SOUTH BAYLO UNIVERSITY

A Clinical Study on the Effects of *Jiao Wei Suo Quan Wan* and Acupuncture on Urinary Incontinence in Middle-Aged and Older Adults

by

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A RESEARCH PROJECT SUBMITTED

IN PARTIAL FULFILLMENT OF THE

REQUIREMENTS FOR THE DEGREE

Doctor of Acupuncture and Oriental Medicine

LOS ANGELES, CALIFORNIA

January 2018

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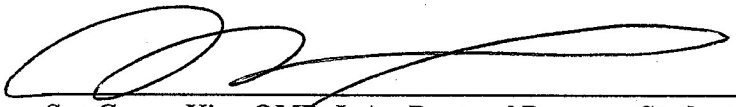

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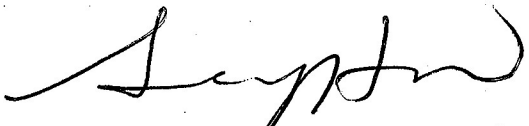

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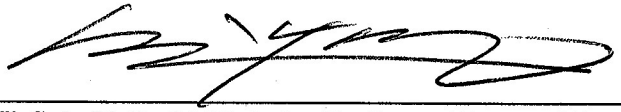

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A Clinical Study on the Effects of *Jiao Wei Suo Quan Wan* and Acupuncture on Urinary Incontinence in Middle-Aged and Older Adults

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ABSTRACT

Objective: The purpose of this study was to assess the effects of the herbal formula *Jiao Wei Suo Quan Wan* and acupuncture on CV-3, CV-4, ST-36, and SP-6 in the treatment of chronic urinary incontinence in middle-aged and older adults.

Method: The study consisted of 14 participants who were at least 55 years of age, reported symptoms of stress and/or urge incontinence, were not currently taking medication to treat urinary incontinence or that which may affect bladder function, did not have a history of pelvic floor or incontinence surgery, and did not have severe cognitive or mental disorders. Participants were randomly assigned to two groups: The control group (n = 7) was given only acupuncture at CV-3(*Zhongji*), CV-4 (*Guanyuan*), ST-36 (*Zusanli*), and SP-6 (*Sanyinjiao*) bilaterally. The experimental group (n = 7) received, in addition to acupuncture, a prescription of *Jiao Wei Suo Quan Wan* that contains equal amounts of *Wu Yao*, *Yi Zhi Ren*, *Shan Yao*, *Shi Chang Pu*, and *Yuan Zhi*. Outcomes were measured using the ICS-recommended ICIQ-SF.

Results: The study concludes that treatment with only acupuncture yields high treatment success rates, but the addition of Jia Wei Suo Quan Wan may enhance the effectiveness of treatment. Both the treatment administered to the control group and that of the experimental group yielded

results that were statistically significant. In comparing the ICIQ scores between the two groups, the experimental group had greater treatment effect, indicating higher effectiveness in the treatment plan that combined acupuncture and the herbal formula, but the results did not show them to be statistically significant.

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ACKNOWLEDGMENTS

I would like to express my sincere gratitude towards Dr. Shan Qin Cui for her continued guidance and support in completing this dissertation. I owe a special thanks to Dr. Joseph H. Suh, from whom I frequently sought advice and feedback while writing this dissertation. I would like to extend my warmest gratitude to Dr. Soo Gyung Kim for her professional guidance during my time at South Baylo University, and I would also like to thank Dr. Seong Hwa Hue, Dr. Suhkyung D. Kim, and Dr. Hanok Lee for their time and patience to review the dissertation. Lastly, I owe a special thanks to the entire community at South Baylo University for its support, without which this dissertation would not have been possible.

I. INTRODUCTION

Urinary incontinence is a distressing symptom that affects a significant proportion of the adult population.[1] The prevalence of urinary incontinence increases with age due to functional deterioration and is therefore higher in middle-aged and older adults.[2] In the United States, urinary incontinence affects 43.8% of the noninstitutionalized population and 36.6% of residential care facility residents over the age of 65.[3] In 2000, urinary incontinence in women was the main cause of over 1.1 million medical office visits.[4]

Nevertheless, urinary incontinence remains an underreported and underdiagnosed symptom. A stigma against individuals with urinary incontinence persists, and the loss of bladder control interrupts social activities and compromises social identities.[5] The psychosocial implications are far-reaching. The fear of or the event of social result due to urinary incontinence may lead to low self-esteem, shame, anxiety, and depression and compromise the patient's ability to cope with his or her circumstances.[6] In a study by Heo et al., reasons cited for not seeking and receiving medical treatment for urinary incontinence included having mild symptoms that did not necessitate immediate care, believing it to be a natural aging process, shame, belief that the condition is incurable, and the cost of treatment.[7]

Treatment approaches vary depending on the classification of the symptom, and many are successful in improving or even curing urinary incontinence.[1] However, routine care and treatment are costly, and severe urinary incontinence that responds poorly to conservative treatments may require surgical intervention. In 2000, the total cost of urinary incontinence in the United States was estimated to be $19.5 billion.[8] On average, women with urinary incontinence spend nearly $750 out-of-pocket per year to manage their symptoms.[8]

Urinary incontinence manifests in different forms, among which urge incontinence and stress incontinence are the most common.[10, 11] Urge incontinence is an involuntary passage of urine that is accompanied by or immediately preceded by urgency. Stress incontinence is associated with increased abdominal pressure, wherein leakage may occur on effort or exertion, such as while sneezing, coughing, or lifting. Urge incontinence is the most common type of urinary incontinence in men and among older adults, and stress incontinence is the most common type in women. Mixed incontinence is the presence of both urge and stress incontinence, and it is more common in women.

Other types of urinary incontinence include continuous, overflow, and functional incontinence. Continuous incontinence occurs when the bladder's ability to store urine is entirely compromised by surgical trauma or a congenital defect. Overflow incontinence is leakage that results from an obstructed bladder and the consequent increase in intravesical pressure, which exceeds that of the sphincter. Functional incontinence is secondary to impaired mobility, psychiatric disorders, or urinary infection. Given the different underlying mechanisms of each incontinence type, treatment approaches are not uniform for all types of urinary incontinence.

