OF THE

REQUIREMENTS FOR THE DEGREE OF

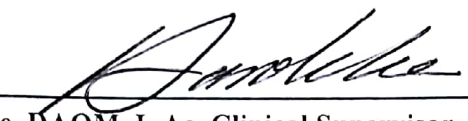
Doctor of Acupuncture and Oriental Medicine

LOS ANGELES CAMPUS, CALIFORNIA

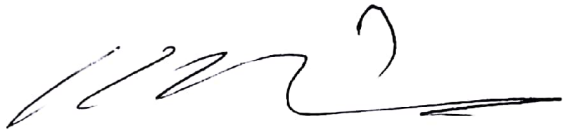
December 2018

DISSERTATION OF BYUNG KYU CHOI

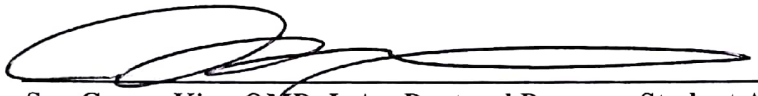
APPROVED BY RESEARCH COMMITTEE



Hanok Lee, DAOM, L.Ac, Clinical Supervisor, Professor

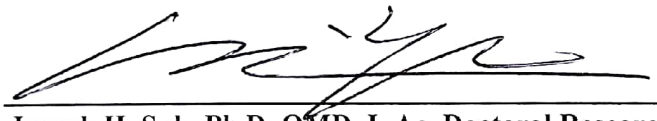


Suhkyung D. Kim, MD, OMD, L.Ac, Professor



Soo Gyung Kim, OMD, L.Ac, Doctoral Program Student Advisor

Seong Hwa Hue, DAOM, L.Ac, Doctoral Clerkship Coordinator



Joseph H. Suh, Ph.D, OMD, L.Ac, Doctoral Research Coordinator, Professor

South Baylo University

Los Angeles, California

December 06, 2018

Effect of Individualized Acupuncture Treatment on Sleep Quality of Secondary Insomnia Patients Corresponding to Their Pain Status: Case series

Byung Kyu Choi

SOUTH BAYLO UNIVERSITY AT LOS ANGELES CAMPUS, 2018

Research Advisor: Shan Qin Cui, OMD, LAc

ABSTRACT

In order to compare the effect of individualized acupuncture treatment corresponding to the causing factors of secondary insomnia, the case series trial for five participants with secondary insomnia caused by chronic pain were conducted. Two participants were treated with Ordinary Insomnia Treatment (OIT) with the Acupoints of HT7, SP6, An-Mian, UB62, KI6 and auricular points on Shen-men, Heart, Sympathetic, and Subcortex. Three participants were treated with the same acupoints added by nerve entrapment point (NEP) and tendon traction point (TTP) needling technique to relieve individual medical disorders aggravating sleep qualities (IIT; Individualized Insomnia Treatment). The changes and differences of insomnia status considering the pain factor were evaluated by Pittsburgh Sleep Quality Index (PSQI), Hamilton Rating Scale of Anxiety (HAM-A), Hamilton Rating Scale of Depression (HAM-D), and Visual Analog Scale of pain level (VAS) scores before 1st, after 6th and 12th treatment. The difference of mean values of PSQI, HAM-A, HAM-D, and VAS of participants treated with OIT method changed before 1st and after 12th treatment were 0, -4, 5, and -1.9, respectively, whereas, those participants treated with

IIT method were -9.3, -14.3, -8.0, and -6.6, respectively. Improvement in Treatment Effect (Relative Risk Reduction) in IIT participants over OIT participants were calculated as 67%, 100%, 33%, and 100% for PSQI, HAM-A, HAM-D, and VAS, respectively. Based on above outcomes, the effect of acupuncture treatment on secondary insomnia corresponding to the individual medical conditions and the potential of supplementary treatment such as tendon traction point (TTP) and nerve entrapment point (NEP) needling technique associated with secondary insomnia were proved. To confirm the potential of outcomes from this trial, larger scale with higher quality clinical trials are proposed.

TABLE OF CONTENTS

I. INTRODUCTION

Insomnia is the most common sleep disorder affecting 30 million Americans[1]. While 30-40 percent of the general U.S. population having insomnia, about 10–15 percent of all U.S. adults suffers from severe and chronic insomnia that affects their daytime functioning[2, 3, 4].

There are two types of insomnia; Primary insomnia (PI) and Secondary insomnia (SI). PI is that a person has sleep problems that are not directly associated with any other health condition or problem. SI is identified that a person is having sleep problems due to other cause, such as medical condition (like asthma, depression, arthritis, cancer, or heartburn); pain; medication they are taking; or a substance they are using (like alcohol).[5]

Both pharmacological and cognitive behavioral therapy (CBT) are used to treat PI. However treatment of SI is usually directed to the cause of medical disorder. Typically, SI patients receive direct treatment for insomnia only as the insomnia is severe or does not respond to treatment of the medical disorder.[6]

Although medications for insomnia are second line treatment[7], the percentage of adults using a prescription sleep aid increases with age reaching 7% among those aged 80 in the United States[6]. Medications used to treatment insomnia include prescription of sleeping pills, antidepressants, over-the-counter sleep aids, antihistamines, melatonin, ramelteon, *etc*.[8], which may cause significant adverse effects. Furthermore, many of aged people with chronic insomnia become dependent on these medications without any practical effect.

From the perspective of East Asian Medicine, insomnia is caused by deficiency of both Heart and Spleen, disharmony between Herat and Kidney, Liver Yang Rising, and Dysfunction of Stomach qi. There is no classification of insomnia type as primary and secondary. Accordingly, acupuncture methods differentiated by the two insomnia types is not established. Nevertheless, many effective acupuncture methods are proposed to treat insomnia[9]. However, most of them are focusing on promoting the sleeping qualities itself for the primary insomnia only. Also there are substantially less reports about the trials to relieve the causes of secondary insomnia, mainly various types of pain, and manifesting the recurrences of insomnia from the follow-up after treatments. Due to lack of evidences corresponding to the clinical conditions causing each kind of insomnia, the same method treating ordinary insomniac is employed to treat participants with secondary insomnia associated with various medical conditions, showing the unclear or unsatisfactory outcomes in improving insomnia.

This case series trial was designed to compare the effect of individualized acupuncture treatment corresponding to the factors causing secondary insomnia. NEP and TTP needling techniques depending on the pain status of each participants were added to Ordinary Insomnia Treatment (OIT) method to relieve the causes of secondary insomnia, and the effect of Individualized Insomnia Treatment (IIT) was analyzed.

OBJECTIVES OF THE STUDY

This research aimed to compare the effect of individualized acupuncture treatment corresponding to the causing factors of secondary insomnia (IIT) to the effect of ordinary insomnia treatment (OIT), and to prove the potential of tendon traction point (TTP) and nerve entrapment point (NEP) needling technique on Secondary Insomnia participants.

Objective 1. To present the evidence of the individualized acupuncture treatment corresponding to the causing factors of secondary insomnia (IIT).

Objective 2. To compare the effect of individualized insomnia treatment (IIT) to the effect of ordinary insomnia treatment (OIT).

Objective 3. To explore the potential of tendon traction point (TTP) and nerve entrapment point (NEP) needling technique associated with secondary insomnia participants.

LITERATURE BACKGROUND

Insomnia is difficulty falling asleep or staying asleep, even when a person has the chance to do so. People with insomnia can feel dissatisfied with their sleep and usually experience one or more of the following symptoms, fatigue, low energy, difficulty concentrating, mood disturbances, and decreased performance in work or at school.

Insomnia has seven different kinds. General insomnia is a classification of sleep disorders in which a person has trouble falling asleep, staying asleep, or waking up early.

Adjustment insomnia, also called acute or short-term insomnia which disturbs your sleep and usually stems from stress.

Behavioral insomnia, which condition occurs when children do not go to bed on time unless a parent or guardian enforces a bedtime.

Idiopathic insomnia is a lifelong sleep disorder that starts during infancy or children and continues into adulthood.

Insomnia due to a drug or substance, which directly related to the use of any of the following substances (Medication, Caffeine, Alchol, a food item).

Insomnia due to a medical condition, which is caused by a mental health disorder.

Psychophysiological insomnia is associated with excessive worrying, specifically focused on not being able to sleep[10].

Treatment option include behavior and lifestyle changes, medicines, and complementary medicines. Behavior and lifestyle changes include relaxation exercises, choosing a health way of thinking, and lifestyle changes. Relaxation exercises are

breathing exercises for relaxation, guided imagery to relax, meditation, progressive muscle relaxation, and relaxing your mind and body. Lifestyle changes include changing sleep area or schedule and keeping regular bedtimes and wake times. Many sleep medicines cause side effects, such as Low blood pressure, Anxiety, and Nausea.

Prescription sleep medicines for short-term insomnia are zolpidem (Ambien), eszopiclone (Lunesta),ramelteon (Rozerem), andzaleplon (Sonata). Orexin receptor antagonists for promoting sleep is suvorexant (Belsomra). Antidepressants that have a calming or sedative effect. Antihistamines can provide short-term relief of sleeplessness.

Complementary medicine are Melatonin which is a hormone produced by the brain and Valerian: an herbal sleep remedy[11].

Insomnia from the perspective of East Asian Medicine, sleep depends on the state of Blood and Yin, especially of the heart and liver, although the Blood and Yin of other organs also influence sleep. During the night, Yin energy predominates and the Mind (Shen) and the Ethereal soul (Hun) should be anchored in heart-Blood and liver-Blood, respectively[12].

From the etiology and pathology of East Asian Medicine, anxiety and overwork damage the heart and spleen. Blood is exhausted and the mind is disturbed in case of damage of the heart, while qi and blood production becomes poor in case of deficiency of the spleen qi. Blood deficiency is unable to nourish the heart, leading to insomnia.

Congenital deficiency, indulgent sexual activity or a prolonged illness damages the kidney Yin. The kidney water fails to ascend smoothly to the heart to check the heart fire, and the heart Yang is therefore hyperactive alternatively.

