

SOUTH BAYLO UNIVERSITY

**Effects of Acupuncture and Jia Wei Di Huang Wan in Lower Limb
Peripheral Neuropathy: Case Series**

침과 가미지황환의 치료가
하지말초신경병에 미치는 효과

by

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IN PARTIAL FULFILLMENT OF THE
REQUIREMENTS FOR THE DEGREE**

Doctor of Acupuncture and Oriental Medicine

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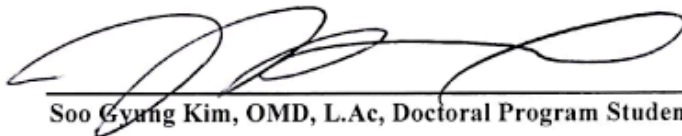
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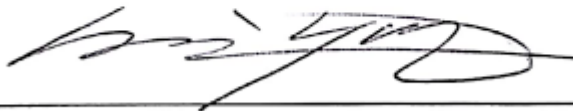
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SOUTH BAYLO UNIVERSITY L.A CAMPUS, 2018

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ABSTRACT

The purpose of this study is to show how the effects of an acupuncture treatment and the Jia Wei Di Huang Wan herbal treatment can reduce pain and eliminate the numbness of peripheral neuropathy of the lower limb in middle-aged and older adults.

The evaluation was made before and after each treatment using methods such as the Visual Analogue Scale (VAS), Michigan Neuropathy Screening Instrument, (MNSI) and Neuropathy Pain Screening Questionnaires (NPSQ). The study conducted included six participants who suffer from lower limb peripheral neuropathy. The acupuncture treatment was given for thirty minutes per week for six weeks. The period was between April 2018 and June 2018 at the CA Natural Acupuncture Center. The study consisted of six participants who were over 40 years of age, had reported symptoms of numbness in the lower limb, and were not currently taking neuropathy medication or a nerve blocker to treat lower limb neuropathy. The participants also did not have a history of nerve surgery

and did not have severe cognitive or mental disorders. Participants (n = 6) were given acupuncture at Li4 (He Gu), Lv3 (Tai Chong), Kd1 (Yong Chuan), Kd3 (Tai Xi), SP-6 (San Yin Jiao), Sp3 (Taibai), Gb 34 (Yang Ling Quan) and Bafeng bilaterally. They (n = 6) also received the herbal medicine Jia Wei Liu Wei Di Huang Wan to take once per day for 6 weeks. The pain level was measured by the Visual Analogue Scale (VAS), Michigan Neuropathy Screening Instrument (MNSI) and Neuropathy Pain Screening Questionnaires (NPSQ) before and after each treatment. This study processed statistical assessments and analyzed the effects of acupuncture and herbal medicine treatment. Outcomes were measured using the Window recommended SPSS V25.0 software.

The values of VAS, MNSI and NPSQ were significantly high after six treatments of acupuncture and Jia Wei Di Huang Wan. The results of this study showed that there were not only significant improvements on lower limb neuropathy, but also the quality of life.

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I. INTRODUCTION

The recent National Health Interview Survey revealed that approximately 42.5 million Americans are suffering from lower limb peripheral neuropathy. Over 20 million out of that 42.5 million who are 50 % of the peripheral neuropathy population is diabetic PN, Alcoholic PN and HIV PN. Additionally, 22.5 million pre-diabetics have peripheral neuropathy.¹ This causes a problem with the functioning of the nerves outside the spinal cord and may include numbness, weakness, and a burning pain, especially at night. This results in a loss of reflexes.² The most common type of neuropathy is lower limb peripheral neuropathy. When those symptoms arise tingling, numbness, and burning sensation cause disruptive sleep.

The majority of peripheral neuropathy patients are over 40 years old. By 2050, the American elderly population will increase dramatically and live longer. Today, people aged 50 and over comprise 24 percent of the U.S. population. In that population, there are 17 million Americans between 75 and 85. By mid-century, that number will likely reach 30 million, according to the National Institute on Aging. Therefore, they have higher a risk of peripheral neuropathy. The risk of this disease is very common for this elderly who are ignorant of having a neuropathy disease.³ Due to the lack of attention to peripheral neuropathy, there are limited numbers of studies that have shown the efficacy of acupuncture on this subject.

In the pilot study, however, acupuncture treatments may have accelerated the nerve regenerative process in peripheral neuropathy participants. Acupuncture treatments

not only improved nerve conduction velocity decreased by PN, but also improved a variety of subjective symptoms associated with this progressive disabling disorder.⁷ In his study of 3000 participants, Steve Phillips, acupuncturist helped most people with peripheral neuropathy. In most cases, they responded well to acupuncture and the symptoms were reduced a lot and some recovered well.⁴²

As for herbal medicine treatment, Jia Wei Liu Wei Di Huang Wan promotes nerve repair and regeneration of Schwann cells and neurotrophic factors in peripheral neuropathy.

This treatment method helped to improve blood and oxygen flow to the nerves.

Furthermore, it had shown to help relieve the pain and burning sensations associated with neuropathy.²⁶

However, unsuccessful western medicine treatments and side effects of medication have also led to frustration and disappointments due to wasted time and money spent on ineffective treatment. These participants explored many treatments to reduce their symptoms, but to no avail. Unlike western medicine, which can have complications, the combination of acupuncture and herbal medicine resulted far more beneficial for peripheral neuropathy. Since the elderly population in the workforce continues to increase, the treatment of acupuncture and Jiawei Di Huang Wan can indeed help them return to work. By balancing and recuperating peripheral neuropathy symptoms with acupuncture and herbal medicine, it is likely the “graying population” will enjoy longer health. For the purpose of this research, this project was designed to explore the efficacy and consistency of acupuncture and herbal treatment in reducing symptoms of lower limb peripheral neuropathy.

II. OBJECTIVES

The purpose of this research was to prove that combining of acupuncture and Jiawei Di Huang Wan treatment of lower limb peripheral neuropathy symptoms were effective for those who suffering.

To perform this research, detail goals were following below:

Objective 1: To demonstrate the effectiveness of acupuncture treatment and daily taking Jia Wei Di Huang Wan before and after each treatment with Visual Analogue Scale (VAS).

Objective 2: To determine the effectiveness of treatments by comparing first treatment and after 6 weeks treatments using the methods of Visual Analogue Scale (VAS).

Objective 3: To ascertain the effectiveness on score of evaluation by comparing before and after each treatment using the methods of Michigan Neuropathy Screening Instrument (MNSI) and Neuropathy Pain Screening Questionnaires (NPSQ).

II. LITERATURE REVIEW

3.1 What is peripheral neuropathy and its' symptoms?

Peripheral neuropathy is a result of damage to your peripheral nerves enervating the extremities, often causes weakness, numbness and pain, usually in your hands and feet, hence the word “peripheral.” “Neuro” means “nerve” and “pathy” means “suffering or disease.”¹ The sensory nerves are most affected, causing sensations of pain, temperature, pain, vibration, tingling sensation and numbness. If the motor nerves are affected, causing problems with movement, muscle weakness, concentration problem or paralysis. If autonomic nerves are affected, signs and symptoms might include like heat intolerance, altered sweating, bowel, bladder, digestive problems, and changes in blood pressure, causing dizziness or light headedness.

In the most common type of neuropathy, the feet are affected first, and the pain and numbness can then progress up the leg. And also the hands can be affected first, with pain progressing up the arms. Some of them are only mono nerve damages like carpal turner syndrome, and other forms of neuropathy are multiple nerve damages called polyneuropathy.¹ Peripheral neuropathy is due to damage to the axons (the long, threadlike portion of the nerve cell), while others are due to damage to the myelin sheath, the fatty protein that coats and insulates the axon. Some neuropathy may also be caused by a combination of both axonal damage and demyelination.²

3.2 What is the cause of peripheral neuropathy?

There are many causes of peripheral neuropathy, including diabetes, chemo-induced neuropathy, hereditary disorders, HIV, inflammatory infections, autoimmune diseases, protein abnormalities, exposure to toxic chemicals (toxic neuropathy), poor nutrition, kidney failure, chronic alcoholism, certain medications, or trauma, such as injuries, infection.¹³ Peripheral neuropathy may occur as a result of malnutrition such as a Vitamin 12 deficiency, or can be caused by an unbalanced diet, alcoholism, and aging.⁴

There are essentially 3 types of peripheral neuropathy, categorized by causality: drug-induced, diabetic and idiopathic. The majority of the patients suffered from the first type, due to all the strong medications (toxins) they had to take. Type 2 is a common side effect of diabetes. Type 3 is more mysterious. The word “idiopathic” is a medical term derived from the Greek language which essentially means that nobody knows what the cause is.

In recent studies, oxidative stress is one of the biggest causes in neuropathy because of toxins from chemotherapy, medication, or chemical exposure. Oxidative stress occurs when there is an imbalance between harmful toxins called free radicals and the antioxidants the body needs to fight them. If the body is unable to neutralize, these destructive free radicals can wreak havoc on the body and the nerves. Two ways the oxidative stress can damage your nerves are kill your nerves and demyelination.^{17, 18}

3.3 How can Western medicine treat peripheral neuropathy?

In Western medicine, medication and physical therapy were provided as treatments. Low-Level Light Therapy was also added to increase blood flow.

1. Pain Reliever Medications containing opioids, such as tramadol (Conzip, Ultram) or oxycodone (OxyContin, Roxicodone, others), can lead to dependence and addiction, so these drugs generally are prescribed only when other treatments fail.
2. Anti-seizure medications - Medications such as gabapentin (Gralise, Neurontin) and pregabalin (Lyrica), developed to treat epilepsy, may relieve nerve pain. Side effects can include drowsiness and dizziness.
3. Topical treatments - Capsaicin cream, which contains a substance found in hot peppers, can cause modest improvements in peripheral neuropathy symptoms. Side effects of topical cream are skin burning and irritation.

To manage and relieve symptoms caused by peripheral neuropathy, Western medicine practitioners use medication as a treatment. Lab tests do not indicate underlying condition, doctors usually recommends watchful waiting to see if the neuropathy symptoms improves.⁵

3.4 How can peripheral neuropathy be diagnosed in oriental medicine?

The Huangdi Neijing (Yellow Emperor's Inner Canon of medicine), one of the four great classics in oriental medicine contains numerous references about peripheral neuropathy, which states that obstructive syndrome of Qi and blood,(痺證) and Blood deficiency. Peripheral neuropathy can be viewed in traditional oriental medicine as qi and blood stagnation, damp accumulation, kidney yin and yang deficiency, and Liver blood

deficiency. Both excess and deficiency may exist for this pattern. Traditional oriental medicine teaches that lower limb peripheral neuropathy is due to dampness moving to the limbs, where it obstructs the flow of Qi (energy) and Blood within them and lack of Yin or nutrient.²²

3.5 What is acupuncture treatment for peripheral neuropathy?

In treating peripheral neuropathy, acupuncture points are used on the affected area (treating the branch) as well as points on various parts of the body to treat the person according to their particular pattern (treating the root).²⁴ Acupuncture is a medical intervention in which needles are used to stimulate certain points generally called acupoints on the body. Huangdineijing also indicates that acupuncture stimulation elicits deqi, a composite of unique sensations. It is regarded that the application of acupuncture through stimulating certain acupoints is to activate the qi and blood of meridians and collaterals and to regulate the function of internal organs so as to prevent and to treat diseases in oriental medicine theory. Since acupuncture has three primary effects which it relieves pain, reduces inflammation and increases immune system. Acupuncture can definitely help the peripheral neuropathy. In an Alexandra Dimitrova study from 2014 to 2015, the points of Liv3, Li4, St36, Baxie, Bafeng, Gb34, Ki1 and Sp6 showed significant improvement. This standardized protocol appears to be effective for the treatment of neuropathy of various causes.¹⁶ In Steve Phillips study, needling on Lv 2 or 3, St 44, Sp 3, GB 43, Bl 65, or one can simply needle the “Bafeng” points were conventionally used and got effective in acupuncture after four treatments.⁴² He found out also acupuncture is effective in HIV-related neuropathy.

The acupuncture points studied in this study in Table 2 were standardized so that participants received exactly the same treatment.

3.6 How can Herbal Jia Wei Di Huang Wan help the Peripheral neuropathy?

Peripheral neuropathy is a symptom of many different patterns of disharmony within the body.²⁷ In study of Korean research, a diabetic neuropathy patient was treated with Liu Wei Di Huang Wan medicine for 2 weeks. The participant reported improvement in both pain score and glucose index. Liu Wei di Huang Wan could therefore be effective for the treatment and prevention of diabetic neuropathy, since Jia Wei Di Huang Wan can nourish yin as well as remove blood stasis. “Protective mechanisms of kidney-nourishing and collateral-unblocking therapy for peripheral neuropathy in experimental diabetic rats,” Jia Wei Di Huang Wan promotes not only nerve repair and regeneration of Schwann cells and neurotrophic factors in diabetic peripheral neuropathy but also improves blood and oxygen flow to the nerves and has been shown to help relieve the pain and burning sensations associated with neuropathy.²⁶ In the studies of the ingredient of Jia Wei Di Huang Wan can actually makes neutralize harmful free radicals and combat the negative effects of oxidative stress on your nerves – getting sufficient antioxidants is the key. Antioxidants scour the body in search of free radicals and neutralize them before they can damage or destroy cells. This powerful antioxidant has the unique ability to regenerate it as well as other antioxidants. Peripheral neuropathy symptoms will definitely improve the pain and numbness and will help the participant to get back to their normal life.²⁹

III. MATERIALS AND METHODS

4.1. Participants

The participants were patients from April 8, 2018 through June 30th, 2018 at the CA Natural Acupuncture Center in Valencia CA. They have suffered lower limb neuropathy in acute and chronic pain conditions. They volunteered to be screened for eligibility and participate in the research. The following are information detailing the study:

- 1) Six participants were selected to screen for the research project treatment.
- 2) The ages were at least over 40 years old. 2 people in their 40's, 3 people in their 50's, 1 person in their 60's, and 1 person in their 70's. In ethnicity, there were one Mexican American and five Caucasians. In sex differentiation, there were four males and two females. In duration of pain, there were two acute and four chronic pain participants.
- 3) The participants suffer from peripheral neuropathy because of stress, graveyard working, and addiction for drugs, medications, alcohol and tobacco.
- 4) Symptoms were numbness, loss of balance, concentration problems, burning sensations, muscle aches, sore feelings, tingling sensations and insomnia.

