SOUTH BAYLO UNIVERSITY

Comparison of the Effectiveness of SaAm Korean Four Needle Acupuncture Combined with TCM Acupuncture vs TCM Acupuncture on Shoulder and Upper Back Pain: Pilot Randomized Controlled Trail

by

Manusanee Chanyaem

A RESEARCH PROJECT SUBMITTED

IN PARTIAL FULFILLMENT OF THE

REQUIREMENTS FOR THE DEGREE

Doctor of Acupuncture And Oriental Medicine

ANAHEIM, CALIFORNIA

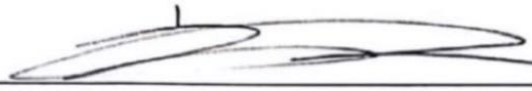
DECEMBER 2022

DISSERTATION OF MANUSANEE CHANYAEM

APPROVED BY RESEARCH COMMITTEE

Mark K. Cho, Ph.D, L.Ac.

Hanok Lee, DAOM, L.Ac.



Shan Qin Cui, OMD, L.Ac.

Anne Ahn, OMD, L.Ac.

Joseph H. Suh, Ph.D, OMD, L.Ac.

South Baylo University

Los Angeles, California

December 31, 2022

Comparison of the Effectiveness of Four Needle Acupuncture Combined with TCM Acupuncture vs TCM Acupuncture on Shoulder and Upper Back Pain

Manusanee Chanyaem

South Baylo University at Anaheim, 2022

Research Advisor: Mark Cho, PhD, L.Ac

ABSTRACT

Korean Four Needles acupuncture is one of the original and outstanding therapeutic modalities representing traditional Korean medicine, was created in the middle of the Cho Sun dynasty, by a Korean Buddhist monk whose name was Saam. The foundation of combining five shu points is based on the theory of Nan-jing. Saam acupuncture, which involves five shu points as the main treatment aspect, has the benefits of increasing parasympathetic nerve activation and adjusting the balance of the autonomic nervous system. This study is to investigate Pain Management Using Traditional Chinese Acupuncture with Korean Four Needle Techniques in Shoulder and upper back pain patients. This study consisted of 14 patients, a pilot randomized controlled trial with two parallel arms: Chinese traditional acupuncture control group (CG), n=7 and a traditional Chinese Acupuncture with Korean Four Needle Techniques experimental group (EG), n=7. The outcomes were analyzed by the visual analog scales (VAS) and range of motion (ROM). Evaluations were performed prior and after to receive treatment, once a week, total four weeks of treatment. Fisher's Exact test, Paired Sample t-test, Wilcoxon Signed Rank test, Cumulative VAS

Difference, Cohen's d on Cumulative Difference and Dichotomous Test were used in this study. VAS before and after third and fourth treatment EG were 3.7±1.70 and 2.6±1.99, *p*-value were 0.02 and 0.005 and first and fourth treatment of CG were 4.3±2.21 and 3.9±1.86, *p*-value were 0.011 and 0.002. For cumulative *p*-value of both groups were greater Thant 0.05, there were no significant between groups. Also Cohen's d on cumulative difference had small issues. In Dichotomous Result: Risk Ratio (RR), the result was 0.51<1, there was difference between group. The risk of having uncured (VAS>3) with treatment was 51% of risk in CG, EG reduced the risk of uncured by 49%. Odds Ratio (OR), the result was 0.31<1, there was difference between groups. EG reduced the odds of uncured to 31% of the odds in CG, EG reduced the odds of uncured by 69%. Risk Difference (RRR). The result showed -0.28<0, there was difference between the groups. EG reduced the risk of uncured by 28%. 57 of 100 people experienced uncured in CG. 28 fewer people experienced uncured with EG.

Dedication

To my parents, Mr. Manus and Brigadier General Dr. Wathit Chanyaem for their endless encouragement and patience, who made all of this possible. Also to all my loved ones for enabling me to complete every step in my education heretofore.

Acknowledgements

This study has helped me to broaden and deepen my understanding of factors to increase my treatment skills and integrated my variety of knowledge in Chinese traditional medicine. Through this study, I felt that my maturity as a researcher and healthcare practitioner advisor reached a higher plateau.

I wish to express my special thanks to Ms. Nitaya Prasertbhakdekul who is my lovely aunty and all my friends from school, church for their pray, support and encouragement during this project.

I felt deeply indebted to Dr. Mark Cho, the chair of my Dissertation Committee, and Dr. Joseph Suh, DAOM director who encouraged me through my entire research. Their constructive criticism and insistence upon high standards of work made me work harder and strive for higher academic quality. Also I would like to especially Thank all South Baylo clinic in Anaheim campus for helping to make me a professional in the international acupuncturist area.

I also give my heartfelt thanks to Dr. Ndayapa Pussadhamma, my DAOM senior friend, for her valuable suggestions as a researcher and healthcare practitioner in Chinese Traditional medicine.

I also give my special thanks to Dr. Kamol Somvichian, who passed away but he was always still be my heart and forever professor for his life philosophy, and his lovely wife. I felt grateful to my husband, Norman Eldon France who sacrificed himself to prove my English and inspired me to finish the best in me. Their dedication to the teaching of all aspects of academic English and their guidance inside and outside of the classroom truly opened my eyes to the world.

My gratitude also goes to Dr. Shilh-hou (Lily) Lin, university Coordinator Anaheim campus (librarian), for the literature search both inside and outside the library.

My special thanks are given to the South Baylo University officers. Without their help, this work would have been nearly impossible.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

I. INTRODUCTION

Shoulder pain is a common musculoskeletal condition that is recognized as a disabling problem and can be associated with substantial economic burden. The pain and disability associated with shoulder pain can have a large impact on individuals and their families, communities, and healthcare systems affecting daily functioning, and ability to work. It is the third most common musculoskeletal complaint presenting to physiotherapy.

The design of the shoulder joint is such that it sacrifices stability for mobility. As an extremely mobile joint that plays a central role in the action of a major extremity (the arm), the shoulder is at high risk for injury. An injury can involve the ligaments, bursae, or tendons surrounding the shoulder joint, the cartilage, menisci (plural for meniscus), or bones of the joint. Pain can also occur in the shoulder from diseases and conditions that involve the shoulder joint, the soft tissues and bones surrounding the shoulder, or the nerves that supply sensation to the shoulder area.

Turning point

Clinical studies of Saam acupuncture were mainly performed in relation to musculoskeletal pain and autonomic nervous system regulation. Meridian identification was predominantly used when Saam acupuncture was applied to musculoskeletal pain. In this research, when shoulder pain on the side was present due to Bi syndrome, Gallbladder tonification was selected. If the symptom occurred towards the back of the shoulder and scapular, and bladder tonification was used , according to the flowing area of the meridian. Musculoskeletal pain-related clinical research of Saam acupuncture mentioned above showed

good results.

Alone of Traditional Chinese acupuncture itself could provide a very nice result to treat shoulder pain. This research would like to find more alternative ways to enhance the best result of treatments.

Conclusion

The goal of this research was to find the optimal result of acupuncture treatment to overcome shoulder pain and improve the quality of life.

Research statement

My research focuses on studying Traditional Chinese medicine and adding on Saam Korean four needle techniques to enhance the result of acupuncture treatment. The TCM itself was a wonderful treatment in pain management. I would like to find more modalities to gain more knowledge and improve patients' quality of life.

Since I was an intern in South Baylo University in 2019-2020. I found many successful cases in shoulder pain with TCM and Korean Four needle techniques.

In this society nowadays, there are many people who suffer from pain. This research should bring more treasures from the ancient Korean medical wisdom to synchronize with the root of TCM to improve the holistic healing process of our human kind.

OBJECTIVES

The objective of this research is to evaluate the effectiveness and safety for 4 weeks of treatment.

1. The change of mean of VAS and ROM within the group will be measured through 1-4 weeks.

2. The follow up treatment will be measured in 2-4 weeks. All pre-test will be tested on visit 1 (before the treatment). For post-test, using VAS and ROM, All post-test will be tested on all visits.

3. Relative Risk Ratio (RR) and Relative Risk Reduction (RRR) from the dichotomous data will be determined at 1 and 4 weeks.

LITERATURE REVIEW

Up to 70% of people will experience shoulder pain at some point in their lives. Shoulder pain can be particularly vexing, because it makes it hard to sleep. Shoulder pain, which may arise from repetitive movements, sports injuries, or slow degeneration of tissues over time, is one of the most common types of musculoskeletal pain.

Most pain in the shoulder is related to the soft tissues of the joints, primarily the rotator cuff tendons and muscles. In most cases doctors recommend medications to reduce pain and inflammation, modifications to normal activity, and take a "wait and see" approach. Serious conditions of frozen shoulder (adhesive capsulitis), torn rotator cuff, or chronic tendonitis in shoulder can be disabling. That is why shoulder pain is one of the complaints most often referred to physical therapy (PT) specialists.

Severe cases of shoulder impingement, collarbone pain due to fractures, or torn tendons may require surgery. Acupuncture and TCM offer an excellent complementary or alternative form of treatment that can reduce pain and inflammation and help restore mobility to a sore shoulder. Shoulder pain can make the simplest activities difficult to perform.

Most shoulder problems fall into four major categories:

- Tendon inflammation (bursitis or tendinitis) or tendon tear
- Instability
- Arthritis
- Fracture (broken bone)

Other much less common causes of shoulder pain are tumors, infection, and nerve-related

problems.

Bursitis

Bursae are small, fluid-filled sacs that are located in joints throughout the body, including the shoulder. They act as cushions between bones and the overlying soft tissues, and help reduce friction between the gliding muscles and the bone.

Sometimes, excessive use of the shoulder leads to inflammation and swelling of the bursa between the rotator cuff and part of the shoulder blade known as the acromion. The result is a condition known as subacromial bursitis.

Bursitis often occurs in association with rotator cuff tendinitis. The many tissues in the shoulder can become inflamed and painful. Many daily activities, such as combing your hair or getting dressed, may become difficult.

Treatment

Treatment for bursitis involves allowing the inflamed bursa to heal. Some other treatment options include:

- resting
- gently stretching
- taking nonsteroidal anti-inflammatory drugs (NSAIDs)
- taking corticosteroids
- taking antibiotics (rare)
- undergoing surgery (rare)

Tendinitis

A tendon is a cord that connects muscle to bone. Most tendinitis is a result of

inflammation in the tendon. Tendinitis

The term “tendinitis” refers to inflammation of a tendon. The most common form of shoulder tendinitis is rotator cuff tendinitis.

Generally, tendinitis is one of two types:

- Acute. Excessive ball throwing or other overhead activities during work or sport can lead to acute tendinitis.
- Chronic. Degenerative diseases like arthritis or repetitive wear and tear due to age, can lead to chronic tendinitis.

The most commonly affected tendons in the shoulder are the four rotator cuff tendons and one of the biceps tendons. The rotator cuff is made up of four small muscles and their tendons that cover the head of your upper arm bone and keep it in the shoulder socket. Your rotator cuff helps provide shoulder motion and stability.

Treatment

Overuse is the most common cause of tendinitis. Treatment can take up to several months and typically involves a combination of the following:

- resting
- modifying normal activities
- taking anti-inflammatory medications
- undergoing physical therapy
- taking corticosteroids

In severe cases, a doctor may recommend surgery. Post-surgical rehabilitation takes time,

and complete pain relief may take up to a year.

Tendon Tears

Splitting and tearing of tendons may result from acute injury or degenerative changes in the tendons due to advancing age, long-term overuse and wear and tear, or a sudden injury. These tears may be partial or may completely separate the tendon from its attachment to bone. In most cases of complete tears, the tendon is pulled away from its attachment to the bone. Rotator cuff and biceps tendon injuries are among the most common of these injuries.

