SOUTH BAYLO UNIVERSITY

Effect of Calm the Spirit Points Acupuncture Treatment for Chronic Pain Accompanied by Depression: Case Series

by

Young Lee

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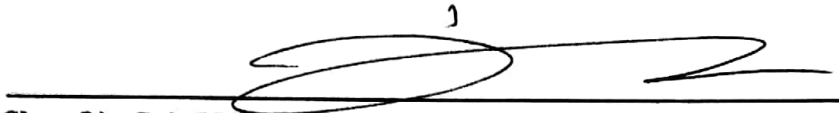
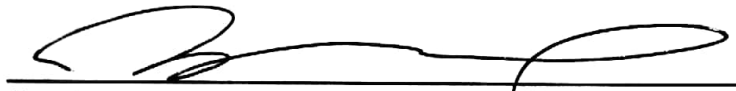


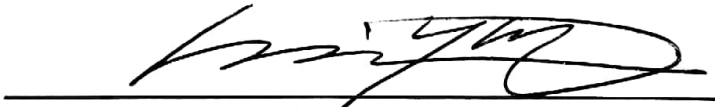
Shan Qin Cui, OMD, L.Ac, Professor

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, Professor / Doctoral Research Coordinator

South Baylo University

Los Angeles, California

March 15, 2018

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Young Lee

SOUTH BAYLO UNIVERSITY AT LA CAMPUS, 2018

Research Advisor: Jae Jong Kim, MD, OMD, L.Ac.

ABSTRACT

A case series trial with seven participants was conducted in order to investigate the effects of Calm the Spirit Points of acupuncture treatment on chronic pain accompanied by depression and the relationship between depressive symptoms and chronic pain.. Acupuncture points P6 and HT7 were used for a course of six times treatments. From the analysis of Numeric Pain Rating Scale (NPRS), dichotomous data showed 0.428 and 0.75 for Risk and Odds of Pain respectively and the improvement of treatment rate was 57.1%. The ordinary NPRS mean score was reduced from 7.14±1.21 to 3.17±0.75, and the mean difference was 3.67±0.82,. The improvement of treatment rate from the trials were within range of significant improvement at 53.8±8.6% (p=0.026). From the analysis of the Hamilton Rating Scale for Depression (HAM-D), dichotomous data showed 0.428 and 0.50

for Risk and Odds of Depression respectively and the improvement of treatment rate was also 57.1%. Continuous HAM-D means scores were reduced from 14.8±5.6 to 4.5±2.0, before and after treatment respectively. The mean difference was 10.3±6.3, showing significant improvement of 65.3±18.0% (p=0.010). From the analysis of Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), the mean score was reduced from 38.2±19.3 to 13.8±5.2, before and after treatment respectively. The mean difference was 24.3±19.5, with significant improvement of 59.3±18.0% (p=0.028). The appropriate number of treatment was calculated as 6 to 7 times by regression analysis (r^2=0.919). It was concluded that Acupuncture Treatment on Calm the Spirit Points is effective for Chronic Pain accompanied by depression. A randomized controlled trial and a supportive trial with larger samples are proposed to provide molecular level imaging displaying the pain-depression relationship.

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I. INTRODUCTION

Chronic pain is not only long term sustained pain, but also central nervous system (CNS) sensitization caused by both neurophysiological and psychometrical issues involved in social environments. [1] It is well known that the etiologically sympathetic neural system and endocrine hormone system involved in chronic pain.[6] Chronic pain is usually accompanied by chronic fatigue, sleep disorders, depression and depressive symptoms such as memory loss and anxiety disorders.[1]

Fibromyalgia is a chronic pain syndrome with depression rates of about 20~40%, which is 3.6 times higher than that of the general population.[1] It has been reported that depression accompanies 50.9% of those with Rheumatoid Arthritis,23.5% of those with Osteosis Arthritis,[2] and 23.5% of those with Lupus.[3] Furthermore, 35% of chronic pain patients developed depression as a result of neural sensitivity in the CNS.

Selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs) are widely used as antidepressants to affect the serotonin and norepinephrine (NE) pathways that are common in both depression and chronic pain.[13] This is evidence of the connection between neural pathways. When activated in the normal pain response, pain intensity increases as several pathways relay the increase in stimulus intensity to brain to activate serotonin/NE pathways through the “Descending Pathway” that is believed to control the “Pain and Ascending Pathway”. Chronic pain from CNS sensitization has been known to have a high possibility of serotonin/NE shortage and decreased activation of the “Descending Pathway”. [16] However, the relationship between pain and depression is not clear,

despite the various studies on the mechanism of their effects on each other.[11][12] Various treatment options besides medication, such as acupuncture, have been developed to allow patients more affordable options [4].

The effect of acupuncture treatment for chronic pain and depression, in conjunction with the use of SSRI medication for chronic pain accompanied by depression[8] has recently seen significant improvement through a study of an 18,000 person sample size ~~of~~ in the meta-analysis by Mac Pherson H. and Vickers et. al of Acupuncture Study Group of York University of England in 2017.[4]

From the point of view of oriental medicine and *The Yellow Emperor`s Classic of Medicine Inner Cannon*, chronic pain and depression, all pains, including inching and inflammation stem from, and thus should be solved from, the "Heart Meridian".[19]

According to Linghsu of *The Yellow Emperor`s Classic of Medicine Inner Cannon*, when a patient's face develops a rash, jaundice, increase in temperature and pain, it is from a disease of the heart and its governor.[21] [20] Once the source of disease, the "Heart Meridian", is corrected through acupuncture, it can be assumed that the negative symptoms mentioned above will resolve as well.

An acupuncture treatment on "Calm the Spirit" points conducted by using "Heart Meridian" point HT7, and "Heart Governor Meridian" point P6 proved effective for chronic pain accompanied by depression. However, a supportive trial and a randomized controlled trial with larger sample sizes alongside molecular level imaging with an fMRI can further explain the pain-depression relationship by attempting to trace the pathways of neurotransmitters.

OBJECTIVES

In order to investigate the effects of the “Calm the Spirit” points of acupuncture treatment on chronic pain accompanied by depression, a case series trial for chronic pain in relation to the NPRS (Numeric Pain Rating Scale), the disability index in daily activity in WOMAC, and depression in HAM-D was conducted using patients with chronic pain accompanied by depression and its symptoms~~,~~

In order to accurately evaluate the effect of acupuncture treatment on depressive symptoms in patients with chronic pain, the levels of depression were measured before and after the 6 treatments using the HAM-D (Hamilton Rating Scale for Depression) and WOMAC was used to analyze the effects treatment.