Similarly, in oriental medicine, differentiation of the diagnostic patterns associated with urinary incontinence is necessary for correct diagnosis. The decline of Qi, particularly that of the Kidney, is part of a natural aging process that is expected in many older adults. The most common etiology for urinary incontinence in old age is Kidney Deficiency and Empty Cold in the Lower Burner, wherein the patient may also experience frequent urination and/or nocturia. Other deficiency-type patterns that may cause urinary incontinence include Spleen Qi Sinking, which may cause urgency and slight incontinence, and Kidney Yin Deficiency, which may cause incontinence of urine in small amounts. Urinary incontinence is also present in Excess and Heat

conditions, such as Empty Fire due to Kidney Yin Deficiency, Damp Heat in the Bladder, and Blood Stasis in the Lower Burner. The observation of key symptoms other than urinary incontinence is necessary for differentiation of diagnostic patterns.

This study assumes that patients who are no less than 55 years old are likely to benefit from treatment of urinary incontinence due to Kidney Deficiency and Empty Cold. The herbal formula *Suo Quan Wan*, found in Chen Ziming's *Fu Ren Da Quan Liang Fang* (1237), is a standard prescription for incontinence patients with Kidney Yang Deficiency. In this study, a modified form of the classic formula, *Jiao Wei Suo Quan Wan*, was given to the experimental group to complement acupuncture treatment. Acupuncture treatment was identical for both the control and experimental groups and consisted of CV-3, CV-4, ST-36, and SP-6.

II. OBJECTIVES

The objectives of this study are as follows:

1. Determine whether administering *Jiao Wei Suo Quan Wan* in conjunction with acupuncture on CV-3 (*Zhongji*), CV-4 (*Guanyuan*), ST-36 (*Zusanli*), and SP-6 (*Sanyinqiao*) reduces the frequency and severity of urinary incontinence in middle-aged and older adults, as indicated by the ICIQ.
2. Compare the effectiveness of a treatment consisting of both *Jiao Wei Suo Quan Wan* and acupuncture on CV-3, CV-4, ST-36, and SP-6 to acupuncture-only treatment.

III. LITERATURE REVIEW

Urinary incontinence can be considered a symptom, sign, and disorder, but it does not have a specific etiology to classify it as a disease. In fact, most cases of urinary incontinence are multifactorial, and their etiologies are not well understood. To address this problem, a more symptomatic approach to evaluate urinary incontinence has surfaced over the years. The International Continence Society (ICS) has modified its definition of urinary incontinence from "the involuntary loss of urine that is a social or hygienic problem and is objectively demonstrable" to the more general "complaint of any involuntary leakage of urine." A patient's complaint of leaking urine without intention now suffices for a diagnosis of urinary incontinence, and it is the symptoms reported by the patient that influence the treatment approach.

Loss of bladder control occurs when there is a disruption in the normal physiology of micturition.[1, 4, 8, 10, 11] A normally functioning bladder relaxes to store urine at a low pressure and empties to completion when the person intends to do so. The typical bladder capacity ranges from 300 to 500 mL, and the first urge to void occurs when the urine volume is between 150 to 300 mL. At the onset of micturition, the brain stem coordinates the relaxation of the sphincter and the contraction of the detrusor muscle, which raises the intravesical pressure.

In stress incontinence, however, a rise in intraabdominal pressure increases the pressure within the bladder past the threshold at which the urethra can resist urinary flow. Oftentimes, this is due to poor pelvic support and intrinsic sphincter deficiency. On the other hand, urge incontinence corresponds to detrusor overactivity due to detrusor myopathy and/or neuropathy. Mixed incontinence is a combination of stress and urge incontinence, wherein the cause of bladder control loss lies in both detrusor overactivity and impaired urethral function.

The prevalence of urinary incontinence is estimated to be 17-40% in the United Kingdom, with increased prevalence in old age. In Japan, more than 50% of people over the age of 60 are reported to have incontinence, with an affected population of 3 to 4 million people. In the United States, 15-50% of women are affected, but many remain undiagnosed with less than half of those with urinary incontinence seeking treatment.

Conventional medical treatments for urinary incontinence vary according to the type of incontinence. In stress incontinence, surgical procedures that increase urethral outlet resistance may be recommended. These include synthetic transobturator or retropubic midurethral slings, autologous fascia pubovaginal slings, bladder neck suspension, and periurethral bulking therapy. In mild cases of stress incontinence not associated with intrinsic sphincter deficiency, pelvic floor physiotherapy can beneficial. However, Kegel exercises are more effective in younger women, whereas older women may have weak pelvic muscle tone or have difficulty identifying the pubococcygeus portion of the levator ani muscles. Vaginal cones may be used in conjunction with Kegel exercises to help postmenopausal women strengthen the pelvic floor.

In patients with urge incontinence, dietary changes may be necessary if the patient's diet contains dietary stimulants that worsen symptoms of incontinence. These include spicy foods, citrus fruits and juices with an acidic pH, and caffeine-containing products such as chocolate, coffee, tea, and colas. Adjusting fluid intake and scheduling frequent and timed voiding are also recommended. Pelvic floor rehabilitation is also advised for patients with urge incontinence. Anticholinergic drugs, antispasmodics, and tricyclic antidepressants may also be used.

In oriental medicine, the most common modalities for treating urinary incontinence are acupuncture, herbal medicine, moxibustion, and, more recently, electroacupuncture.[12] The author of this study intended to examine a treatment plan that was cost-effective and practical without

sacrificing the effectiveness of the prescribed treatment.[13] Although this study uses traditional acupuncture for both its control and experimental groups with the addition of herbal medicine for the latter, it is worth examining existing research that combined other modalities on the same acupuncture points.