Tendon tear

Sometimes, a tendon can tear as a result of overuse or acute injury. Common tendon tears of the shoulder area include rotator cuff tears and bicep tendon tears.

Treatment

Treatment for a tendon tear may involve the following:

- applying ice
- taking NSAIDs
- resting the shoulder joint
- undergoing physical therapy
- receiving corticosteroid injections
- undergoing surgery

Injury to the shoulder joint

Impingement

Shoulder impingement occurs when the top of the shoulder blade (acromion) puts pressure on the underlying soft tissues when the arm is lifted away from the body. As the arm is

lifted, the acromion rubs, or "impinges" on, the rotator cuff tendons and bursa. This can lead to bursitis and tendinitis, causing pain and limiting movement.

Nerve problems

A pinched nerve occurs when a nerve becomes compressed by its surrounding tissues, such as bones, cartilage, or tendons.

Treatment

Some treatment options for a pinched nerve include:

- undergoing physical therapy
- taking pain-relieving medications, such as NSAIDs or corticosteroids
- wearing a cervical collar, to reduce neck movement and prevent further nerve irritation
- undergoing surgery

Instability

Shoulder instability occurs when the head of the upper arm bone is forced out of the shoulder socket. This can happen as a result of a sudden injury or from overuse.
Shoulder dislocations can be partial, with the ball of the upper arm coming just partially out of the socket. This is called a subluxation. A complete dislocation means the ball comes all the way out of the socket.

Once the ligaments, tendons, and muscles around the shoulder become loose or torn, dislocations can occur repeatedly. Recurring dislocations, which may be partial or complete, cause pain and unsteadiness when you raise your arm or move it away from your body. Repeated episodes of subluxations or dislocations lead to an increased risk of developing arthritis in the joint.

Arthritis

Shoulder pain can also result from arthritis. There are many types of arthritis. The most common type of arthritis in the shoulder is osteoarthritis, also known as "wear and tear" arthritis. Symptoms such as swelling, pain, and stiffness, typically begin during middle age. Osteoarthritis develops slowly and the pain it causes worsens over time.

Osteoarthritis, may be related to sports or work injuries or chronic wear and tear. Other types of arthritis can be related to rotator cuff tears, infection, or an inflammation of the joint lining.

Often people will avoid shoulder movements in an attempt to lessen arthritis pain. This sometimes leads to a tightening or stiffening of the soft tissue parts of the joint, resulting in a painful restriction of motion.

Arthritis

Two types of arthritis may affect the shoulder and other joints in the body: osteoarthritis and rheumatoid arthritis.

Treatment

Treatment for arthritis of the shoulder usually involves the following:

- resting
- avoiding activities that cause or exacerbate pain
- taking NSAIDs, to alleviate pain and inflammation
- receiving corticosteroid injections into the joint, to temporarily alleviate pain and inflammation
- applying ice or moist heat to the affected joint several times per day

- doing some light exercises, to help manage pain

If the arthritis is severe, a doctor may recommend debridement or joint replacement surgery.

Some people take supplements to treat joint pain, but there is limited evidence to suggest that they are effective for this purpose.

Fracture

Fractures are broken bones. Shoulder fractures commonly involve the clavicle (collarbone), humerus (upper arm bone), and scapula (shoulder blade).

Shoulder fractures in older patients are often the result of a fall from standing height. In younger patients, shoulder fractures are often caused by a high energy injury, such as a motor vehicle accident or contact sports injury.

Fractures often cause severe pain, swelling, and bruising about the shoulder.

Disorders of the shoulder

Rotator cuff tendinitis is the most common cause of shoulder pain. The supraspinatus tendon is most frequently involved and the subscapularis is second. Active abduction in an arc of 40 to 120° and internal rotation cause pain. Passive abduction causes less pain, but abduction against resistance can increase pain.

Bicipital tendinitis causes pain in the biceps tendon that is aggravated by shoulder flexion or resisted supination of the forearm. Examiners can elicit palpable tenderness proximally over the bicipital groove of the humerus by rolling (flipping) the bicipital tendon under their thumb. Also, the Speed test may be done. In this test, the arm is extended behind the body plane while the elbow is straight and the forearm is supinated.

Acromioclavicular joint injury is tested for using the cross-body adduction test. In this test, the examiner stabilizes the shoulder with one hand, flexes the shoulder forward to 90° with the elbow pronated, and brings the arm straight across the front of the body, toward the opposite side. Elicitation of pain is a positive test.

Anterior glenohumeral joint instability is tested by stabilizing the joint by holding it from behind and then pulling back on the arm with the shoulder abducted to 90° and the elbow flexed to 90° (increasing abduction and external rotation). A positive result is apprehension of joint instability (not pain).

Shoulder pain can sometimes occur due to a dislocation, a fracture, or another acute injury to the shoulder joint.

Treatment

Treatment for an acute shoulder injury varies depending on the type of injury and its severity. Some injuries heal on their own. However, surgery may be necessary if the damage is significant or there are torn ligaments that require repair.

Tumors

Chronic shoulder pain can sometimes occur as a result of a growth within the structures of the shoulder. Such growths may be either benign or cancerous.

Treatment

Treatment for a tumor within the shoulder depends on whether or not it is cancerous. Benign, slow growing tumors may not require any treatment. However, a person who has a cancerous tumor may require chemotherapy, radiation therapy, or a combination of these treatments.

Symptom of Shoulder Pain

Shoulder pain may accompany other symptoms, which vary depending on the underlying disease, disorder or condition. Shoulder pain may originate in the shoulder itself or may be caused by conditions that affect other body areas, such as the neck, abdomen, chest, or upper arms.

Additional symptoms that may occur with shoulder pain include:

- Achilles
- Back, neck or arm pain
- Bruising
- Clicking and other noises when you move your arm
- Fatigue
- Fever
- Grinding or popping feeling
- Muscle stiffness and weakness
- Painful movement of the arm
- Swelling (edema) of the arm
- Warmth or burning

Symptoms that might indicate a serious or life-threatening condition

In some cases, shoulder pain may occur with other symptoms that might indicate a serious or life-threatening condition, such as a heart attack, which should be immediately evaluated in an emergency setting. **Seek immediate medical care (call 911)** if you or someone you are with has shoulder pain accompanied by any of the following symptoms:

- Chest pain, pressure or tightness
- Deformity or serious swelling of the shoulder or arm
- Difficulty breathing or shortness of breath
- Difficulty moving or inability to move the arm
- Jaw or neck pain, especially if it occurs with chest pain
- Neck stiffness after an injury or trauma, such as a fall or motor vehicle accident
- Severe abdominal pain

Diagnosis of Shoulder Pain

Several conditions lead to shoulder pain.

A thorough clinical evaluation helps pinpoint the cause. A doctor will take a medical history and carry out a physical examination, during which they may ask the individual to perform several specific movements to assess the injury. They may also order lab and imaging tests if they need additional information.

If the pain is mild, it may not be necessary to visit a doctor right away. Some people prefer to rest and see if the pain will go away. If the pain does not improve, it is best to go to the doctor for further evaluation.

People should see a doctor right away if they experience any of the following signs or symptoms:

- intense pain
- sudden swelling
- weakness or numbness in the arm or hand

- inability to use the shoulder
- deformity

In addition to a complete medical history and physical examination (to determine range-of-motion, location of pain, and level of joint instability/stability), diagnostic procedures for shoulder problems may include the following:

- **X-ray.** A diagnostic test that uses invisible electromagnetic energy beams to produce images of internal tissues, bones, and organs onto film.
- **Magnetic resonance imaging (MRI).** A diagnostic procedure that uses a combination of large magnets, radio frequencies, and a computer to produce detailed images of organs and structures within the body; can often determine damage or disease in a surrounding ligament or muscle.
- **Computed tomography scan (also called a CT or CAT scan).** A diagnostic imaging procedure that uses a combination of X-rays and computer technology to produce horizontal, or axial, images (often called slices) of the body. A CT scan shows detailed images of any part of the body, including the bones, muscles, fat, and organs. CT scans are more detailed than general X-rays.
- **Electromyogram (EMG).** A test to evaluate nerve and muscle function.
- **Ultrasound.** A diagnostic technique that uses high-frequency sound waves to create an image of the internal organs.
- **Laboratory tests** (to determine if other problems may be the cause)
- **Arthroscopy.** A minimally-invasive diagnostic and treatment procedure used for conditions of a joint. This procedure uses a small, lighted, optic tube (arthroscope) that is

inserted into the joint through a small incision in the joint. Images of the inside of the joint are projected onto a screen; used to evaluate any degenerative and/or arthritic changes in the joint; to detect bone diseases and tumors; to determine the cause of bone pain and inflammation.

Acupuncture

Classics

Shoulder pain generally includes shoulder joint pain, and shoulder muscle pain. Because the pain is around the shoulder area, it is called shoulder pain. Traditional Chinese medicine (TCM) thinks the shoulder pain is due to the stagnation of Qi and blood, or attacked by wind, cold, dampness, or phlegm, which can block the meridians and lead to limited movement of the shoulder. TCM classifies it in “Bi syndrome”. Shoulder pain often happens to the people around fifty years old. It is also called “fifty shoulder” in China. Since the shoulder pain is caused by different reasons, different pathogenesis, different environments, patients’ body conditions are different, the treatment plan and method are different.

Pattern diagnosis of disorder

Bi syndromes are the syndromes characterized by obstruction of qi and blood in meridians and collaterals due to invasion of pathogenic wind, cold and damp, and manifested by soreness, pain, numbness and heavy sensation of the limbs and joints, and limitation of movement. Clinically, bi syndromes are common in the areas where the weather is cold, wet and windy, occurring in persons of either sex and any age. In mild cases there is only soreness and pain in limbs and joints, aggravated by the change of weather. In severe cases the soreness and pain are marked and recur repeatedly, accompanied by swelling of the jointS and even deformity

and limitation of movement.

Bi syndromes may be classified into four types according to etiology and manifestations: 1. Wandering bi is characterized by migrating pain and caused chiefly by pathogenic wind; 2. Painful bi is characterized by severe pain and caused chiefly by pathogenic cold; 3. Fixed bi is characterized by marked soreness, numbness and heaviness and caused chiefly by pathogenic damp; and 4. Heat bi is characterized by heat manifestations and sudden onset.

There are 4 main kinds of shoulder pain in the clinic

The first kind of shoulder pain is due to wind and cold. In traditional Chinese medicine, it is mentioned that one of the pathogenic factors is six exogenous factors, which includes wind, cold, summer heat, dampness, dryness and fire. This is a general term for the six climatic conditions. Human beings live in nature and have certain adaptability to various climatic variations, so the six normal natural factors cannot make people contract pains. But if the climatic variations are too unusual, the six natural factors will affect the human body and cause pains. When the shoulder is attacked by the wind and cold, the muscle around the shoulder is aching. This kind of shoulder pain is not very serious. The course of problems is shorter. The pain level is low. The character of the pain is an aching or secret anguish, which does not limit the movement of the upper limb. The range of the pain may only be around the shoulder; or pin down the connected scapula and upper back after the back of shoulder is affected; or if the pain is in the front of the shoulder, usually there may be a feeling of contraction around neck and upper arm. Patient may have a cold feeling around the pain area and will have the pain relieved if putting a heat pad on. The tongue is covered with white coating. The pulse is superficial. Acupuncture with cupping is recommended.

The second kind of shoulder pain is due to wind and dampness. The shoulder is not only painful, but also has a heavy or distended feeling. The pain is not moving. It is not convenient to move the shoulder. The muscle may be numb. The tongue is covered with thin white coating. The pulse is superficial and retarded. The treatment is suggested to use acupuncture and TuiNa.