II. LITERATURE REVIEW

2.1. Pain Processes

There are four major processes in processing pain-related information transduction, transmission, modulation, and perception. Transduction refers to the processes by which tissue-damaging stimuli activate nerve endings. Transmission refers to the relay functions by which the message is carried from the site of tissue injury to the regions of the brain responsible for perception. Modulation is a recently discovered neural process that acts specifically to reduce activity in the transmission system. Perception is the subjective awareness produced by sensory signals; it involves the integration of many sensory messages into a coherent and meaningful whole. Perception is a complex function of several processes including attention, expectation, and interpretation.[35]

2.2. Pain in the Nervous Pathways

Primary afferent nociceptors transmit impulses into the spinal cord (or if they arise from the head, into the medulla oblongata of the brain stem). In the spinal cord, the primary afferent (pain-signaling) terminate near second-order nerve cells in the dorsal horn (DH) of the gray matter. The primary afferent nociceptors then release chemical transmitter substances from their spinal terminals. These transmitters then activate the second-order pain-transmission cells. The identity of these transmitters has not been established yet, but candidates include small polypeptides such as Substance P and somatostatin, as well as amino acids such as glutamic or aspartic acid. [36]

Upon receipt in the DH of the spinal cord, nociceptive information from the viscera, skin and other organs, is subject to extensive processing by a wide range of mechanisms, some of which enhance, and others of which inhibit, its transfer to higher centers. In this regard, a network of descending pathways projecting from cerebral structures to the DH plays a complex and crucial role in the sensation of pain. Specific centrifugal pathways either suppress (descending inhibition) or potentiate (descending facilitation) passage of nociceptive messages to the brain. For example, the engagement of descending inhibition by the opioid analgesic, morphine, fulfills an important role in its pain-relieving properties, while induction of analgesia by the adrenergic agonist, clonidine, reflects actions at alpha (2)-adrenoceptors (alpha(2)-ARs) in the DH normally recruited by descending pathways.[16] However, opioids and adrenergic agents exploit but a tiny fraction of the vast panoply of mechanisms now known to be involved in the induction and/or expression of descending controls. For example, no drug interfering with descending facilitation is currently available for clinical use. The present review focuses on: (1) the organization of descending pathways and their pathophysiological significance, (2) the role of individual transmitters and specific receptor types in the modulation and expression of mechanisms of descending inhibition and facilitation and (3) the advantages and limitations of established and innovated analgesic strategies which act by manipulating descending controls. Knowledge of descending pathways has increased exponentially in recent years, so this is an opportune moment to survey their operation and therapeutic relevance to the improved management of pain. [38]

2.3. Acute Versus Chronic Pain

Little is known about the effects of prolonged pain on the central nervous system. There is some evidence that the transition from acute to chronic pain alters patients' neurophysiology in a way that differentiates them from those with acute pain. In arthritic rats, for example, there are changes in the peripheral nerves that alter their range of response to applied stimuli when compared to that of non-arthritic rates, which may mean that there may be changes in the central pathways for pain transmission as well. [37]

People with recurrent headaches, arthritis, low back pain, angina, or low-grade malignancies may have pain for years. The complaints, treatment, and patients' reactions may be different for each of these conditions. In some cases, psychological factors loom greatly over these factors. They are particularly prominent in patients with lower back pain, facial pain, and headaches and seem to become more so the longer the pain persists. [1]

Psychological and somatical factors are not completely separate in maintaining pain. For example, stress and anxiety increase both muscle contraction and sympathetic outflow and would be expected to exacerbate any ongoing pain problem to which they already contribute. Conversely, any treatment that induces relaxation will reduce these factors and lessen pain. This may be an important connection between the psychosocial and the somatic factors that influence pain tolerance. [35]

2.4. Serotonin as a Neurotransmitter

Serotonin is a neurotransmitter involved in the transmission of nerve impulses. Neurotransmitters are chemical messengers within the brain that allow for the communication between nerve cells.

Packets of serotonin (vesicles) are released from the end of a presynaptic cell into the synaptic cleft. The serotonin molecules can then bind to receptor proteins within the postsynaptic cell, which causes a change in the electrical state of the cell. This change in electrical state can either excite the cell, passing along the chemical message, or inhibit it. Excess serotonin molecules are taken back up by the presynaptic cell and reprocessed.

The neurons in the brain that release serotonin are found in small dense collections of neurons called Raphe Nuclei. The Raphe Nuclei are found in the medulla, pons and midbrain which are all located at the top of the spinal cord. Serotonergic neurons have axons that project to many different parts of the brain; therefore serotonin affects many different behaviors. [8][33]

2.5. Interactions Among the Brain Pattern: Default-Mode, Salience, and Central-Executive Networks during Perceptual Decision-Making of Moving Dots.

Cognitively demanding goal-directed tasks in the human brain are thought to involve the dynamic interplay of several large-scale neural networks, including the default-mode network (DMN), salience network (SN), and central-executive network (CEN). Resting-state functional magnetic resonance imaging (rsfMRI) studies have consistently shown that the CEN and SN negatively regulate activity in the DMN, and this switching is argued to be controlled by the right anterior insula (rAI) of the SN. However, what remains to be investigated is the pattern of directed network interactions during difficult perceptual decision-making tasks.

rsfMRI data was recorded while participants categorized the left-right motion of moving dots. Regions of interest were defined, fMRI time series were extracted, and directed connectivity analysis using Granger causality techniques were performed. Analyses of the data demonstrated that the slow oscillation (0.07-0.19 Hz) mediated the interactions within and between the DMN, SN, and CEN nodes-for both easier and harder decision-making tasks. We found that the rAI, a key node of the SN, played a causal control role over the DMN and CEN for easier decision-making tasks. The combined effort of the rAI and dorsal anterior cingulate cortex of the SN produced causal control over the DMN and CEN for harder tasks. These findings provide important insights into how a sensory signal organizes itself among the DMN, SN, and CEN during sensory information-guided, goal-directed tasks.[32]

2.6. Brain Response to Activate Ascending Pathway and Descending Pathway After Acupuncture Stimulation:

According to Scientific Report (impact factor 5.578) dated July 27, 2016 by YB Chae, a Professor of KHU College of Korean Medicine, verification of bilateral sensory pathways (ascending and descending) from the study of cortical activation patterns of bodily attention triggered by acupuncture stimulation was reported. The brain's functional response during acupuncture treatment was measured through rsfMRI, which stimulated meridian points Ht7 (the Ulnar Nerve) and P6 (the Median Nerve) repeatedly and the response was evaluated by position and strength, in order to activate the SN related to the **"**Descending Pathway**"** and no activated DMN related **"**Ascending Pathway**"**.[17] This is one of the explanations for the

sensory change of the body with neurophysiology, and how treatment processes from the neural system are triggered by Acupuncture stimulation.[5]

2.7. Etiology of Depression

Depression is often referred to as the "cold/flu"in Psychiatry, because it is such a common disease. 10-25% of women and 5-12% of men will have experienced depression at least once in their lifetimes. However, other than to these 10%, depression is not commonly referred to as a disease. An imbalance of neurotransmitters of serotonin, norepinephrine and other hormones from a biochemistry approach, the effects of genetics on mood, stressful Life events, early losses, seasonal affective disorders, side effects of alcohol and medication abuse, and other medical problems were listed as the top causes of of depression, a disease ranked 4th in the 2001 yearly report and anticipated to rank 2nd in the 2020 report by WHO.[24]

2.8. Diagnosis of Depression

Two popular diagnosis systems used for depression are the Diagnostic and Statistical Manual of Mental Disorders, 5^{th} edition: DSM-5 and International Classification of Mental Disorders, and the 10th edition: ICD-10 that make decision the grade of seriousness and duration of Depression.[25]

Other common systems of diagnosing depression include the BDI (Beck Depression Inventory) as a self-estimation, and HAM-D (Hamilton Rating Scale for Depression). [26]