For instance, electroacupuncture has gained popularity and is often used to improve self-controlled bladder function by delivering electric stimulation to the sacral nerves S2-S4, which are responsible for bladder contraction.[14, 15] The acupuncture points BL-32 (*Ciliao*), BL-33 (*Zhongliao*), and BL-34 (*Xialiao*) correspond to the second, third, and fourth sacral foramen, respectively, and have been shown to benefit patients with urinary incontinence.[16] Liu et al. hypothesized that electroacupuncture on these '*liao*' points may elicit a therapeutic effect like that of sacral neuromodulation, the surgical implantation of a device that delivers low-amplitude electrical pulses to the sacral nerve via the S3 foramen. In a study involving patients with bladder dysfunction secondary to traumatic spinal cord injury, they demonstrated that electroacupuncture on BL-32, BL-33, and BL-35 (*Huiyang*) decreased the postvoid residual urine volume and the frequency of urinary incontinence.[17, 18] Ko et al. studied BL-32 exclusively and found that electroacupuncture improved the quality of life scores of UI patients, particularly in social functioning.[19] However, available evidence is insufficient to conclude that electroacupuncture is effective for both stress and urge incontinence. A separate study should be conducted to investigate the effectiveness of electroacupuncture on stress, urge, and mixed continence.

Moxibustion, although not used in this study, is a favored modality for the treatment of urinary incontinence, particularly that which results from Kidney Deficiency and Empty Cold, because of its warm, Yang-tonifying properties.[20] Park et al. reported a case of a 63-year-old

woman with stress incontinence who benefited from moxibustion on ST-28 (*Shuidao*) twice a day.[21] Lee et. al at Dongeui University studied the effects of moxibustion at CV-3 (*Zhongji*) and CV-8 (*Shenque*) on urinary incontinence in women and saw a decrease in the severity of incontinence in the experimental group, finding the treatment an effective, non-invasive intervention with symptomatic relief and no adverse effects.[20]

Other studies use a combination of the different modalities available in oriental medicine. Kim et al. at Daegu University studied the effect of moxibustion at CV-3 and CV-6 (*Qihai*) combined with acupuncture on BL-23 (*Shenshu*), BL-28 (*Pangguangshu*), and SP-9 (*Yinlinqiao*) and showed statistically significant results.[22, 23] One case study by Jeong et al. at Dongguk University examined a 55-year-old woman with stress incontinence who benefited from treatment that included acupuncture on CV-3, PC-6 (*Neiguan*), and SP-6 (*Sanyinqiao*). The same authors conducted a retrospective study of 64 patients with overactive bladder who received treatment that consisted of acupuncture on CV-3, PC-6, and SP-6, electroacupuncture on BL-28 and BL-32, and moxibustion on CV-4 (*Guanyuan*) for 30 days.[24] The symptoms disappeared in 27 patients and improved in 28 patients, while the remaining 9 patients did not show any improvement.

Kim et al. at Kyunghee University also investigated the following medical literature involving acupuncture treatment on urinary incontinence.[25]

In a Swedish study in 2000, 15 elderly women with urge or mixed incontinence were treated with acupuncture twelve times on BL-23, BL-31, BL-32, BL-33, SP-6, KI-3 (*Taixi*), and LI-1 (*Dadun*) and showed significant improvement. An American study in 2005 showed significant symptomatic improvement in 85 women with urge incontinence in both the acupuncture (CV-4, SP-6, BL-28, BL-39 [*Weiyang*]) and "placebo" (BL-12 [*Fengmen*], ST-36

[*Zusanli*], CV-12 [*Zhongwan*], GB-31 [*Fengshi*]) groups. An Austrian study in 2005 showed improvement in urgency in 55 women between six and ten weeks of gestation after treatment that included acupuncture on BL-28, SP-6, and KI-3 and moxibustion on CV-4, CV-5, CV-6, GV-4, BL-23, BL-24 (*Qihaishu*), BL-25 (*Dachangshu*), BL-26 (*Guanyuanshu*), BL-27 (*Xiaochangshu*), and BL-28. A Chinese study in 2009 that included 71 women with stress incontinence showed significant decrease in ICIQ-SF scores after acupuncture on CV-3, LU-5 (*Chize*), and EX-CA1 (*Zigong*) and moxibustion on CV-8. An American study in 2009 that included 9 women with urge and mixed incontinence showed a reduction in daytime accidents after acupuncture on BL-23, BL-31, BL-32, BL-33, SP-6, and KI-3 for six weeks.

Although several formulas have been studied in clinical trials for their effects in the treatment of urinary incontinence, *Suo Quan Wan* is best suited for patients whose incontinence derives from Kidney Deficiency and Empty Cold. One of its principal ingredients, *Alpinia oxyphylla* (*Yi Zhi Ren*), is widely used to inhibit diuresis. Moreover, Li et al. studied the effects of *Alpinia oxyphylla* extracts on chronic kidney disease and found that the herb can delay kidney damage and improvement of renal function.[26, 27] Another study concluded that the seed of the *Alpiniae oxyphyllae* has both diuretic and anti-diuretic properties, its inhibitory function prevailing initially and increasing urine volume excretion over time. A study by Yuan et al. found that the herb contains the flavonoid izalpinin, which plays an inhibitory role in the muscarinic receptor-related detrusor contractile activity.[28] This suggested a positive effect on symptoms of an overactive bladder, including urinary incontinence, urgency, and frequency.

There are few studies that examine the effects of the herbal formula *Suo Quan Wan*. However, a study by Kim et al. at Woosuk University investigated the effects of *Suo Quan Wan* extracts on the urine metabolism of rats.[29] The formula consisted of 75 g of *Radix linderae*, 75 g

of *Fructus zingiberis nigri*, and 150 g of *Rhizoma batatatis* decocted in 3,000 ml of water for four years and processed in a rotary evaporator. The rats were administered the formula (200 mg/kg/day, p.o.) for fourteen days. The volume of excreted urine increased after seven days but showed marked decrease in the second week. The study concluded that the formula may treat various urinary conditions, not limited to incontinence, without significant changes in the levels of urine glucose, ketones, leukocyte esterase, urobilinogen, bilirubin, nitrite, or pH.