The third kind of shoulder pain is due to retention of phlegm and dampness. Retention of phlegm, in traditional Chinese medicine, is pathological products in the body, which can be concrete and formless. It can form in the course of pain. It is also one of the pathogenic factors. This kind of shoulder pain is serious. The course of the pain is longer. Even the function of the shoulder joint is normal, because moving can lead to more pain. For a long time without recovering, the shoulder joint is locked. The patient may have a cold feeling around the shoulder. The heat can temporarily reduce the pain. The ice can make the pain worse. After that, the pain and cold feeling will be the same as before. Since the pain level is high, generally disturbed the sleeping, eating and normal working. The patients commonly combine with the deficiency of Chi, such as, spontaneous sweating, short breath, easy tiredness, or frequent catching a cold etc. The tongue is pale red, covered with thick white coating. The pulse is wiry and smooth, or wiry and thready. The treatment is advised to use acupuncture, cupping, Tui Na and Chinese herbs and special exercise for shoulder function.

The fourth kind of shoulder pain is due to blood stasis. This kind of shoulder pain comes from trauma, such as twisting, falling down, accident pulling etc. The pain may be severe or twinge. The tongue is red and purple or with purple spots. The pulse is thready and uneven. If the pain is not recovered for a long time, no matter what kinds of pain it is, it will change into the fourth kind of blood stasis shoulder pain. If the pain results from injury, the pain may combine

with tenderness, swollen distend. Both of them have symptoms of frozen shoulder. The treatment should be to use acupuncture, cupping, Tui Na and Chinese herbs to remove blood stasis, stimulate blood circulation and stop pain.

Treatment of disorder

Treatment Ashi points together with the local and distal points along the yang meridians supplying the diseased areas are selected for the purpose of eliminating wind, cold and damp. Wandering bi, heat bi and tendon bi are mainly treated by the reducing method. Subcutaneous needles may also be applied. For painful bi and vessel bi, it is better 10 use moxibustion, and apply needling as an adjuvant treatment with deep insertion and prolonged retaining of the needles. For severe pain, intradermal needles or indirect moxibustion with ginger may be used. Fixed bi, skin bi, muscle bi and bone bi may also be treated by combined acupuncture and moxibustion, or together with a warming needle, or tapping plus cupping.

Prescriptions: Pain in the shoulder joint and upper back: Jianyu (LI 15), Jianliao (TE 14), Jianzhcn (SI9), Naoshu (SI I 0), Fengchi (GB20), Jianjing (GB21), ashi points.

Saam Korean Four needle techniques.

Origin and applicable principles of Sa-Am Acupuncture

The Yellow Emperor's Inner Classic (Huang Di New Jing) says:

"Treating the right when the disease is on the left, treating the left when the disease is on the right, treating the lower half when the disease is in the upper half, treating the upper half when the disease is in the lower half, in the case of Deficiency tonify the Mother, in the case of Excess sedate the Child." It also say: "controlling the controller", this is saying that the function of controller is to always control. And "control the controller" was first introduced by Buddhist

Sa-Am. Saam acupuncture was invented about 400 years ago by him. He is one of the three greatest doctors of the Cho-Sun Era of Korea. He created this acupuncture technique from the philosophy that disease of the mind appears as a bodily disease, meaning bodily disease is caused by one's mind.

Therefore, it is one of the original therapeutic modalities representing traditional Korean medicine. To practice Sa-Am acupuncture, the image and nature of the 12 channels and the law of the Yin-Yang, Five Movements and Six-Qi (Taiyang, Yangming, Shaoyang, Taiyin, Shaoyin, Jueyin) movements need to taken into careful consideration. The basic characteristic of combining five shu points in Saam acupuncture is the selection of the tonification and sedation points along the self-meridian and other meridians based on creation and governor relationships. In China, five element acupuncture, tonification, and sedation points along only the self-meridian are selected. The basis of Korea Saam acupuncture conception of the combined five shu points.

There are two modifications of Saam in this research which were GB and UB tonification. Gall Bladder tonification: GB44 and UB65 tonification, GB43 and LI1 sedation Bladder tonification: UB67 and LI1 tonification, UB40 and ST36 sedation.

II. METHODOLOGY

1. Study Design

As shown in Figure 1, this study is designed as a two-arm parallel pilot randomized controlled trial with 14 participants, 7 participants for experimental group (EG) using traditional Chinese Acupuncture with Korean Four Needle Techniques and traditional Chinese Acupuncture in upper back and shoulder pain patients, 7 participants for the control group (CG) using traditional Chinese Acupuncture only.

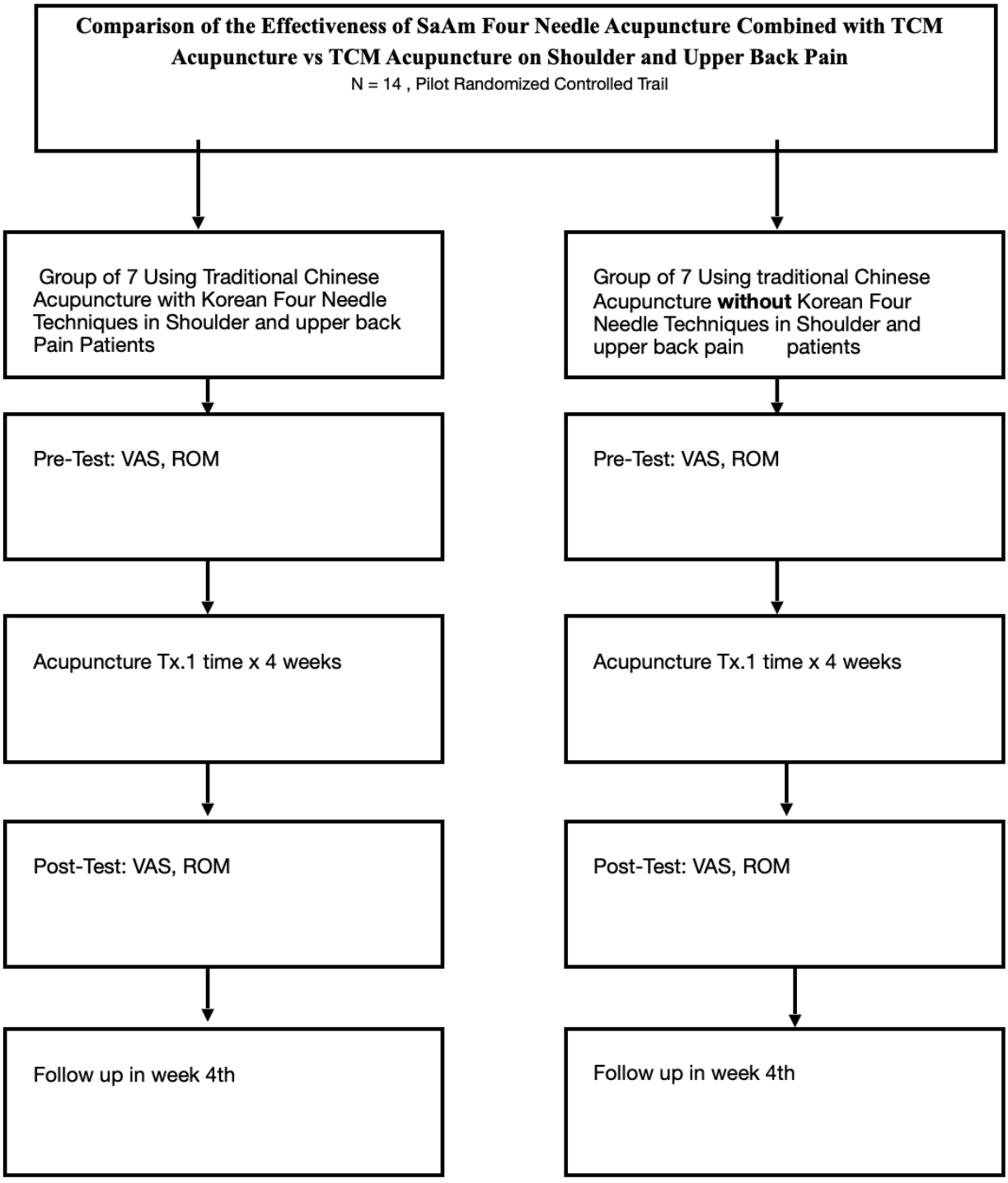


Figure 1. Schematic Diagram of Study Process

2. Staging Criteria

According to the VAS for a diagnosis of shoulder pain (Table 1).

Table 1. Staging Criteria for Upper Back and Shoulder Pain

Stage	Pain Level
Normal	0 - 3
Mild	3-5
Moderate	5-8
Severe	8-10

PRE AND POST VISUAL ANALOGUE SCALE

NAME _____ **DATE** _____ **DATE OF INJURY** _____

PRE-TREATMENT VAS

Please place a mark through the line below that most accurately represents the pain level that you are feeling *RIGHT NOW*. Please note that "UNBEARABLE PAIN" is located on the right hand side of the line and "NO PAIN" is located on the left.

No Pain _____ Unbearable

FOLD HERE----------

POST-TREATMENT VAS (fold in half when completing post-test VAS)

Please place a mark through the line below that most accurately represents the pain level that you are feeling *RIGHT NOW*. Please note that "UNBEARABLE PAIN" is located on the right hand side of the line and "NO PAIN" is located on the left.

No Pain _____ Unbearable

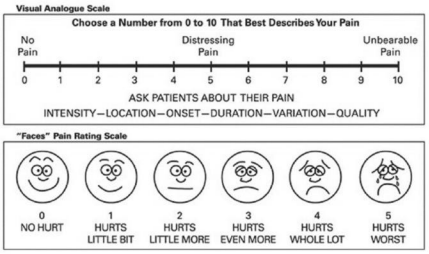


Figure 2. Visual Analogue Scale (VAS)

3. Patient Eligibility and Exclusion Criteria

1) Inclusion criteria

- Female and male
- Be aged 18–72 years old
- Completed and submitted an Informed Consent Form (ICF)

2) Exclusion criteria

- Endocrine disease, such as hyperthyroidism, auto allergic disease, cancer or other serious or potentially fatal illness
- Pregnancy, preparation for pregnancy or active lactation in women
- Patients with mental illness or those who are uncooperative
- Refusal to provide consent for the study

4. Registration Procedure

Researcher will recruit participants mainly from advertisements on Facebook, words of mouth in local Thai community in Los Angeles. All of the participants will be screened and identified by the researcher.

5. Randomization Procedure and Stratification

1) Randomization

Randomization of the trial will be completed by a random number generator provided by www.random.org. According to a random sequence generated by random.org, participants who satisfy the inclusion criteria will be randomly allocated into one of the two groups in a ratio of 1:1. Unique identification codes and

randomization numbers will be generated for each participant.

2) **Allocation concealment**

All researchers will receive training in allocation concealment before the study. The randomization sequence schedule will be managed by an appointed research member who will not be involved in the screening or enrolling of participants. The assignments will be unknown to all researchers except for the Acupuncturist responsible for diagnoses, acupuncture, and herbal medicine formulas.

3) **Blinding**

Because of the unique characteristics of the Acupuncture methods used in this trial, double blinding would be difficult. However, as the participants in both groups will be receiving acupuncture treatment, the single blinding for the participants will be achievable.