Emotional depression causes the stagnation of qi in the liver. The stagnant qi of long duration is transformed into fire, which flares up to disturb the mind, and then insomnia occurs.

Irregular food intake damages the sleep and stomach. The accumulated undigested food produces phlegm heat in the middle energizer, which in turn, causes dysfunction of the stomach and insomnia as stated in "Internal Classic" that sleep is disturbed if the function of the stomach is in disharmony[13].

From the differentiating of insomnia in East Asian Medicine, Qi of spleen and blood insufficiency, which is the difficulty in falling asleep and disturbed sleep accompanied by palpitation, poor memory, lassitude, listlessness, anorexia, sallow complexion, and thread weak pulse. Disharmony of heart and kidney, which is the irritability and insomnia accompanied by dizziness, tinnitus, low back pain, seminal emission, leukorrhagia, and rapid weak pulse. Upward disturbance of liver fire is the mental depression, quick temper and dream-disturbed sleep accompanied by headache, distending pain in the costal and hypochondriac region, bitter taste in mouth and wiry pulse. Lastly, dysfunction of stomach, which is a insomnia accompanied by fullness and suffocating feeling in the epigastrium region, abdominal distension, belching, and full forceful pulse[14].

Treatment aims to relax liver qi, clear heat, and calm the Shen for Liver Qi stagnation leading to heat or fire. For the Stomach disharmony and phlegm heat, treatment is designed to relieve food stagnation, harmonize stomach, clear heat, transform phlegm and calm Shen. For the Heart Blood & Spleen Deficiency, treatment will strengthen and nourish heart and spleen to promote the production of blood and calm the

Shen. For the Yin deficiency with heat, treatment focuses on nourishing the heart, liver, and kidney Yin, clearing heat and calming the Shen. And for the Heart & Gallbladder Qi deficiency, treatment will aim to strengthen the qi to alleviate fearfulness and calm the Shen and Mind[15].

Meditation strengthens the most important sleep Brain Region: Meditation builds up a big and strong sleep centered "Pons" which regulates the main dreamtime (REM stage of sleep) chemical, melatonin. Meditation cools the Brainwaves of insomnia & Boosts the brainwaves of sleep. Studies show that meditators have far fewer nasty insomnia causing beta brainwaves and much higher levels of the far more beneficial alpha, theta, and delta brainwave patterns[16].

Herbal medicine for insomnia

- Insomnia due to liver stagnation and heat: Suan Zao Ren Tang
- Insomnia due to blood deficiency: Gui Pi Tang
- Insomnia due to Yin deficiency: Tian Wang Bu Xin Dan
- Insomnia due to indigestion: Bao He Wan[17]

In some case, moxibustion is indicated along with acupuncture to activate qi and blood flows in the meridians. For each treatment, choose one to four acupoints and warm with a moxa stick for 5 – 15 minutes at each point. Especially, KI1 (Yong Quan) and KI6 (Zhao Hai) can be stimulated to promote sleep

Acupuncture is often used in the treatment of insomnia and other mind disorders. In East Asian Medicine (EAM), mental activities are referred as Shen (spirit), so insomnia is a manifestation of the Shen disorder in which various internal disharmonies make the spirit restless and thus creates sleeping problems. There is no general acupuncture remedy suitable for all insomnia sufferers.

Acupuncture points for insomnia are as follows.

KI 6 (Zhao Hai) & UB 62 (She Mai) are Yang and Yin heel vessel. Regulating heel vessels and calming spirit to facilitate sleep. In EAM, there are two meridians, the yin heel vessel and yang heel vessel, which dominate the activity and rest of the body and also control the opening and closing of the eyes. The yin heel vessel rules the body to rest and the closing of eyelids; the yang heel vessel rules the body to be active and the opening of eyelids. Since these two meridians do not have their own acupuncture points, physicians can only use their confluent points, KI 6 and UB 62 to promote their functioning. For KI 6, twirl and rotate the needles with a reinforcing technique, while for UB 62, twirl and rotate the needles with a reducing technique.

Shen Men (HT 7) is the source poin t of the heart meridian, it promotes the heart and calms the spirit.

San Yin Jiao (SP 6) belongs to the spleen meridian, but the liver meridian and kidney meridian intersect with the spleen meridian at this location. It is used to regulate the blood and qi circulation invigorate the spleen and disperse the liver[18].

An Mian (Extra) is an extra point for insomnia[17].

Auricular Acupuncture is a beneficial treatment tool for insomnia. Auricular acupuncture is based on a reflex somatotopic system organized on the surface of the external ear, one of many such micro systems on the body[19].

The "Su Wen and Ling Shu" make references to the Yin channels converging on the ear and the Yang channels passing through the ear[19]. The lesional correspondence points are identified by inspecting the skin for irregularities and painful responses to probing and by scanning with a point detection device. There is also a collection of general auricular points which are used in combinations in treatment of insomnia[20].

Lesional points for insomnia treatment are as follows. Shen-Men, which alleviates anxiety and enlivens the spirit. It is active in almost all patients. Sympathetic point Influences blood circulation and autonomic function. Subcortex is located at the base of the wall of the antitragus, adjacent to the inferior concha. It is used for stimulating hormonal system[20].

There are two needling NEP (nerve entrapment point) and TTP (tendon traction point) technique. In an isometric muscle contraction, the muscle fires but there is no movement at a joint. Pains or sympathetic nerve entrapment syndrome are resulted from hyperexcitability of sympathetic preganglionic fibers.

In case of hyperexcitability of somatic motor nerve entrapment, an ischemic pain occurs on the corresponding muscle. It is called somatic motor nerve entrapment point.

In case of hyperexcitability of somatic sensory nerve entrapment, it causes pains and weird sensations on corresponding tissues and joint capsule. It is somatic sensory nerve entrapment point.

In case of hyperexcitability of sympathetic motor and/or sensory nerve entrapment, pains or dysfunction occurs on corresponding organs. We call it sympathetic nerve entrapment point[26].

In an isotonic contraction, tension remains the same, whilst the length of muscle changes. If the muscle is injured, the length of muscle may be shortened in accordance with healing process. When an isotonic contraction happens on injured and shortened muscle, tension might pull the sites where shortened muscle's tendon or ligaments insert into the bone and causes pain or inflammation. The source of pulling force in insertion site comes from the origin site[26]. NEP and TTP are the important points for diagnosing and acupuncture treatment of the pain and weird sensation.

We assess the stage or degree of insomnia by PSQI, HAM-D, HAM-A, and VAS The Pittsburgh Sleep Quality Index (PSQI) is a self-rated questionnaire which assesses sleep quality and disturbances over a 1-month time interval. 19 individual items generates 7 "component" scores: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. The sum of scores for these 7 components yields one global score[21]. Global PSQI scores were divided into three categories; optimal (≤ 5), borderline (6-7), and poor (≥ 8) sleep quality[22].

The Hamilton Rating Scale for Depression (often abbreviated to HRSD or Ham-D) was designed to evaluate the performance of the first group of antidepressants[23]. The scale is widely available and has two common versions with either 17 or 21 items and scored between 0 and 4 points. The first 17 items measure the severity of depressive

symptoms and as examples the interviewer rates the level of agitation clinically noted during the interview or how the mood is impacting on an individual's work or leisure pursuits. The extra four items on the extended 21-point scale measure factors that might be related to depression, but are not thought to be measures of severity, such as paranoia or obsessional and compulsive symptoms. Scoring is based on the 17-item scale and scores of 0 – 7 are considered as being 'Normal'; 8 – 16 'Mild Depression'; 17 – 23 'Moderate Depression'; and scores over 24 are indicative of 'Severe Depression'[24]; the maximum score being 52 on the 17 –point scale.

Hamilton Anxiety Rating Scale (HAM-A) is a widely used and well-validated tool for measuring the severity of patient's anxiety. It should be administered by an experienced clinician. The major value of HAM-A is to assess the patient's response to a course of treatment, rather than as a diagnostic or screening tool. By administering the scale serially, a clinician can document the results of drug treatment or psychotherapy. The HAM-A probe 14 parameters and takes 15 – 20 minutes to complete the interview and score the results. Each item is scored on a 5-point scale, ranging from 0=not present to 4=severe. That is, from the sum the scores from all 14 parameters, 14 -17 score points represent 'Mild Anxiety'; 18 -24, 'Moderate Anxiety'; and 25 -30, 'Severe Anxiety'[25].

Analogue Scale (VAS) is a measurement instrument that tries to measure a characteristic or attitude that is believed to range across a continuum of values and easily be directly measured[28]. It is often used in epidemiologic and clinical research to measure the intensity or frequency of various symptoms[27]. From the patient's perspective, this spectrum appears continuous + and/or – their pain does not take discrete jumps, as a categorization of none, mild, moderate, and severe would suggest. It was to capture this

idea of an underlying continuum that the VAS was devised[27]. The simplest VAS is a straight horizontal line of fixed length of 100 mm. The ends are defined as the extreme limits of the parameter to be measured symptom and pain from the far left (normal) to the far right (worst)[29].

II. MATERIALS AND METHODS

1. Study Design

As shown in Figure 1, it presented the effect of acupuncture treatment on participants treated with Ordinary Insomnia Treatment (OIT) or Individualized Insomnia Treatment (IIT) method. Outcomes were measured and assessed at baseline, after 6^{th}, 12^{th} treatment. The protocol was approved by the Institutional Review Board of South Baylo University on May 31, 2018.

2. Participants

Five (5) participants were recruited mainly by advertisements from the Integrative Medicine Research Institute of South Baylo University. The candidates; (1) diagnosed as insomnia based on Diagnostic and Statistical Manual of Mental Disorders – Text Revision, 4^{th} Ed. (DSM-IV-TR) and followed the prescription; (2) experienced insomnia for four weeks or longer before the start of trial period; (3) showed more than 7 points of PSQI test; (4) had the ability to communicate clearly included; (5) differential diagnosed as secondary insomnia according to their presence of medical disorders. There was no limitation on sex, race, age, or medication status. However, they had to provide information about their medication history on insomnia. After signing on the" Informed Consent Form", participants were made to stop medication before the trial to prevent the potential interaction with the prescription.