5) The participants signed an information consent form, the purpose and method of this research. It also fully explained regardless of age, religion, and sex. The study was performed after reviewing.

6) Exclusion Criteria

- Those who had surgery for cardiac vascular disease and history of Surgery that affect the nerve system
- Those who were pregnant or a breast feeder
- Those who were extremely weak and have serious disease.
- Those who were taking medication to treat PN
- Those who had no serious cognitive or mental disorders

For this research, the participants were selected for peripheral neuropathy treatments. All of them were diagnosed by an MD or a specialist for peripheral neuropathy.

4.2 Research plan

4.2.1 Method of Treatment

The acupuncture treatment was performed once a week for six weeks. Jia Wei Di Huang Wan was distributed after the treatment to take daily 30 minutes after dinner. The values from Visual Analogue Scale (VAS), (Michigan Neuropathy Screening Instrument) MNSI and (Neuropathy Pain Screening Questionnaire) NPSQ before and after the treatment were collected to be analyzed for the data.

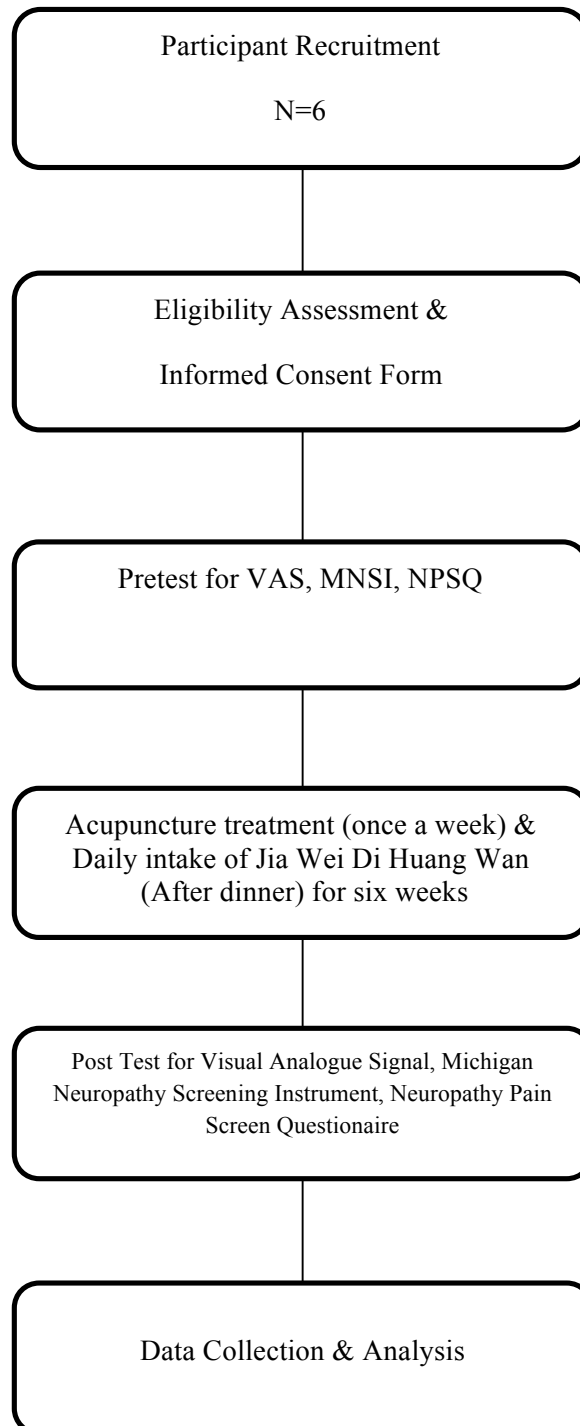


Figure 1. Schematic Diagram of Study Design

4.3 Materials

4.3.1 Needles

The KM Needles and SEIRIN needles were used for this research. The sizes of the needles were 0.16x1.5mm for SEIRIN needles and 0.20X30mm and 0.20x0.50 mm for KM needles. Both of them were sterilized stainless steel. The used needles were used based on Clean Needle Technique (CNT) and discarded after treatments based on the CA Medical Waste Management Law.

The skin on the sole of foot was especially sensitive and was painful when inserting the needle, therefore, thinner needles were necessary to use. Since many neuropathy participants complained of numbness in the feet, however, it was common for them not to feel the insertions at all. When the insertions did begin to hurt after a few treatments, it was a sign that the condition was starting to improve.



Figure 2. KM Sterilized Needles



Figure 3. SEIRIN Sterilized Needles

4.3.2 Herbal Treatment for Jia Wei Di Huang Wan

Jinguiyaolue (Synopsis of Prescriptions of the Golden Chamber)'s classical formula Liu Wei Di Hwang Wan was pulverized into a fine granule powder. Additional herbs such as Zhimu (Rhizoma Anemarrhenae) mildly nourishes Yin, Huangbai (Cortex Phellodendri) clears heat and dry dampness, Danggui (Radix Angelicae sinensis) invigorates blood circulation for numbness in the extremities, nourishes the blood: for blood deficiency, Chuanxiong (Rhizoma Chuanxiong) invigorates blood and moves Qi, expels wind and relieves pain, Baishao (Radix Paeoniae alba) nourishes blood and preserves yin and alleviates pain, Taoren (Semen Persicae) invigorates blood and moves Qi, expels wind and relieves pain, Honghua (Flos Carthamitinctorii) increases blood circulation, were added to Jia Wei Di Huang Wan which is based on the degree of symptoms of peripheral neuropathy.

The herbal medicine was provided as supplement for enhancing the treatment and nourishing the nerve system.

According to diagnosis in Table 2, the granule particles of herbs were provided to six participants for six weeks. The herbal medicine was given to take 3g after dinner every day. The granules were taken with warm water after dinner. All these herbal medicine were provided from Han Joong Pharmaceutical Company.

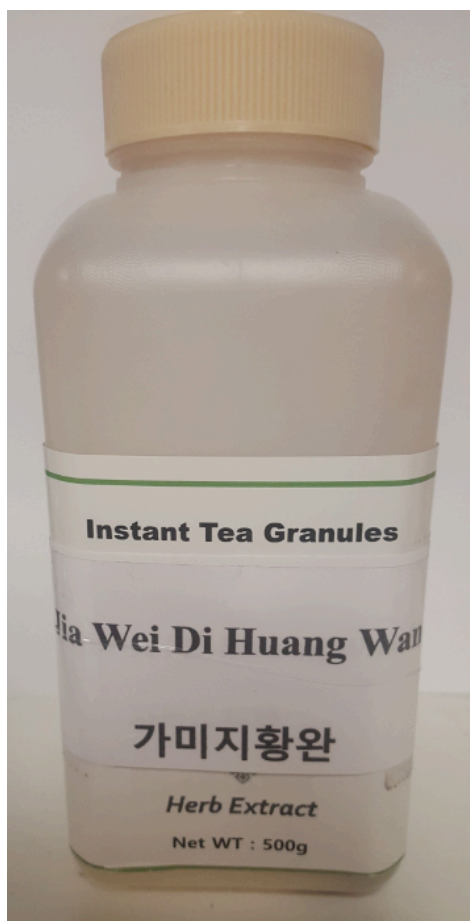


Figure 4. Jia Wei Di Huang Wan

Table 1. Jia Wei Di Huang Wan

Pattern	Deficiency of Yin and blood stasis
Clinical Manifestation	Numbness and burning pain in feet extends to the entire limbs aggravated at night; night sweating; spontaneous sweating, heat sensation in the chest, palms and soles; soreness and weakness, of the lumbar region and knees joints, dry mouth; thirsty; dry stool, dark-red tongue
Therapeutic principle	Nourish Yin and remove blood stasis
Therapeutic formula	1. Jinguiyaolue (Synopsis of Prescriptions of the Golden Chamber); 2. Yizongjinjian (Golden Mirror of Medicine)
Components	Shudihuang (Radix Rehmanniae preparata), Shanzhuyu (Fructus Corni), Shanyao (Rhizoma Dioscoreae), Zexie (Rhizoma Alismatis), Fuling (Poria), Mudanpi (Cortex Moutan), Zhimu (Rhizoma Anemarrhenae), Huangbai (Cortex Phellodendri), Danggui (Radix Angelicae sinensis), Chuanxiong (Rhizoma Chuanxiong), Baishao (Radix Paeoniae alba), Taoren (Semen Persicae), Honghua (Flos Carthamitinctorii)

4.4 Method

4.4.1 Acupuncture points

The acupuncture points were Li4, Lv3, Sp6, Sp3, Kd1, K3, Ba Feng, Gb 34 for the peripheral neuropathy. Depends on participant's root of disease and location of pain, the ashi points was treated as well. The treatments last 30 minutes, and also the participants were treated once a week for six weeks.

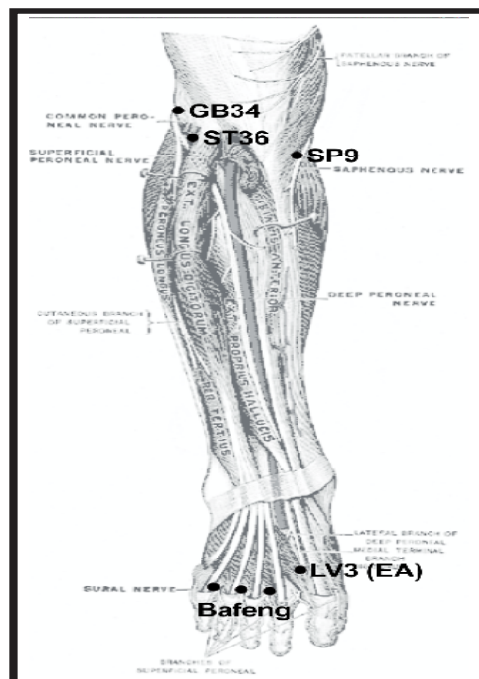


Figure 5. Anterior Leg view of Acupuncture points with correlations of nerve

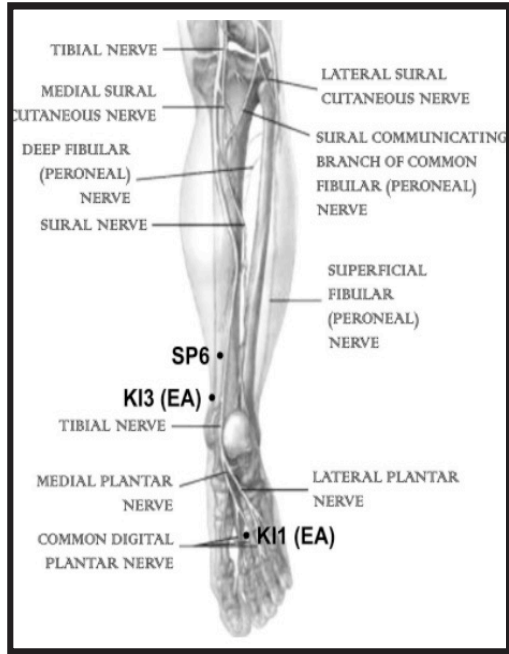


Figure 6. Posterior Leg view of Acupuncture points with correlations of nerve

Table 2. Acupuncture points with anatomical correlations of nerve

Acupuncture point	Li4
Traditional function	Disperses Wind, relieves Exterior conditions, suppresses pain & clears the channels
Traditional indications	Common cold, headache, diseases of the sensory organs, facial paralysis, hemiplegia , global weakness, chronic fatigue & pain in general
Relation to nerve	Radial
Acupuncture point	Lv3
Traditional function	Pacifies the Liver, clears Heat, regulates the lower <i>Jiao</i> & opens the channels
Traditional indications	Headache, vertigo, hypertension, insomnia, hepatitis, mastitis, irregular menstruation, thrombocytopenia soreness of the joints of the extremities.
Relation to nerve	Deep peroneal
Acupuncture point	Sp6
Traditional function	Strengthens the Spleen & transforms Dampness, spreads the Liver Qi & benefits the Kidneys
Traditional indications	Incontinence, reproductive problems, abdominal pain and distention, diarrhea, hemiplegia , chronic fatigue & generalized weakness
Relation to nerve	Posterior tibial
Acupuncture point	Sp3
Traditional function	Transforms Damp Stagnation & benefits the lower <i>Jiao</i>
Traditional indications	Abdominal distention, ascites, urinary retention, incontinence, urinary-tract infection, irregular menses
Relation to nerve	Medial saphenous (femoral)
Acupuncture point	K1
Traditional function	Strengthens all senses, stops adverse flow of Stomach Qi to stop vomiting, clears Heart-Fire, replenishes, Yang & prevents collaps
Traditional indications	Shock, heat exhaustion, insomnia, stroke, cerebral hemorrhage, hypertension, seizures, psychosis, mental, illness, vertex headache, lower-limb paralysis, lower-limb spasms & low back pain
Relation to nerve	Medial plantar (posterior tibial)
Acupuncture point	K3
Traditional function	Relieves Heat by controlling Yin, strengthens Kidney-Yang, regulates the Uterus & strengthens the waist & knees
Traditional indications	Nephritis, cystitis, irregular menses, spermatorrhea, enuresis, toothache, chronic laryngitis, stomatitis, tinnitus, pulmonary emphysema, cough, asthma, chronic fatigue, global weakness, sciatica, paralysis of the lower limbs , painful heel, vomiting & constipation.
Relation to nerve	Posterior tibial
Acupuncture point	Ba Feng

Traditional function	Enhances collateral circulation and regulates Blood flow
Traditional indication	Headache, toothache, stomach pain, irregular menses, inflammation of the dorsum of the foot & toes, foot numbness, neuropathy
Relation to nerve	Superficial perone
Acupuncture point	GB34
Traditional function	Tonifies Liver and Gallbladder, relaxes muscles, helps with smoothness of movement & removes Dampness & Heat
Traditional indication	Muscle cramps, musculoskeletal pain, rigidity, weakness Dampness, spreads the Liver Qi & benefits the Kidneys, hemiplegia, sciatica , acute hepatitis & acute, cholecystitis
Relation to nerve	Common peroneal

*Bold lettering: Nerve related problem

In Table 2, these eight acupuncture points were used for lower limb peripheral neuropathy treatment since these points were not only correlated to nerve on foot but also associated with deqi on the foot for low limb neuropathy based on the researches and books.