4) **Sample size**

Given the difficulty determining an adequate sample size due to the lack of sufficient preliminary studies, we adopted a pilot study design with 7 participants per group, considering the limited research funds.

$$n_i = \frac{(Z_{1-\alpha/2}+Z_{1-\beta})^2\sqrt{p_1(1-p_1)+p_2(1-p_2)\cdot r}}{(p_1-p_2)^2}$$

p1, p2 = proportion (incidence) of groups #1 and #2

Δ = |p2-p1| = absolute difference between two proportions

n1 = sample size for group #1

n2 = sample size for group #2

α = probability of type I error (usually 0.05)

β = probability of type II error (usually 0.2)

z = critical Z value for a given α or β

K = ratio of sample size for group #2 to group #1

6. Treatment Program

1) Four Needle and TCM Acupuncture Intervention

All participants in the treatment group will visit the researchers two times a week and be treated with acupuncture. The acupoint selection for acupuncture will be as follows: the principal acupoints include Gall Bladder tonification: GB44 and UB65 tonification, GB43 and LI1 sedation. Bladder tonification: UB67 and LI1 tonification, UB40 and ST36 sedation. Prescriptions TCM: Jianyu (LI15), Jianliao (SJ14), Jianzhen (SI9), Naoshu (SI10), Fengchi (GB20), Jianjing (GB21), Tiaokou (ST38), ashi points.

All Korean Four Needles will use GB or UB channels depending on where the pain location is. and Use tonification and sedation method, and the needles will be left in the acupoints for 30 min before withdrawal.

TCM acupoints will be stimulated by neutral reinforcement and reduction of movement, and the needles will be left in the acupoints for 30 min before withdrawal. The acupuncture treatment will be once a week for 4 weeks, during which each participant will receive a total 4 treatment sessions.

Table 2**.** Acupuncture Points: Location and Action.

Points	Location	Actions
TCM Acupoints		
Jianyu (LI 15)	In the depression which lies anterior and inferior to the acromion, at the origin of the deltoid muscle.	- Dispels wind-damp, alleviates pain and benefits the shoulder joint - Eliminates wind and regulates qi and blood - Regulates qi and dissipates phlegm nodules
Jianliao (SJ 14)	At the origin of the deltoid muscle, in the depression which lies posterior and interior to the lateral extremity of the acromion.	- Dispels wind-damp - Alleviates pain and benefits the shoulder joint
Jianzhen (SI9)	On the posterior aspect of the shoulder, 1 can superior to the posterior axillary crease when the arm hangs in the adducted position.	- Expels wind and benefits the shoulder - Activates the channel and alleviates pian
Naoshu (SI I 0)	On the posterior aspect of the shoulder, in the depression inferior to the scapular spine, directly superior to the posterior axillary crease when the arm hangs in the adducted position.	- Benefits the shoulder - Activates the channel and alleviates pain
Fengchi (GB20)	Below the occiput, approximately midway between Fengfu Du16 and Wangu GB12, in the hollow between the origins of the sternomastoid and trapezius muscles.	- Eliminates wind - Benefits the head and eyes - Clears the sense organs - Activates the channel and alleviates pain
Jianjing (GB21)	Midway between Dazhui Du14 and the tip of the acromion, at the crest of the trapezius muscle.	- Regulates qi, activates the channel and alleviates pain - Transforms and lowers phlegm and dissipates nodules - Benefits the breast and expedites delivery
Tiaokou (ST38)	On the lower leg, midway between the tibiofemoral joint line (level with the popliteal crease) and the prominence of the lateral malleolus, one finger-breadth lateral to the anterior crest of the tibia.	-Expels wind-damp and alleviates pain - benefits the shoulder
ashi points	Where is the pain or tenderness area, this is ashi point.	- move qi and blood - Relieve the pain

Four Needle

Acupoints

GB tonification		
Zutonggu (UB66 +)	On the lateral side of the foot, in the depression anterior and inferior to the fifth metatarsi-phalangeal joint.	- Clear the head: heaviness of the head, neck pain, visual dizziness, redness of the eyes, nosebleed. - Descends Lung and Stomach qi: coughing, dyspnea, fullness of the chest, vomiting.
Zuqiaoyin (GB44+)	On the dorsal aspect of the 4th toe, at the junction of lines draw along the lateral border of the nail and the base of the nail, approximately 0.1 can from the corner of the nail.	- clears heat and benefits the head - Benefits the chest and lateral costal region - Calms the spirit
Xaixi (GB43-)	Between the fourth toe and the little toe, 0.5 cun proximal to the margin of the web.	- clears heat and benefits the head, ears and eyes - Clears damp-heat from the channel and reduces swelling
Shangyang (LI1-)	On the dorsal aspect of the index finger, at the junction of lines drawn along the radial border of the nail the base of the nail, approximately 0.1 can from the corner of the nail.	- clears heat, reduces swelling and alleviates pain - Revives consciousness
or		
UB Tonification Shangyang (LI1+)	On the dorsal aspect of the index finger, at the junction of lines drawn along the radial border of the nail the base of the nail, approximately 0.1 can from the corner of the nail.	- clears heat, reduces swelling and alleviates pain - Revives consciousness - Expels wind and clears the head and eyes - Turns the fetus and facilitates labour
Zhiyin (UB67+)	On the dorsal aspect of the little toe, at the junction of lines drawn along the lateral border of the nail and the base of the nail, approximately 0.1 can from the corner of the nail.	- benefits the lumbar region and knees, bladders - Activates the channel and alleviates pain - Cools the blood
Wiezhong (UB40-)	At the back of the knee, on the popliteal crease, in a depression midway between the tendons of biceps femurs and semitendinosus.	- Clears summer-heat and stops vomiting and diarrhea - harmonizes the stomach - Fortifies the Spleen and resolves dampness - Supports the correct qi and fosters the original qi - Tonifies qi and nourishes blood and yin
Zusanli (ST36-)	Between the knee, 3 can inferior to Dubi ST35, oneifnger-breathe lateral to the anterior crest of the tibia.	- Activates the channel and alleviates pain

7. Dosage Modification/Side Effects

For individual treatment, the changes in participants' symptoms will be recorded carefully according to four diagnostic methods of TCM including inspection, listening and smelling, inquiry, and pulse-taking and palpation, ((list potential side effect from acupuncture, fainting, bleeding, paralysis, extreme pain, etc) For the case of AEs, depending on the seriousness, follow-up action will be implemented following the emergency manual (Appendix-)

8. Treatment Evaluation

1) **Endpoint events**

- VAS ≤ 3
- ROM

2) **Primary outcomes**

- VAS
- ROM

3) **Secondary outcomes**

- VAS
- ROM

All the secondary outcomes were tested on visit 1-4 after first-fourth treatment.

10. **Adverse Event and Toxicity Management**

1) Reporting of adverse events

Participants will be required to immediately report adverse events (AEs) to researchers when they occur. Researchers will also ensure that the study is proceeding as intended every 8 days when participants visit them at the clinic.

When serious adverse events (SAEs) occur, researchers must complete an SAE Form and immediately report the event to the project leader and the IRB of the South Baylo University. The event should also be reported to the Food and Drug Administration (FDA) within 24 h.

2) Documentation of adverse events

The AE Report Form must be completed according to the actual circumstances. Some additional information, including the event time, severity, duration, measure adopted, and the outcome should be noted as well.

3) Relationship between adverse event and study treatments

The researchers will assess the relationship between the AE and the treatments being studied with the following criteria:

- Whether the suspected adverse reaction appears after treatment administration
- Whether the suspected adverse reaction belongs to the known adverse reactions of the investigated drug
- Whether the suspected adverse reaction disappeared or was mitigated after discontinuation of treatment
- Whether the same reaction occurred again after resuming the investigated drug
- Whether the suspected adverse reaction cannot be explained by the participant's diseases or consumption of the combination of drugs

4) Relationship between adverse events and changes in symptoms

This trial differs from other trials, as the formulas prescribed to the participants will be adjusted according to the changes in symptoms caused by receiving the last formula.

Therefore, AEs can be useful to the Acupuncturist for adjusting the prescribed formulas.

5) Criteria for the evaluation of safety

As an adverse reaction could not be the criterion of safety in this trial, the safety of the ACUPUNCTURE interventions will be assessed by hepatic and renal function as follows:

- Safe without any significant changes in hepatic or renal function
- Relatively safe with less than 20% changes in hepatic and renal function
- Termination of the interventions due to more than 20% changes in hepatic and renal function

11. **Serial Measurement/Study Calendar**

1) Data collection points

Figure 1 shows the table of data collection points as follows;

- Screening period: 1 week before the intervention
- Intervention period: 4 weeks; once a week for 4 weeks
- Follow-up period: 4 weeks after the intervention

12. **Statistical Analysis**

1) Analysis parameters

All parameters will be analyzed using R version 4.1.0

2) Analysis of datasets and missing data

Full analysis set (FAS): according to the intention-to-treat (ITT) principle of analysis, the outcomes from participants dropped-out or rejected will be treated as worst case. For the early termination, the last observation carried forward (LOCF) method will be used

for missing data.

3) Statistical analysis method

Paired *t*-test will be used for the comparison of primary outcomes and secondary outcomes within-group. Independent *t*-test will be used for the comparison of primary outcomes and secondary outcomes between-groups. The chi-square test will be used for comparing the endpoint events (when VAS score reaches below 3).

4) Effect Size

Effect sizes of the acupuncture treatment will be determined from the outcome depending on the type of variables; Relative Risk Ratio (RR), Odds Ratio (OR) and Relative Risk Reduction (RRR) from the dichotomous data, and Mean Difference (MD) and Standardized Mean Difference (SMD) from the continuous data.

The VAS and ROM outcomes will be converted to dichotomous value, 'cured' or 'uncured' depending on whether the outcome reached the goal of VAS ≤ 3 or ROM, respectively. Then following the equation (1) and (2) in the Table 4, OR, RR and RRR will be determined, respectively.

Meanwhile, Mean Differences of VAS and ROMs between-groups will be calculated from the respective Mean Change before and after the treatment within-group as in the equation (3).

Table 3. Contingency Table to Analyze the Dichotomous Result of Acupuncture Treatment in Terms of VAS

	Uncured (VAS > 3)	Cured (VAS ≤ 3)	Total
TCM + 4Needles (EG)	a	b	a+b
TCM (CG)	c	d	c+d

Table 4. Calculation Process of Relative Risk (RR) Odds Ratio (OR) and Relative Risk Reduction (RRR) of Pain in Terms of the VAS score after Acupuncture Treatment.

Effect Size	Definition		Calculation Equation	
Relative Risk (RR) =	$\frac{\text{Risk from Experimental Group}}{\text{Risk from Control Group}}$	=	$\frac{a/(a+b)}{c/(c+d)}$	(1)
Odds Ratio (OR) =	$\frac{\text{Odds from Experimental Group}}{\text{Odds from Control Group}}$	=	$\frac{a/b}{c/d}$	(2)
Relative Risk Reduction (RRR) =	$\frac{\text{Absolute Risk Reduction}}{\text{Risk from Control Group}}$	=	$\frac{\lvert a/(a+b)-c/(c+d)\rvert}{c/(c+d)}$	(3)
Mean Difference (MD)=	$\text{Mean Change}_{exp}\ (M_{before} - M_{after}) - \text{Mean Change}_{control}\ (M_{before} - M_{after})$			(4)
Standardized Mean Difference (SMD)=	$\frac{\text{Mean Difference (MD)}}{SD^*}$			(5)

*pooled standard deviation

13. **Data recording, Management, Monitoring – essentials**

Researcher will use modified SBU Patient Progress Form as a Case Report Form (CRF) as attached in Appendix -2 to manage the trial data. All data will be entered into CRF, and access to the CRF will be protected by the principal investigator of the study. Once the data have been input into CRF, any changes can be tracked by CRF to ensure the accuracy of the data. All the data will be checked by a Research Advisor.

14. **Ethics**

This research follows the Declaration of Helsinki, and complies with Common Rule based on the Belmont Report. This proposal with the Informed Consent Form (Appendix-1) will be evaluated by the Institutional Review Board (IRB) of South Baylo University.