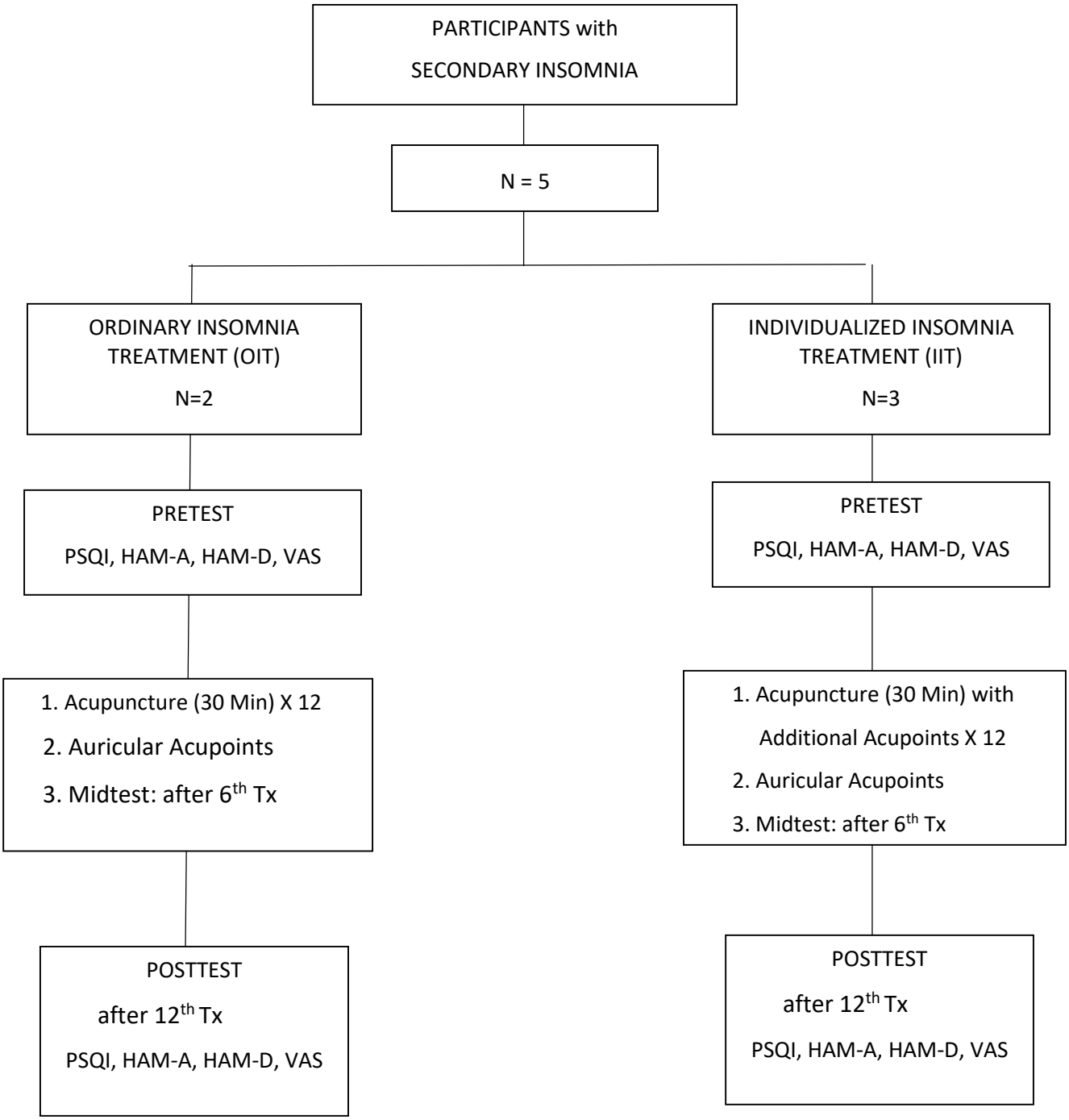


Figure 1. Schematic Diagram of Research Procedure

3. Differential Diagnosing Primary and Secondary Insomnia and treatment

There are the differences between the two insomnia to distinguish primary from secondary. Primary Insomnia is a case of unwanted sleeplessness with no other apparent health problems coinciding with it.

ICD CODE	F51.01:	Primary Insomnia
	F51.02:	Adjustment Insomnia
	F51.03	Paradoxical Insomnia
	F51.04:	Psychophysiologic Insomnia
	F51.05:	Insomnia Due to Other Mental Disorder
	F51.09:	Other Insomnia not Due to a Substance or Known Physiological Condition

The vast majority suffer from Secondary Insomnia with their sleeping quality disturbed or worsened by chronic pain, breathing problems, depression, anxiety, etc.

ICD CODE	G47.0:	Insomnia
	G47.00:	Insomnia, Unspecified
	G47.01:	Insomnia Due to a Medical Condition
	G47.09:	Other Insomnia

The acupuncture treatment for participants treated with OIT method were performed twice a week up to twelve times or until reaching the treatment goal of PSQI score less than 7 points. As shown in Table 1. An-Mian, HT7, SP6, KI6, and UB62 were taken as primary acupuncture

points. After inserting acupuncture needles in a supine posture, participants were stayed for 20 minutes. All the process was completed within 30 minutes including the preparation time. After acupuncture treatment, Ear-seeds on Shen- Men, Heart, Subcortex, and Sympathetic Auricular points in the both ears were added.

Table 1. Acupuncture Points of Ordinary Insomnia Treatment

Type of Acupuncture Treatment	Acupuncture Points
Acupuncture Points	An-Mian, HT7, SP6, KI6, UB62
Auricular Points	Shen-Men, Heart, Sympathetic, Subcortex

The Individualized Insomnia Treatment (IIT) was performed the same as Ordinary Insomnia Treatment (OIT) followed by treatment on additional points of nerve entrapment point (NEP) and tendon traction point (TTP) for relieving the medical disorders[26].

4. Outcome measurement

Pittsburgh Sleep Quality Index (PSQI), Hamilton Rating Scale of Depression (HRSD), Hamilton Rating Scale of Anxiety (HAH-A), and Visual Analog Scale (VAS) questionnaires were performed before 1st, after 6^{th,} and 12th treatment individually. When participants reaches treatment goal of seven points of PSQI before 12th treatment, the treatment will be terminated earlier, and the last data will be used for evaluation. The other missing data due to incompliance was analyzed using repeated mixed model of generalized linear model.

5. Statistical Analysis

Based on the sample size (n), descriptive effect measures such as mean, standard deviation, minimum, and maximum value were obtained to compare the effect between two groups. From the dichotomous value, the treatment effect on participants treated with IIT method over participants treated with OIT method was calculated using 2×2 Table (Table 2) and following equation;

Table 2. 2×2 Table to Analyze the Treatment Effect of Acupuncture on Various Clinical Conditions

	Disorder	
	Uncured	cured
INDIVIDUALIZED INSOMNIA TREATMENT (IIT)	A	b
ORDINARY INSOMNIA TREATMENT (OIT)	C	d

$$\textbf{Treatment effect (Relative Risk Reduction)} = \frac{c/(c+d) - a/(a+b)}{c/(c+d)}$$

6. Ethics

The study was conducted in accordance with the Declaration of Helsinki. The study was conducted after getting approval from the Institutional Review Board of South Baylo University on May 31, 2018.

III. RESULTS

INDIVIDUALIZED INSOMNIA TREATMENT CASES

Case One

First visit on April 23, 2018

A 59 year-old, Asian woman presented in our research center clinic with insomnia for ten years, hot sensation on upper back, and pain on toe-side sole bilateral. Those pain and weird sensation making her wake up several times during the sleeping caused her insomnia. She was diagnosed as secondary insomnia and from the East Asian medicine perspective as Lung-Yin Deficiency, Heart-Yin Deficiency, and Bi syndrome.

As shown in Table 3, the scores of PSQI, HAM-A, HAM-D and VAS before 1st treatment were 14, 24, 22 and 8.9, respectively.

First treatment was performed by acupuncture points on HT7, SP6, KI6, UB62, An-Mian, and auricular points on Shen-Men, Heart, Sympathetic, and Subcortex. Additional acupuncture was also performed along the tender points which is nerve entrapment point (NEP) of the Multifidus at the T3, T4, T5, and T6 spinal cord levels and tendon traction point (TTP) on Flexor Digitorum Brevis bilateral.

Sixth visit on May 10, 2018

The participant came in to our clinic with hot sensation on upper back and bitter taste in the mouth when getting sun shine. She had brushed her tongue coating around 10 times a day for that bitter tasting matter. As checking her tongue, it was like a mirror.

On Sixth visit, she had the same treatment as first one.

As shown in Table 3, the scores of PSQI, HAM-A, HAM-D and VAS after 6th treatment were 5, 15, 17 and 3.4, respectively.

Twelfth visit on May 31, 2018

She presented to our clinic with light pain on left toe side sole.

We gave her the same treatment of acupuncture and auricular points with tendon traction point (TTP) on left Flexor Digitorum Brevis.

As shown in Table 3, the scores of PSQI, HAM-A, HAM-D and VAS after 12th treatment were 5, 6, 11 and 0.7, respectively, and most of complains were resolved.

Table 3. Assessment of Case One

ASSESSMENT	Before 1ST TREATMENT	After 6TH TREATMENT	After 12TH TREATMENT
PSQI	14	5	5
HAM-A	24	15	6
HAM-D	22	17	11
VAS	8.9	3.4	0.7

Case Two

First visit on July 19, 2018

A 69 year-old, 230 lb obesity, African-American woman presented in our clinic with insomnia for three years. She also had low back pain radiated down to knee and numbness and tingling on left forearm to fingers. Those medical disorders disturbed her sleeping quality and led to insomnia. She was diagnosed as secondary insomnia and from the Eastern medicine perspective as Spleen-Yang Deficiency and Fixed Bi syndrome.