IV. MATERIALS AND METHODS

4.1. Participants

Participants were patients at the South Baylo University Clinic in Los Angeles who volunteered to be screened for eligibility and participate in the research. For inclusion in the study, they had to fulfill the following criteria: (1) at least 55 years of age; (2) UI on effort, exertion, sneezing, or coughing and/or UI accompanied by or immediately preceded by urgency; (3) not taking medication to treat UI or that which may affect bladder function; (4) no history of incontinence surgery or pelvic floor surgery; and (5) no serious cognitive or mental disorders.

4.2. Study Design

A total of 14 participants were randomly assigned to two groups on a 1:1 ratio. The control group (n = 7) received acupuncture on CV-3 (*Zhongji*), CV-4 (*Guanyuan*), ST-36 (*Zusanli*), and SP-6 (*Sanyinjiao*). The experimental group (n = 7) received the same acupuncture treatment in addition to the herbal formula *Jiao Wei Suo Quan Wan*. Participants of both the control and experimental groups had weekly acupuncture sessions for three weeks. (Figure 1)

4.3. Acupuncture Protocol

4.3.1. Point Location

The selected acupuncture points are located according to the proportional *cun* measurement system. The locations of CV-3 (Figure 2) and CV-4 (Figure 3) are relative to the five-*cun* distance between the center of the umbilicus and the upper border of the symphysis pubis. ST-36 (Figure 4) is found three *cun* below the lower border of the patella, one finger-breadth lateral to the anterior crest of the tibia. The location of SP-6 (Figure 5) is relative to the

thirteen-*cun* distance between the lower border of the medial condyle of tibia and the medial malleolus.