III. RESULTS

The study examined 14 chronic shoulder and upper back pain patients the age of 20-75 years old. 7 of these patients belonged to the control group and were treated with only acupuncture, and the other 7 patients that comprised the experimental group received in addition to Saam four needle technique acupuncture with traditional TCM. After determining qualification for participation in the study, each eligible patient was provided with and filled out an informed consent form that explained what the treatments entailed, as well as their possible risks and benefits. Treatments for both the control and experimental groups were to be administered once a week for four weeks for a total of four treatment sessions. Patients were asked to complete the VAS-Pain level Questionnaire (VAS) before the first treatment of every week and one week following the last treatment. The data collected from the VAS and ROM results were analyzed to determine statistical significance.

3.1. Homogeneity Test

3.1.1. Homogeneity Test for the General Characteristics of Patients

The gender and age of patients in the control and experimental groups are outlined through a homogeneity test for general characteristics, as shown in Table 5. The p-value for Fisher's Exact Test was greater than 0.05 in both groups, confirming that the experiment was performed under the same conditions for the two variables.

Table 5. Homogeneity Test for General Characteristics of Patients

Group		EG	CG	*p*-value*
Gender	Female	6	6	1.000
	Male	1	1	
Age	20s	1	1	0.487
	30s	2	0	
	40s	3	3	
	50s	1	0	
	60s	0	2	
	70s	0	1	
Onset	≤ 6 months	1	1	1.000
	> 6 months	6	6	

* Fisher's exact test

3.1.2. Homogeneity Test for visual analogue scale (VAS)

A homogeneity test for the variable VAS was performed before treatment, as shown in Table 6. The *p*-value for Mann Whitney U test was greater than 0.05 in both groups, confirming that the experiment was performed under the same conditions for the two variables.

Table 6. Homogeneity Test for Variable VAS

Treatment	EG	CG	p-value*
Before 1st	6.3 ± 2.36	6.1 ± 2.12	1.000

* Mann Whitney U test

3.2 VAS

3.2.1. Change of VAS Before and After Treatment

VAS value was measured to assess the symptomatic relief of patient with shoulder and upper back pain. Table 7 compares the results of the experimental group with those of the control group measuring the change of VAS difference in every before and after each treatment session. Where assumption of normality was met, the VAS value before and after treatment was evaluated using the Paired Samples t-test. When assumption of normality was not met, the Wilcoxon Signed Rank Test was used. As shown in Table 6, the VAS value in the experimental group decreased from 6.3 ± 2.36 to 5.6 ± 1.90 after the first treatment, showing a decrease of 0.7 ± 1.25 (p = 0.182). After the second treatment, the value decreased from 4.9 ± 2.04 to 4.0 ± 2.16 after the second treatment, showing a decrease of 0.9 ± 0.90 (p = 0.071). After the third treatment, the value decreased from 4.6 ± 1.90 to 3.7 ± 1.70 after the third treatment, showing a decrease of 0.9 ± 0.38 (p = 0.02). After the fourth treatment, the value decreased from 3.7 ± 2.36 to 2.6 ± 1.99 after the fourth treatment, showing a decrease of 1.1 ± 0.69 (p = 0.005). There were significant VAS difference after 3rd and 4th treatment in EG. VAS value in the control group decreased from 6.1 ± 2.12 to 4.3 ± 2.21 after the first treatment, showing a decrease of 1.9 ± 1.35 (p = 0.011). After the second treatment, the value decreased from 5.1 ± 1.95 to 4.7 ± 2.23 after the second treatment, showing a decrease of 0.4 ± 1.75 (p = 0.407). After the third treatment, the value decreased from 5.6 ± 1.62 to 4.6 ± 1.27 after the third treatment, showing a decrease of 1.0 ± 1.29 (p = 0.086). After the fourth treatment, the value decreased from 4.7.± 1.98 to 3.9 ± 1.86 after the fourth treatment, showing a decrease of 0.9 ± 0.38 (p = 0.002). The result of first and

fourth treatment are statistically significant, but the result after the second and the third treatment did not show them to statistically significant.

Figure 3.1 Displays VAS Values Before and After the Treatment Using the Bar Graph, and Figure 3.2 Displays a VAS Before First and After the Treatment Using the Line Graph

Table 7. VAS Before and After Each Treatment and Its Difference

Group	Treatment	Before	After	Difference	p-value
EG	1st	6.3 ± 2.36	5.6 ± 1.90	0.7 ± 1.25	0.182*
	2nd	4.9 ± 2.04	4.0 ± 2.16	0.9 ± 0.90	0.071**
	3rd	4.6 ± 1.90	3.7 ± 1.70	0.9 ± 0.38	0.02**
	4th	3.7 ± 2.36	2.6 ± 1.99	1.1 ± 0.69	0.005*
CG	1st	6.1 ± 2.12	4.3 ± 2.21	1.9 ± 1.35	0.011*
	2nd	5.1 ± 1.95	4.7 ± 2.23	0.4 ± 1.75	0.407*
	3rd	5.6 ± 1.62	4.6 ± 1.27	1.0 ± 1.29	0.086*
	4th	4.7.± 1.98	3.9 ± 1.86	0.9 ± 0.38	0.002**

* Paired Samples t-Test

**Wilcoxon signed ranks test

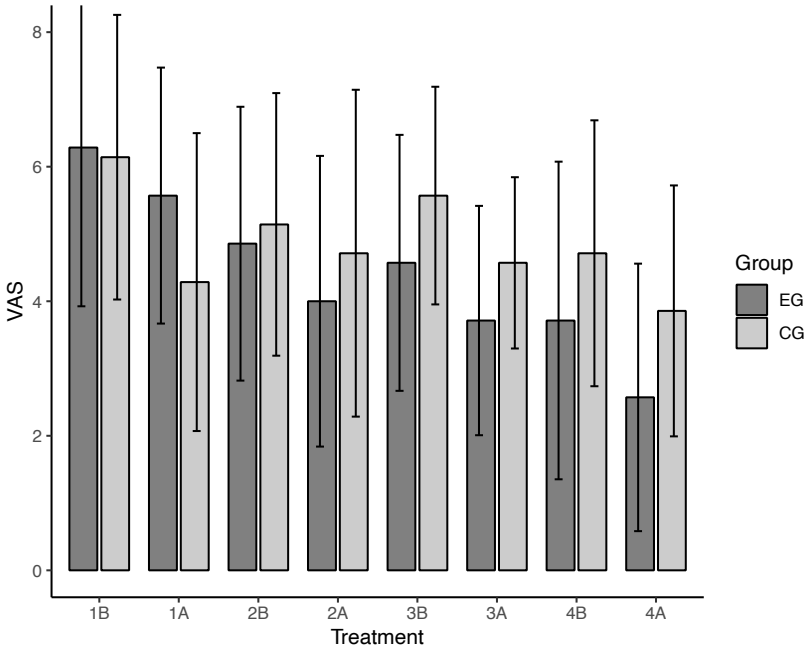


Figure 3.1. Bar Group of VAS Before and After Treatment

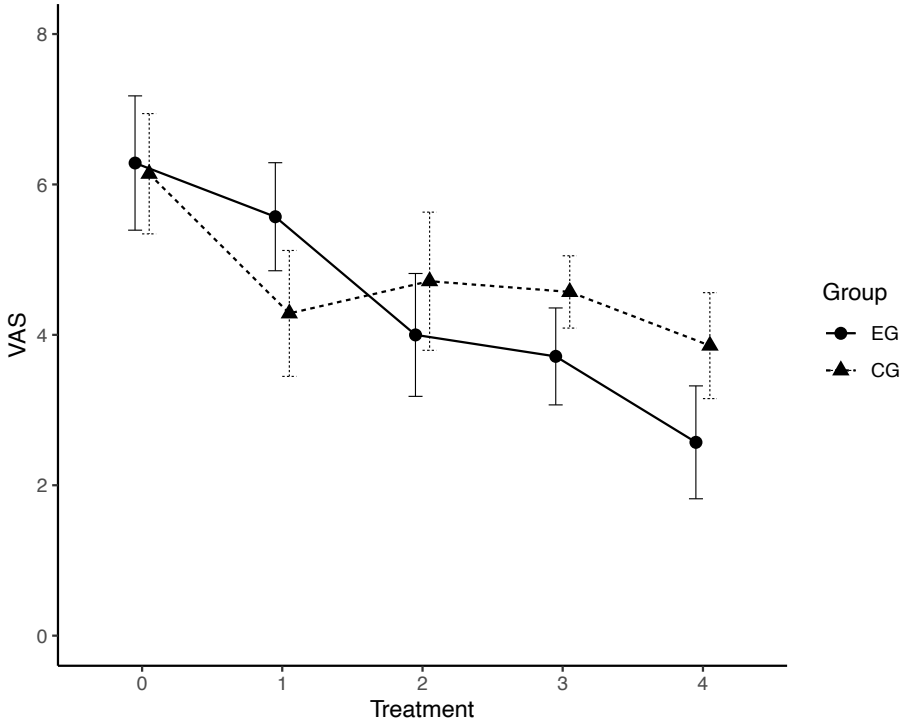


Figure 3.2. Line Graph of VAS Before 1st and After Each Treatment

3.2.2 Cumulative VAS difference

Cumulative VAS Difference = VAS before 1st Tx – VAS After nth Tx.

As shown on Table 8, In comparing the VAS value of the experimental and control groups, the VAS difference after first treatment of experimental group was 0.7 ± 1.25 and 1.9 ± 1.35 for the control group (p = 0.126). After second treatment, the cumulative VAS difference was 2.3 ± 1.38 for experimental group and 1.4 ± 2.76 for control group (p = 0.477). After third treatment, the cumulative VAS difference was 2.6 ± 1.90 for experimental group and 1.6 ± 2.37 for control group (p = 0.401). After fourth treatments, the cumulative VAS difference was 3.7 ± 3.25 for experimental group and 2.3 ± 3.20 for control group (p = 0.424).

The experimental group were appeared a higher cumulative VAS difference after 2nd and 3rd treatment (Table 8). All the p-value of after first, second, third and fourth treatments were greater than 0.05, it was appeared them not to be statistically significant. Figure 3-3 shows a bar graph of the cumulative treatment effect after each treatment between EG and CG as determined by VAS value respectively.

Table 8. Cumulative VAS Difference and Comparison Between Groups

Treatment	EG	CG	*p*-value*	Cohen's d**
Before 1st - After 1st	0.7 ± 1.25	1.9 ± 1.35	0.126	0.92
Before 1st - After 2nd	2.3 ± 1.38	1.4 ± 2.76	0.477	0.41
Before 1st - After 3rd	2.6 ± 1.90	1.6 ± 2.37	0.401	0.47
Before 1st - After 4th	3.7 ± 3.25	2.3 ± 3.20	0.424	0.43