As shown in Table 4, the scores of PSQI, HAM-A, HAM-D, and VAS before treatment were 16, 33, 14 and 7.3, respectively.

First treatment was performed by acupuncture on HT7, SP6, KI6, UB62, An-Mian and auricular on Shen-Men, Heart, Sympathetic, Subcortex points.

Additional acupuncture was performed on NEPs of Piriformis bilateral and left Anterior Scalene.

Sixth visit on August 6, 2018

She came to our clinic with pain on lateral knee bilateral.

The acupuncture points were same as first treatment except NEP on left Biceps Femoris.

As shown in Table 4, the scores of PSQI, HAM-A, PDRS, and VAS after 6^{th} treatment were 9, 25, 8, and 5.7, respectively.

Twelfth visit on September 04, 2018

She showed up our clinic with light tingling on lateral knee bilateral.

The final acupuncture treatment was performed on NEPs of Piriformis and Biceps Femoris bilateral.

As shown in Table 4, the scores of PSQI, HAM-A, HAM-D, and VAS were 6, 9, 5, and 1.3, respectively.

Table 4. Assessment of Case Two

ASSESSMENT	Before 1ST TREATMENT	After 6TH TREATMENT	After 12TH TREATMENT
PSQI	16	9	6
HAM-A	33	25	9
HAM-D	14	8	5
VAS	7.3	5.7	1.3

Case Three

First visit on April 16, 2018

A 75 year-old, Asian man presented in our clinic with ten years history of insomnia and tingling and cramping along lateral lower leg bilateral which mostly disturbed his sleeping. He was diagnosed as secondary insomnia and from the Eastern perspective as Heart and Kidney-not- harmonized and Wandering Bi syndrome.

As shown in Table 5, the scores of PSQI, HAM-A, HAM-D, and VAS were 20, 8, 14, and 7.1, respectively.

Treatment was performed by acupuncture on HT7, SP6, KI6. UB62, An-Mian, and auricular Shen-Men, Heart, Sympathetic, Subcortex points and additional acupuncture points on NEPs of Psoas Major and Piriformis bilateral.

Sixth visit on May 07, 2018

He came to our clinic with lateral lower leg tingling and pain bilateral.
Acupuncture treatment was performed by the same points as first treatment.
As shown in Table 5, the scores of PSQI, HAM-A, HAM-D, and VAS were 11, 7, 15, and 5.9, respectively.

Twelfth visit on May 29, 2018

The participant showed up with light tingling sensation on lateral lower leg bilateral.
Final treatment was performed by the same acupuncture points and methods as first one.
As shown in Table 5, the scores of PSQI, HAM-A, HAM-D, and VAS were 11, 7, 10, and 1.5, respectively.

Table 5. Assessment of Case Three

ASSESSMENT	Before 1^{ST} TREATMENT	After 6^{TH} TREATMENT	After 12^{TH} TREATMENT
PSQI	20	11	11
HAM-A	8	7	7
HAM-D	14	15	10
VAS	7.1	5.9	1.5

ORDINARY INSOMNIA TREATMENT

Case Four

First visit on April 26, 2018

A 57 year- old, Asian woman presented our research center clinic with insomnia for ten years. The participant had no specified medical disorders. She had light nasal allergy and neck stiffness. But those minor problems did not seem to be the causes of her insomnia. Instead, she had unique style of sleeping pattern since her early twenties. She had never tried to go to bed before two o'clock in the morning. We gave her advice to try to go to bed earlier than midnight. She was diagnosed as secondary insomnia and from the Eastern medicine perspective as Liver-Yang Rising and Deficiency of both Heart and Spleen.

As shown in Table 6, the scores of PSQI, HAM-A, HAM-D, and VAS were 16, 23, 22, and 9.0, respectively. First treatment was performed by acupuncture points on HT7, SP6, KI6, UB62, An-Mian and Auricular on Shen-Men, Heart, Sympathetic, and Subcortex points without any additional acupuncture treatment for medical disorders.

Sixth visit on May 18, 2018

She came in to our clinic with nasal allergy and stiff neck. She complained of no improvement in her insomnia. On sixth treatment, we added acupuncture on NEP of Anterior Scalene and Splenius Capitis left for relieving her stiff neck and nasal allergy, but it did not work well.

As shown in Table 6, the scores of PSQI, HAM-A, HAM-D, and VAS were 16, 15, 25, and 8.0, respectively.

Twelfth visit on July 06, 2018

The participant showed up our clinic with insomnia and complaints of dizziness, fatigue. Acupuncture treatment was performed on HT7, SP6, KI6, UB62, An-Mian, and auricular points on Shen-Men, Heart, Sympathetic, Subcortex.

As shown in Table 6, the scores of PSQI, HAM-A, HAM-D, and VAS were 19, 15, 30, and 7.9, respectively.

Table 6. Assessment of Case Four

ASSESSMENT	Before 1^{ST} TREATMENT	After 6^{TH} TREATMENT	After 12^{TH} TREATMENT
PSQI	16	16	19
HAM-A	23	15	15
HAM-D	22	25	30
VAS	9.0	8.0	7.9

Case Five

First visit on April 12, 2018

A 77 year-old, Asian woman presented in our research center clinic with chronic insomnia for thirty years. The participant had no specified medical disorders. Besides there was no bad sleeping pattern either. But due to aging, degenerating phenomena appeared here and there of the whole body.

As shown in Table 7, the scores of PSQI, HAM-A, HAM-D, and VAS were 15, 8, 6, and 7.3, respectively.

Sixth visit on April 30, 2018

The participant came in to our clinic with insomnia and dull pain on left medial knee when she stretched her leg out. Acupuncture treatment was performed the same points and methods as the first treatment except TTP on left Semi Membranosus.

As shown in Table 7, the scores of PSQI, HAM-A, HAM-D< and VAS were 15, 6, 6, and 5.4, respectively.

Twelfth visit on May 21, 2018

The participant presented in our clinic with insomnia. Participant's response to whole treatment for her chronic insomnia revealed no signs of improvement.

As shown in Table 7, the scores of PSQI, HAM-A, HAM-D, and VAS were 12, 8, 8, and 4.7, respectively.

Table 7, Assessment of Case Five

ASSESSMENT	Before 1^{ST} TREATMENT	After 6^{TH} TREATMENT	After 12^{TH} TREATMENT
PSQI	15	15	12
HAM-A	8	6	8
HAM-D	6	6	8
VAS	7.3	5.4	4.7

FACTORIAL ANALYSIS ON THE EFFECT OF ACUPUNCTURE TREATMENT ON SLEEP QUALITY

Effect of Acupuncture treatment on Pittsburg Sleep Quality Index

As shown in Table 8, the mean value of PSQI for participants treated with Ordinary Insomnia Treatment (OIT) method change as from 15.5±0.7 before acupuncture treatment to 15.5±5.0 after 12th treatment. Whereas, the mean value of PSQI for participants treated with Individualized Insomnia Treatment (IIT) method was changed from 16.7±3.1 before acupuncture treatment to 7.3±3.2 after 12th treatment, which will show significant difference between two factors in a larger group as shown in Figure 2. Meanwhile, as shown in Table 9, two participants out of three participants treated by IIT method and zero out of two participants treated with OIT method reached the treatment goal of score below 7, of which the improvement of treatment effect (Relative Risk Reduction) on PSQI for participants treated by IIT method over participants treated with OIT method was calculated as 67%.

Table 8. Effect of Acupuncture Treatment on PSQI

GROUP		PSQI 0	PSQI 6TH	PSQI 12TH
OIT	MEAN	15.50	15.50	15.50
	N	2	2	2
	Std. Deviation	.707	.707	4.950
	MINIMUM	15	15	12
	MAXIMUM	16	16	19
IIT	MEAN	16.67	8.33	7.33
	N	3	3	3
	Std. Deviation	3.055	3.055	3.215
	MINIMUM	14	5	5
	MAXIMUM	20	11	11
TOTAL	MEAN	16.20	11.20	10.60
	N	5	5	5
	Std. Deviation	2.280	4.494	5.595
	MINIMUM	14	5	5
	MAXIMUM	20	16	19

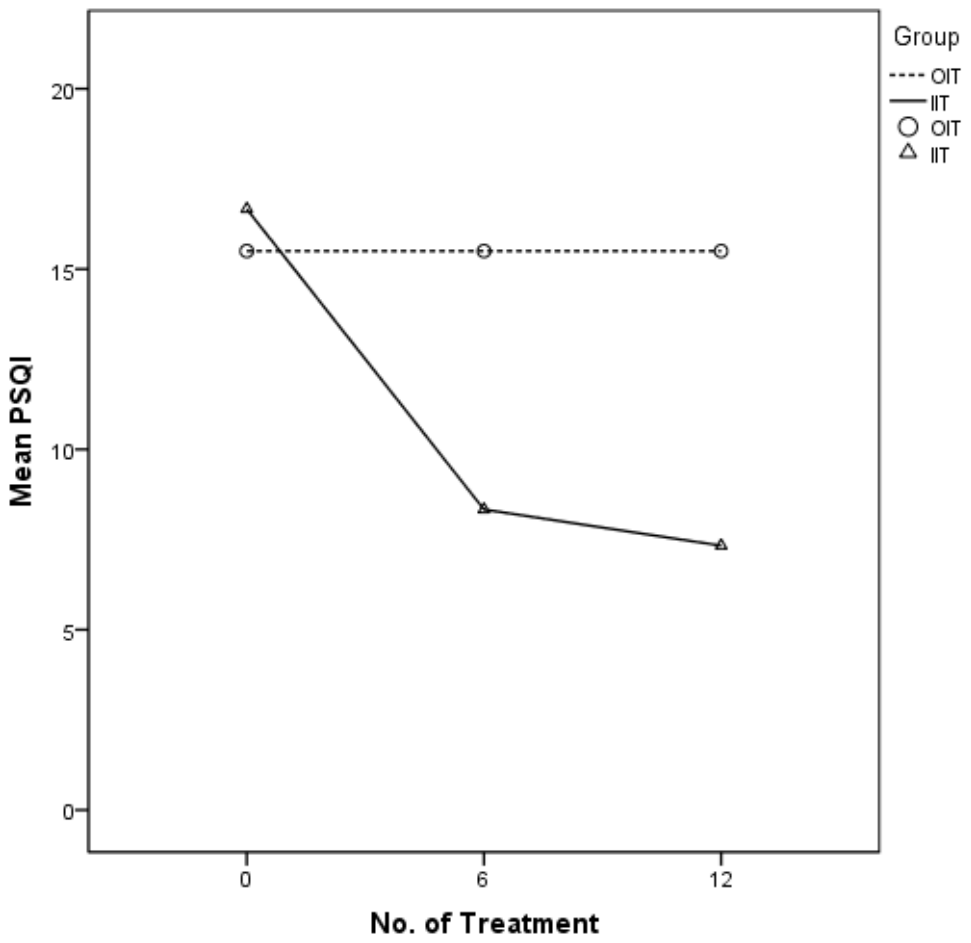


Figure 2. Effect of Acupuncture Treatment on PSQI between Ordinary Insomnia Treatment (OIT) Method and Individualized Insomnia Treatment (IIT) Method