2.9. Treatment for Depression

2.9.1. Medication

Treatment for Depression should be based on medication etiologically. Currently the popular theory of the causation of depression is a disturbance of serotonin, norepinephrine, dopamine neurotransmitters.[27] It is recommended to an antidepressant according to personal symptoms and various clinical experiences. [28] SSRIs and SNRIs are most popular, and venlafaxine is often used for resistant symptoms and duloxetine for diabetic peripheral neuropathic pain (fibromyalgia) while Bupropion and Mirtazapine are used selectively. [29]

2.9.2. Non-medication Treatment

Exercise, reading therapy, cognitive reaction therapy, psychotherapy, and social relation therapy are some of the recommended non-medication treatments for depression. These can be coupled with alternative clinical trials such as electroconvulsive therapy, trans cranial magnetic stimulation, deep brain stimulation, valgus nerve stimulation, and phototherapy [29][30]

2.9.3. Next Generation Treatment for Depression – Pharmacogenomics

There has yet to be a guideline to prescribe the right antidepressant medication initially. Instead, the current system generally considers treatment goals, side effects of the medication,

experience, patient's medication and allergic history, economic conditions, and so on, resulting in a faulty system of trial and error that must be corrected.

The goal of Pharmacogenomics is to create an efficient and effective strategy for prescription medication and is a current hot spot study the effect of medication. In the beginning stages of Pharmacogenomics studies, attention was drawn to figuring out the difference of the single nucleotide polymorphism: SNP. This was then reported throughout studies worldwide on the effect of antidepressants on serotonin transporters (SLC6A4), serotonin receptors (HTR1A and HTR2A), FK506 binding proteins 5(FKBP5), Catechol-O-methyltransferase (COMT), Brain-derived neurotrophic factors(BDNF), Tryptophan hydroxylases(TPH1 and TPH2), G protein beta polypeptides 3(GNB3), Glucocorticoid receptors(NR3C1) and etc.[30]

2.10. Review of Depression in Oriental Medicine

The point of view of depression from an oriental medicine is described by Suwen from *The Yellow Emperor`s Classic of Medicine Inner Cannon* "it is not easy to know unless [closely examining] the patient, [asking about the] patient`s mood, and then [understanding] patient's mind privately". His words reflect the difficulty of diagnosing depression. It is believed that depression is caused by mood disorders, sleep disorders, and/or eating disorders which are then classified into five types of stagnation to create the reason like qi, wet, damp, heat, and blood. [19]

III. MATERIALS & METHODS

3.1. Materials

3.1.1. Acupuncture Fine Needle

A fine disposable sterile stainless steel acupuncture needle was utilized in this research in accordance with the specifications made by DBC, which were discarded after use into a Biohazard sharps container in accordance with CNT (Clean Needle Technique).

Table 1. The tool name, size, manufacturer, and purpose of the acupuncture needles used in treatments

Tool	Specification	Manufacturer	Purpose
Acupuncture Needle	15G, 20mm	Dong Bang Acupuncture (DBC)	Acupuncture treatment

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3.2. Methods

3.2.1. Recruitment Criteria

Following the approval of the study from South Baylo University IRB (Institutional Review Boards) for the Research Proposal and Informed Consent Form, 7 patients with chronic pain in conjunction with severe depression in accordance to HAM-D were recruited by volunteering from Creatur clinic regardless of age, occupation, and gender and were asked to sign and agree on the Informed Consent Form prior to the beginning of the experiment.

3.2.2. Exclusion Criteria

Anyone who had participated in another treatment, had the sole intention to change dosage of current medication, pregnant patients, physically weak patients, and those with acute pain and depression were excluded from consideration for the trials.

3.3. Study Design

In order to thoroughly investigate the effects of Calm the Spirit Points of acupuncture treatment on chronic pain accompanied by depression, a case series trial with seven participants was conducted. Treatment was provided twice a week for three weeks for a total of six treatments from Oct. 2017 to Sep. 2017. The statistical data was evaluated and collected from before and after treatment for chronic pain measured through NPRS, disability index in daily activity measured through WOMAC, and depression in measured through HAM-D before and after 6 treatments.

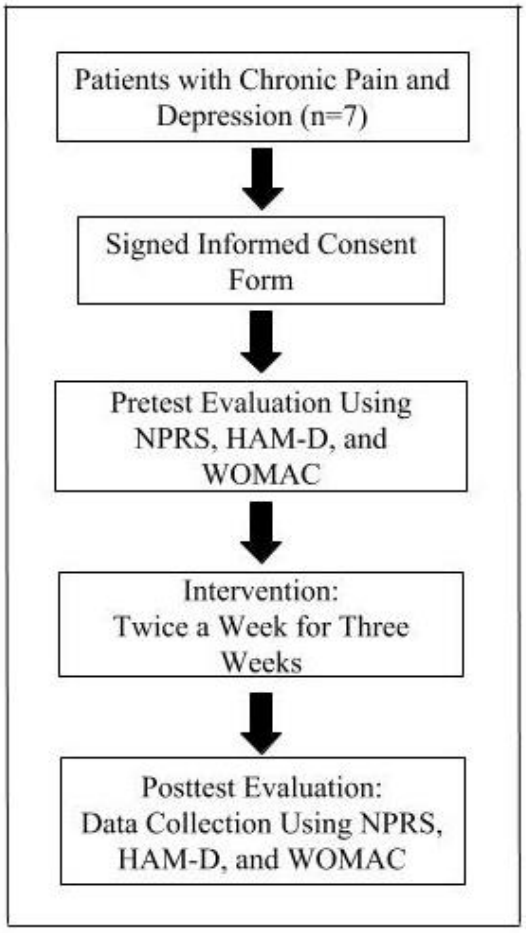

Figure 1. Process used to conduct experiment beginning with screening and selection of seven patients, receipt of consent, pretest evaluations utilizing NPRS, HAM-D, and WOMAC scales, treatment (intervention), and posttest evaluation utilizing the same scales and the pretest.

3.4. Acupuncture Treatment

3.4.1. Acupuncture points

Table 2. The two acupuncture points (P6 and HT7) used in study alongside their anatomical position and their functionality.

Basic Acupuncture Points	Anatomy Position	Functionality
P6	2cm from wrist in between the Palmaris Longers and Flexor Carpi Radialis	Calms the Spirit
HT7	Ulnar of wrist at medial flexor Carpi Ulnaris	Heart pain, depressive symptoms, palpitations, and insomnia

3.4.2. Treatment Method

Treatment was executed 2 times a week for 3 weeks. Each session was 30 minutes long and needles were placed with a depth between 0.3mm-0.5mm depending on the individual.

3.4.3. Measurement*

3.4.3.1. Numeric Pain Rating Scale (NPRS)

The Numeric Pain Rating Scale (NPRS) is a unidimensional measure of pain intensity in adults, including those with chronic pain due to rheumatic diseases.