Table 3. Acupuncture points insertion order

Area of pain or Severity	Acupuncture points and Insertion order
	Starts with gate opening points Li4, Lv3
(1) Bilateral (right to left for female) (left to right for male)	Sp6 GB34 K3
(2) Right Limb	Left point first
(3) Left Limb	Right point first
(3) Severe case	Bafeng, Kd1, Sp3

The order of insertion in acupuncture treatment was based on the principle of acupuncture in oriental medicine: which is called the Guja rule “treat the left side when disease in the right side, treat the right side when disease in the left side. According to modern research, the neural control of the brain crosses the left and right sides of the brain and transmits neural information to the brain. It promotes the secretion of synthetic hormones, which can be seen as a result of the superior clinical experience of the ancestors.

In other words, the right side is sick, and it will be natural to treat the left side.

4.4.2 Tool to measure the values

4.4.2.1 Visual analog scale (VAS)

Pain usually is the major complaint of participants with problems, thus making pain evaluation is a fundamental requisite in the outcome assessment in pain management. Visual analog scale (VAS) is a measure of pain intensity. It is a continuous scale comprised of a horizontal (called horizontal visual analogue scale) or, vertical called vertical visual analog scale usually 10 cm or 100 mm For pain intensity, the scale is most commonly used by “no pain” (score of 0) and “pain as bad as it could be” or “worst imaginable pain” (score of 10) In the Appendix, to determine the effectiveness of treatments by comparing before and after treatment, the methods and values of Visual Analogue Scale (VAS) were used through out the dissertation.

4.4.2.2 Michigan Neuropathy Screening Instrument

The Michigan Neuropathy Screening Instrument (MNSI) is used to assess distal symmetrical peripheral neuropathy. The questionnaire is self-administered by the participant. Responses are added to obtain the total score. Responses of “yes” to items 1-3, 5-6, 8-9, 11-12, 14-15 are each counted as one point. A “no” response on items 7 and 13 counts as 1 point.

4.4.2.3 Neuropathy Pain Screening Questionnaire

Neuropathy Pain Screening Questionnaire (NPSQ) includes 6 yes/no questions and pain-location diagram. It developed to differentiate between nociceptive and neuropathic pain validated speaker’s notes. It also called as the ID pain questionnaire which is a participant-completed screening tool that was designed to differentiate between

nociceptive and neuropathic pain. If participants have more than one painful area, they are to consider the one area that is most relevant to them when answering the ID Pain questions. Scoring is from -1 to 5. Higher scores are more indicative of pain with a neuropathic component. A score of 3 or higher indicates likely presence of neuropathic pain and justifies a more detailed evaluation.

IV. RESULTS AND DISSCUSION

The case study examined six peripheral neuropathy participants from the age of 40 to 70 who were treated with acupuncture treatment, and also received the herbal medicine Jia Wei Di Huang Wan. After determining qualification for participation in the study, each eligible participant was filled out an informed consent form that explained what the treatments in detailed, as well as their possible risks and benefits. Treatments were to be administered total six treatments for six weeks of period between April 2018 and June 2018 at the CA Natural Acupuncture Center. Since the location has large population of Caucasians, participants were asked to complete the recommended Michigan Neuropathy Screening Instrument (MNSI), Visual Analogue Scale (VAS) and Neuropathy Pain Screening Questions (NPSQ) before the first treatment of every week and after the last treatment. The data was collected from the visual analog scale (VAS), Michigan Neuropathy Screening Instrument (MNSI), and Neuropathy Pain Screening Questions (NPSQ). The results were analyzed to determine statistical significance with Window SPSS Version 25.

5.1 Total view of cases

Table 4. Six cases of demography and medical history

Participant's ID	Case 1	Case 2	Case 3	Case 4	Case 5	Case 6
Gender	Male	Male	Male	Male	Female	Female
Age	70	63	52	48	52	43
Ethnicity	Caucasian	Caucasian	Caucasian	Mexican American	Caucasian	Caucasian
Duration	2 year	8 months	1 year	2 years	8 months	2 months
Location	calves	Bottom of foot and calves	Left foot	Back hill side of sole	Right foot and right sole near Kd 1	dorsom of the foot
Symptoms	Sharp pain, numbness	Pricking pain or numbness	Numbness	Numbness on the foot	Burning Pricking sensation	Numbness
Cause of disease	Aging and Overdose of medication, addicted to Alcohol	Overdose of medication after back surgery	Working in night time	Overworking	Addicted to Alcohol	Stress and worry, malnutrient

5.2 Individual view of cases

5.2.1 Case 1

1) Participant:

Male, 70 years old, Caucasian, CEO of his own company

2) Diagnosis:

He suffered lower limb neuropathy for two years.

He was an alcoholic for last 40 years and he quit drinking 3 years ago.

Both calves would become numb while he was sleeping.

3) Medical history

No diabetes, He used to take baby aspirin for clogging his heart artery and took pain medication but after the treatment, he does not take any more pain medication.

4) Symptoms

Sharp pain, numbness

5) VAS changes:

This participant had strong desired to get better for his own company and family.

Therefore, after the fourth treatment, his pain level from 10 went down to 2. After the fifth and the sixth treatment, his tingling sensation got better.

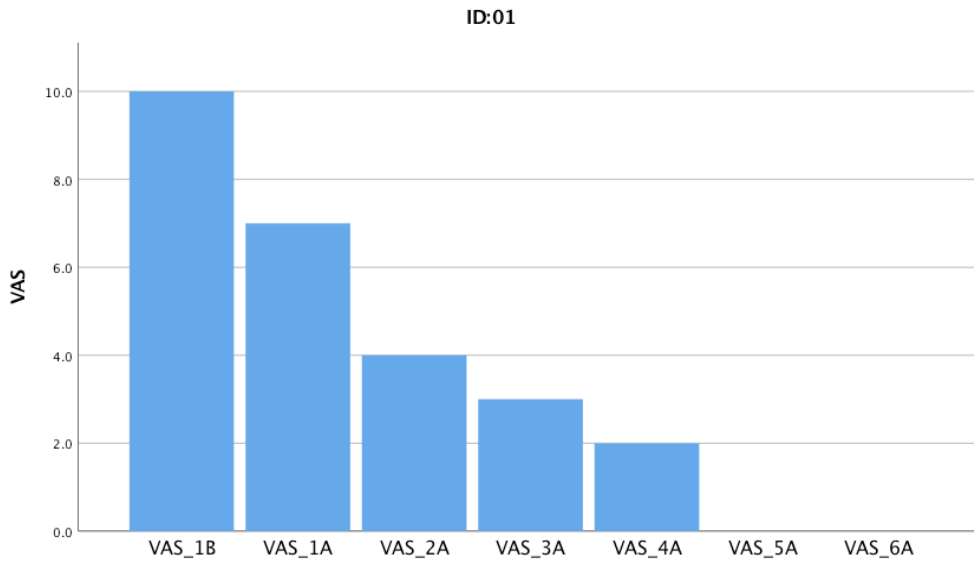


Figure 7. Case 1 id's VAS change before treatment and after treatment

Table 5. Case 1 id's VAS change before and after treatment

	N	Mean
VAS_1B	1	10.000
VAS_1A	1	7.000
VAS_2A	1	4.000
VAS_3A	1	3.000
VAS_4A	1	2.000
VAS_5A	1	.000
VAS_6A	1	.000

5.2.2 Case 2

1) Participant:

Male, 63 years old, Caucasian, retired city worker, wood chopper at night

2) Diagnosis:

Specialist diagnosed with lower limb neuropathy for 8 months.

3) Medical history

He had back surgery (L3 to L5) on last Jan. He used to take lots of pain medication and had steroid shots often. He also had pain all over the body and he could not sleep well because of the pain.

4) Symptoms

Pricking pain or numbing

5) VAS changes:

After surgery, his pain level was 8, but after the second and the third treatments, the pain was reduced. He did not take any medication after the fourth treatment, since his pain was not sharp as before. He was very happy that just acupuncture and herbal medicine could reduce his pain instead of surgery or medication. He wants to continue having acupuncture treatments.

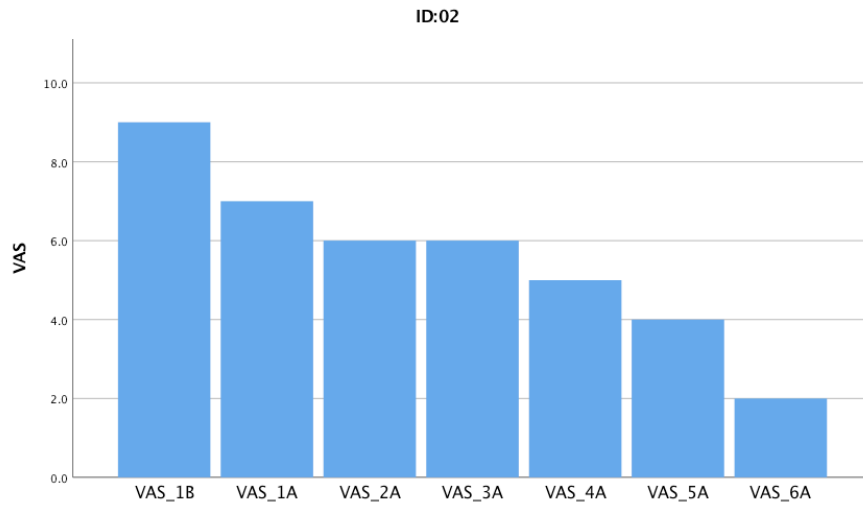


Figure 8. Case 2 id's VAS change before treatment and after treatment

Table 6. Case 2 id's VAS change before and after treatment

	N	Mean
VAS_1B	1	9.000
VAS_1A	1	7.000
VAS_2A	1	6.000
VAS_3A	1	6.000
VAS_4A	1	5.000
VAS_5A	1	4.000
VAS_6A	1	2.000

5.2.3 Case 3

1) Participant:

Male, 52 years old, Caucasian, he is a stage manager

2) Diagnosis:

He had neuropathy for more than 1 year in the left foot and left arm.

He took my advice for eating healthy food and exercising more.

3) Medical history

No diabetes. No HBP. He had pain and numbness in the left foot. He also had a disk problem on the neck. He only works in the night time.

4) Symptoms

Numbness and tingling sensation on the left foot while sleeping.

5) VAS change:

After the first treatment, his pain levels improved and the level of numbness decreased in his foot. After the fourth treatment, he did not have any numbness (pain level 0). After that treatment, he had to leave for summer vacation for two weeks.

While he was gone, he had a great condition. However, he did not continue the treatment, so when he came for his fifth and six treatment, the pain level had gone up to 2.

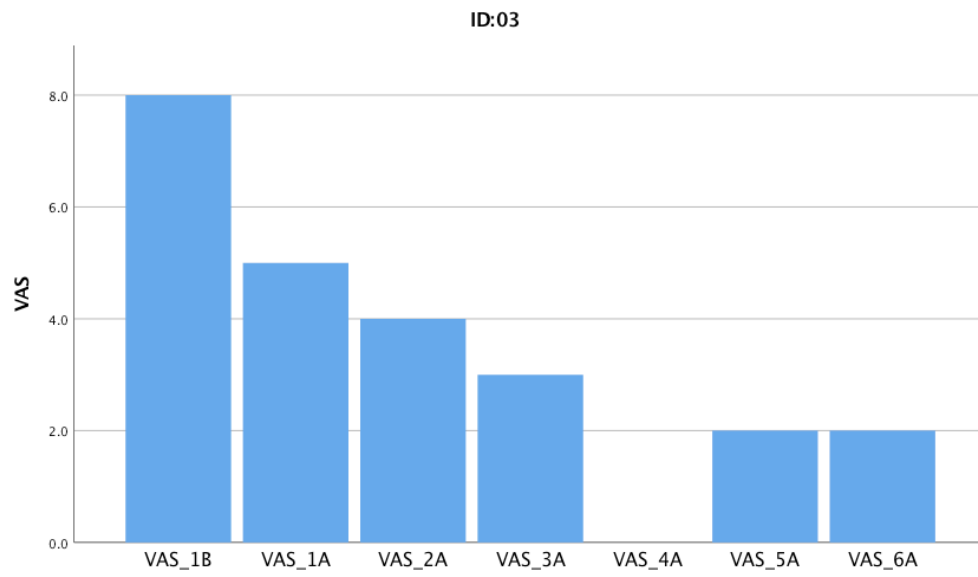


Figure 9. Case 3 id's VAS change before treatment and after treatment

Table 7. Case 3 id's VAS change before and after treatment

	N	Mean
VAS_1B	1	8.000
VAS_1A	1	5.000
VAS_2A	1	4.000
VAS_3A	1	3.000
VAS_4A	1	0.000
VAS_5A	1	2.000
VAS_6A	1	2.000

5.2.4 Case 4

1) Participant:

Male, 48 years old, Mexican American, is an electrician in the movie industry.

2) Diagnosis:

He had neuropathy for more than 2 years in right foot hill.

3) Medical history

He has a tough job which is to move heavy cables with his hands. He worked for 16 hours everyday. He went to chiropractic and physical therapy treatment but it did not help much. He used to take lots of pain medication.

4) Symptoms

Numbness on the hill of the right foot

5) VAS change

After the third treatment, he could feel that the numbness was diminishing. After the fifth treatment, he did not have numbness anymore.

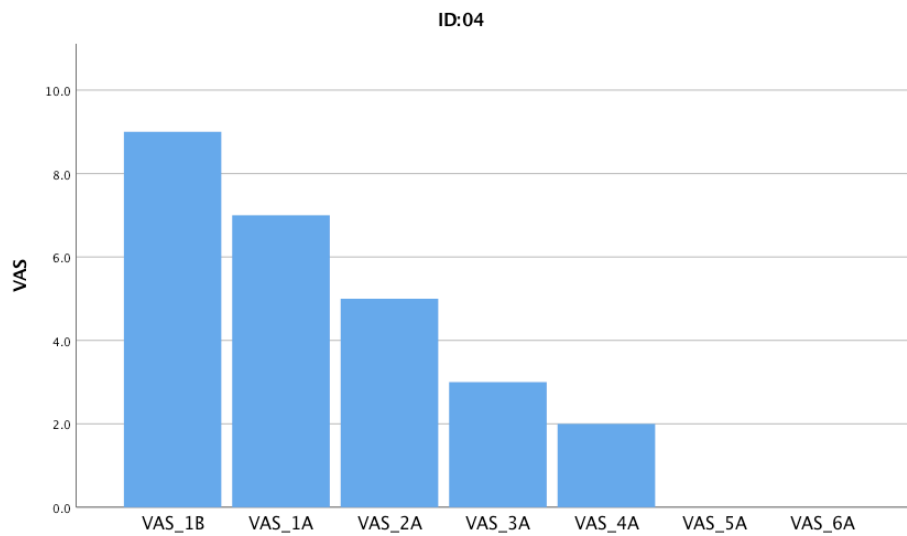


Figure 10. Case 4 id's VAS change before treatment and after treatment

Table 8. Case 4 id's VAS change before and after treatment

	N	Mean
VAS_1B	1	9.000
VAS_1A	1	7.000
VAS_2A	1	5.000
VAS_3A	1	3.000
VAS_4A	1	2.000
VAS_5A	1	.000
VAS_6A	1	.000

5.2.5. Case 5

1) Participant:

Female, 52 years old, Caucasian, works as a Contractor

2) Diagnosis:

She was diagnosed with neuropathy from a specialty doctor. And he had neuropathy for more than 8 months in right foot and right sole near Kd 1 area.