* Independent Samples t-Test

** Size effect using Cohen's d

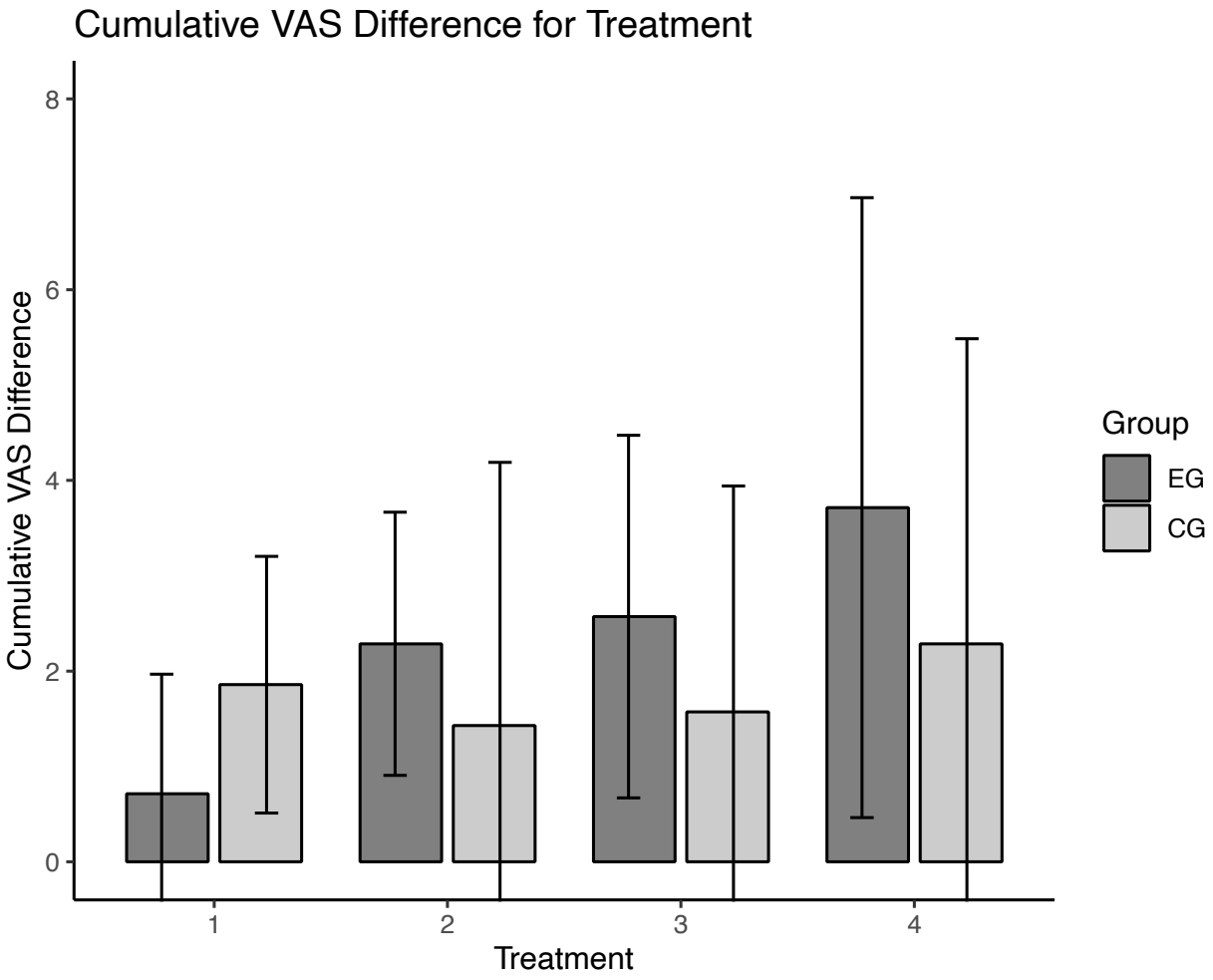


Figure 3.3. Bar Graph of Cumulative VAS Difference for Treatment

3.2.3 Cohen's d on Cumulative Difference

$$d = \frac{M_2 - M_1}{\sqrt{\frac{{SD_1}^2 + {SD_2}^2}{2}}}$$

M1: Mean of EG, M2: Mean of CG

SD1: Standard deviation of EG, SD2: Standard deviation of CG

CD: Cohen's d

CD < 0.2 Negligible

CD < 0.5 Small

CD < 0.8 Medium

Otherwise Large

As shown in Table 8, Cohen's d was used to see effect size between two groups. The Cohen's d was 0.92 (large) after 1st treatment, 0.41 (small) after 2nd treatment, 0.47 (small) after 3rd treatment, and 0.43 (small) after 4th treatment.

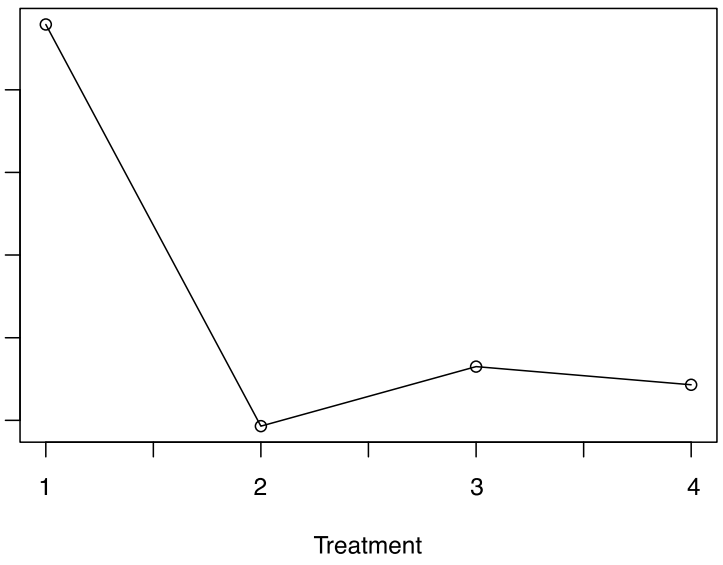


Figure 3.4. Line Graph of Cohen's d For Cumulative VAS Difference

Table 9. Contingency Table to Analyze the Dichotomous Result of Acupuncture Treatment between TCM+4needles (EG) and TCM (CG) in Terms of VAS

	Uncured VAS > 3	Cured VAS ≤ 3	Total
TCM + 4Needles (EG)	a =2	b = 5	a+b = 7
TCM (CG)	c = 4	d = 3	c+d = 7

Table 10. Calculation Process of Relative Risk (RR) Odds Ratio (OR) and Relative Risk Reduction (RRR) of Pain in Terms of the VAS score after Acupuncture Treatment

Effect Size	Definition	Calculation Equation
Relative Risk (RR) =	Risk from Experimental Group / Risk from Control Group	= a/(a+b) = 2/(2+5) = 0.29 / c/(c+d) = 4/(4+3) = 0.57 = 0.51
Odds Ratio (OR) =	Odds from Experimental Group / Odds from Control Group	= a/b = 2/5 = 0.4 / c/d = 4/3 = 1.33 = 0.31
Relative Risk Reduction (RRR) =	Absolute Risk Reduction / Risk from Control Group	= |a/(a+b)-c/(c+d)| = |2/(2+5)-4/(4+3)| = 0.29-0.57 / c/(c+d) = 4/(4+3) = 0.57 = -0.28

*pooled standard deviation

- Risk Ratio (RR)
    - risk of event with intervention = 2/7 = 0.29
    - Risk of event with control = 4/7 = 0.57
    - Risk ratio = intervention risk/control risk = 0.29/0.57 = 0.51

Where risk ratio = 1, there is no difference between group, the result is 0.51 < 1, this is difference between group. The risk of having uncured (VAS>3) with treatment was 51% of risk in the TCM (control) group. TCM+4needles (Intervention) reduced the risk of uncured (VAS>3) by 49%.

- Odds Ratio (OR)
    - Odds of event with intervention = 2/5 = 0.4
    - Odds of event on control = 4/3 = 1.33
    - Odds ratio = 0.4/1.33 = 0.31
    - Where odds ratio = 1, there is no difference between the groups. The result showed 0.31 < 1, there is difference between the groups. TCM+4needles (Intervention) reduced the odds of uncured (VAS>3) to 31% of the odds in the TCM (control) group. TCM+4needles (Intervention) reduced the odds of uncured (VAS>3) by 69%.
- Risk difference (RRR)
    - Risk of event with intervention = 2/7 = 0.29
    - Risk of event on control = 4/7 = 0.57
    - Risk difference = 0.29- 0.57 = -0.28
    - When risk difference = 0, there is no difference between the groups. The result showed -0.28 is less than 0, there is difference between the groups. Risk difference was -0.28

means TCM + 4Needles (experimental) group reduced the risk of uncured by 28 percentage points. 57 of 100 people experienced uncured (VAS>3) in TCM (control) group. 28 fewer people experienced uncured with TCM + 4Needles (experiment) group.

IV. DISCUSSION

Shoulder pain is a common and disabling complaint. The reported annual incidence of shoulder pain in primary care is 14.7 per 1000 patients per year with a lifetime prevalence of up to 70% . Recovery from shoulder pain can be slow and recurrence rates are high with 25% of those affected by shoulder pain reporting previous episodes, and 40 to 50% reporting persisting pain or recurrence at 12-month follow-up.

The research's purpose is to compare traditional TCM and TCM plus Saam Korean Four Needles techniques modalities acupuncture. As results, both of acupuncture techniques have shown to be effective in reducing and management the pain.

4.1 VAS Values

The VAS values were measured pre-treatments and post-treatments for both groups and every times participants visited. The VAS values of two groups were confirmed that the two groups were tested under the same condition at the start of treatments. VAS before and after third and fourth treatment EG were 3.7$\pm$1.70 and 2.6$\pm$1.99, P-value were 0.02 and 0.005 and first and fourth treatment of CG were 4.3$\pm$ 2.21 and 3.9$\pm$1.86, P-value were 0.011 and 0.002. For cumulative *p*-value of both groups were greater Thant 0.05, there were no significant between groups. Also Cohen's d on cumulative difference had small issues.

In Dichotomous Result: Risk Ratio (RR), the result was 0.51<1, there was difference between group. The risk of having uncured (VAS>3) with treatment was 51% of risk in CG, EG reduced the risk of uncured by 49%. Odds Ratio (OR), the result was 0.31<1, there was difference between groups. EG reduced the odds of uncured to 31% of the odds in CG, EG

reduced the odds of uncured by 69%. Risk Difference (RRR). The result showed -0.28<0, there was difference between the groups. EG reduced the risk of uncured by 28%. 57 of 100 people experienced uncured in CG. 28 fewer people experienced uncured with EG.

4.2. Strengths of Saam Korean Four Needles Techniques

As a results were shown, Saam Korean Four Needles techniques were applied to make more enhance the better results in shoulder and upper back pain patients.

First of all, it was deeper layer of therapeutic process, mother and son, supportive and sedation to balance the problem muscle-skeletal areas in upper back and shoulder area.

Second, working on five shu points were generated more of parasympathetic nerves. Therefore, the root cause of problem including mindfulness restlessness in busy people in this local communities could calm down. When participants had more rest and could turn their mode to parasympathetic mode or resting mode, their fixing and regenerated new tissues in the problem area would be ease to recovery.

The third, Giovanni : “The sections of channel between fingers/toes and elbows/knees are more superficial than the rest, which is one of the reasons for the importance of the points lying along its path. The energetic action of the points along a section of such a channel is much more dynamic than other points, which explains their frequent use in clinical practice. Another reason for the dynamism of these points is that, at the tips of fingers and toes, the energy changes polarity from Yin to Yang or vice versa and, due to this polarity change, the Qi of the channel is more unstable and thus more easily influenced”.

Saam acupuncture principally uses the acupoint below the elbow and knee joint. The five shu points occupy large areas in the cortical representation in the post-central sensory gyrus in the brain. Cho et al. stated that, based on their knowledge of Western medicine, it is difficult to believe that acupuncture treats organ-related disorders and diseases by direct control of organs. Acupuncture may first stimulate or activate the corresponding brain cortex via the central nervous system, thereby controlling chemical or hormone release to the diseased or disordered organs for treatment. From this point of view, inserting a needle in the distal limb may be more advantageous for inducing physiological activity caused by acupuncture than needling in the trunk.

Therefore, Korean Four Needle techniques could enhance and would speed up the better results in shoulder and upper back pain patients.

4.3. Further research

In the neurobiological model, point specificity does not appear to exist with regard to musculoskeletal action, but five shu points, including PC5, PC6, and ST36, have some point specificity with regard to systemic action at the brain level. This acupuncture-point specificity has been attributed to the presence of a deep nerve. However, other acupuncture points overlying the same deep nerve are not effective.