The NPRS is a segmented numeric version of the visual analog scale (VAS) in which a respondent selects a whole number (0–10 integers) that best reflects the intensity of their pain. The common format is a horizontal bar or line with integers scattered in equal increments. Similar to the VAS, the NPRS is anchored by terms describing pain severity extremes same as **Figure 2.**

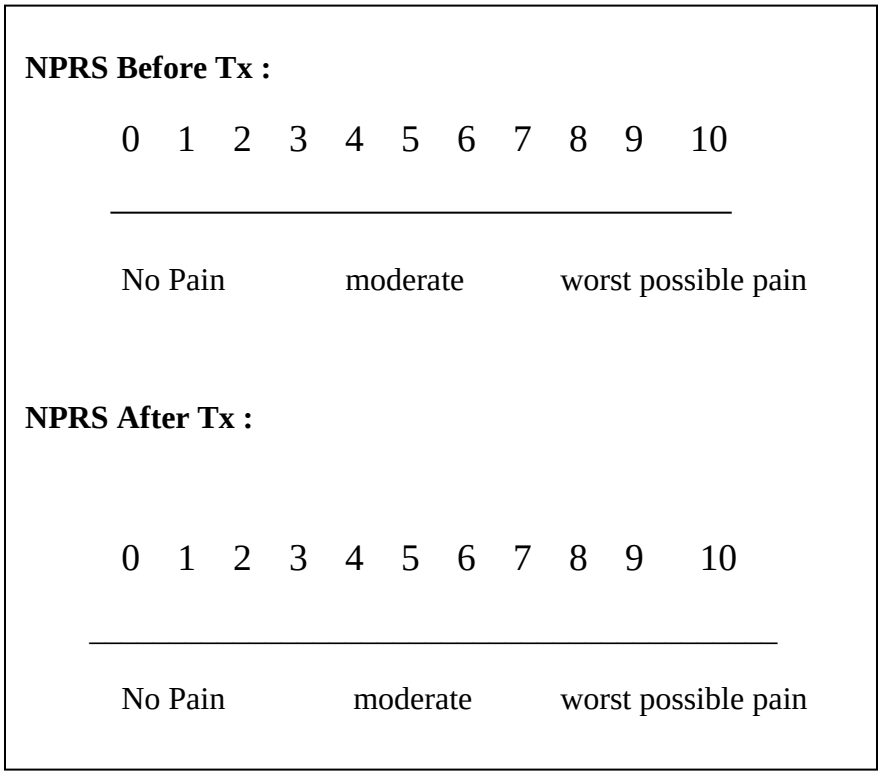

Figure 2. NPRS chart for the measurement of the pain level before and after treatment on a scale of 1 to 10 where 1 is no pain and 10 is the worst possible pain.

3.4.3.2. HAM-D (Hamilton Depression Rating Scale = Hamilton Rating Scale for Depression):

HAM-D is a multiple item questionnaire used to provide an indication of depression, and as a guide to evaluate recovery. Max Hamilton originally published the scale in 1960 then revised it in 1966, 1967, 1969, and 1980. The questionnaire is designed for adults and is used to rate the severity of their depression by probing mood, feelings of guilt, suicide ideation, insomnia, agitation or retardation, anxiety, weight loss, and somatic symptoms.

The original 1960 version contained 17 items (HAMD-17), but four other questions not added to the total score were used to provide additional clinical information. Each item on the questionnaire is scored on a 3 or 5 point scale, depending on the item, and the total score is compared to the corresponding descriptor.

The patient is rated by a clinician on 17 to 29 items (depending on version) scored either on a 3-point or 5-point Likert-type scale. For the 17-item version, a score of 0–7 is considered to be normal. Scores of 20 or higher indicate moderate, severe, or very severe depression. Questions 18–20 may be recorded to give further information about the depression (such as whether diurnal variation or paranoid symptoms are present), but are not part of the scale. A structured interview guide for the questionnaire is available.

3.4.3.3 Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC, appendix 2)

Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) is a widely used, proprietary set of standardized questionnaires used by health professionals to

evaluate the condition of patients with osteoarthritis of the knee and hip, including pain, stiffness, and physical functioning of the joints. The WOMAC has also been used to assess back pain, rheumatoid arthritis, juvenile rheumatoid arthritis, systemic lupus erythematosus, and fibromyalgia. It can be self-administered and was developed at Western Ontario and McMaster Universities in 1982.

The WOMAC measures five items for pain (score range 0–20), two for stiffness (score range 0–8), and 17 for functional limitation (score range 0–68). Physical functioning questions cover everyday activities such as using stairs, standing up from a sitting or lying position, standing, bending, walking, getting in and out of a car, shopping, putting on or taking off socks, lying in bed, getting in or out of a bath, sitting, and performing heavy and light household duties. The questions on the WOMAC are a subset of the questions of the Hip Disability and Osteoarthritis Outcome Score (HOOS). Thus, a HOOS survey may also be used to determine a WOMAC score.

*Psysiopedia and Wikipedia

3.5. Evaluation of Result for Acupuncture Treatment

In order to evaluate dichotomous result of acupuncture in treatment of chronic pain by NPRS and Depression by HAM-D. Table 3, 1 x 2 Contingent Table was created to analyze the dichotomous result of acupuncture treatment in terms of NPRS and HAM-D for chronic pain accompanied with depression. The goal of NPRS is to achieve a score below and above pain

level 3, and in HAM-D below and above score 7, and then calculated Risk of Pain, Risk of Depression, Odds of Pain, or Odds of Depression same as Table 4.

Table 3. 1×2 Contingent Table to Analyze the Dichotomous Result of Acupuncture Treatment in Terms of NPRS or HAM-D for Chronic Pain Accompanied with Depressive Symptom

	NPRS >3	NPRS 3	Total
Treatment group	A	B	a+b

Table 4. Calculation Process of Reduced Risk and Odds of Pain in Terms of the NPRS score after Acupuncture Treatment for Chronic Pain Accompanied with Depressive Symptom.

Statistic Items	Calculation Process		Summarized Statistics
Risk =	$\frac{\text{No. of Pt NOT Cured}}{\text{Total No. of Pt}}$	=	$\frac{a}{a+b}$
Odds =	$\frac{\text{No. of Pt NOT Cured}}{\text{No. of Pt Cured}}$	=	$\frac{a}{b}$

In order for the treatment to be a success, the NPRS score, calculated by the Wilcoxon Rank Test, must continuously decrease during the treatment cycle.

The reduction ratio of NPRS, HAM-D, and WOMAC were calculated by equation (1),

$$\text{Reduction Ratio (\%)} = \frac{\text{Mean Difference}(M_1 \pm SD_1 - M_6 \pm SD_6)}{\text{Before Treatment}(M_1 \pm SD_1)} \quad 100 \quad (1)$$

Where normality of HAM-D and WOMAC score measured by the Kolmogorov-Smirnov model and Shapiro-Wilk model after the six treatments, and the significance by a paired t-test.

Through the Wilcoxon Signed Rank Test and the paired t-test, it was found that there was a significant difference as the NPRS score continuously decreased after six treatments. The trend of acupuncture treatment was found with a box plot based on the intermediate value.

The regression of the mean value of NPRS as a appropriated functional number of treatment to reach the goal under pain level 3, it was adapted finally that R square (r2) as a regression correlation coefficient closed the number 1 to reach the goal after evaluation by the linear and Quadratic regression based on the Mean Value of NPRS. Analysis of Statistics followed SPSS (Statistical Program for Social Science) V. 18.0 Window.