3) Medical history

He had cholecystectomy and lower back pain. He was addicted to alcohol and tobacco for the last eight years.

4) Symptoms

Burning sensation, pricking pain during the night time, insomnia and anxiety

5) Was changes

Since he was younger than the other participants, and the duration of his pain was acute, his recovery was quick. After the second treatment, the symptoms were improved (pain level 8 to 2). However, he had to go on vacation for three weeks, and therefore, could not come and continue. After the third treatment, his pain level went up little bit since he had a long term of absence in the treatment. But after the fifth treatment, his numbness was gone.

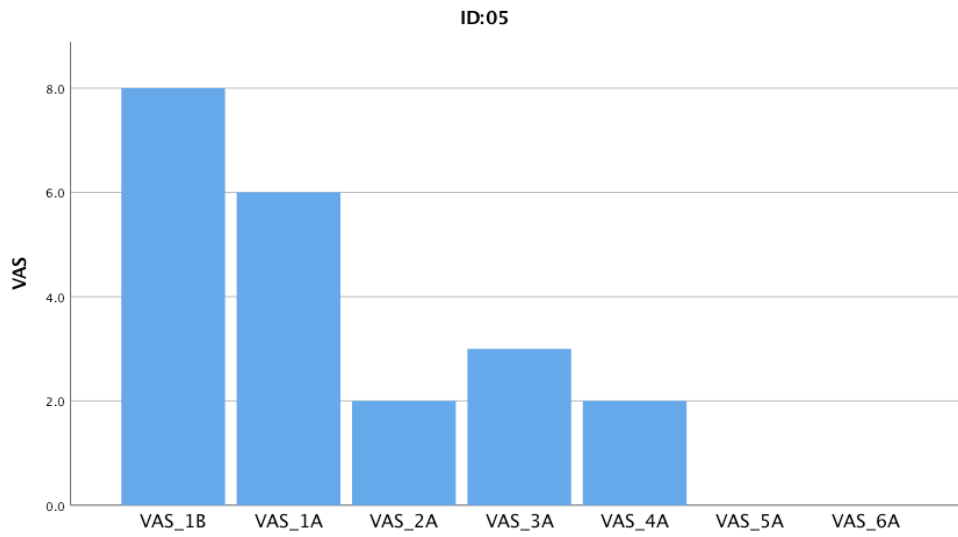


Figure 11. Case 5 id's VAS change before treatment and after treatment

Table 9. Case 5 id's VAS change before and after treatment

	N	Mean
VAS_1B	1	8.000
VAS_1A	1	6.000
VAS_2A	1	2.000
VAS_3A	1	3.000
VAS_4A	1	2.000
VAS_5A	1	.000
VAS_6A	1	.000

5.2.6. Case 6

1) Participant:

Female, 43 years old, Caucasian, Accountant

2) Diagnosis:

She had neuropathy for more than 2 months in dorsom of the foot.

3) Medical history

Anxiety, depression and insomnia after divorce

4) Symptoms

Numbness

5) VAS change acupuncture and herbal medicine

His chiropractor referred this participant to our center after he had treated her for the last two months. Since she was younger than other participants, her response for treatment was very quick. After her third treatment, the pain level went from 8 to 2. After the fourth treatment, she even got better and did not detect any numbness and she was very happy. Finally, she could end the six months of disability benefit.

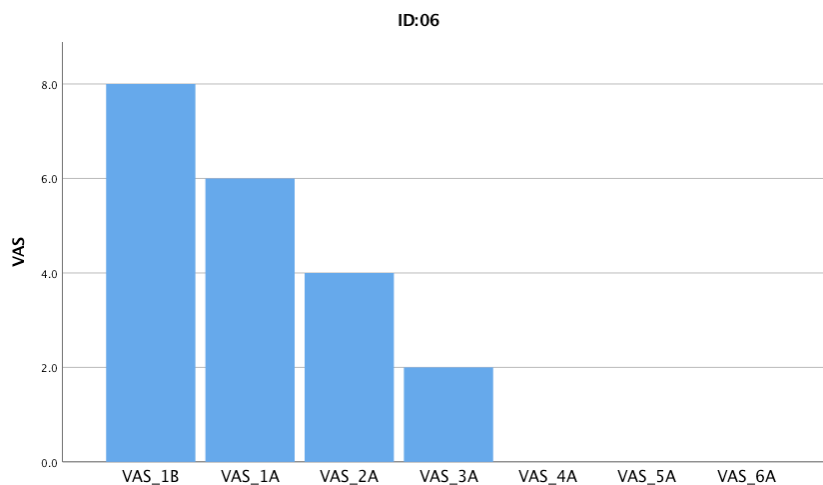


Figure 12. Case 6 id's VAS change before treatment and after treatment

Table 10. Case 6 id's VAS change before and after treatment

	N	Mean
VAS_1B	1	8.0
VAS_1A	1	6.0
VAS_2A	1	4.0
VAS_3A	1	2.0
VAS_4A	1	0.0
VAS_5A	1	0.0
VAS_6A	1	0.0

5.3. VAS analysis of all cases

5.3.1. Visual Analogue Scale (VAS) before and after treatment

To figure out the effectiveness of acupuncture and herbal treatment in lower limb peripheral neuropathy, each time we recorded the VAS before the treatment and after treatment. The VAS values were measured to assess the pain relief of participants with lower limb peripheral neuropathy. Table 12, Figure 14 and Figure 15 showed the results of the effectiveness after the treatments when the assumption of normality was met, the VAS values before and after treatment were evaluated using the paired t-test. When assumption of normality was not met, the Wilcoxon signed-Rank Test was used. As shown in Table 12 the VAS values in before the treatment was higher than VAS after the treatment. The values were decreased from 8.7 ± 0.82 to 6.3 ± 0.82 after the first treatment, showing a decrease of 2.3 ± 0.52 ($p = 0.023$). After the second treatment, the scores went down to 6.8 ± 1.17 to 4.2 ± 1.33 indicating a decrease of 2.6 ± 1.63 ($p = 0.0$). After the third treatment, the values were measured at 5.0 ± 1.55 to 3.3 ± 1.37 indicating a decrease of 1.6 ± 1.03 ($p = 0.023$). After the fourth treatment, the values were measured at 3.3 ± 2.73 to 1.8 ± 1.83 indicating a decrease of 1.5 ± 1.76 ($p=0.034$). After the fifth treatment, the values were measured at 2.7 ± 1.75 to 1.0 ± 1.67 indicating a decrease of 1.7 ± 1.36 ($p=0.041$). After the six treatment, the values were measured at 2.0 ± 1.26 to 0.7 ± 1.03 indicating a decrease of 1.3 ± 1.03 ($p=0.046$). In the effects of VAS after each treatment, the values were distinctively decreased from the treatment before. The results for the VAS were statistically, and highly significant. Boxplots of VAS before and after each treatment especially on Figure 16 show no overlap on the graph that there is a significant difference between treatments.

Table 11. Difference of VAS before and after each treatment

Treatment	Before	After	Difference	p-value
1 st	8.7 ± 0.82	6.3 ± 0.82	2.3 ± 0.52	0.023*
2 nd	6.8 ± 1.17	4.2 ± 1.33	2.6 ± 1.63	0.010**
3 rd	5.0 ± 1.55	3.3 ± 1.37	1.6 ± 1.03	0.023*
4 th	3.3 ± 2.73	1.8 ± 1.83	1.5 ± 1.76	0.034*
5 th	2.7 ± 1.75	1.0 ± 1.67	1.7 ± 1.36	0.041**
6 th	2.0 ± 1.26	0.7 ± 1.03	1.3 ± 1.03	0.046*

* Wilcoxon Signed Ranks Test

** Paired Samples T-Test

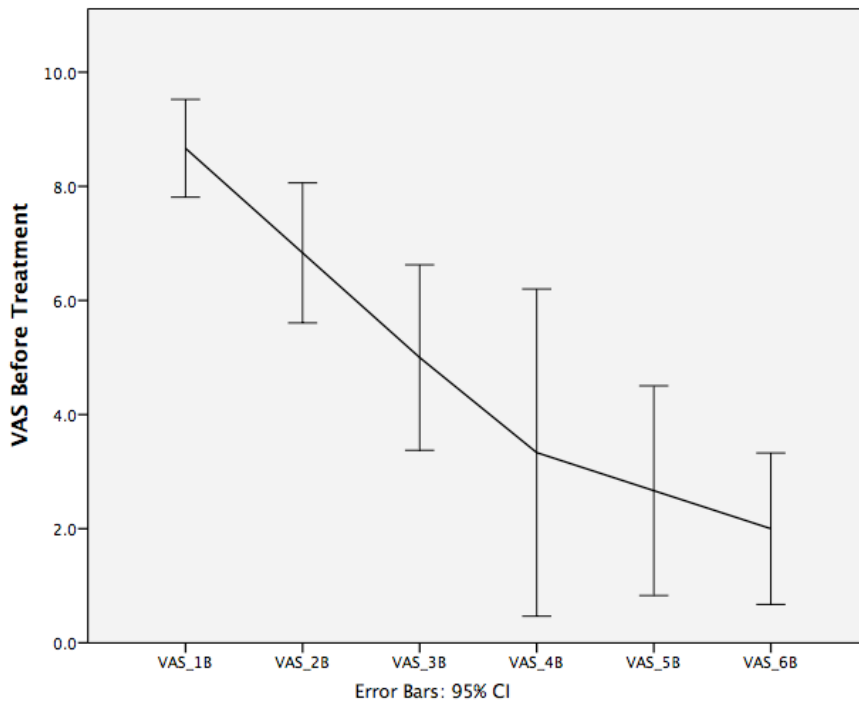


Figure 13. Line Graph of VAS before Each Treatment

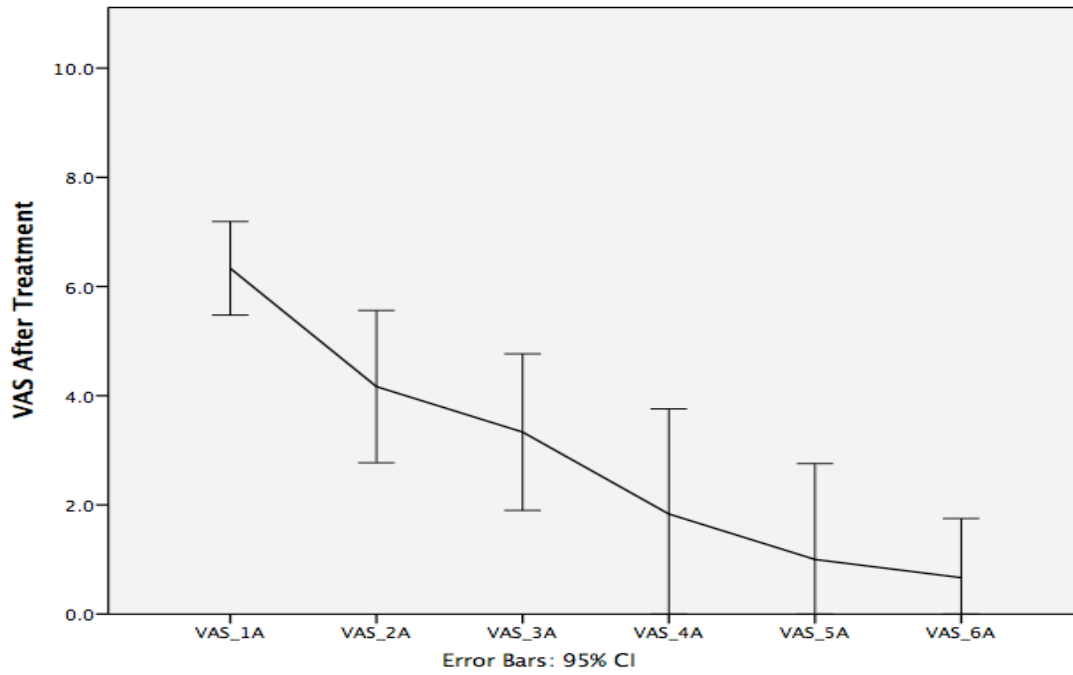


Figure 14. Line Graph of VAS after Each Treatment

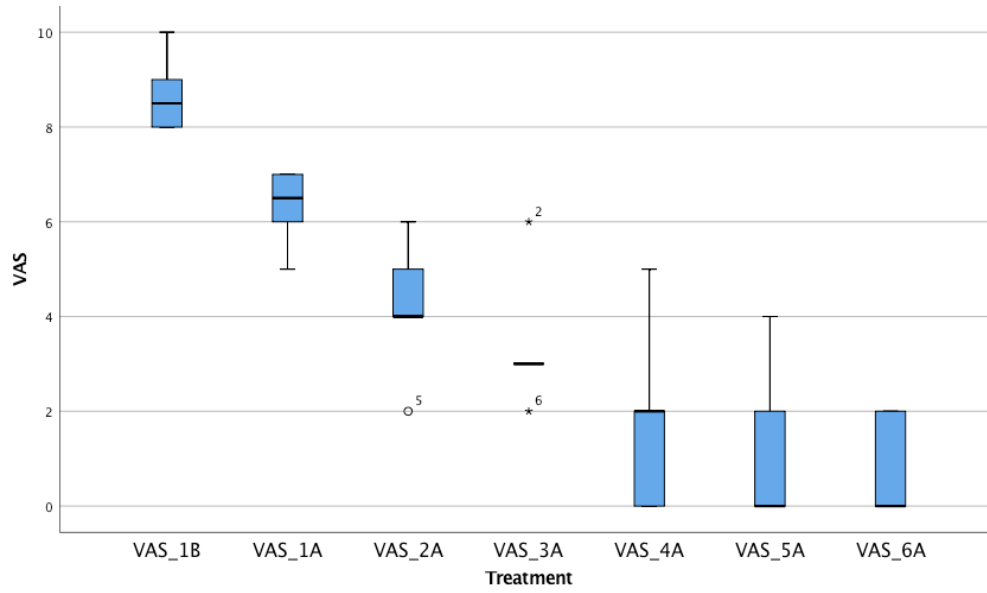


Figure15. Boxplot of VAS before and after each treatment

5.3.2. Cumulative treatment effect

Nth cumulative treatment effect = (initial pre-treatment VAS value) - (VAS value after the Nth treatment)

In comparing the Visual Analogue Scale(VAS) values of the treatment effect after the first session was 2.3 ± 0.52 ($p = 0.023$). After the second session, the treatment effect was 4.5 ± 1 ($p = 0.026$). After the third session, the treatment effect was 5.3 ± 1 ($p = 0.027$). After the fourth session, the treatment effect was 6.8 ± 1.60 ($p = 0.026$). After the fifth session, the treatment effect was 7.6 ± 1.86 ($p = 0.027$). After the sixth session, the treatment effect was 8.0 ± 1.41 ($p = 0.027$). The treatment showed a higher cumulative treatment effect in all cases, but the results were also statistically significant according to Wilcoxon Signed Test (Table 11). In the effects of VAS after each treatment, the values were distinctively decreased from the before treatment. The results for the VAS were statistically highly significant. A box plot for the MNSI and NTQ values is shown in Figure 17 represents showed bar graph of the cumulative treatments before and after each treatment as determined by VAS values. The Cumulative treatment effect showed in Table 11 and treatment rate on VAS and Figure 18. Bar graph of Cumulative treatment effect on VAS and the formula is following below.