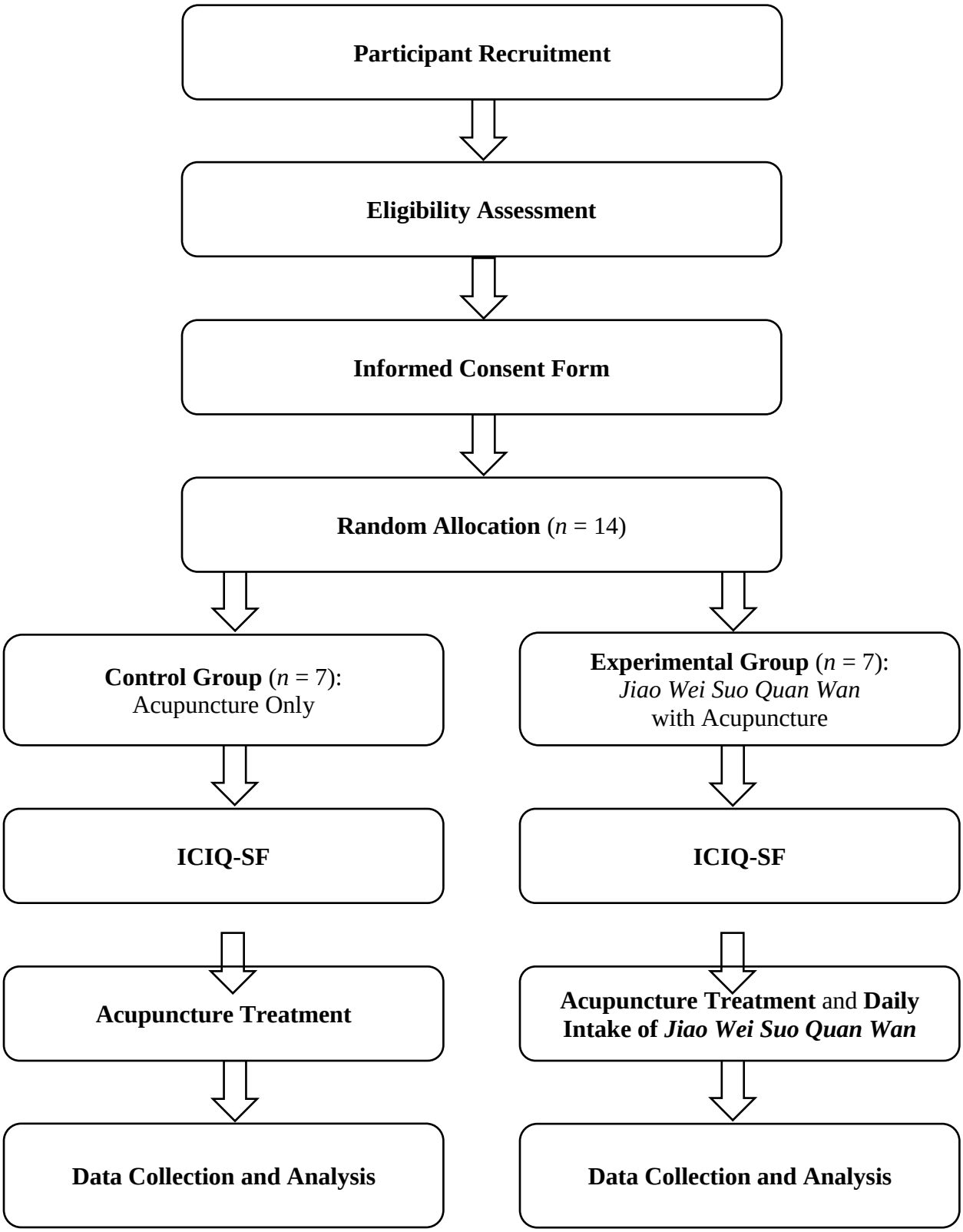

Figure 1. Schematic Diagram of Research Design

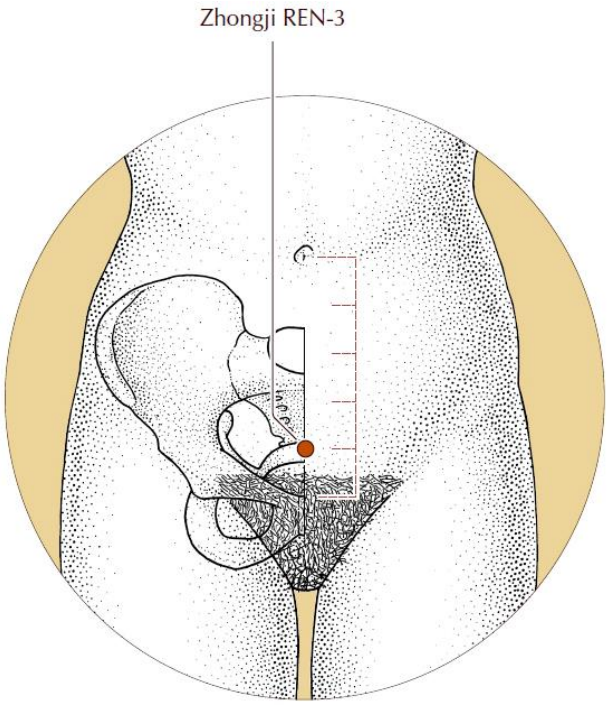

Figure 2. CV-3 (*Zhongji*) is located 5 *cun* below the umbilicus on the midline of the lower abdomen. It coincides with the upper border of the symphysis pubis.

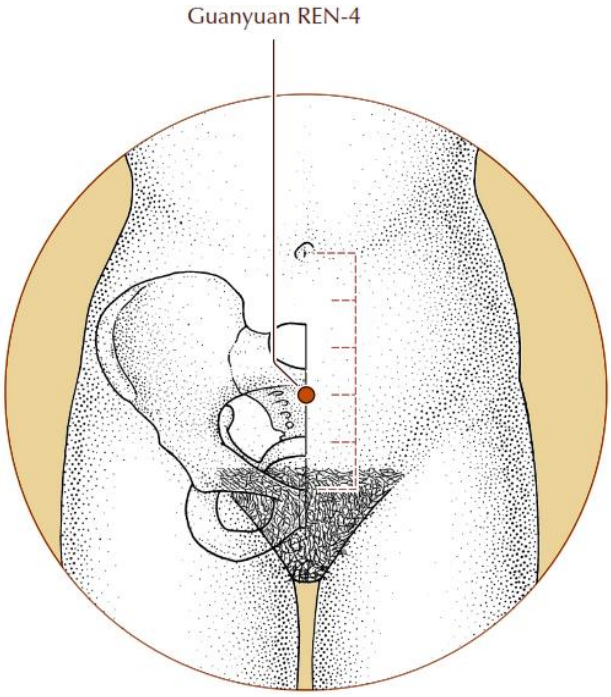

Figure 3. CV-4 (*Guanyuan*) is located 4 *cun* below the umbilicus and 1 *cun* above the upper border of the symphysis pubis on the midline of the lower abdomen.

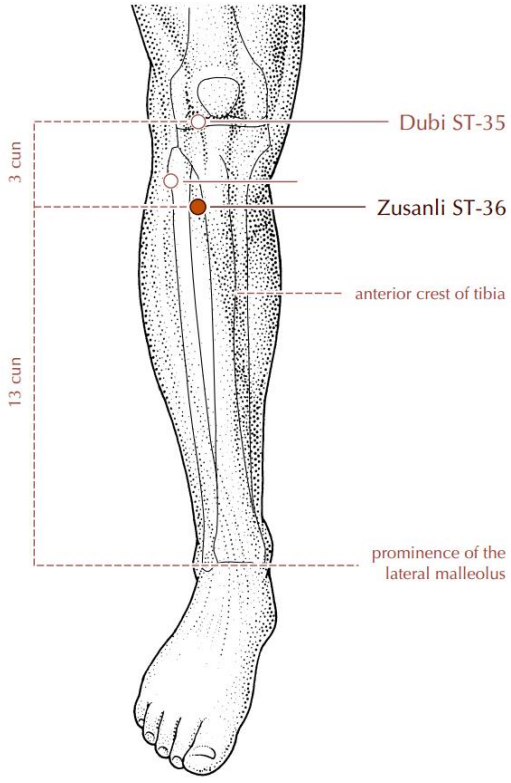

Figure 4. ST-36 (*Zusanli*) is found three *cun* below the lower border of the patella, one finger-breadth lateral to the anterior crest of the tibia.

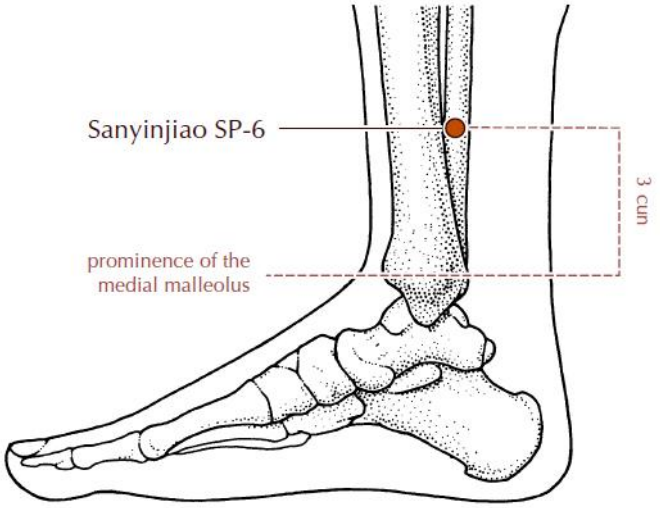

Figure 5. SP-6 (*Sanyinqiao*) is located 3 *cun* superior to the prominence of the medial malleolus, on the posterior border of the medial crest of the tibia.

4.3.2. Point Indications

CV-3 is the Front-*mu* point for the Bladder. It benefits the Bladder, drains Dampness and Damp-Heat, dispels stagnation, benefits the Lower Burner, and strengthens the Kidneys.