IV. RESULTS

In order to investigate the effects of acupuncture treatment of the “Calm the Spirit” points on chronic pain accompanied by depression, a case series trial with seven participants was conducted to determine the relationship between the two. Acupuncture points P6 and HT7 were used for a course of six times treatments starting from Oct. 2017 and lasting until Sep. 2017. Statistical data was collected before and after the treatments for chronic pain and measured through NPRS, the disability index in daily activity in WOMAC, and depression through HAM-D .

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Table 5. Average characteristic of all seven participants in trial including physical, psychological and social information such as weight, height, marital status, smoking habits, and pain levels.

Characteristic		Score
Mean Age (years)		54.4
Gender	Male / Female	2 / 5
Height (inch)		66.3
Weight (pounds)		140.1
Body Mass Index		25.5
Married/Living together		4 out of 7
Employed		3 out of 7
Smoking		None
Duration of Pain(month)		11.8
Initial NPRS		7.1
Initial WOMAC Score	Baseline	14.8
Initial HAM-D Score	Baseline	38.2

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Table 6. NPRS, HAM-D, and WOMAC scores of all seven participants before and after treatment was administered. Data for patient number seven is unavailable due to Drop out.

	NPRS (before)	**HAM-D (before)**	**WOMAC (before)**	**NPRS (after)**	**HAM-D (after)**	**WOMAC (after)**
Case 1	**7**	**8**	**32**	**3**	**3**	**16**
Case 2	**8**	**21**	**73**	**3**	**3**	**11**
Case 3	**7**	**19**	**40**	**3**	**9**	**14**
Case 4	**5**	**15**	**16**	**2**	**8**	**5**
Case 5	**7**	**9**	**40**	**4**	**5**	**18**
Case 6	**7**	**15**	**28**	**4**	**5**	**17**
Case 7	**9**	**40**	**77**	**n/a**	**n/a**	**n/a**

4.1. The Goal of Acupuncture Treatment

1. To set under Pain Level 3 in NPRS.

2. To set under score 7 by HAM-D Questionnaires for Depression.

4.2. Analysis for Result of Acupuncture Treatment

4.2.1. Analysis from Dichotomous Result of Acupuncture Treatment

4.2.1.1. The Result of Acupuncture Treatment in NPRS for Chronic Pain

Table 7. The result of acupuncture treatment in NPRS for Chronic Pain, after treatments measured by NPRS. Four patients reached the goal of experiencing pain under level 3 and three patients did not achieve the goal.

	NPRS >3	NPRS ≤3	Total
Treatment group n=7	3	4	7

Table 8. Reduced risk and odds of pain in terms of NPRS scores after the six treatments*

Statistic Items	Calculation Process				Summarized Statistics
Risk (of Pain) =	No. of Pt NOT Cured / Total No. of Pt	=	3 / 7	=	0.428 (42.8%)
Odds (of Pain) =	No. of Pt NOT Cured / No. of Pt Cured	=	3 / 4	=	0.75 (75.0%)

* Dichotomous data was calculated by dividing the number of cured or not cured by the total number of patients to show values 0.428 and 0.75 for risks and odds of pain respectively. The improvement of pain levels following treatment rate was 57.1% where three out of seven patients did not reach the goal of pain levels under 3.

4.2.1.1. Dichotomous Result of Acupuncture Treatment in HAM-D for Depression

Table 9. The Result of acupuncture treatment in HAM-D for depression, after 6 treatments where three patients were not able to achieve the goal of HAM-D score under 7..

	HAM-D >7	HAM-D< 7	Total
Treatment group n=7	3	4	7

Table 10. Reduced Risk and Odds of Depression in Terms of the HAM-D score after Acupuncture Treatment for Depression.*

Statistic Items	Calculation Process				Summarized Statistics
Risk (of Depression) =	No. of Pt NOT Cured / Total No. of Pt	=	3 / 7	=	0.428 (42.8%)
Odds (of Depression) =	No. of Pt NOT Cured / No. of Pt Cured	=	3 / 4	=	0.75 (75%)

***** Dichotomous data was calculated by dividing the number of cured or not cured by the total number of patients to show values 0.428 and 0.75 for risks and odds of depression respectively and 57.1% in reduced risk and odds of depressive symptoms in terms of the HAM-D score after the six treatments.

4.2.2. The Effect of Acupuncture Treatment in NPRS for Chronic Pain based on Ordinary data.

Table 11. Analysis of Numeric Pain Rating Scale (NPRS) where ordinary NPRS mean score**

Item	Before Treatment ($M_1 \pm SD_1$)	After Treatment ($M_6 \pm SD_6$)	Mean Difference ($M_1 \pm SD_1 - M_6 \pm SD_6$)	*p*-value*
NPRS	7.14±1.21	3.17±0.75	3.67±0.82	0.026

**p*-value from Wilcoxon Signed Rank Test

** Analysis of Numeric Pain Rating Scale (NPRS) where ordinary NPRS mean score was reduced from 7.14±1.21 to 3.17±0.75, before and after treatment respectively. The mean difference was 3.67±0.82, which is equivalent to significant improvement at 53.8±8.6% (p=0.026) as reduction ratio same as followings.

$$\text{NPRS Reduction Ratio (\%)} = \frac{\text{NPRS Mean Difference}(M_1 \pm SD_1 - M_6 \pm SD_6)}{\text{NPRS Before Treatment}(M_1 \pm SD_1)} 100$$

4.2.3. Analysis of Hamilton Rating Scale for Depression (HAM-D) Based on Continuous HAM-D Mean Score

4.2.3.1. Test of Normality for HAM-D Score

Table 12. Result of normality test of HAM-D score*

Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	Df	Sig.	Statistic	Df	Sig.
HRSD_A	.276	6	.170	.801	6	.060
HRSD_B	.198	6	.200*	.877	6	.255

***** Result of normality test of HAM-D score before and after the treatment was calculated using the Kolmogorov Smirnov and Shapiro Wilk models to show that the data is not statistically significant value of 0.170 and 0.060 respectively.

4.2.3.2. The Effect of Acupuncture Treatment in HAM-D for Depression Based on Continuous HAM-D Scores

Table 13. Effect of Acupuncture Treatment in Continuous HAM-D means score**

Item	Before Treatment ($M_1 \pm SD_1$)	After Treatment ($M_6 \pm SD_6$)	Mean Difference ($M_1 \pm SD_1 - M_6 \pm SD_6$)	*p*-value*
HAM-D	14.8±5.6	4.5±2.0	10.3±6.3	0.010

* *p*-value from paired *t*-test

** Continuous HAM-D means score as a course of 6 times treatment was reduced from 14.8±5.6 to 4.5±2.0, before and after treatment respectively. The mean difference was 10.3±6.3, showing significant improvement of 65.3±18.0% (p=0.010) as a reduction ratio same as followings.

$$\text{HAM-D Reduction Ratio (\%)} = \frac{\text{HAM-D Mean Difference}(M_1 \pm SD_1 - M_6 \pm SD_6)}{\text{HAM-D Before Treatment}(M_1 \pm SD_1)} \times 100$$

4.2.3. The Analysis of Acupuncture Treatment for Chronic Pain Based on Continuous WOMAC Scores

4.2.3.1. Test of Normality of WOMAC Score

Table 14. Result of Normality Test of WOMAC Score before and after the Treatment*

Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	Df	Sig.
WOMAC_B	.295	6	.111	.895	6	.346
WOMAC_A	.179	6	.200*	.921	6	.512

* The results of the normality test of WOMAC scores before and after treatment using a paired t-test reveals that the difference in data is not significant after being measured by Kolmogorov-Smirnov model and Shapiro-Wilk model as a course of 6 times treatment.