Table 12. Cumulative treatment effect and treatment rate on VAS

Treatment	Difference	Rate (%)	p-value*
1st-1 st	2.3 ±0.52	27.0 ± 5.88	0.023
1st-2 nd	4.5 ±1.22	52.1 ± 14.19	0.026
1st-3 rd	5.3 ±1.37	61.7 ± 14.67	0.027
1st-4 th	6.8 ±1.60	79.5 ± 20.46	0.026
1st-5 th	7.6 ±1.86	88.4 ± 18.96	0.027
1st-6 th	8.0 ±1.41	92.1 ± 12.22	0.027

*Wilcoxon Signed Test

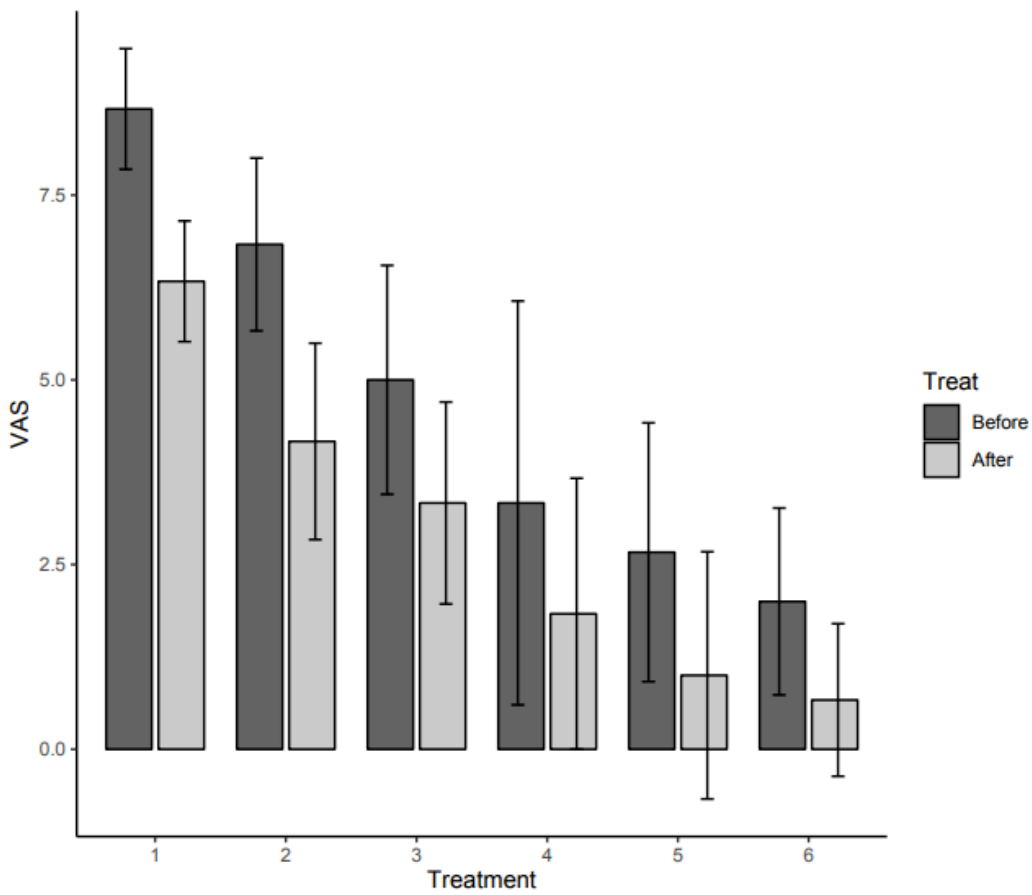


Figure 16. Bar graph VAS before and after treatment of 6 cases

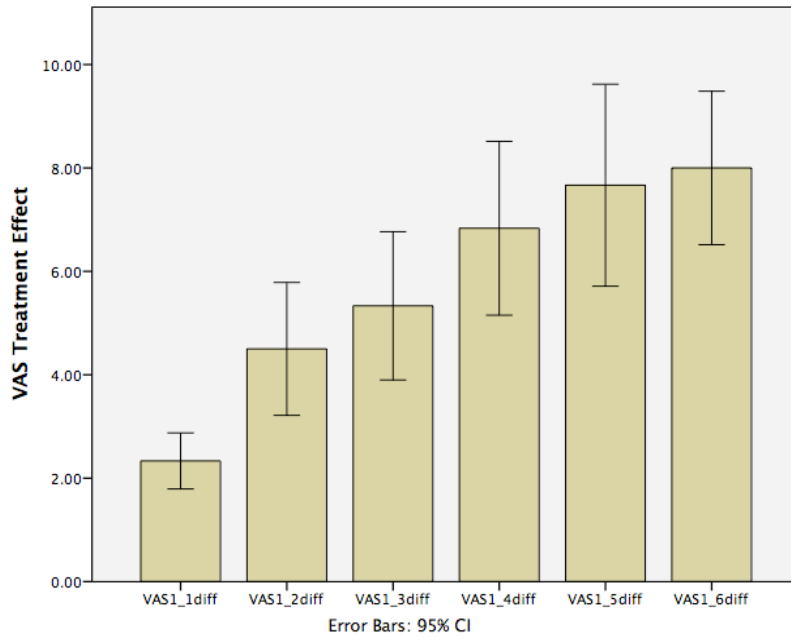


Figure 17. Bar graph of Cumulative treatment Effect on VAS

5.3.3 Cumulative treatment rate

Nth VAS cumulative treatment rate (%) = $(\text{VAS before 1}^{\text{st}} \text{ treatment} - \text{Nth VAS after treatment}) / \text{VAS before 1}^{\text{st}} \text{ treatment} \times 100$

In comparing the Visual Analogue Scale, (VAS) values of the treatment effects after the first session were a percentage of rate of $27.0 \pm 5.88\%$. After the second session, the treatment effect in the percentage of rate was $52.1 \pm 14.19\%$ ($p = 0.026$). After the third session, the treatment effect in the percentage of rate was $61.7 \pm 14.67\%$ ($p = 0.027$).

After the fourth session, the treatment effect in the percentage of rate was $79.5 \pm 20.46\%$ ($p = 0.026$). After the fifth session, the treatment effect in the percentage of rate was $88.4 \pm 18.96\%$ ($p = 0.027$). After the sixth session, the treatment effect was in the percentage of rate was $92.1 \pm 12.22\%$ ($p = 0.027$). The treatment showed a higher cumulative treatment effect in all cases, but the results were also statistically significant according to Wilcoxon Signed Test (Table 13). In the effects of VAS after each treatment, the values were distinctively decreased from the before treatment. The results for the treatment rate on VAS were statistically highly significant. Figure 18 represents bar graph of the cumulative treatments rates are effective after each treatment as determined by VAS values.

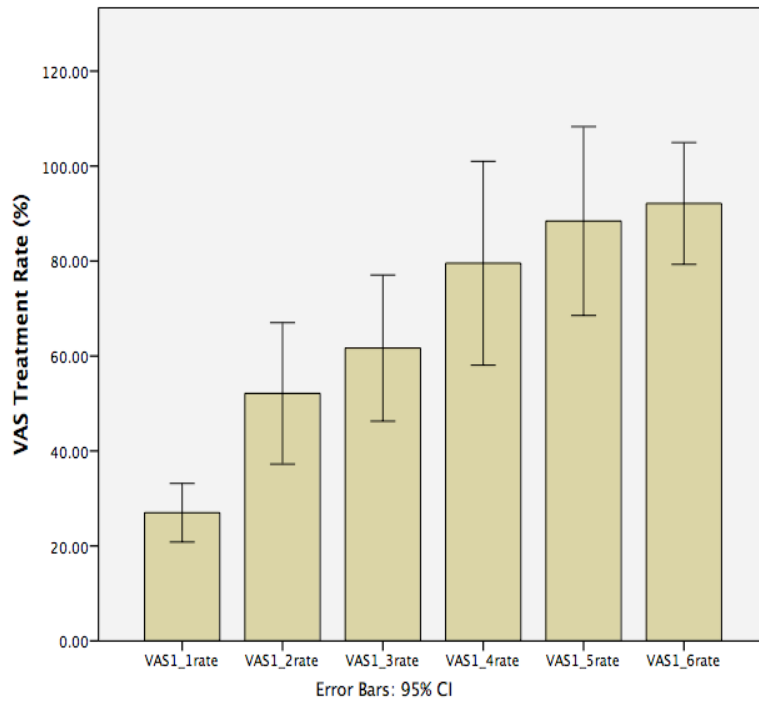


Figure 18. Bar graph of Cumulative treatment rate (%) on VAS

After a total of 6th treatments, the more numbers of treatments that increased, the rate on VAS were increased also. After the final treatment, the rate of treatment was increased 65%.

5.4 Linear regression of visual analogue signal (VAS)

In analysis of linear regression, Table 12, $F(1, 10) = 78.23$, and $P = 0.000$ close to 0, which is significance coefficient and is less than 0.05 (95%). It explains well that significant value is statistically significant.

x = treatment of before and after

Y = VAS values

$Y = 8.02 + (-0.65x)$

After each treatment, the visual analogue scale (VAS) value was reducing 0.65 each time, therefore, the treatment was effective.

Table 13. Linear Regression of model and estimates summary before and after

	R Square	F	df1	df2	Sig.	Constant	b1
Linear	.887	78.230	1	10	.000	8.020	-.646

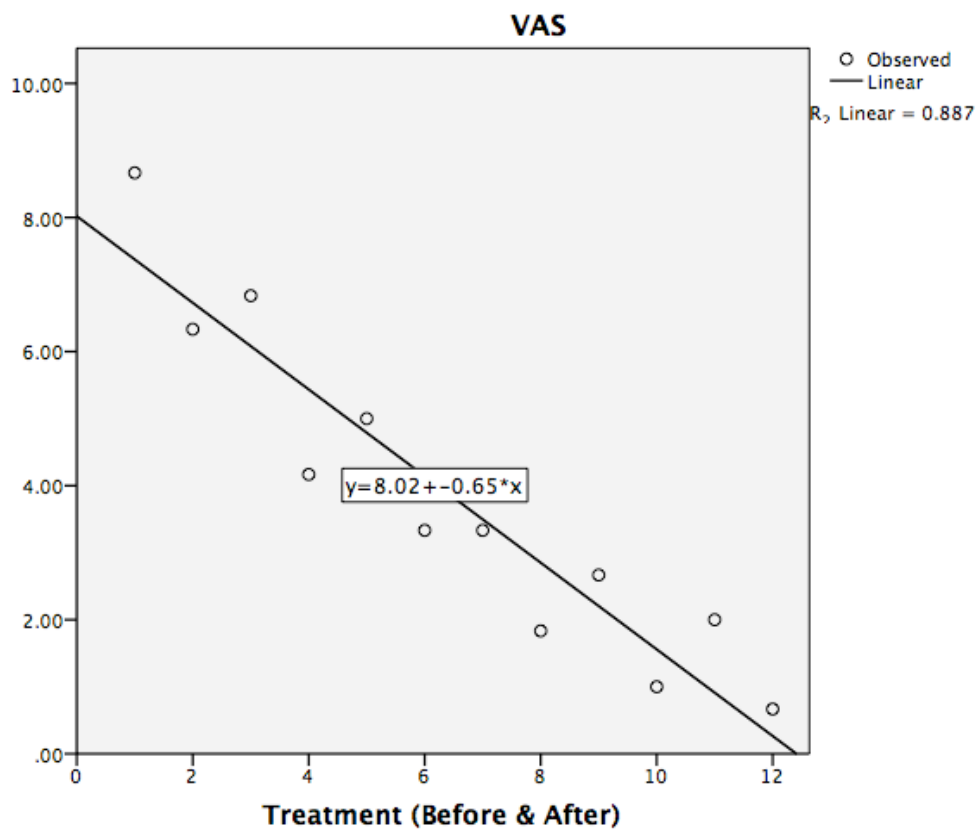


Figure 19. Linear regression of treatment before and after with VAS values

In results of analysis of linear regression Table 13, $F(2,3) = 90.71$, and $p = 0.000$ close to 0, which is α is less than 0.01. It explains well that Sig. value is statistically highly significant.

x = treatment of before and after

Y = VAS values

$Y = 8.02 \pm 0.65x$ (linear)

After each treatment, the visual analogue scale (VAS) value is reducing 0.65 each time, therefore, the treatment is effective.