The Saam acupuncture method includes a variety of combinations of five shu points, and each combination is believed to have a distinct effect. However, the specificity of each Saam acupuncture treatment has not been yet identified from a neurobiological perspective. Therefore, when applying Saam acupuncture in the clinic as medical acupuncture, an approach that focuses on the balance and

homeostasis of the autonomic nervous system appears to be desirable. Further, revealing the difference between the Yin meridian and Yang meridian treatments, which are anatomically divided into the medial and lateral sides of the body, is necessary from the viewpoint of the neurobiological mechanism.

More participants will provide better results, and would want to see the result with more than four treatments in four to six weeks and longer period of time will get more mature results. Consistency of participants were very important factor to receive more accuracy results.

V. CONCLUSION

This study was to investigate Pain Management Using Traditional Chinese Acupuncture with Korean Four Needle Techniques in Shoulder and upper back pain patients. This study consisted of 14 patients, a pilot randomized controlled trial with two parallel arms: Chinese traditional acupuncture control group (CG), n=7 and a traditional Chinese Acupuncture with Korean Four Needle Techniques experimental group (EG), n=7. The outcomes were analyzed by the visual analog scales (VAS) and range of motion (ROM). Evaluations were performed prior and after to receive treatment, once a week, total four weeks of treatment. Fisher's Exact test, Paired Sample t-test, Wilcoxon Signed Rank test, Cumulative VAS Difference, Cohen's d on Cumulative Difference and Dichotomous Test were used in this study.

The findings were as follows:

1. VAS before and after third and fourth treatment EG were 3.7 ± 1.70 and 2.6 ± 1.99, P-value were 0.02 and 0.005 and first and fourth treatment of CG were 4.3 ± 2.21 and 3.9 ± 1.86, P-value were 0.011 and 0.002.
2. For cumulative P-value of both groups were greater Thant 0.05, there were no significant between groups. Also Cohen's d on cumulative difference had small issues.
3. In Dichotomous Result: Risk Ratio (RR), the result was $0.51<1$, there was difference between group. The risk of having uncured (VAS>3) with treatment was 51% of risk in CG, EG reduced the risk of uncured by 49%. Odds Ratio (OR), the result was $0.31<1$, there was difference between groups. EG reduced the odds of uncured to 31% of the odds in CG, EG reduced the odds of uncured by 69%. Risk Difference (RRR). The result showed $-0.28<0$,

there was difference between the groups. EG reduced the risk of uncured by 28%. 57 of 100 people experienced uncured in CG. 28 fewer people experienced uncured with EG.

This study showed both of traditional Chinese acupuncture and TCM with Saam Korean four needle techniques were effective for upper back and shoulder pain patients. Both groups' results were statistically significant and the experimental group had greater results in lower in pain level as cured more cases than control group.

REFERENCES

1. Hopkinsmedicine. (2022). *Shoulder Pain and Problems*. https://www.hopkinsmedicine.org/health/conditions-and-diseases/shoulder-pain-and-problems

2. Linaker, C. H., & Walker-Bone, K. (2015). Shoulder disorders and occupation. *Best practice & research. Clinical rheumatology*, *29*(3), 405–423. https://doi.org/10.1016/j.berh.2015.04.001. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4836557/

3. Medical News Today.(2020). *Everything you need to know about chronic shoulder pain.* https://www.medicalnewstoday.com/articles/chronic-shoulder-pain#exercises

4. Li Hua, L. Ac TCMD. (2012). *Shoulder Pain.* http://www.aac2000.com/\html111.htm#:~:text=Because%20the%20pain%20is%20around,limited%20movement%20of%20the%20shoulder.

5. Deng'Liangyue, Gan Yijun, He Shuhui, Ji Xiaoping, Li Yang, Wang Rufen, Wang Wenjing, Wang Xuetai, Xu Hengze, Xue Xiuling and Yuan Jiuling. (2003). *Chinese Acupuncture and Moxibustion*. Foreign Languages Press, Beijing, China.

6. Van der Windt DAWM, Koes BW, De Jong BA, Bouter LM. (1995) *Shoulder disorders in general practice: Incidence, patient characteristics, and management.* Ann Rheum Dis 1995, 54(12):959-964.

7. Luime JJ, Koes BW, Hendriksen IJM, Burdorf A, Verhagen AP, Miedema HS, Verhaar JA. (2004). *Prevalence and incidence of shoulder pain in the general population: a systematic review*. Scand J Rheumatol 2004, 33(2):73-81.

8. Croft PR, Pope DP, Silman AJ. (1996). *The clinical course of shoulder pain: prospective cohort study in primary care.* Br Med J 1996, 313(7057):601-602.

9. Urwin M, Symmons D, Allison T, Brammah T, Busby H, Roxby M, Simmons A, Williams G. (1998). *Estimating the burden of musculoskeletal disorders in the community*: the comparative prevalence of symptoms at different anatomical sites, and the relation to social deprivation. Ann Rheum Dis 1998, 57:649-655.

10. van der Windt DAWM, Koes BW, Bocke AJP, Deville W, de Jong BA, Bounter LM. (1996). *Shoulder disorders in general practice: prognostic indicators of outcome*. Br J Gen Pract 1996, 46:519-523.

11. Angela Cadogan, Mark Laslett, Wayne A Hing, Peter J McNair, and Mark H Coates. (2011). *A prospective study of shoulder pain in primary care: Prevalence of imaged pathology and response to guided diagnostic blocks*. Cadogan et al. BMC Musculoskeletal Disorders 2011, 12:119 http://www.biomedcentral.com/1471-2474/12/119

12. Luime, J. J., Koes, B. W., Hendriksen, I. J., Burdorf, A., Verhagen, A. P., Miedema, H. S., & Verhaar, J. A. (2004). Prevalence and incidence of shoulder pain in the general population; a systematic review. *Scandinavian journal of rheumatology*, *33*(2), 73–81. https://doi.org/10.1080/03009740310004667

13. Chang-BeohmAhn, Kyung-JunJang, Hyun-MinYoon, Cheol-HongKim, Young-KwangMin, Chun-HoSong, Jang-Cheo Lee. 2009. A Study of the Sa-Am Five Element Acupuncture Theory. *Journal of Acupuncture and Meridian Studies*. Volume 2, Issue 4, December 2009,. 309-320. https://www.sciencedirect.com/science/article/pii/S2005290109600741#bib2

14. Manyong P, **Sungchul K**. (2015). A Modern Clinical Approach of the Traditional Korean Saam Acupuncture. *Evidence-Based Complementary and Alternative Medicine.* Volume 2015. Article ID 703439. https://doi.org/10.1155/2015/703439

15. Hanok Lee. (2015). *Combined Effect of Traditional Acupuncture and SaAm Four Needling Acupuncture on the Treatment of Chronic Low Back Pain*. South Baylo University Doctoral Research project.

16. Maciocia, G. (2005) *The Foundation of Chinese Medicine.* Churchill Livingstone, Edinburgh.

17. Sang-Ju Cha, Kwang-Joong Kim (2011) Review on the relationship between 65 twelve-meridian muscle system and modern pain treatment. The Journal of EastWest Medicine. Vol 36, No.3:23-33.

18. Helene M. Langevin, Jason A. Yandow. (2002). Relationship of acupuncture points and meridians to connective tissue planes. *The Anatomical Records.* Volume269, Issue6. Pages 257-265.

19**.** Sanghoon Lee & Suk-Kyun Hahn. (2009). *Saam Five Element Acupuncture.* Jimoondang.

20. Giovanni, Maciocia. (1994). The Practice of Chinese Medicine; The Treatments of Diseases with Acupuncture and Chinese Herbs (p. 605-627) Edinburgh, London, Madrid, Melbourne, New York, and Tokyo: Churchill Livingstone.

21. Giovanni, Maciocia (1989) The Foundation of Chinese Medicine; A Comprehensive Text for Acupuncturists and Herbalists. (p. 249-263) Edinburgh, London, Madrid, Melbourne, New York, and Tokyo: Churchill Livingstone.

22. Dongchul Yang, (2019). *Comparison of Effects Between Five Elements Acupuncture and Traditional Acupuncture on Kidney Deficiency Lower Back Pain: Pilot Randomized Controlled Trial*. South Baylo university.

23. Jun Koo Youn. (2011). *The Practice of Sa-Am Acupuncture*. (2nd ed.). The Book & Publishing H.

24. Ilza Veith. (1949). *The Yellow Emperor's Classic of Medicine*. (Moashing Ni, English translator; 1st ed). Shambhala.

25. Sharkey, J. (2016). *The Concise Book of Dry Needling*. Lotus Publishing.

26. Hu You-Ping, Al Stone, Wu Jun-mei. (2014). *TCM Case Studies: Pain Management*. People's Medical Publishing House.

27. Deadman, P., Al-Khafaji, M., & Baker, K. (2011). *A Manual of Acupuncture*. North America by Eastern Publications.

28. Maciocia, G. (1994). *The Practice of Chinese Medicine*. [2nd ed. 2008]. Churchill Livingstone Elsevier.

29. Mahoney, E. (2017). *Saam Medical Meditation: Transcendental Acupuncture Experience (Saam Acupuncture and Medical Meditation)*. Independently Published.

30. Cohen, B.J., & Hull, K. L. (2015). *Memmler's The Human Body in Health and Disease*. (13th ed). Jones & Barlett Learning.

31. HB Kim. (2015). *Handbook of Oriental Medicine*. (5th ed). HB Kim Publisher.

32. HB Kim. (2015). Minibook *of Oriental Medicine*. (3rd ed). HB Kim Publisher.

33. Cho Z. H., Na C. S., Wong E. K., Lee S. H., Hong I. K. Functional magnetic resonance imaging of the brain in the investigation of acupuncture. In: Stux G., Hammerschlag R., editors. *Clinical Acupuncture: Scientific Basis.* Berlin, Germany: Springer; 2001. pp. 83–95. [Google Scholar]

34. Tanaka T. H., Leisman G., Nishijo K. The physiological responses induced by superficial acupuncture: a comparative study of acupuncture stimulation during exhalation phase and continuous stimulation. *International Journal of Neuroscience.* 1997;90(1-2):45–58. doi: 10.3109/00207459709000625. [PubMed] [CrossRef] [Google Scholar]

35. Kim D. H. The literary study on the written date and the background of Sa-Ahm's 5 element acupuncture method. *Journal of Korean Medical Classics.* 1993;7:113–160. [Google Scholar]

36. Kim S. C., Won J. H., Kim K. W. *Korea Traditional Sa-Am Acupuncture.* Jimoondang; 2009. [Google Scholar]

37. Oh J., Ki N. A study on the acupuncture methods of Joseon Dynasty using five viscera diagnosis. *Korean Journal of Oriental Medicine.* 2010;16(4):1–31. [Google Scholar] 13. Cha R., Yoon D., Kim J., Lee M., Lee G. A study of Sa-Ahm's thoughts on the four-needle acupuncture technique with the five-element theory. *Journal of Acupuncture and Meridian Studies.* 2014;7(5):265–273. doi: 10.1016/j.jams.2014.06.002. [PubMed] [CrossRef] [Google Scholar]

38. Hicks A., Hicks J., Mole P. *Five Element Constitutional Acupuncture.* Edinburgh, UK: Churchill Livingstone; 2005. [Google Scholar]

39. Shin K. H., Lee S. H., Park K. B., Cho J. H. Clinical study Sa-am acupuncture of insomnia in traffic accident. *The Journal of the Korea Institute of Oriental Medical Informatics.* 2004;10(2):51–60. [Google Scholar]

40. Yin C. S., Park H.-J., Nam H. J. Acupuncture for refractory cases of sudden sensorineural hearing loss. *Journal of Alternative and Complementary Medicine.* 2010;16(9):973–978. doi: 10.1089/acm.2009.0542. [PubMed] [CrossRef] [Google Scholar]

APPENDICES

APPENDIX -1. Informed Consent Form

Informed Consent Form

The treatment will be total 4 times, once a week in 4 -6 weeks.