4.2.3.3. The Effect of Acupuncture Treatment for Chronic Pain based on Continuous WOMAC score.

Table 15. Effect of Acupuncture Treatment in WOMAC**

Item	Before Treatment ($M_1 \pm SD_1$)	After Treatment ($M_6 \pm SD_6$)	Mean Difference ($M_1 \pm SD_1$ – $M_6 \pm SD_6$)	*p*-value*
WOMAC	38.2±19.3	13.8±5.2	24.3±19.5	0.028

* *p*-value from paired *t*-test

** The effects of acupuncture treatment for chronic pain based on continuous WOMAC score was reduced from 38.2±19.3 to 13.8±5.2, before and after treatment respectively. The

mean difference was 24.3±19.5, with significant improvement of 59.3±18.0% (p=0.028) as a reduction ratio same as followings,

$$\text{WOMAC Reduction Ratio (\%)} = \frac{\text{WOMAC Mean Difference } (M_1 \pm SD_1 - M_6 \pm SD_6)}{\text{WOMAC Before Treatment } (M_1 \pm SD_1)} \times 100$$

4.2.4. The Effect of Acupuncture Treatment for Chronic Pain based on Continuous NPRS Scores

4.2.4.1. Analysis of the Effect of Acupuncture Treatment in NPRS

After analysis of the effect of acupuncture treatment before and after each treatment using the Wilcoxon Signed Rank Test as seen in Table 16, the pain levels measured by NPRS scores continuously decreased throughout the six treatments

Table 16. The Effect of Acupuncture Treatment in NPRS before and after Each Treatment for Chronic Pain Accompanied with Depression**

No of Tx	Before Treatment ($M_1 \pm SD_1$)	After Treatment ($M_6 \pm SD_6$)	Mean Difference ($M_1 \pm SD_1 - M_6 \pm SD_6$)	*p*-value*
1	7.1±1.2	5.4±0.8	1.7±0.8	0.016
2	6.1±0.7	5.0±0.8	1.1±0.4	0.011
3	5.9±1.1	4.4±0.8	1.4±0.5	0.015
4	5.3±1.0	4.3±1.0	1.0±1.0	0.008
5	4.7±0.5	3.3±0.8	1.3±0.5	0.023
6	4.3±0.8	3.2±0.8	1.2±0.4	0.020

*Wilcoxon Signed Rank Test

**The effect of acupuncture treatment in NPRS scores before and after each treatment shown with mean difference and pair-t test p-values. For each patient, there was a statistically significant decrease in NPRS scores from before and after treatment since the p-values for all patients are less than 0.05.

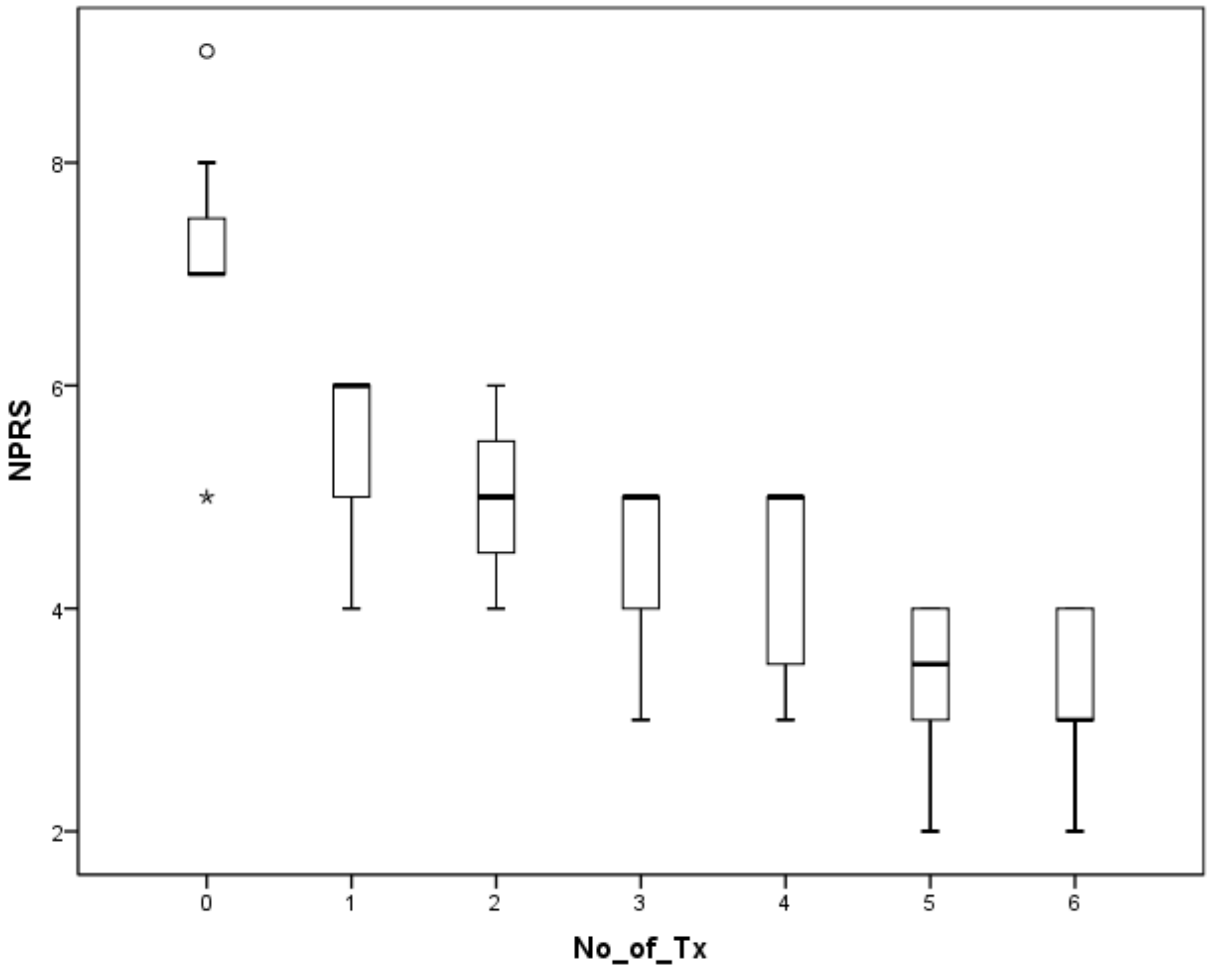
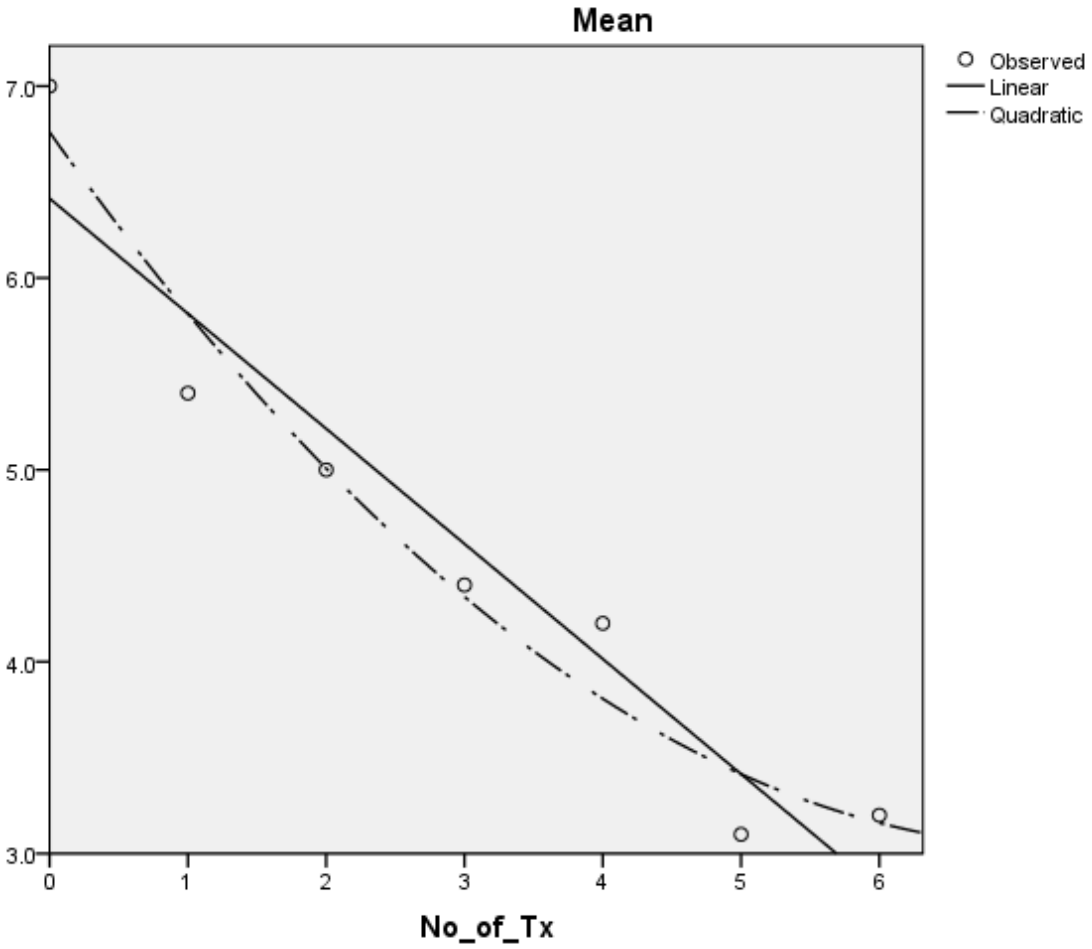