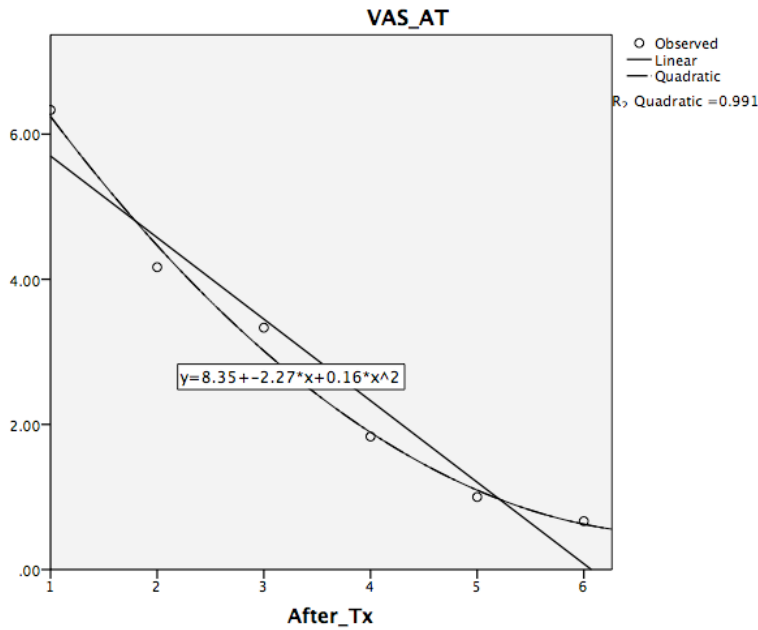


Figure 20. Linear regression of graph for after treatment and VAS value

In results of analysis of quadratic regression, Table 14, $F(2, 3) = 465.21$, and $p = 0.000$ close to 0, which is α is less than 0.01. It explains well that Sig. value is statistically highly significant.

x=treatment of before and after

Y=VAS values

$$Y=11.25-2.67x+0.19x^2$$

Table 14. Linear and quadratic regression of summary and estimates before treatment

Equation	Model Summary					Parameter Estimates		
	R Square	F	df1	df2	Sig.	Constant	b1	b2
Linear	.958	90.705	1	4	.001	9.500	-1.357	
Quadratic	.997	465.206	2	3	.000	11.251	-2.670	.188

Table 15. Linear and quadratic regression of summary and estimates after treatment

Equation	Model Summary					Parameter Estimates		
	R Square	F	df1	df2	Sig.	Constant	b1	b2
Linear	.948	72.854	1	4	.001	6.822	-1.124	
Quadratic	.991	163.064	2	3	.001	8.350	-2.270	.164

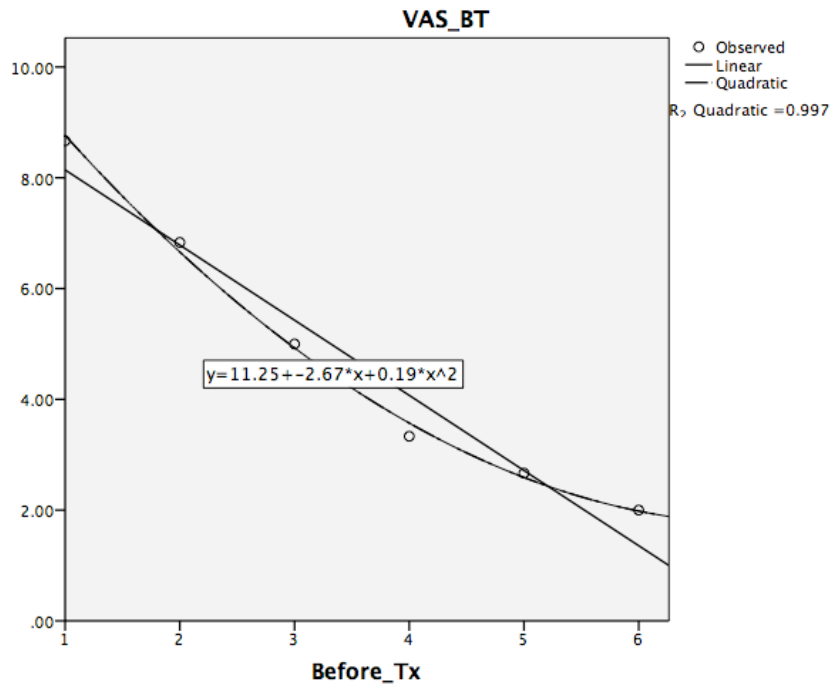


Figure 21. Linear and Quadratic graph for before treatment and VAS values

5.4.1 Pearson correlation on VAS before and after treatment

The Pearson correlation coefficient is a measure of the strength of a linear association between two variables: Y- VAS after treatment and X- VAS before the treatment.

$$Y = -1.04 + 0.83x$$

$$R = 0.993$$

In the results of correlation analysis, it describes well two variables are highly correlated.

$P = 0.000$ which is a Sig value of α is less than 0.01. It explains well that sig. value has correlation with coefficient which is statistically very significant.

Furthermore, it can predict how the treatment's direction will be after the treatment.

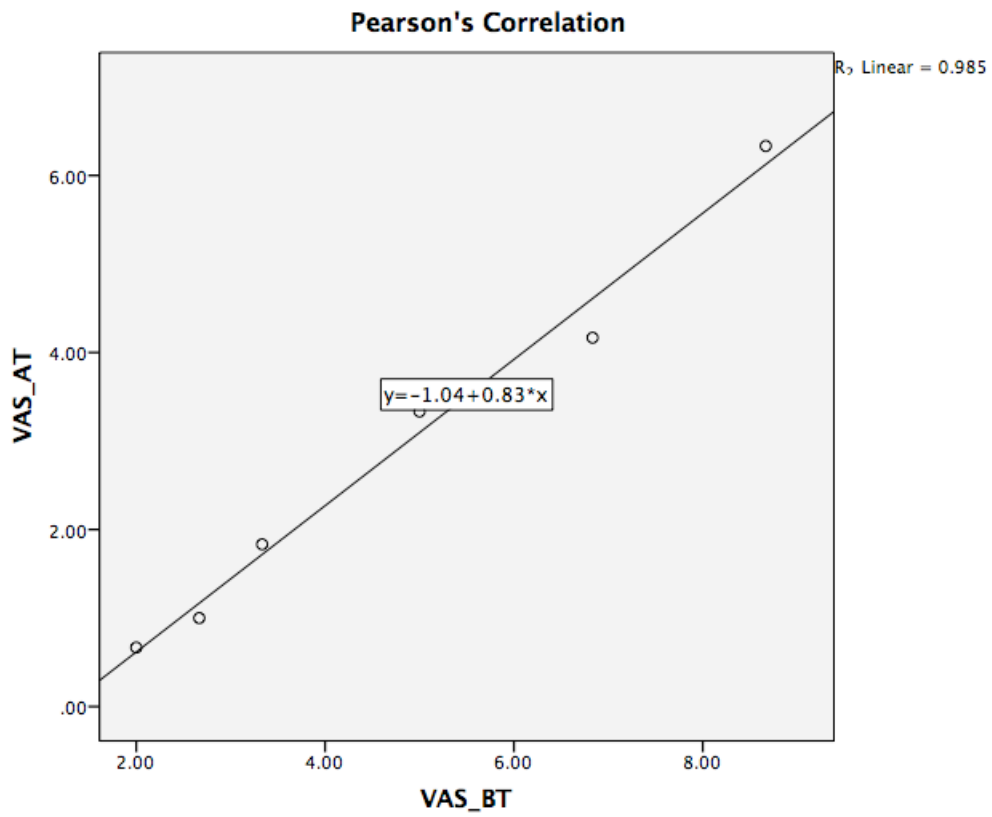


Figure 22. Pearson's Correlation VAS before treatment and after treatment

5.5 MNSI analysis

In the effects of Michigan Neuropathy Screening Instrument(MNSI) after treatment, the values decreased from the before starting treatment 12.2 ± 1.47 to the values after the treatment 10.3 ± 1.03 and showing the decrease of 1.8 ± 0.75 and percentage rate was 14.8 ± 5.0 ($p=0.002$). The effects on Michigan Neuropathy Screening Instrument (MNSI) were statistically highly significant. A Bar graph for the MNSI values is shown in Table 14 and Figure 20. In the effects of score on MNSI after each treatment, the values were decreased from the before treatment. It tells that the symptoms on the MNSI questionnaire was reduced and the treatment was effective.

Table 16. Effects of score on MNSI after treatment

Group	Before	After	Difference	Rate (%)	p-value
MNSI	12.2 ± 1.47	10.3 ± 1.03	1.8 ± 0.75	14.8 ± 5.0	0.002*

*Paired Sample T-Test

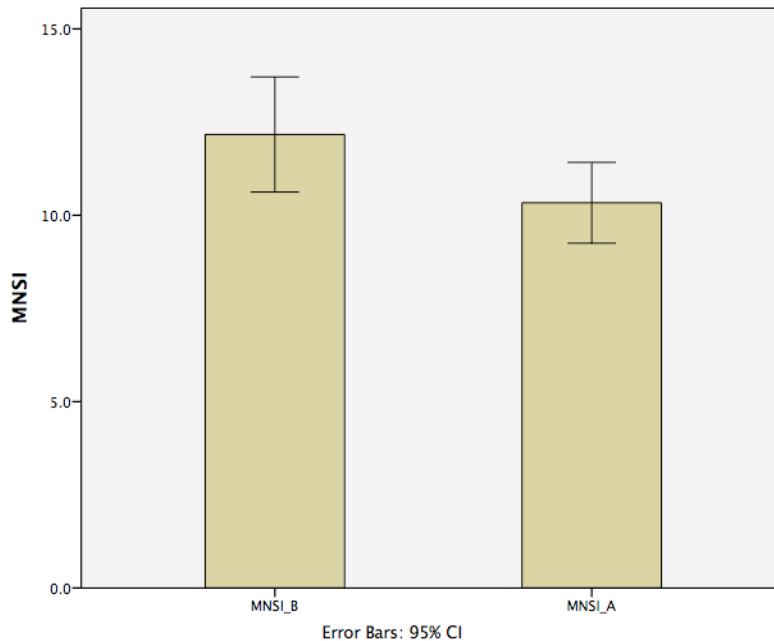


Figure 23. The Effects of score on MNSI before and after treatment

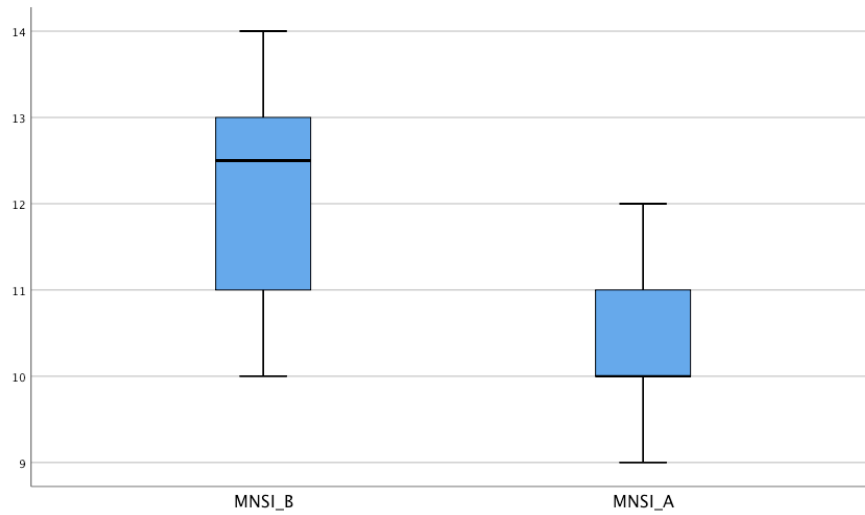


Figure 24. Boxplot of MNSI before and after treatment

5.6 Neuropathy Pain Screening Questionnaire analysis

In the effects of Neuropathy Pain Screening Questionnaire (NPSQ) after the treatment, the values decreased from the starting treatment before, 4.5 ± 0.84 , to the values after the treatment 1.5 ± 1.05 and showing the decrease of 3.0 ± 0.63 and the percentage rate was 69.2 ± 20.60 ($p=0.024$). The effects of score on NPSQ were statistically significant. A bar graph for the NPSQ values is shown in Figure18. In the effects of score on NPSQ after each treatment, the values were distinctively decreased from the before treatment. The symptoms on the questionnaire were reduced and the treatment was effective.

Table 17. Effects of score on NPSQ after treatment

Group	Before	After	Difference	Rate (%)	p-value
NTQ	4.5 ± 0.84	1.5 ± 1.05	3.0 ± 0.63	69.2 ± 20.60	0.024^{**}