Table 9. 2X2 Table Analysis of Acupuncture Treatment on PSQI between Ordinary Insomnia Treatment (OIT) Method and Individualized Insomnia Treatment (IIT) Method

	PSQI	
	≥7	<7
IIT	1	2
OIT	2	0

$$\text{Treatment effect (Relative Risk Reduction)} = \frac{2/2 - 1/3}{2/2} = 0.67 = 67\%$$

Effect of Acupuncture treatment on Anxiety

As shown in Table 10, the mean value of HAM-A for participants treated with OIT method did not change as from 15.5±10.1 before acupuncture treatment to 11.5±5.0 after 12^{th} treatment. Whereas, the mean value of HAM-A for treated with IIT method was changed from 21.7±12.7 before acupuncture treatment to 7.3±1.5 after 12^{th} treatment, which will show significant difference between two factors in a larger group as shown in Figure 3. Meanwhile, as shown in Table 11, three out of three participants treated with IIT method and one out of two participant treated with OIT method reached the treatment goal of score below 14, of which the improvement of treatment effect (Relative Risk Reduction) on HAM-A for participants treated with IIT method over participants treated with OIT method was calculated as 100%.

.

Table 10. Effect of Acupuncture Treatment on HAM-A

Group		HAM-A 0	HAM-A 6th	HAM-A 12th
OIT	Mean	15.50	10.50	11.50
	N	2	2	2
	Std. Deviation	10.067	6.364	4.950
	Minimum	8	6	8
	Maximum	23	15	15
IIT	Mean	21.67	15.67	7.33
	N	3	3	3
	Std. Deviation	12.662	9.018	1.528
	Minimum	8	7	6
	Maximum	33	25	9
Total	Mean	19.20	13.60	9.00
	N	5	5	5
	Std. Deviation	10.941	7.668	3.536
	Minimum	8	6	6
	Maximum	33	25	15

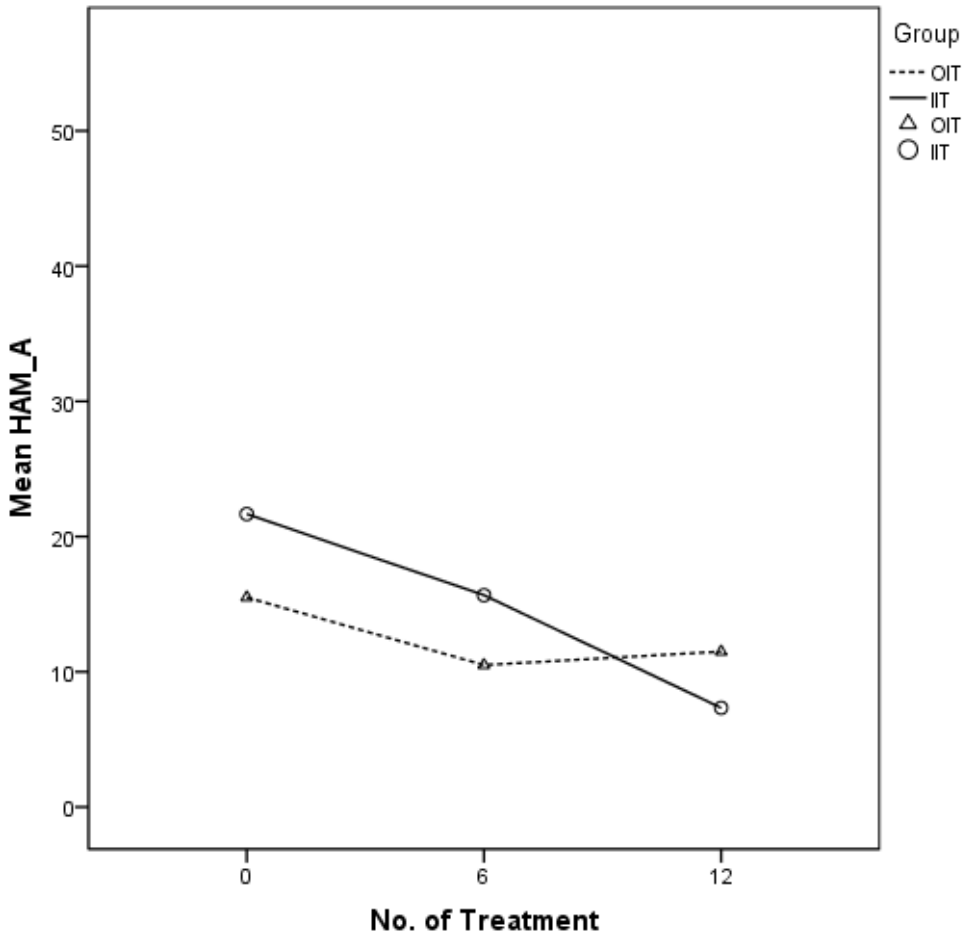


Figure 3. Effect of Acupuncture Treatment on HAM-A between Ordinary Insomnia Treatment (OIT) Method and Individualized Insomnia Treatment (IIT) Method

Table 11. 2X2 Table Analysis of Acupuncture Treatment on HAM-A between Ordinary Insomnia Treatment (OIT) Method and Individualized Insomnia Treatment (IIT) Method

	HAM-A	
	≥14	<14
IIT	0	3
OIT	1	1

$$\text{Treatment effect (Relative Risk Reduction)} = \frac{1/2 - 0/3}{1/2} = 1.0 = 100\%$$

Effect of Acupuncture Treatment on Depression

As shown in Table 12, the mean value of HAM-D for participants treated with OIT method did not change as from 14.0±11.3 before acupuncture treatment to 19.0±15.6 after 12th treatment. Whereas, the mean value of HAM-D for participants treated with IIT method was changed from 16.7±4.6 before acupuncture treatment to 8.7±3.2 after 12th treatment, which will show significant difference between two factors in a larger group as shown in Figure 4. Meanwhile, as shown in Table 13, two out of three participants treated with IIT method and one out of two participant treated with OIT method reached the treatment goal of score below 7, of which the improvement of treatment effect (Relative Risk Reduction) on HAM-D for participants treated with IIT method over participants treated with OIT method was calculated as 33%.

Table 12. Effect of Acupuncture Treatment on HAM-D

Group		HAM-D 0	HAM-D 6th	HAM-D 12th
OIT	Mean	14.00	15.50	19.00
	N	2	2	2
	Std. Deviation	11.314	13.435	15.556
	Minimum	6	6	8
	Maximum	22	25	30
IIT	Mean	16.67	13.33	8.67
	N	3	3	3
	Std. Deviation	4.619	4.726	3.215
	Minimum	14	8	5
	Maximum	22	17	11
Total	Mean	15.60	14.20	12.90
	N	5	5	5
	Std. Deviation	6.693	7.596	9.884
	Minimum	6	6	5
	Maximum	22	25	30

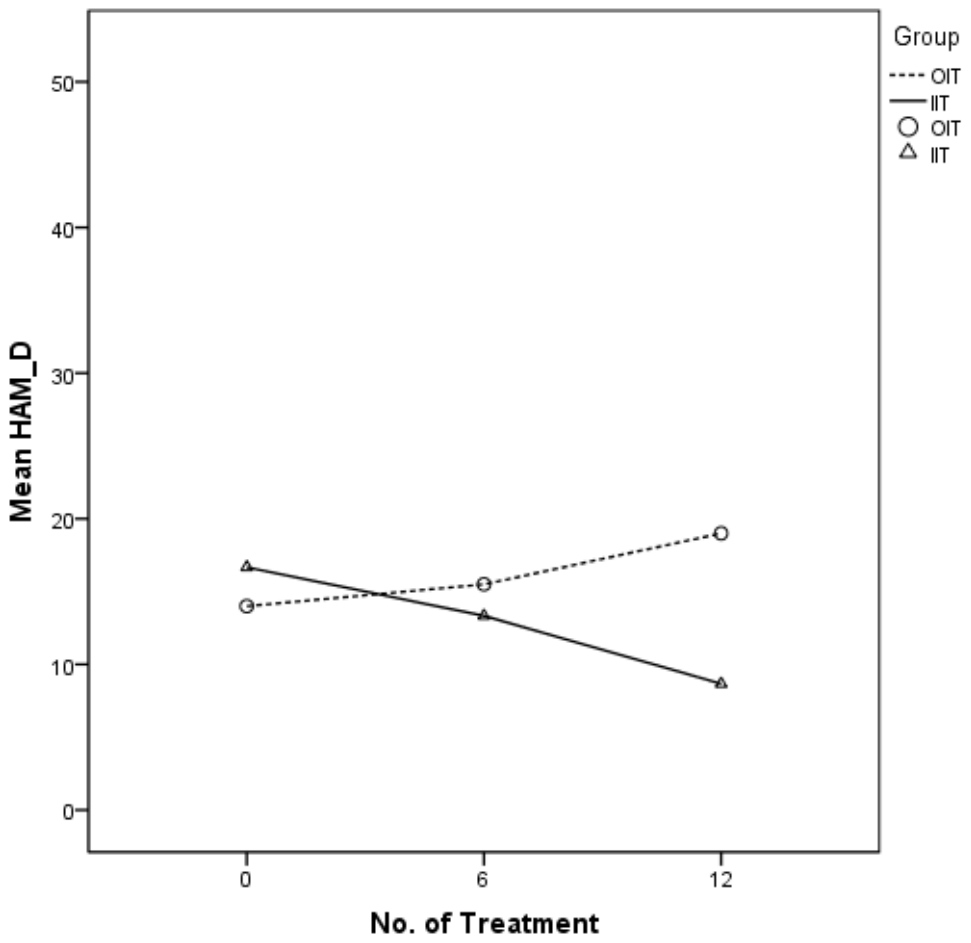


Figure 4. Effect of Acupuncture Treatment on HAM-D between Ordinary Insomnia Treatment (OIT) Method and Individualized Insomnia Treatment (IIT) Method