Figure 3. Change of pain in NPRS depending on the number of treatment show with standard deviation margins. There is an inverse trend between the NPRS scores and number of trials as the NPRS scores decrease as the treatment progresses.

4.2.4.2. Regression of the Mean Value of NPRS as an Appropriated Function of the Number of Treatment

According to Figure 4 for the regression curve of the mean value of NPRS, it was found that the R-squared (r^2) value as a regression correlation coefficient based linear equation of

regression was 0.919 compared to the r^2 value of 0.956 based on the quadratic equation (y=0.069x2 -1.014x+6.760). Although this value seems to be closer, it does not fulfill the goal of achieving an NPRS score below 3 after using by regression of the mean value of NPRS in accordance with the number of treatments in order to evaluate a functional number. The linear equation was y=-0.6x+6.414, gives the appropriate number of treatments as 6 to 7 times in order to achieve the goal of an NPRS score below 3 because the actual mean value of the NPRS scores were 3.2 according to the linear equation regression analysis (r^2=0.919) .


Mean
Observed
Linear
Quadratic
7.0
6.0
5.0
4.0
3.0
0
1
2
3
4
5
6
No_of_Tx

Equation	Model Summary					Parameter Estimates		
	R Square	F	df1	df2	Sig.	Constant	b1	b2
Linear	.919	56.720	1	5	.001	6.414	-.600	
Quadratic	.956	42.944	2	4	.002	6.760	-1.014	.069

The independent variable is No of_Tx.

Figure 4. Regression of the mean value of NPRS as a function of the number of treatments graphed alongside the linear and quadratic equations for the treatment.

4.2.5. Analysis Compounding of Facts on NPRS of Acupuncture Treatment for Chronic Pain

The compounding facts ~~to~~ on the effect on NPRS acupuncture treatment for chronic pain has possible to analyze with a small sample size of only two males and five females, who had been tried against gender, age, and race by using the two-way ANOVA method.

According to Figure 5, gender had no effect on result of treatment NPRS score diminished in accordance with the number of treatments with 0.792 as a correlation factor, and p=value over 0.05.

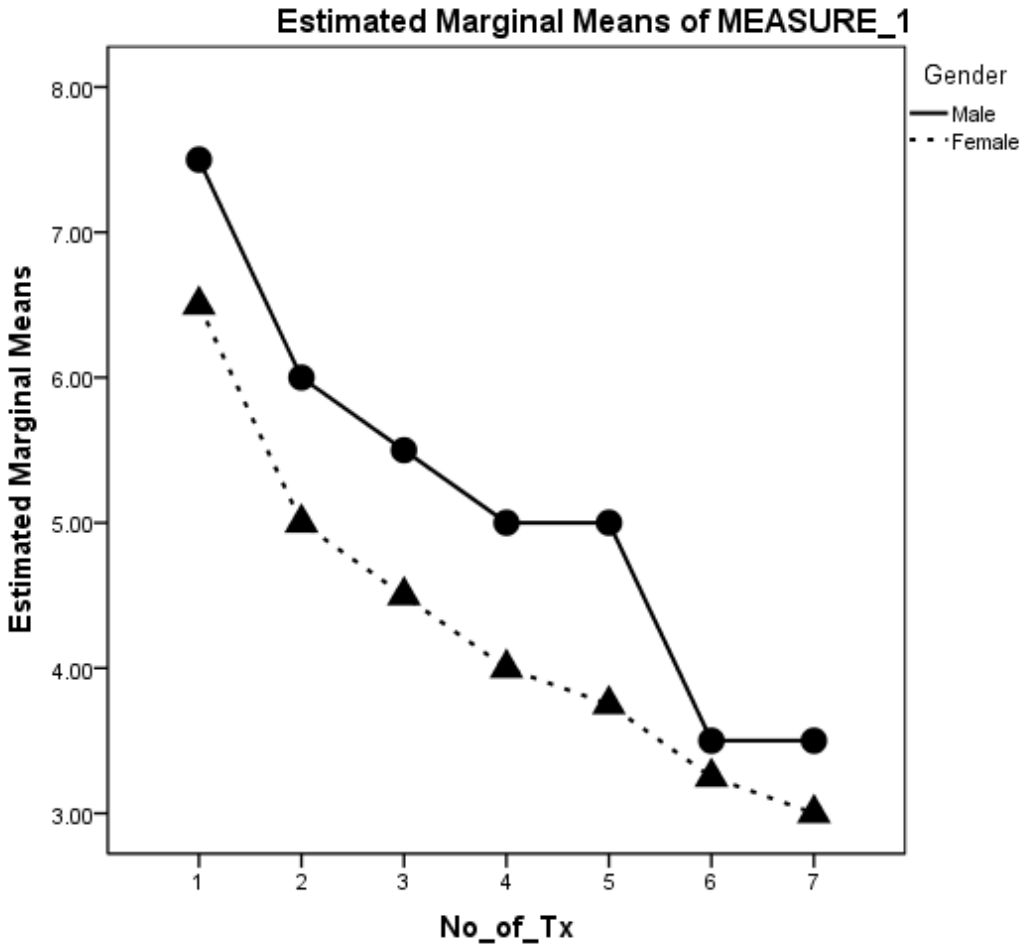


Figure 5. Estimated marginal means of males and females at each treatment session. Although the estimated marginal means for the males seems to be generally higher than that of females, the general trend regardless of gender is decrease as number of treatments increase.