**Wilcoxon Signed Ranks Test

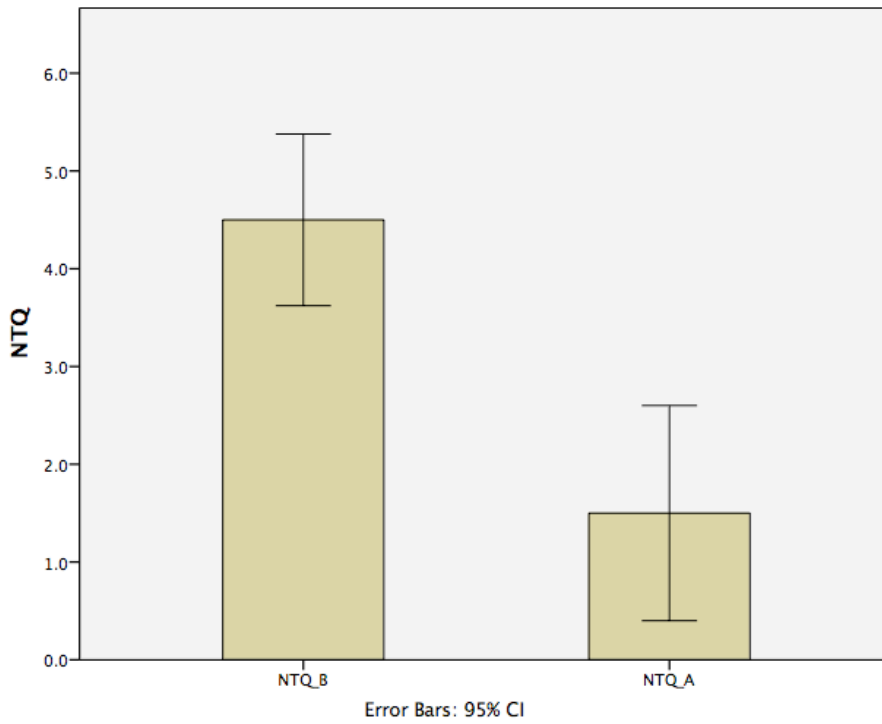


Figure 25. The Effects of score on NPSQ before or after treatment

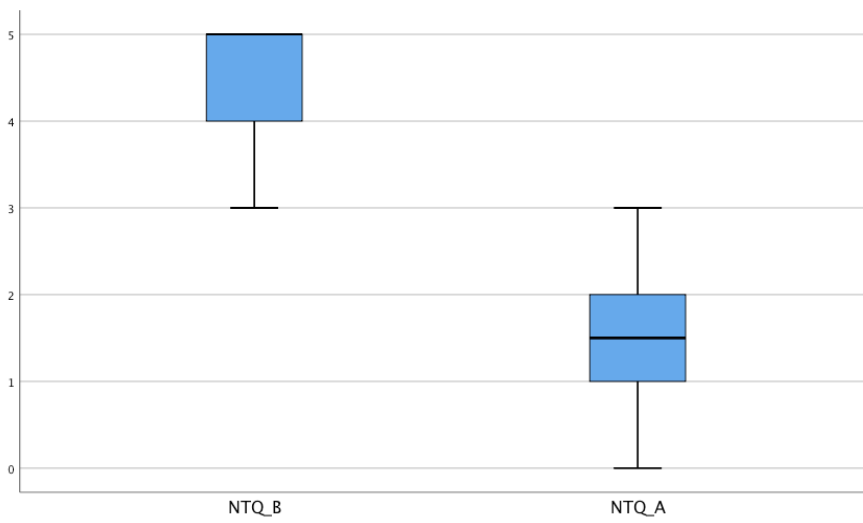


Figure 26. Boxplot of NPSQ before and after treatment

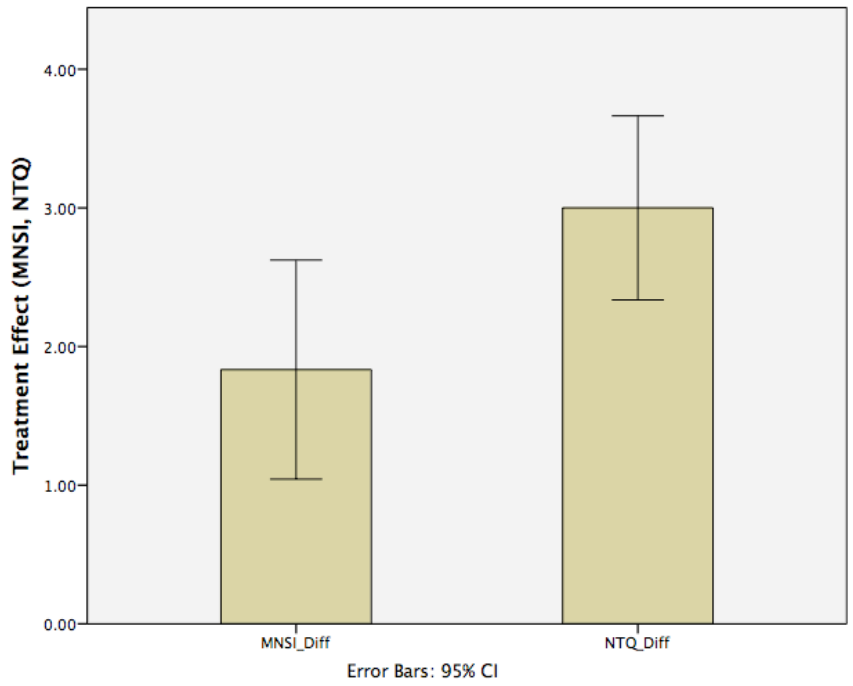


Figure 27. The treatment effect on MNSI and NPSQ before and after treatment

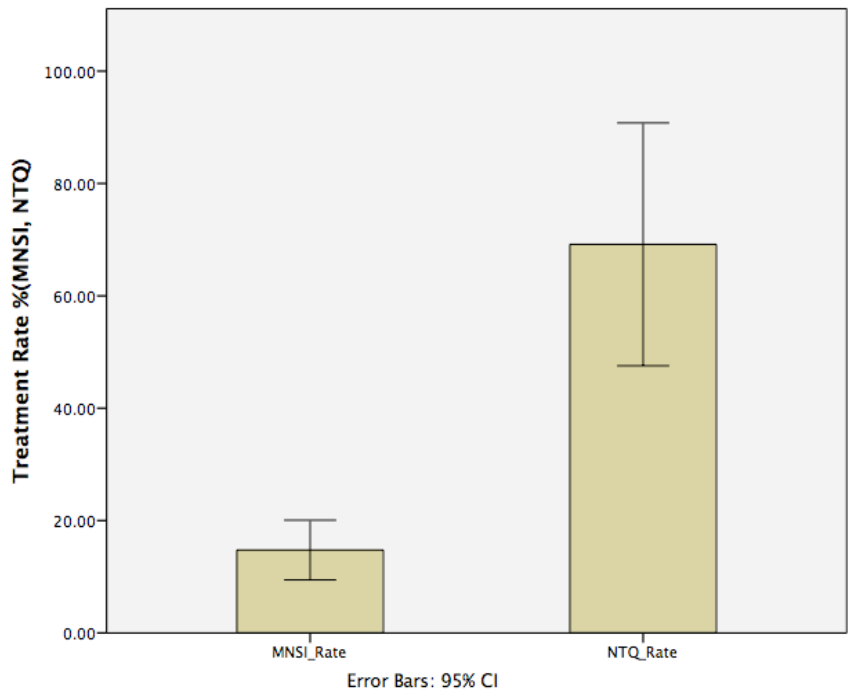


Figure 28. The treatment rate (%) MNSI and NPSQ after treatment

5.7 The analysis of MNSI and NPSQ in each cases

Table18. The results of MNSI and NPSQ before and after treatments

ID	Treatment	MNSI	NPSQ
Case1	Before	13	5
	After	11	3
Case2	Before	13	5
	After	10	2
Case3	Before	14	5
	After	12	1
Case4	Before	11	5
	After	10	2
Case5	Before	12	4
	After	10	1
Case6	Before	10	3
	After	9	0

In the treatment of Case 1, Michigan Neuropathy Screening Instrument (MNSI) values decreased from the before treatment 13 to the values after the treatment 11. And also, the values of Neuropathy Pain Screening Questionnaire (NPSQ) decreased from 5 to 3. The effects on Michigan Neuropathy Screening Instrument (MNSI) and NPSQ were statistically significant. A Bar graph of MNSI and NPSQ values were shown in Table 17 and Figure 29. In the effects of score on MNSI and NPSQ, the values were decreased from the before treatment. It showed the symptoms on the MNSI and NPSQ questionnaire were reduced and the treatments were effective.

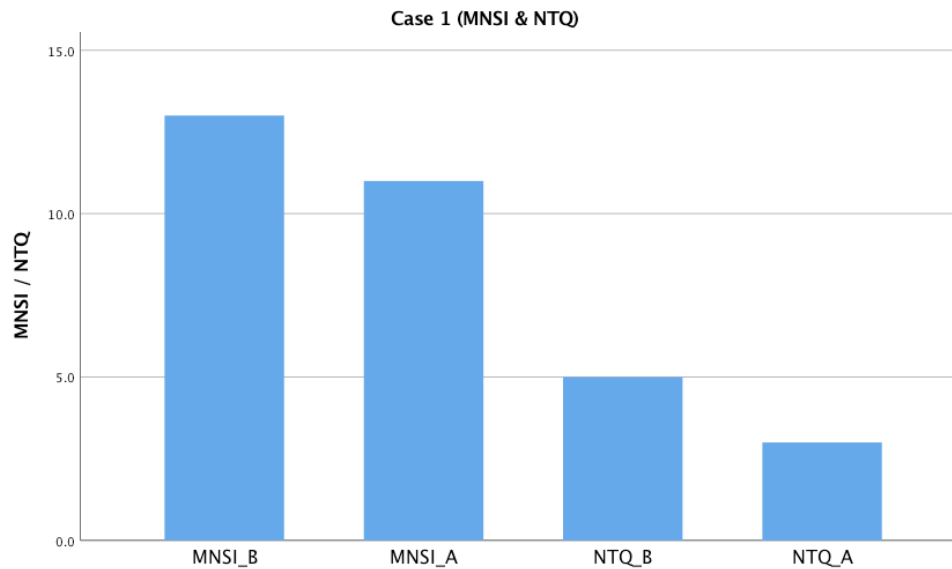


Figure 29. Case 1's Bar graph for MNSI and NPSQ before and after each treatment. In the treatment of Case 2, Michigan Neuropathy Screening Instrument (MNSI) values decreased from 13 to 10. And also, the values of Neuropathy Pain Screening Questionnaire (NPSQ) decreased from 5 to 2. The effects on MNSI and NPSQ were statistically significant. A Bar graph for the Case 2 of MNSI and NPSQ values were shown in Table 17 and Figure 30. In the effects of score on MNSI and NPSQ after each treatment, the values were decreased from the before treatment. It showed the symptoms on the MNSI and NPSQ questionnaire were reduced and the treatment was effective.

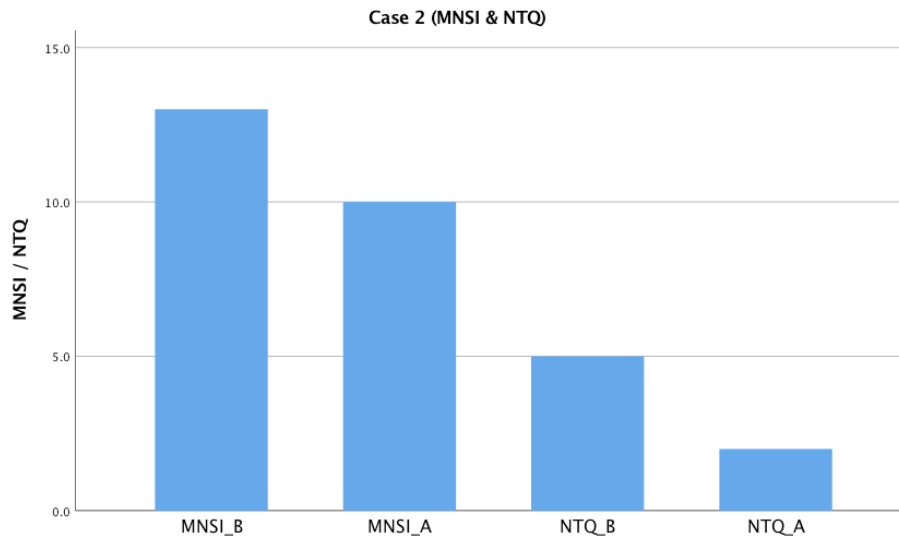


Figure 30. Case 2's Bar graph for MNSI and NPSQ before and after each treatment. In the results of treatment in Case 3, Michigan Neuropathy Screening Instrument (MNSI) values decreased from 14 to 12. And also, the values of Neuropathy Pain Screening Questionnaire (NPSQ) decreased from 5 to 1. The effects of score on MNSI and NPSQ were statistically significant. A Bar graph for the Case 3 of MNSI and NPSQ values is shown in Table 17 and Figure 31. In the effects of score on MNSI and NPSQ after each treatment, the values were decreased from the before treatment. It tells the symptoms on the MNSI and NPSQ questionnaires were reduced and the treatments were effective.

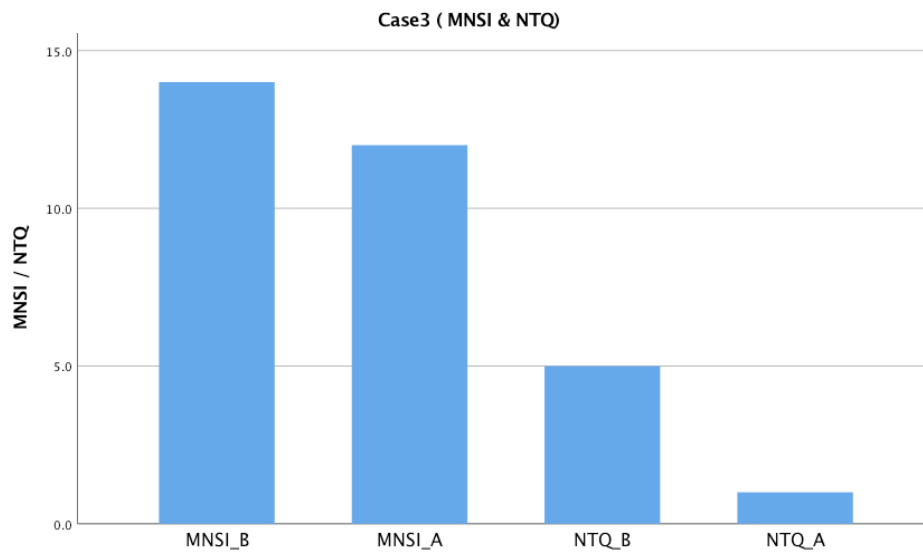


Figure 31 Case 3's Bar graph for MNSI and NTQ before and after each treatment. In the treatment in Case 4, Michigan Neuropathy Screening Instrument (MNSI) values decreased from a 13 to 11. And also, the values of Neuropathy Pain Screening Questionnaire (NPSQ) decreased from 5 to 3. The effects MNSI were statistically significant. A Bar graph for the Case 4 of MNSI and NPSQ values were shown in Table 17 and Figure 32. In the effects of score on MNSI and NPSQ, the values were decreased from the before the treatment. It showed the symptoms on the MNSI questionnaire were reduced and the treatment was effective.

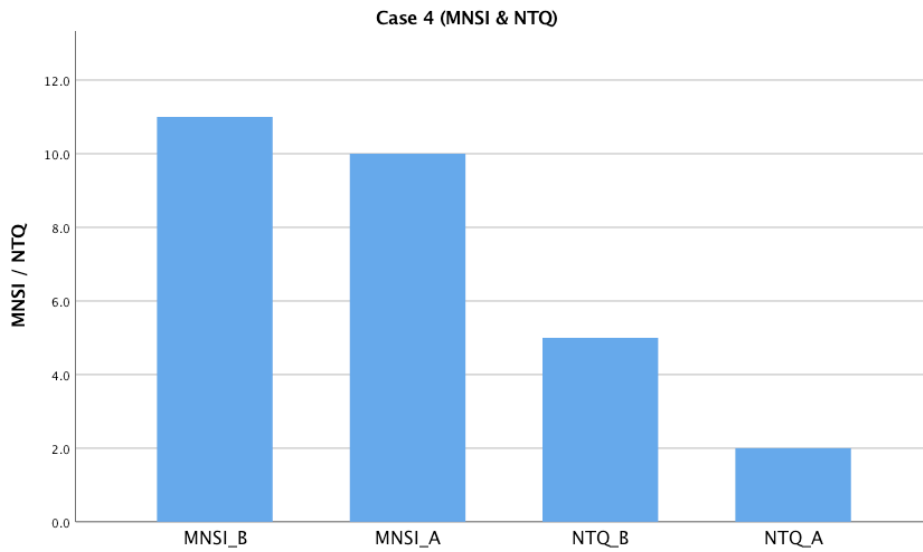


Figure 32. Case 4's Bar graph for MNSI and NPSQ before and after each treatment. In the treatment of Case 5, Michigan Neuropathy Screening Instrument (MNSI) values decreased from a 12 to 10. And also, the values of Neuropathy Pain Screening Questionnaire (NPSQ) decreased from 4 to 1. The effects on Michigan Neuropathy Screening Instrument (MNSI) were statistically significant. A Bar graph of MNSI and NPSQ values were shown in Table 17 and Figure 33. In the effects of score on MNSI and NPSQ after each treatment, the values were decreased from the before treatment. It showed the score on the MNSI and NPSQ questionnaire were reduced and the treatments were effective.