CV-4 is the Front-*mu* point for the Small Intestine. It tonifies the Original Qi, benefits the Essence, strengthens the Kidneys, nourishes the Blood and Yin, and eliminates Cold and Dampness in the Lower Burner.

ST-36 is the *He*-Sea point of the Stomach channel and the point of Sea of Water and Grain and is particularly important in the treatment of the Stomach, Spleen, and Kidney. It assumes a profound role in tonifying the Qi of the entire body, as the Stomach and Spleen produce the Qi and Blood necessary to supplement Post-Heaven Essence.

SP-6 is a meeting point with the Liver and Kidney Channels and the Yin Motility Vessel (*yin qiao mai*). It is particularly important for the treatment of Lower Burner disorders, including urinary conditions, and tonifies the Spleen and Stomach, eliminates Dampness, regulates urination, harmonizes the Lower Burner, nourishes the Blood and Yin, regulates menstruation, promotes labor, and calms the Shen.

4.3.3. Intervention

Two 0.30 × 75mm Cloud & Dragon needles were used for CV-3 and CV-4, and four 0.25 × 40mm Dong Bang (DBC) needles were used for ST-36 and SP-6 bilaterally. All needles were stainless steel filiform needles that had been sterilized by gamma irradiation.

The depth of needle insertion was at the discretion of the acupuncturist, appropriately adjusted according to the body size of the patient, but was no less than 75% and did not exceed 90% of the needle body. Once inserted, the needle was manipulated to elicit a *deqi* response from the patient and retained for forty minutes.

4.4. Herb Formula

Chen Ziming's classical formula *Suo Quan Yuan* calls for equal amounts of *Wu Yao* (Radix Linderae) and *Yi Zhi Ren* (Fructus Alpiniae Oxyphyllae) to be pulverized into a fine powder and mixed with *Shan Yao* (Rhizoma Dioscoreae), which serves as an adhesive for molding the mixture into individual pills.

This study instead used the modified formula *Jiao Wei Suo Quan Yuan*, which included in addition to the original formula equal amounts of *Shi Chang Pu* (Rhizoma Acori Tatarinowii) and *Yuan Zhi* (Radix Polygalae).

The herbs were thoroughly cleansed and dried in a clean environment before delivery to U.S. Deer Antlers Import & Export Company for processing.

Participants of the experimental group were administered *p.o.* 15 pills three times a day for three weeks. The pills were taken with salt water before or in lieu of meals.

4.5. Outcome Measurement

The International Continence Society (ICS) highly recommends the use of the International Consultation on Incontinence Questionnaire – Short Form (ICIQ-SF) to evaluate the patient's perspective of UI, as well as a bladder diary to document history of fluid consumption and micturition.

Participants were asked to complete the ICIQ before the first treatment session and one week after the final treatment session for comparison between the baseline and follow-up scores.

4.6. Statistical Analysis

SPSS Statistics v. 22.0 and nonparametric tests were used for statistical analysis.

V. RESULTS AND DISCUSSION

The study examined 14 chronic urinary incontinence patients over the age of 55. 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 acupuncture the herbal formula *Jia Wei Suo Quan Wan*. 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 twice a week for three weeks for a total of six treatment sessions. Patients were asked to complete the ICS-recommended International Consultation on Incontinence Questionnaire (ICIQ) before the first treatment of every week and one week following the last treatment. The data collected from the ICIQ results were analyzed to determine statistical significance.

5.1. Homogeneity Test

5.1.1. 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 1. The p-value for the Pearson's chi-squared test was greater than 0.05 in both groups, confirming that the experiment was performed under the same conditions for the two variables.

Table 1. Homogeneity Test for the General Characteristics of Patients

Variable	Group	EG	CG	p-value*
Gender	Male	2	2	1.000
	Female	5	5	
Age	50’s	0	1	0.572
	60’s	4	4	
	70’s	2	2	
	90’s	1	0	

* *Pearson’s chi-squared test*

5.1.2. Homogeneity Test for the ICIQ

The results of the independent sample t-test for the control and experimental groups in the pre-treatment measurements of each variable (i.e., the ICIQ scores) are outlined in Table 2. The p-value of the independent sample t-test was greater than 0.05, confirming that the two groups were tested under the same conditions at the start of the treatment.

Table 2. Homogeneity Test for the ICIQ Before Treatment

Variables	EG	CG	p-value*
ICIQ	10.1 ± 6.8	8.6 ± 4.7	0.623

* *Independent sample t-test*

5.2. ICIQ Score Changes

5.2.1. Comparing Pre- and Post-Treatment ICIQ Scores

The ICIQ values were measured to assess the symptomatic relief of patients with chronic urinary incontinence. Table 3 and Figure 6 compare the results of the experimental group with those of the control group. Where assumption of normality was met, the ICIQ 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 Tables 5-3 and 5-4, the ICIQ values in the control group decreased from 8.6 ± 4.7 to 7.3 ± 4.6 after the first treatment, showing a decrease of 1.3 ± 0.9 ($p = 0.024$). After the second treatment, the scores went down to 5.0 ± 4.8, indicating a decrease of 3.6 ± 1.9 ($p = 0.003$). After the third treatment, the values were measured at 3.7 ± 4.6, indicating a decrease of 4.9 ± 2.0 ($p = 0.001$). In the experimental group, the ICIQ values decreased from 10.1 ± 6.8 before starting treatment to 8.0 ± 6.1 after the first treatment, showing a decrease of 2.1 ± 2.2 ($p = 0.041$). After the second treatment, the scores went down to 5.6 ± 3.8, a decrease of 4.6 ± 3.3 ($p = 0.011$). After the third treatment, the values were measured at 2.3 ± 4.1, indicating a decrease of 7.9 ± 4.3 ($p = 0.003$).

The results for both the control and experimental groups were statistically highly significant. A box plot for the ICIQ values is shown in Figure 7.