V. DISCUSSION

Pain is neurophysiologically closely related to serotonin, norepinephrine, and endogenous hormones as neurotransmitters, which is why the “Descending Neural Pathway” proactivation are two of the prevailing theories on the control of pain. Depression is also involved in serotonin and norepinephrine metabolism which ties depression to chronic pain.

The purpose of Research is prove the effect of acupuncture treatment for chronic pain and depression as a case study, and consequently confirm that chronic pain measured by NPRS and WOMAC, and depression measured by HAM-D through acupuncture treatment are related.

It was concluded that acupuncture treatment on “Calm the Spirit” points is effective for chronic pain accompanied by depression. However, it is not clear how work in relation to each other due to the lack of test groups and treatment repetitions. A supportive trial provided with randomized controlled trial with larger sample and molecular level image proof like fMRI would explain the depression-pain relationship by tracing the kinds of neurotransmitters is proposed.

VI. CONCLUSIONS

The conclusions of this study after analyzation for the effect of acupuncture treatment on "Calm the Spirit" points for chronic pain accompanied by depression in patients through a course of six treatments and measured by the Numeric Pain Rating (NPRS), Hamilton Rating Scale (HAM-D) as a method of measuring Depression, and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) as a method of measuring disability index of daily activity and details are as followings:

1. From the analysis of Numeric Pain Rating Scale (NPRS), dichotomous data showed 0.428 and 0.75 for Risk and Odds of Pain respectively and the improvement of treatment rate was 57.1%. Ordinary NPRS mean score was reduced from 7.14±1.21 to 3.17±0.75, before and after treatment respectively. The mean difference was 3.67±0.82, equivalent to significant improvement of 53.8±8.6% (p=0.026).

2. From the analysis of Hamilton Rating Scale for Depression (HAM-D), dichotomous data showed 0.428 and 0.50 for Risk and Odds of Depression respectively and the improvement of treatment rate was 57.1%. Continuous HAM-D means score was reduced from 14.8±5.6 to 4.5±2.0, before and after treatment respectively. The mean difference was 10.3±6.3, showing significant improvement of 65.3±18.0% (p=0.010).

3. From the analysis of (WOMAC), mean score was reduced from 38.2±19.3 to 13.8±5.2, before and after treatment respectively. The mean difference was

24.3±19.5, with significant improvement of 59.3±18.0% (p=0.028). The appropriate number of treatment was calculated as 6 to 7 times from the regression analysis (r^2=0.919).

4. The appropriate number of treatment was calculated as 6 to 7 times from the regression analysis (r^2=0.919).

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APPENDIX - 1

South Baylo University

Informed Consent Form

You are invited to participate in a research study about Clinical Case Studies on the Effect of Calm the Spirit Points Acupuncture Treatment for Chronic Pain Accompanied with Depression.

The goal of this research study is to measure the effect of the treatment for the Chronic Pain Accompanied with Depression. This research will help developing and applying systemic and effective treatment plans in clinic.

This study design is that the patients will receive Calm the Spirit Points Acupuncture treatment.

The treatment will be done twice a week for three weeks which is a total of six times.

This study is being conducted by Young Lee L.Ac.

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 that is routinely offered in this clinic. 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.

This treatment can have some unwanted effects. It can cause pain, bleeding, blue and some temporary swelling around the place where needles are injected. It is possible that is may also cause some problems that we are not aware of. However, we will follow you closely and keep track of any unwanted effects or any problems. We may use some other medicines to decrease the symptoms of the side effects or reactions. Or we may stop the use of one or more drugs. If this is necessary we will discuss it together with you and you will always be consulted before we move to next stop.

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 doesn't work even as well as the old one. If however, the medicine or treatment is not working, we will give the medication or treatment 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 full 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 except Young Lee L.Ac.

If you have any question about this study, please contact Young Lee L.Ac., at 213-294-8564 or hobslee2001@gmail.com. If you have more questions or concerns regarding your rights as a subject in this study, you may contact Dr. Edwin D Follick, Chair of the South Baylo University Institutional Review Board (IRB) at 714-533-6077 or edfollick@southbaylo.edu.

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 been answered to my satisfaction. I consent voluntarily to participate as a participate as a participant in this research.

Name of Participant (print) Name of Witness (print)

Signature of Participant Signature of Participant

Date : Day / Month / Year Date : Day / Month / Year

Statement by the researcher/person taking consent:

I have accurately explained the information sheet the potential participant. I confirm that the participant was given an opportunity to ask about the study, and all the question 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 giving freely and voluntary.

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

_____

Print Name of Researcher

_____

Signature of Researcher

_____

Date : Day / Month / Year

APPENDIX – 2

WOMAC

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

Name:_____ Date:_____

Instructions: Please rate the activities in each category according to the following scale of difficulty: 0 = None, 1 = Slight, 2 = Moderate, 3 = Very, 4 = Extremely

Circle one number for each activity_____

Pain 1. Walking 0 1 2 3 4

2. Stair Climbing 0 1 2 3 4

3. Nocturnal 0 1 2 3 4

4. Rest 0 1 2 3 4

_____5. Weight bearing 0 1 2 3 4

Stiffness 1. Morning stiffness 0 1 2 3 _ 4

_____2. Stiffness occurring later in the day 0 1 2 3 4

Physical Function 1. Descending stairs 0 1 2 3 4

2. Ascending stairs 0 1 2 3 4

3. Rising from sitting 0 1 2 3 4

4. Standing 0 1 2 3 4

5. Bending to floor 0 1 2 3 4

6. Walking on flat surface 0 1 2 3 4

7. Getting in / out of car 0 1 2 3 4

8. Going shopping 0 1 2 3 4

9. Putting on socks 0 1 2 3 4

10. Lying in bed 0 1 2 3 4

11. Taking off socks 0 1 2 3 4

12. Rising from bed 0 1 2 3 4

13. Getting in/out of bath 0 1 2 3 4

14. Sitting 0 1 2 3 4

15. Getting on/off toilet 0 1 2 3 4

16. Heavy domestic duties 0 1 2 3 4

17. Light domestic duties 0 1 2 3 4

Total Score: _____ / 96 = _____%

Comments / Interpretation (to be completed by therapist only):

APPENDIX - 3

HAM-D

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

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.