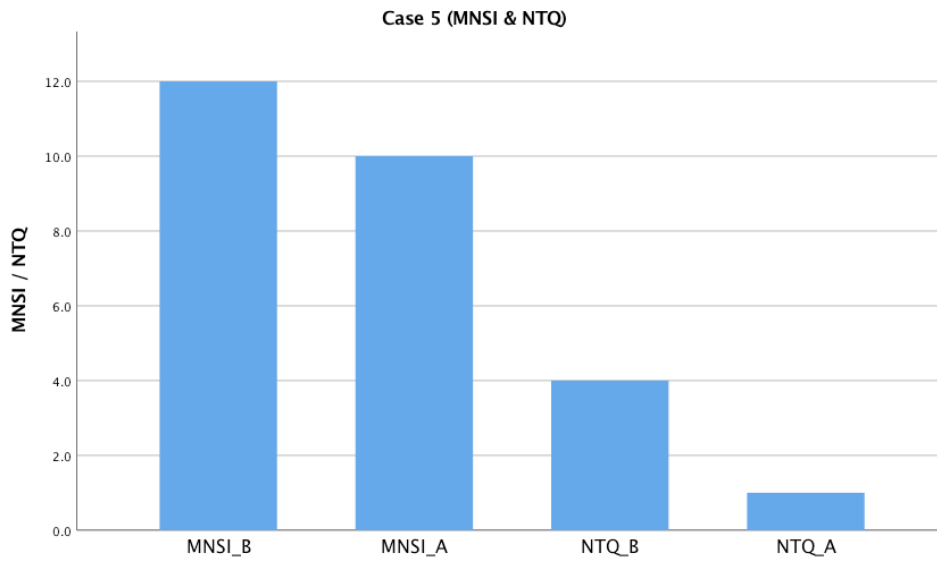


Figure 33. Case 5's Bar graph for MNSI and NPSQ before and after each treatment

In the treatment of Case 6, results showed that Michigan Neuropathy Screening Instrument (MNSI) values decreased from a 13 to 11. The values of Neuropathy Pain Screening Questionnaire (NPSQ) also decreased from 5 to 3. The effects on MNSI and NPSQ were statistically significant. A bar graph for MNSI and NPSQ values were shown in Table 17 and Figure 34. In the effects of score on MNSI and NPSQ after each treatment, the values were decreased from the before treatment. It showed the symptoms on the MNSI and NPSQ questionnaires were reduced.

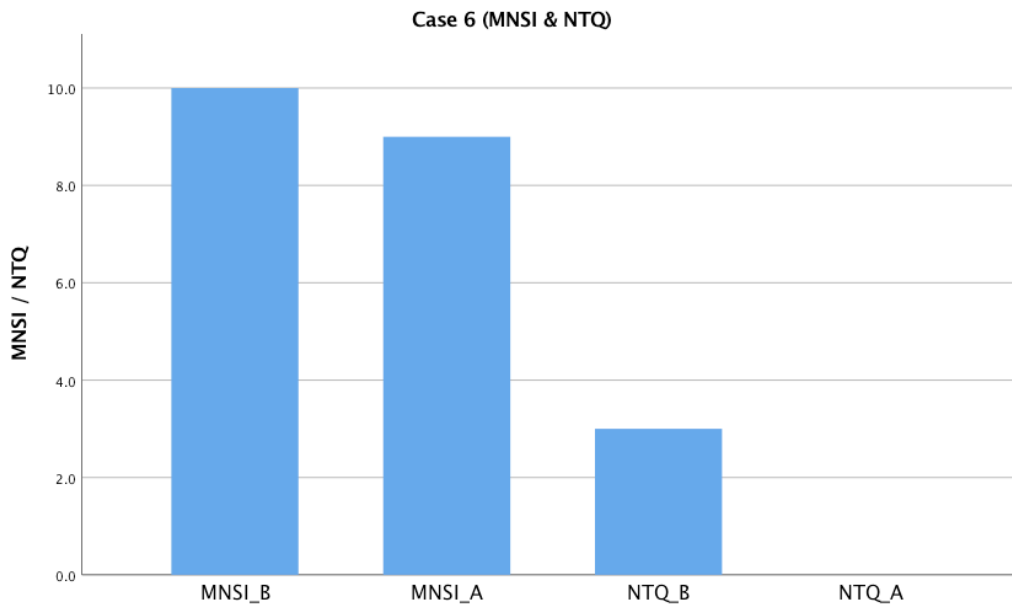


Figure 34. Case 6's Bar graph for MNSI and NPSQ before and after each treatment

The beginning hypothesis and research plan were proven that there were significant improvements in combining acupuncture and herbal medicine treatments. In the study, the younger the participant, the more effective the treatments were. If there is continued research for determining the effectiveness of acupuncture and herbal medicine on age and time span, the research for the acupuncture treatment will be more effective. Comparative analysis will be far more accurate effective in the future.

VI. CONCLUSIONS

This study was conducted for six lower limb peripheral neuropathy participants; they were treated with acupuncture and herbal medicine by Jia Wei Di Huang Wan.

The conclusion was as follows:

1. Effects of Visual Analogue Scale (VAS) before and after each treatment resulted in conclusion of decreased pain. The VAS values before the treatment were higher than the values afterward. The values decreased from 8.7 ± 0.82 to 0.7 ± 1.03 after six treatments. The results for the VAS were statistically significant. The boxplot graph of VAS before and after each treatment in Figure 16 showed no overlapping. Therefore, the results proved a significant difference between treatments.
2. The effectiveness of treatments was determined by comparing the results before and after each treatment using the methods of VAS for the first treatment and the treatment after six weeks. After a total of 6 treatments, the number of treatments increased, and the rates on the visual analog scale (VAS) also increased. After the final treatment, the rate of treatment increased 65%. The six participants were satisfied with the improvement after the treatments.
3. The results of the Michigan Neuropathy Screening Instrument (MNSI) score before and after the treatment were statistically significant. The difference value before and after the treatment was 1.8 ± 0.75 , and the percentage of rate was 14.8 ± 5.0 ($p = 0.002$). The Michigan Neuropathy Screening Instrument (MNSI) results showed that after each treatment, the values were decreased. The treatment difference before and after as seen in the Neuropathy Pain Screening Questionnaire (NPSQ) is 3.0 ± 0.63 and the percentage was

69.2±20.60 (%) p=0.024. It proved that the treatments of acupuncture and herbal medicine were highly effective, as the questionnaires provided data that proved this reduction of pain. In conclusion, acupuncture treatments revealed the efficacy in reducing pain intensity to treat the lower limb peripheral neuropathy in all six case studies. The combining of acupuncture treatment and herbal medicine showed not only the significant efficacy of value of Visual Analogue Signal (VAS), Michigan Neuropathy Screening Instrument (MNSI) and Neuropathy Pain Screening Questionnaire (NPSQ), but also the treatment period was shorter than a treatment with just acupuncture.

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APPENDICES

Informed Consent Form

The purpose of research is to prove that acupuncture and herbal medication Jia Wei Di Huang Wan are effective for peripheral neuropathy treatment. This research will help developing and applying systemic and effective treatment plans in clinic.

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 though you agreed earlier.

The treatment will be conducted from March 2018 to September 2018, twice a week for 6 weeks. We will measure the level of your pain twice before and after treatment. You will be asked to mark the pain level on Visual Analogue Scale (VAS) and for objective results, of the affected side for Peripheral Neuropathy. If you consent to participate in this study, you are expected to answer the questions by Michigan Neuropathy Screening Instrument (MNSI) and Neuropathy Pain Screening Questionnaire (NPSQ). This study uses both acupuncture and Jiawei Di Huang Wan. These treatments can have some unwanted effects. It can cause pain, bleeding, bruise, and some temporary swelling around the place where needles are inserted.

It is possible that it may also cause some problems that are not aware of Jiawei Di Huang Wan as well. However, we will follow you closely and keep track of any unwanted

effects or any problems. We may stop or use some other treatments to decrease the symptoms of the side effects or reaction necessary, we will discuss it together with you and you will always be consulted before we move to the next step. 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 the medicine or treatment is not working, we will give the medication routinely offered to make you more comfortable. While the possibility of this happening is very low, you should still be aware of possibility.

This information you will share with us 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 Ki young Kim, L.Ac.

If you have any question about this study, please contact Ki Young Kim at 323-286-2635 or hellolaurenkim@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 this consent form. The research has been explained to me, including risks and possible benefits, and other options for treatment. I have had the opportunity to ask questions. I consent voluntarily to participate as a participant in this research.

Name of Participant (print)

Name of Witness (print)

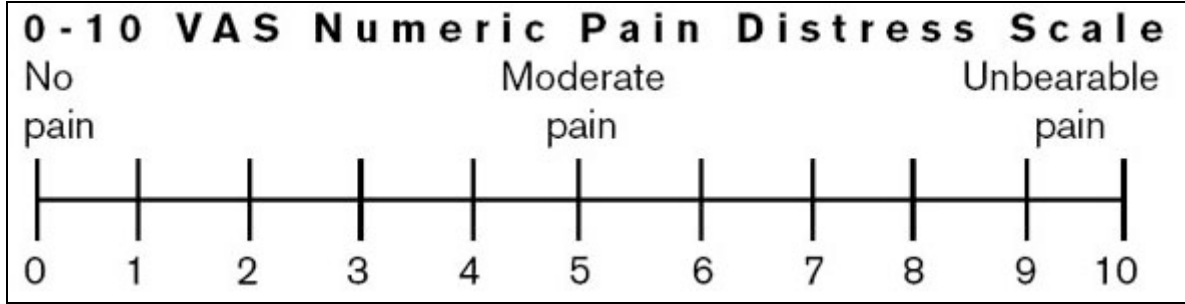
Signature of Participant

Signature of Witness

Date: Day / Month / Year

Date: Day / Month / Year

Visual Analogue Scale



Michigan Neuropathy Screening Instrument

Participant Version

A. History (To be completed by the person with diabetes)

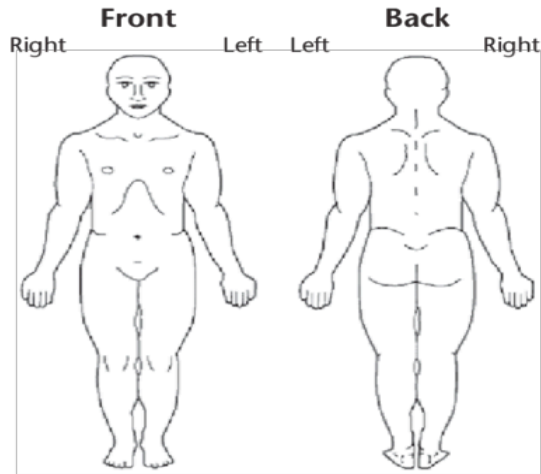
Please take a few minutes to answer the following questions about the feeling in your legs and feet. Check yes or no based on how you usually feel. Thank you.

1. Are your legs and/or feet numb? Yes No
2. Do you ever have any burning pain in your legs and/or feet? Yes No
3. Are your feet too sensitive to touch? Yes No
4. Do you get muscle cramps in your legs and/or feet? Yes No
5. Do you ever have any prickling feelings in your legs or feet? Yes No
6. Does it hurt when the bed covers touch your skin? Yes No
7. When you get into the tub or shower, are you able to tell the
hot water from the cold water? Yes No
8. Have you ever had an open sore on your foot? Yes No
9. Has your doctor ever told you that you have diabetic neuropathy? Yes No
10. Do you feel weak all over most of the time? Yes No
11. Are your symptoms worse at night? Yes No
12. Do your legs hurt when you walk? Yes No
13. Are you able to sense your feet when you walk? Yes No
14. Is the skin on your feet so dry that it cracks open? Yes No
15. Have you ever had an amputation? Yes No

Total score: _____

Neuropathy Pain Screening Questionnaire

On the diagram, below, shade in the areas where you feel pain. If you have more than one area, circle the area that bothers you the most.



Mark 'Yes' to the following items that describe your pain over the past week and 'No' to the ones that do not.

Question	Score	
	Yes	No
1. Did the pain feel like pins and needles?	1	0
2. Did the pain feel hot/burning?	1	0
3. Did the pain feel numb?	1	0
4. Did the pain feel like electrical shocks?	1	0
5. Is the pain made worse with the touch of clothing or bed sheets?	1	0
6. Is the pain limited to your joints?	-1	0

Total score = 3-5: 69% probability of NeP (using c-index)

Original data from participants

ID	Group	Gender	Age	Duration	VAS 1B	VAS 1A	VAS 2B	VAS 2A	VAS 3B	VAS 3A	VAS 4B	VAS 4A	VAS 5B	VAS 5A	VAS 6B	VAS 6A	MN SIB	MN SIA	NPS QB	NPS QA
1	1	1	70	2	10	7	8	4	6	3	7	2	4	0	2	0	13	11	5	3
2	1	1	63	2	9	7	8	6	7	6	6	5	5	4	4	2	13	10	5	2
3	1	1	52	2	8	5	7	4	6	3	0	0	3	2	2	2	14	12	5	1
4	1	1	48	2	9	7	6	5	4	3	3	2	2	0	2	0	11	10	5	2
5	1	2	52	1	8	6	7	2	4	3	3	2	2	0	2	0	12	10	4	1
6	1	2	43	1	8	6	5	4	3	2	1	0	0	0	0	0	10	9	3	0