Table 13. 2X2 Table Analysis of Acupuncture Treatment on HAM-D between Ordinary Insomnia Treatment (OIT) Method and Individualized Insomnia Treatment (IIT) Method

	HAM-D	
	≥7	<7
IIT	1	2
OIT	1	1

$$\text{Treatment effect (Relative Risk Reduction)} = \frac{1/2 - 1/3}{1/2} = 0.33 = 33\%$$

Effect of Acupuncture Treatment on Pain

As shown in Table 14, the mean value of VAS for participants treated with OIT method did not change as from 8.2±1.2 before acupuncture treatment to 6.3±2.2 after 12th treatment. Whereas, the mean value of VAS for participants treated with IIT method was changed from 7.8±1.0 before acupuncture treatment to 1.2±0.4 after 12th treatment, which will show significant difference between two factors in a larger group as shown in Figure 5. Meanwhile, as shown in Table 15, three out of three participants treated with IIT method and zero out of two participant treated with OIT method reached the treatment goal of score below 7, of which the improvement of treatment effect (Relative Risk Reduction) on VAS for participants treated with IIT method over participant treated with OIT method was calculated as 100%.

Table 14. Effect of Acupuncture Treatment on VAS

Group		VAS 0	VAS 6th	VAS 12th
OIT	Mean	8.150	6.700	6.250
	N	2	2	2
	Std. Deviation	1.2021	1.8385	2.1920
	Minimum	7.3	5.4	4.7
	Maximum	9.0	8.0	7.8
IIT	Mean	7.767	5.000	1.167
	N	3	3	3
	Std. Deviation	.9866	1.3892	.4163
	Minimum	7.1	3.4	7
	Maximum	8.9	5.9	1.5
Total	Mean	7.920	5.680	3.200
	N	5	5	5
	Std. Deviation	.9445	1.6362	3.0067
	Minimum	7.1	3.4	.7
	Maximum	9.0	8.0	7.8

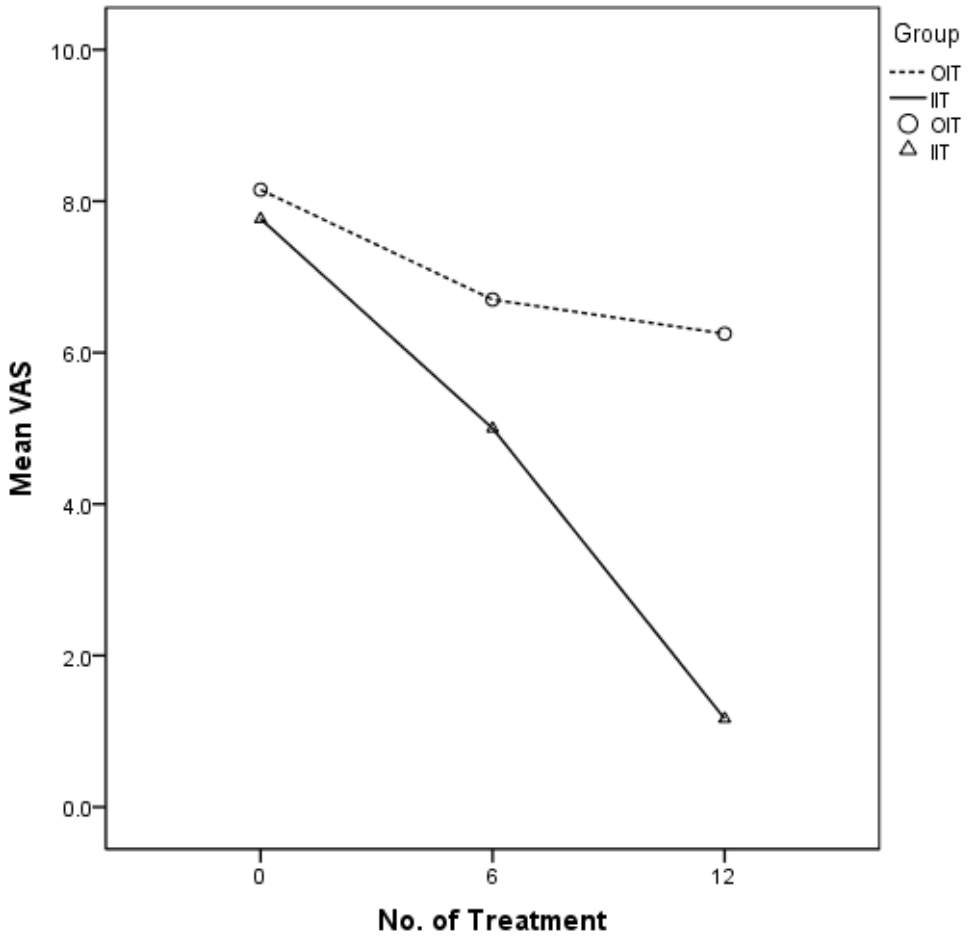


Figure 5. Effect of Acupuncture Treatment on VAS between Ordinary Insomnia Treatment (OIT) Method and Individualized Insomnia Treatment (IIT) Method

Table 15. 2X2 Table Analysis of Acupuncture Treatment on VAS between Ordinary Insomnia Treatment (OIT) Method and Individualized Insomnia Treatment (IIT) Method

	VAS	
	>3	≤3
IIT	0	3
OIT	2	0

$$\text{Treatment effect (Relative Risk Reduction)} = \frac{2/2 - 0/3}{2/2} = 1.0 = 100\%$$

IV. DISCUSSION

This study aimed to identify the effect of corresponding acupuncture treatment on secondary insomnia by considering factors of causing insomnia.

As mentioned in Results, the mean value of PSQI, HAM-A, HAM-D, and VAS for participants treated with OIT method changed as from 15.5±0.7, 15.5±10.1, 14.0±11.3, and 8.2±1.2 before 1st acupuncture treatment to 15.5±5.0, 11.5±5.0, 19.0±15.6, and 6.3±2.2 after 12th treatment, respectively. Whereas, the mean value of PSQI, HAM-A, HAM-D, and VAS for participants treated with IIT method changed as from 16.7±3.1, 21.7±12.7, 16.7±4.6, and 7.8±1.0 before 1st acupuncture treatment to 7.3±3.2, 7.3±1.5, 8.7±3.2, and 1.2±0.4 after 12th acupuncture treatment, respectively. Improvement in Treatment Effect (Relative Risk Reduction) on PSQI, HAM-A, HAM-D, and VAS, were calculated using 2X2 table method as 67%, 100%, 33%, and 100%, respectively.

According to above outcomes, we could recognize the effect of acupuncture treatment depending on the correct distinguishing pattern diagnosis of insomnia. Following the correct distinguishing diagnosis, the additional acupuncture treatment exerted on medical disorders could achieve more benefits than simply relying on treating the insomnia itself. On this clinical cases study, we employed the tendon traction point (TTP) and nerve entrapment point (NEP) needling technique for treating participants with medical disorders.

When treating insomnia, general treatment methods employed are medical and non-medical ways. Non-medical treatment is a Cognitive Behavioral Therapy (CBT) and medical one is prescription or over-the-counter (OTC) medicine therapy[4]. Those treating insomnia methods do not focus on medical disorders but on insomnia itself. Therefore, the outcomes of those methods focusing on insomnia itself have not been identified as well valuable clinically.

An acupuncture treatment has been relatively beneficial for general disease. But on insomnia especially on Secondary Insomnia, there has been low success rate of treating that insomnia by acupuncture treatment.

When we try to focus on medical disorders for treating Secondary Insomnia, we can expect to achieve more clinical positive results not only with insomnia but also with releasing from the suffered medical disorders together at a time whatever kind of methods to try to treat Secondary Insomnia is.

Meanwhile, due to the limitation of time and location, the trial was conducted with only five participants. That might cause the loss of the validity as well as the representativeness of the results of the trial as it was impossible to apply inferential statistics. However, as the effect of corresponding treatment and the potential of supplementary treatment such as tendon traction point (TTP) and nerve entrapment point (NEP) needling technique are not underestimated, we are proposing to confirm them through the larger scale and higher quality clinical trial.

V. CONCLUSION

From the case series trial with five insomnia participants to prove the effect of corresponding treatment by considering factors of causing insomnia and the potential of supplementary acupuncture treatment focusing on the disorders associated with secondary insomnia, we could conclude;

1. The mean values of PSQI, HAM-A, HAM-D, and VAS for participants treated with OIT method changed from 15.5±0.7, 15.5±10.1, 14.0±11.3, and 8.2±1.2 before 1st acupuncture treatment to 15.5±5.0, 11.5±5.0, 19.0±15.6, and 6.3±2.2 after 12th treatment, respectively.
2. The mean values of PSQI, HAM-A, HAM-D, and VAS for participants treated with IIT method as from 16.7±3.1, 21.7±12.7, 16.7±4.6, and 7.8±1.0 before 1st acupuncture treatment to 7.3±3.2, 7.3±1.5, 8.7±3.2, and 1.2±0.4 after 12th acupuncture treatment, respectively.
3. Improvement of Treatment Effect (Relative Risk Reduction) in participants treated with IIT method over participants treated with OIT method were calculated as 67%, 100%, 33%, and 100% for PSQI, HAM-A, HAM-D, and VAS, respectively.
4. Nerve entrapment point (NEP) and tendon traction point (TTP) needling showed potential as a new technique to treat nerve related muscles and bones-diseases and sympathetic nerve entrapment syndromes associated with insomnia.