Table 3. ICIQ Score Changes Before and After Treatment in the CG and EG

Group	1st (*)	2nd	3rd	4th
EG	10.1 ± 6.8	8.0 ± 6.1	5.6 ± 3.8	2.3 ± 4.1
CG	8.6 ± 4.7	7.3 ± 4.6	5.0 ± 4.8	3.7 ± 4.6

* *Before treatment*

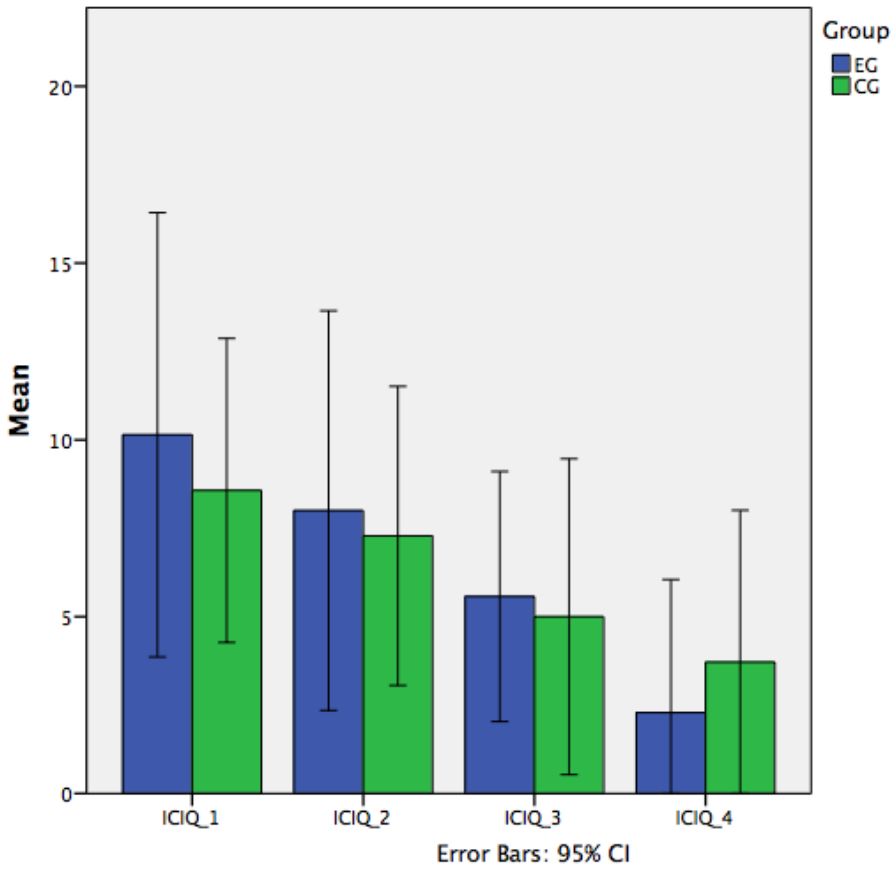

Figure 6. ICIQ Score Changes Before and After Treatment

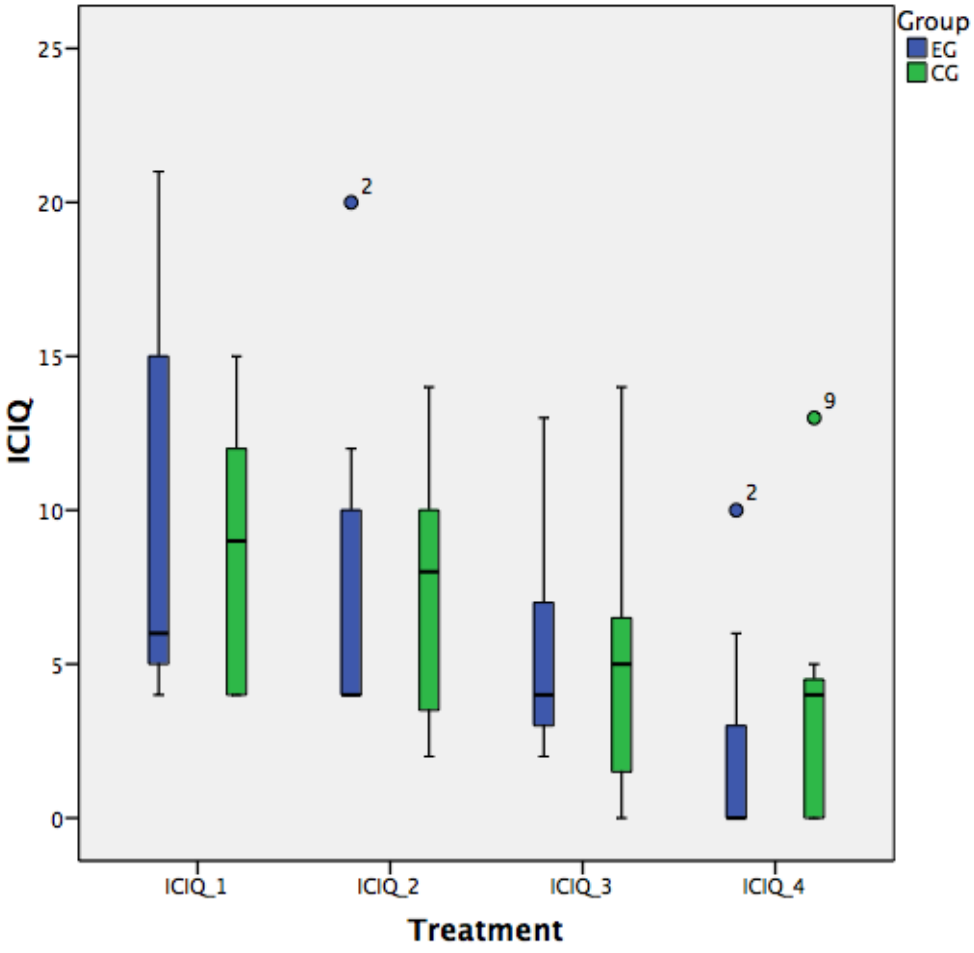

Figure 7. Box Plot of ICIQ Scores Before and After Treatment

5.2.2. Cohen's Distance of ICIQ Scores

Cohen's distance = (M2-M1) / √{(SD12 + SD 22) /2}

CG Cohen's d = (8.6 - 3.7)/4.65 = 1.05

EG Cohen's d = (10.1 - 2.3)/5.61 = 1.39

Cohen's distance was used to compare the effectiveness of the control group treatment to that of the experimental group treatment. Cohen's distance was 1.05 in the control group and 1.39 in the experimental group, showing that the treatment given to the latter showed higher effectiveness.