This study is being conducted by Manusanee Chanyaem, 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 and Asian Medicine.

By Participating in this research, it is possible that you will be at greater risk than you would otherwise be. There is, for example, a risk that your condition will not get better and that the new medicine or treatment 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. Your information collected during the research will be put away and no-one but the researchers will be able to access. Any information about you will have a file 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 John Doe, L.Ac.

If you have any questions about this study, please contact Manusanee Chanyaem, L.Ac, at 2323-578-3632 and chanyaemma203@southbaylo.edu. If you have any questions or concerns regarding your rights as a subject in this study, you may contact Dr. Ki Haeng Cho, Chair of the South Baylo University. Institutional Review Board (IRB) at 213-738-0712 or khcho@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 asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

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

Statement by the researcher/person taking consent:

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

A copy of this Informed Consent Form has been provided to the participant.

Manusanee Chanyaem**, L.Ac.**

_____

Print Name Researcher (Print)

_____

Signature of Researcher

_____

Date: Day/Month/Year

APPENDIX -2. Data(Case Report) Forms

Case Report Form

Time____:____**am/pm**

Patient's Name _____ **Date** ____/___/_____ **File #** _____

"S"
-Subjective Complaint

How do you feel since last time treatment?
□Resolved □Improved □Slightly Improved □Unchanged

Chief Complaint _____

Present Illness & Physical Examination _____

-Vital Signs

Heart Rate_____*BPM* **Heart Rhythm**___*Normal/Abnormal*___ **Respiratory Rate**_____*BPM*

BP_____/_____*mmHg* **Temperature**_____*℉* etc._____

"O"
-Objective Findings

Tongue_____

Pulse *Lt:*_____ *Rt:*_____

"A"
-Assessment

AOM Diagnosis_____

Western Medical Diagnosis *(Only if the patient brings in)* _____

"P"
-Treatment Plan

Treatment Principles _____

Acupuncture Points Lt: _____

Rt: _____

Middle: _____ No. of Needles: _____

Auricular Acupuncture / Seeds_____

Herbal Treatment:._____

Other Treatment: ☐ H.P ☐ Acupressure ☐ Tui-na ☐ E.A ☐ Moxa ☐ Cupping ☐ Taiji 1 ☐ Taiji 2

Recommendations _____

Name of Practitioner: _____ LAc

PRE AND POST VISUAL ANALOGUE SCALE

NAME _____ **DATE** _____ **DATE OF INJURY** _____

PRE-TREATMENT VAS

Please place a mark through the line below that most accurately represents the pain level that you are feeling *RIGHT NOW*. Please note that "UNBEARABLE PAIN" is located on the right hand side of the line and "NO PAIN" is located on the left.

No Pain _____ Unbearable

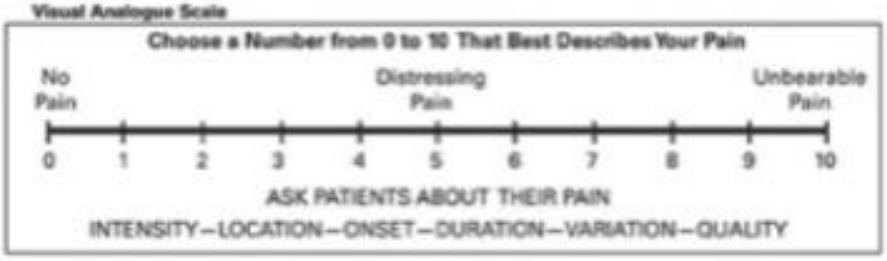
FOLD HERE----------

POST-TREATMENT VAS (fold in half when completing post-test VAS)

Please place a mark through the line below that most accurately represents the pain level that you are feeling *RIGHT NOW*. Please note that "UNBEARABLE PAIN" is located on the right hand side of the line and "NO PAIN" is located on the left.

No Pain _____ Unbearable

Visual Analogue Scale



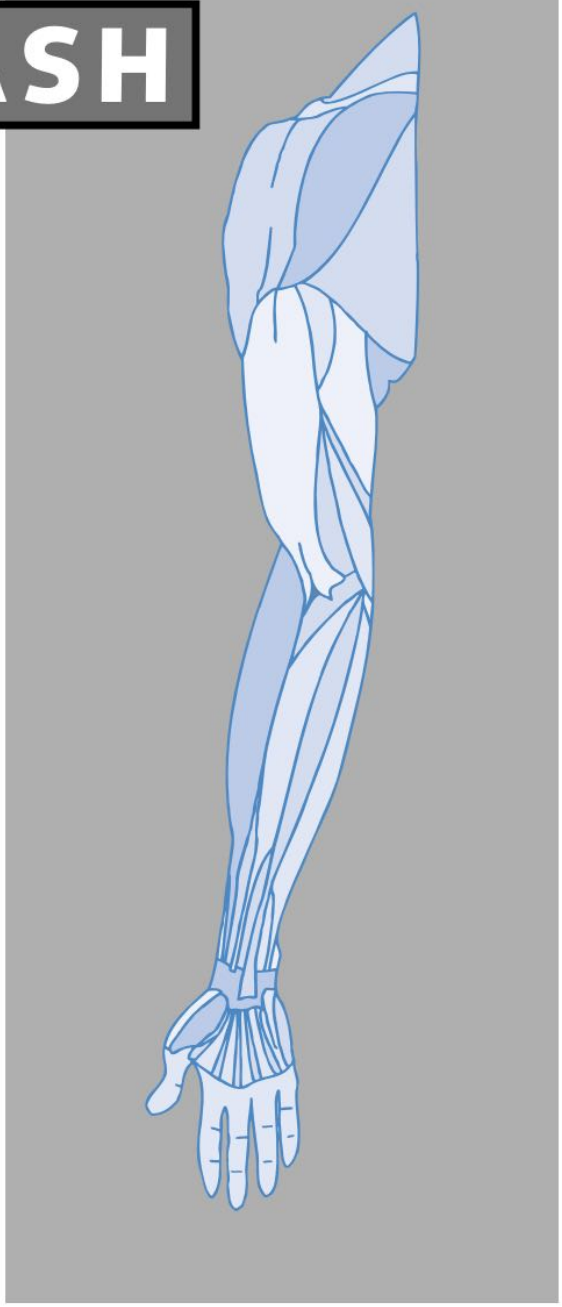
"Faces" Pain Rating Scale

APPENDIX -3. (Test Methods)

e.g. DASH. https://www.myoptumhealthphysicalhealth.com/Documents/Forms/DASH.pdf

DISABILITIES OF THE ARM, SHOULDER AND HAND

THE DASH



INSTRUCTIONS

This questionnaire asks about your symptoms as well as your ability to perform certain activities.

Please answer *every question*, based on your condition in the last week, by circling the appropriate number.

If you did not have the opportunity to perform an activity in the past week, please make your *best estimate* on which response would be the most accurate.

It doesn't matter which hand or arm you use to perform the activity; please answer based on your ability regardless of how you perform the task.

DISABILITIES OF THE ARM, SHOULDER AND HAND

Please rate your ability to do the following activities in the last week by circling the number below the appropriate response.

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. Open a tight or new jar.	1	2	3	4	5
2. Write.	1	2	3	4	5
3. Turn a key.	1	2	3	4	5
4. Prepare a meal.	1	2	3	4	5
5. Push open a heavy door.	1	2	3	4	5
6. Place an object on a shelf above your head.	1	2	3	4	5
7. Do heavy household chores (e.g., wash walls, wash floors).	1	2	3	4	5
8. Garden or do yard work.	1	2	3	4	5
9. Make a bed.	1	2	3	4	5
10. Carry a shopping bag or briefcase.	1	2	3	4	5
11. Carry a heavy object (over 10 lbs).	1	2	3	4	5
12. Change a lightbulb overhead.	1	2	3	4	5
13. Wash or blow dry your hair.	1	2	3	4	5
14. Wash your back.	1	2	3	4	5
15. Put on a pullover sweater.	1	2	3	4	5
16. Use a knife to cut food.	1	2	3	4	5
17. Recreational activities which require little effort (e.g., cardplaying, knitting, etc.).	1	2	3	4	5
18. Recreational activities in which you take some force or impact through your arm, shoulder or hand (e.g., golf, hammering, tennis, etc.).	1	2	3	4	5
19. Recreational activities in which you move your arm freely (e.g., playing frisbee, badminton, etc.).	1	2	3	4	5
20. Manage transportation needs (getting from one place to another).	1	2	3	4	5
21. Sexual activities.	1	2	3	4	5

DISABILITIES OF THE ARM, SHOULDER AND HAND

	NOT AT ALL	SLIGHTLY	MODERATELY	QUITE A BIT	EXTREMELY
22. During the past week, *to what extent* has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups? *(circle number)*	1	2	3	4	5

	NOT LIMITED AT ALL	SLIGHTLY LIMITED	MODERATELY LIMITED	VERY LIMITED	UNABLE
23. During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem? *(circle number)*	1	2	3	4	5

Please rate the severity of the following symptoms in the last week. *(circle number)*

	NONE	MILD	MODERATE	SEVERE	EXTREME
24. Arm, shoulder or hand pain.	1	2	3	4	5
25. Arm, shoulder or hand pain when you performed any specific activity.	1	2	3	4	5
26. Tingling (pins and needles) in your arm, shoulder or hand.	1	2	3	4	5
27. Weakness in your arm, shoulder or hand.	1	2	3	4	5
28. Stiffness in your arm, shoulder or hand.	1	2	3	4	5

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	SO MUCH DIFFICULTY THAT I CAN'T SLEEP
29. During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand? *(circle number)*	1	2	3	4	5

	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
30. I feel less capable, less confident or less useful because of my arm, shoulder or hand problem. *(circle number)*	1	2	3	4	5

DASH DISABILITY/SYMPTOM SCORE = _____ ([(sum of n responses / n) - 1] x 25, where n is the number of completed responses.)

A DASH score may <u>not</u> be calculated if there are greater than 3 missing items.

DISABILITIES OF THE ARM, SHOULDER AND HAND

WORK MODULE (OPTIONAL)

The following questions ask about the impact of your arm, shoulder or hand problem on your ability to work (including homemaking if that is your main work role).

Please indicate what your job/work is:_____

❒ I do not work. (You may skip this section.)

Please circle the number that best describes your physical ability in the past week. Did you have any difficulty:

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. using your usual technique for your work?	1	2	3	4	5
2. doing your usual work because of arm, shoulder or hand pain?	1	2	3	4	5
3. doing your work as well as you would like?	1	2	3	4	5
4. spending your usual amount of time doing your work?	1	2	3	4	5

SPORTS/PERFORMING ARTS MODULE (OPTIONAL)

The following questions relate to the impact of your arm, shoulder or hand problem on playing *your musical instrument or sport or both*.
If you play more than one sport or instrument (or play both), please answer with respect to that activity which is most important to you.

Please indicate the sport or instrument which is most important to you:_____

❑ I do not play a sport or an instrument. (You may skip this section.)

Please circle the number that best describes your physical ability in the past week. Did you have any difficulty:

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. using your usual technique for playing your instrument or sport?	1	2	3	4	5
2. playing your musical instrument or sport because of arm, shoulder or hand pain?	1	2	3	4	5
3. playing your musical instrument or sport as well as you would like?	1	2	3	4	5
4. spending your usual amount of time practising or playing your instrument or sport?	1	2	3	4	5

SCORING THE OPTIONAL MODULES: Add up assigned values for each response; divide by 4 (number of items); subtract 1; multiply by 25.
An optional module score may <u>not</u> be calculated if there are any missing items.

Other appendices – optional

i. **ethics review documentation, toxicity criteria, flow sheets, etc.**

Glossary – optional

ii. definitions of special or unfamiliar terms.