5. The effect of corresponding treatment was identified, and the improvement in the outcomes for Secondary Insomnia participants by paying more attention to accompanying disorders than simply focusing on insomnia symptom itself was confirmed.

REFERENCES

1. Institute of Medicine (IOM) Committee on Sleep Medicine and Research, Colten, H. R. and Altevogt, B. M. (ed.). (2006*) Sleep Disorders and Sleep Deprivation: An Unmet Public Health Problem.* Washington DC: National Academy of Sciences.
2. Schutte-Rodin, S., Broch L., Buysse, D., Dorsey C., and Sateia, M. (2008), Clinical guideline for the evaluation and management of chronic insomnia in adults. *J Clin Sleep Med*; 4(5), 487-504.
3. Roth, T., (2007), Insomnia. Definition, prevalence, etiology, and consequences. *Journal of Clinical Sleep Medicine.* Supplement to 3(5), S7-S10.
4. National Sleep Foundation. Can't Sleep? What to Know About Insomnia, Arlington: NSF, no date. Available at: http://sleepfoundation.org/article/ sleep-related problems/insomnia-and-sleep.
5. WebMed Medical Reference-An over view of insomnia (2017) (http://www.webmed.com).
6. *Sleep Medicine Review* (2000). 5(1), 47-61(http://www.ideallibrary.com)
7. Oaseem, A., Kansagara, D., Forciea, M. A., Cooke, M., and Denberg, T. D. (2016), Clinical guidelines Committee of the American College of, Physicians (19 July 2016*).* Management of Chronic Insomnia Disorder in Adults: A Clinical Practice Guideline from the American College of Pysicians, *Annals of Internal Medicine*. 165 (2), 125-33.
8. Chong Y., Frayr, C D., and Gu, Q. (2013). Prescription Sleep Aid Use Among Adults; United States, 2005-2010. Hyattsville, MD; U.S. Department of Health and Human Services, National Center for Health Statistics.

9. Treatment of insomnia (https://www.medicalnewstoday.com/articles/9155.p10.
10. The kinds of insomnia, sleep. (2017), *Health* (http://www.health.com).
11. Insomnia-Treatment overview. (2018), (http://www.w ebmed.com).
12. Maciocia, G. (2015). *The Foundation of Chinese Medicine*: (http://www.elsevierhealth.com).
13. Cheng, X. (1999). *Chinese Acupuncture and Moxibustion*. (Revised Edition).Beijing, China: Foreign Language Press.
14. The Acupuncture Institute of the Academy of Traditional Chinese Medicine. (1980). *Essentials of Chinese Acupuncture*. (1st Edition). Beijing, China.
15. Sleep Better-TCM for insomnia, *Vitality Magazine*. (1989). (http://www.vitalitymagazine.com), (Searched in 2018).
16. How Meditation Helps Sleep Problems. *Is best remedy for Insomnia*, EDC Institute. (http://www.eocinstitute.org> meditation).
17. Natural way to treat insomnia: Chinese herbal medicine. (http://www.dcacupuncture.com).
18. Acupuncture and Moxibustion Therapies for insomnia (http://www.shen-nong.com).
19. Connor, J & Bensky, D. (1997). *Acupuncture: A comprehensive text*/ Shanghai College of Traditional Medicine: Chicago. East land Press. .
20. Helms, J. (1997). *Acupuncture Energetics: A clinical approach for physicians*. Salt Lake City, Utah: Publishers Press.
21. Buysse, D. J., Reynolds, C. F. 3rd, Monk, T. H., Berman, S. R., and Kupfer, D. J. (1989), The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and Research, *Psychiatry Res.* 28(2):193-213.

22. Lund, H. G., Reider, B. D., Whiting, A. B., and Prichard, J. R.(2010). Sleep patterns and predictors of disturbed sleep in a large population of college students**.** *Journal of Adolescent Health,* 46: 124-132.

23. Hamilton, M. (1960). A rating scale for depression. *J Neurol Neurosurg Psychiatry*. 23:56-62.

24. Zimmerman, M., Martinez, J. H., Young, D., Chelminski, I., and Dalrymple, K. (2013). Severity classification on the Hamilton Depression Rating Scale. *J Affect Disord,* 150. 384-388.

25. Hamilton Anxiety Rating Scale (HAM-A). (http://www.psychcongress.com).

26. Seong, J. W. (2015). *Principles and Insights into Pain*. Seoul, South Korea: Koonja Press.

27. Gould, D., Kelly, D., Goldstone, L., and Gammon, J., (2001). Examining the validity of pressure ulcer risk assessment scales: developing and using illustrated patient simulations to collect the data, INFORMATION POINT: Visual Analogue Scale (VAS).*Journal of Clinical Nursing*, 10, 697-706.

28. Paul-Dauphin, A., Guillemin, F., Virion, J. M., and Briançon, S., (1999), Bias and Precision in Visual Analogue Scale: A randomized Controlled Trial. *American Journal of Epidemiology.* 150(10)1117-1127.

29. Scott, J., and Huskisson, E. C., (1979), Vertical or horizontal visual analogue scales, *.Ann Rheum Dis* 38, 560.

APPENDIX 1

Name_____ Date_____

Sleep Quality Assessment (PSQI)

What is PSQI, and what is it measuring?

The Pittsburgh Sleep Quality Index (PSQI) is an effective instrument used to measure the quality and patterns of sleep in adults. It differentiates "poor" from "good" sleep quality by measuring seven areas (components): subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medications, and daytime dysfunction over the last month.

INSTRUCTIONS:

The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

During the past month,

1. When have you usually gone to bed? _____
2. How long (in minutes) has it taken you to fall asleep each night? _____
3. What time have you usually gotten up in the morning? _____
4. A. How many hours of actual sleep did you get at night? _____
   B. How many hours were you in bed? _____

5. During the past month, how often have you had trouble sleeping because you	Not during the past month (0)	Less than once a week (1)	Once or twice a week (2)	Three or more times a week (3)
A. Cannot get to sleep within 30 minutes				
B. Wake up in the middle of the night or early morning				
C. Have to get up to use the bathroom				
D. Cannot breathe comfortably				
E. Cough or snore loudly				
F. Feel too cold				
G. Feel too hot				
H. Have bad dreams				
I. Have pain				
J. Other reason (s), please describe, including how often you have had trouble sleeping because of this reason (s):				
6. During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep?				
7. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?				
8. During the past month, how much of a problem has it been for you to keep up enthusiasm to get things done?				
9. During the past month, how would you rate your sleep quality overall?	Very good (0)	Fairly good (1)	Fairly bad (2)	Very bad (3)

Scoring

Component 1	#9 Score	C1 _____
Component 2	#2 Score (<15min (0), 16-30min (1), 31-60 min (2), >60min (3)) + #5a Score (if sum is equal 0=0; 1-2=1; 3-4=2; 5-6=3)	C2 _____
Component 3	#4 Score (>7(0), 6-7 (1), 5-6 (2), <5 (3)	C3 _____
Component 4	(total # of hours asleep) / (total # of hours in bed) x 100 >85%=0, 75%-84%=!, 65%-74%=2, <65%=3	C4 _____
Component 5	# sum of scores 5b to 5j (0=0; 1-9=1; 10-18=2; 19-27=3)	C5 _____
Component 6	#6 Score	C6 _____
Component 7	#7 Score + #8 score (0=0; 1-2=1; 3-4=2; 5-6=3)	C7 _____

Add the seven component scores together _____ ***Global PSQI*** _____

A total score of "5" or greater is indicative of poor sleep quality.
If you scored "5" or more it is suggested that you discuss your sleep habits with a healthcare provider

APPENDIX 2

Hamilton Anxiety Rating Scale (HAM-A)

Reference: **Hamilton M. The assessment of anxiety states by rating. Br J Med Psychol 1959; 32:50–55.**

Rating Clinician-rated

Administration time 10–15 minutes

Main purpose To assess the severity of symptoms of anxiety

Population Adults, adolescents and children

Commentary

The HAM-A was one of the first rating scales developed to measure the severity of anxiety symptoms, and is still widely used today in both clinical and research settings. The scale consists of 14 items, each defined by a series of symptoms, and measures both psychic anxiety (mental agitation and psychological distress) and somatic anxiety (physical complaints related to anxiety). Although the HAM-A remains widely used as an outcome measure in clinical trials, it has been criticized for its sometimes poor ability to discriminate between anxiolytic and antidepressant effects, and somatic anxiety versus somatic side effects. The HAM-A does not provide any standardized probe questions. Despite this, the reported levels of inter-rater reliability for the scale appear to be acceptable.

Scoring

Each item is scored on a scale of 0 (not present) to 4 (severe), with a total score range of 0–56, where <17 indicates mild severity, 18–24 mild to moderate severity and 25–30 moderate to severe.

Versions

The scale has been translated into: Cantonese for China, French and Spanish. An IVR version of the scale is available from Healthcare Technology Systems.

Additional references

Maier W, Buller R, Philipp M, Heuser I. The Hamilton Anxiety Scale: reliability, validity and sensitivity to change in anxiety and depressive disorders. J Affect Disord 1988;14(1):61–8.

Borkovec T and Costello E. Efficacy of applied relaxation and cognitive behavioral therapy in the treatment of generalized anxiety disorder. J Clin Consult Psychol 1993; 61(4):611–19

Address for correspondence

The HAM-A is in the public domain.

Hamilton Anxiety Rating Scale (HAM-A)

Below is a list of phrases that describe certain feeling that people have. Rate the patients by finding the answer which best describes the extent to which he/she has these conditions. Select one of the five responses for each of the fourteen questions.

0 = Not present, 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Very severe.

1 Anxious mood [0] [1] [2] [3] [4]

Worries, anticipation of the worst, fearful anticipation, irritability.

2 Tension [0] [1] [2] [3] [4]

Feelings of tension, fatigability, startle response, moved to tears easily, trembling, feelings of restlessness, inability to relax.

3 Fears [0] [1] [2] [3] [4]

Of dark, of strangers, of being left alone, of animals, of traffic, of crowds.

4 Insomnia [0] [1] [2] [3] [4]

Difficulty in falling asleep, broken sleep, unsatisfying sleep and fatigue on waking, dreams, nightmares, night terrors.

5 Intellectual [0] [1] [2] [3] [4]

Difficulty in concentration, poor memory.

6 Depressed mood [0] [1] [2] [3] [4]

Loss of interest, lack of pleasure in hobbies, depression, early waking, diurnal swing.

7 Somatic (muscular) [0] [1] [2] [3] [4]

Pains and aches, twitching, stiffness, myoclonic jerks, grinding of teeth, unsteady voice, increased muscular tone.

8 Somatic (sensory) [0] [1] [2] [3] [4]

Tinnitus, blurring of vision, hot and cold flushes, feelings of weakness, pricking sensation.

9 Cardiovascular symptoms [0] [1] [2] [3] [4]

Tachycardia, palpitations, pain in chest, throbbing of vessels, fainting feelings, missing beat.

10 Respiratory symptoms [0] [1] [2] [3] [4]

Pressure or constriction in chest, choking feelings, sighing, dyspnea.

11 Gastrointestinal symptoms [0] [1] [2] [3] [4]

Difficulty in swallowing, wind abdominal pain, burning sensations, abdominal fullness, nausea, vomiting, borborygmi, looseness of bowels, loss of weight, constipation.

12 Genitourinary symptoms [0] [1] [2] [3] [4]

Frequency of micturition, urgency of micturition, amenorrhea, menorrhagia, development of frigidity, premature ejaculation, loss of libido, impotence.

13 Autonomic symptoms [0] [1] [2] [3] [4]

Dry mouth, flushing, pallor, tendency to sweat, giddiness, tension headache, raising of hair.

14 Behavior at interview [0] [1] [2] [3] [4]

Fidgeting, restlessness or pacing, tremor of hands, furrowed brow, strained face, sighing or rapid respiration, facial pallor, swallowing, etc.

APPENDIX 3

HAMILTON DEPRESSION RATING SCALE (HAM-D)

(To be administered by a health care professional)

Patient Name _____ Today's Date _____

The HAM-D is designed to rate the severity of depression in patients. Although it contains 21 areas, calculate the patient's score on the first 17 answers.

☐ 1. DEPRESSED MOOD
(Gloomy attitude, pessimism about the future, feeling of sadness, tendency to weep)
0 = Absent
1 = Sadness, etc.
2 = Occasional weeping
3 = Frequent weeping
4 = Extreme symptoms

☐ 2. FEELINGS OF GUILT
0 = Absent
1 = Self-reproach, feels he/she has let people down
2 = Ideas of guilt
3 = Present illness is a punishment; delusions of guilt
4 = Hallucinations of guilt

☐ 3. SUICIDE
0 = Absent
1 = Feels life is not worth living
2 = Wishes he/she were dead
3 = Suicidal ideas or gestures
4 = Attempts at suicide

☐ 4. INSOMNIA - Initial
(Difficulty in falling asleep)
0 = Absent
1 = Occasional
2 = Frequent

☐ 5. INSOMNIA - Middle
(Complains of being restless and disturbed during the night. Waking during the night.)
0 = Absent
1 = Occasional
2 = Frequent

☐ 6. INSOMNIA - Delayed
(Waking in early hours of the morning and unable to fall asleep again)
0 = Absent
1 = Occasional
2 = Frequent

☐ 7. WORK AND INTERESTS
0 = No difficulty
1 = Feelings of incapacity, listlessness, indecision and vacillation
2 = Loss of interest in hobbies, decreased social activities
3 = Productivity decreased
4 = Unable to work. Stopped working because of present illness only. (Absence from work after treatment or recovery may rate a lower score).

☐ 8. RETARDATION
(Slowness of thought, speech, and activity; apathy; stupor.)
0 = Absent
1 = Slight retardation at interview
2 = Obvious retardation at interview
3 = Interview difficult
4 = Complete stupor

☐ 9. AGITATION
(Restlessness associated with anxiety.)
0 = Absent
1 = Occasional
2 = Frequent

☐ 10. ANXIETY - PSYCHIC
0 = No difficulty
1 = Tension and irritability
2 = Worrying about minor matters
3 = Apprehensive attitude
4 = Fears

HAMILTON DEPRESSION RATING SCALE (HAM-D)

(To be administered by a health care professional)

☐ 11. ANXIETY - SOMATIC
Gastrointestinal, indigestion
Cardiovascular, palpitation, Headaches
Respiratory, Genito-urinary, etc.
0 = Absent
1 = Mild
2 = Moderate
3 = Severe
4 = Incapacitating

☐ 12. SOMATIC SYMPTOMS - GASTROINTESTINAL
(Loss of appetite, heavy feeling in abdomen; constipation)
0 = Absent
1 = Mild
2 = Severe

☐ 13. SOMATIC SYMPTOMS - GENERAL
(Heaviness in limbs, back or head; diffuse backache; loss of energy and fatiguability)
0 = Absent
1 = Mild
2 = Severe

☐ 14. GENITAL SYMPTOMS
(Loss of libido, menstrual disturbances)
0 = Absent
1 = Mild
2 = Severe

☐ 15. HYPOCHONDRIASIS
0 = Not present
1 = Self-absorption (bodily)
2 = Preoccupation with health
3 = Querulous attitude
4 = Hypochondriacal delusions

☐ 16. WEIGHT LOSS
0 = No weight loss
1 = Slight
2 = Obvious or severe

☐ 17. INSIGHT
(Insight must be interpreted in terms of patient's understanding and background.)
0 = No loss
1 = Partial or doubtfull loss
2 = Loss of insight

TOTAL ITEMS 1 TO 17: _____
0 - 7 = Normal
8 - 13 = Mild Depression
14-18 = Moderate Depression
19 - 22 = Severe Depression
≥ 23 = Very Severe Depression

☐ 18. DIURNAL VARIATION
(Symptoms worse in morning or evening. Note which it is.)
0 = No variation
1 = Mild variation; AM ( ) PM ( )
2 = Severe variation; AM ( ) PM ( )

☐ 19. DEPERSONALIZATION AND DEREALIZATION
(feelings of unreality, nihilistic ideas)
0 = Absent
1 = Mild
2 = Moderate
3 = Severe
4 = Incapacitating

☐ 20. PARANOID SYMPTOMS
(Not with a depressive quality)
0 = None
1 = Suspicious
2 = Ideas of reference
3 = Delusions of reference and persecution
4 = Hallucinations, persecutory

☐ 21. OBSESSIONAL SYMPTOMS
(Obsessive thoughts and compulsions against which the patient struggles)
0 = Absent
1 = Mild
2 = Severe

* Adapted from Hamilton, M. Journal of Neurology, Neurosurgery, and Psychiatry. 23:56-62, 1960.

APPENDIX 4

Informed Consent Form

You are invited to participate in a research study about "Effect of Individualized Acupuncture Treatment on Sleep Quality of Secondary Insomnia Patients Corresponding to Their Pain Status: Case Series".

The goal of this research study is to compare the effect of individualized acupuncture treatment corresponding to the causing factors of secondary insomnia.

The study design is a case series trial. Acupuncture treatment will be provided. The change of insomnia will be evaluated by Pittsburgh Sleep Quality Index (PSQI) score. Hamilton Rating Scale of Anxiety (HAM-A), Hamilton Rating Scale of Depression (HAM-D), and Visual Analog Scale of pain level (VAS) at the same time. The evaluation can be conducted when judged appropriated. Photographs or video recording might be taken when appropriate.

This study is being conducted by Byung Kyu Choi, LAc. and other members of **SBU** Integrative Medicine Research Institute.

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment, test and diagnoses, and a pack of herb. You may change your mind later and stop participating even if you agreed earlier.

Participating in this study may not benefit you directly, but it will help to enrich the knowledge on Acupuncture and East Asian Medicine.

By participating in this research, it is possible that you will be at greater risk than you would otherwise be. There is, for example, a risk that your condition will not get better and that the new medicine or treatment does not work even as well as the old one. If, however, the medicine or treatment is not working, we will give the medication or routinely offered to make you more comfortable. While the possibility of this happening is very low, you should still be aware of the possibility.

The information you will share with us if you participate in this study will be kept completely confidential to the extent of the law. The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone Byung Kyu Choi, LAc. and other authorized members of **SBU** Integrative Medicine Research Institute.

If you have any questions about this study, please contact Byung Kyu Choi, LAc at, 425-770-0976 and bkc912@gmail.com. If you have any questions or concerns regarding your rights as a subject in this study, you may contact Dr. Jaejong Kim, Chair of the South Baylo University Institutional Review Board (IRB) at 213-320-2888 or jaejongkim621@gmail.com.

YOU WILL BE GIVEN A COPY OF THIS FORM WHETHER OR NOT YOU AGREE TO PARTICIPATE

Certificate of Consent:

I have read the foregoing information, or it has been read to me, I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Name of Participant (Print)	Name of Witness (Print)
Signature of Participant	Signature of Witness
Date: Day/Month/Year	Date: Day/Month/Year

Statement by the researcher/person taking consent:

I have accurately explained the information sheet to the potential participant, I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

_____

Name of Practitioner (Print)

_____

Signature of Practitioner

_____

Date: Day/Month/Year