5.2.3. Cumulative Treatment Effect

nth cumulative treatment effect = (initial pre-treatment ICIQ score) - (ICIQ score after the nth treatment)

In comparing the ICIQ values of the control and experimental groups, the treatment effect after the first session was 1.3 ± 0.9 for the control group and 2.1 ± 2.2 for the experimental group ($p = 0.620$). After the second session, the treatment effect was 3.6 ± 1.9 for the control group and 4.6 ± 3.3 for the experimental group ($p = 0.719$). After the third session, the treatment effect was 4.9 ± 2.0 for the control group and 7.9 ± 4.3 for the experimental group ($p = 0.165$).

The experimental group showed a higher cumulative treatment effect in all cases, but the results are not statistically significant according to the Mann-Whitney test (Table 4).

Figure 8 shows a bar graph of the cumulative treatment effect after each treatment as determined by ICIQ scores.

Table 4. The Comparison of Cumulative Effect on ICIQ between CG and EG

Treatment	EG (p-value*)	CG (p-value*)	p-value**
1st - 2nd	2.1 ± 2.2 (0.041)	1.3 ± 0.9 (0.024)	0.620
1st - 3rd	4.6 ± 3.3 (0.011)	3.6 ± 1.9 (0.003)	0.710
1st - 4th	7.9 ± 4.3 (0.003)	4.9 ± 2.0 (0.001)	0.165

** Paired t-test / Wilcoxon signed-rank test within group*

*** Mann-Whitney Test between groups*

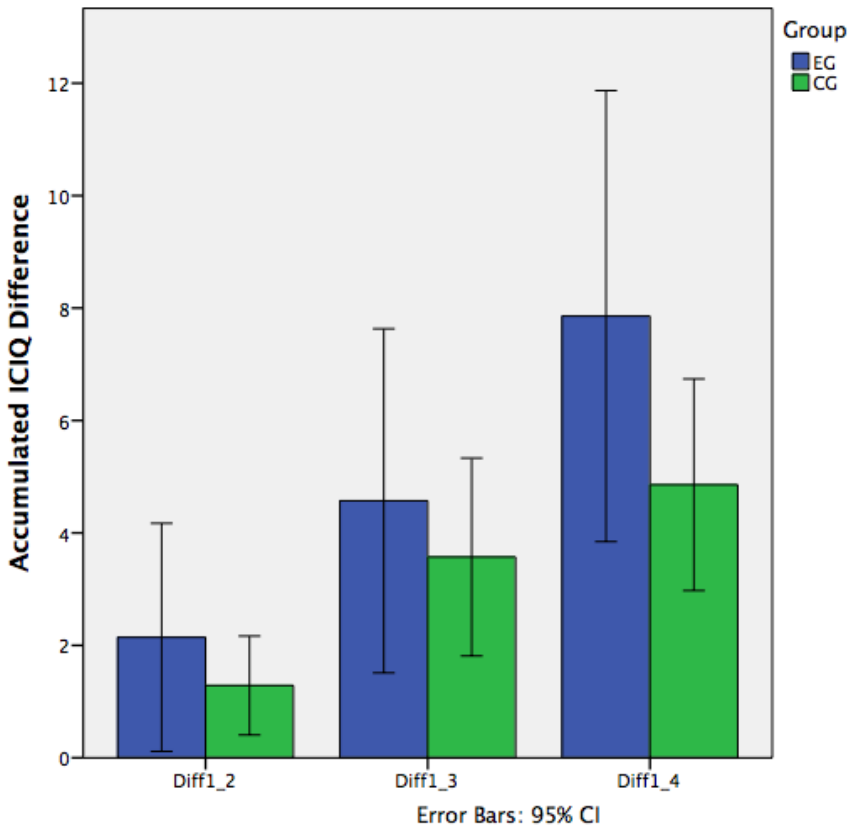

Figure 8. Cumulative Effect After Each Treatment According to ICIQ Scores

5.2.4. Cumulative Treatment Rate

Cumulative treatment rate (%) = 100 * (pre-treatment ICIQ score - ICIQ score after the nth treatment) / pre-treatment ICIQ score

The results of the comparison between cumulative treatment rate of the control group and that of the experimental group are shown in Table 5. The cumulative treatment rates of the control and experimental groups after the first treatment were 18.2 ± 17.1 (%) and 19.9 ± 18.0 (%), respectively (p = 0.8630). After the second treatment, the cumulative treatment rate of the control group was 52.5 ± 35.4 (%) and that of the experimental group was 43.2 ± 11.3 (%) (p - 0.521). After the third treatment, the cumulative treatment rate of the control group was 70.6 ± 32.2 (%) and that of the experimental group was 87.1 ± 22.1 (%) (p = 0.396).

The cumulative treatment rate increased as the number of treatment sessions increased in both groups. The experimental group showed a cumulative treatment rate that was 17% higher than that of the control group, but these results were not statistically significant. Figures 5-4 and 5-5 show the bar graph and box plot of the two groups' treatment rates.

Table 5. Cumulative Treatment Rate on ICIQ between CG and EG

Treatment	EG (%)	CG (%)	p-value
1st - 2nd	19.9 ± 18.0	18.2 ± 17.1	0.863*
1st - 3rd	43.2 ± 11.3	52.5 ± 35.4	0.521*
1st - 4th	87.1 ± 22.1	70.6 ± 32.2	0.396**

* *Independent sample t-test*

** *Mann-Whitney U test*

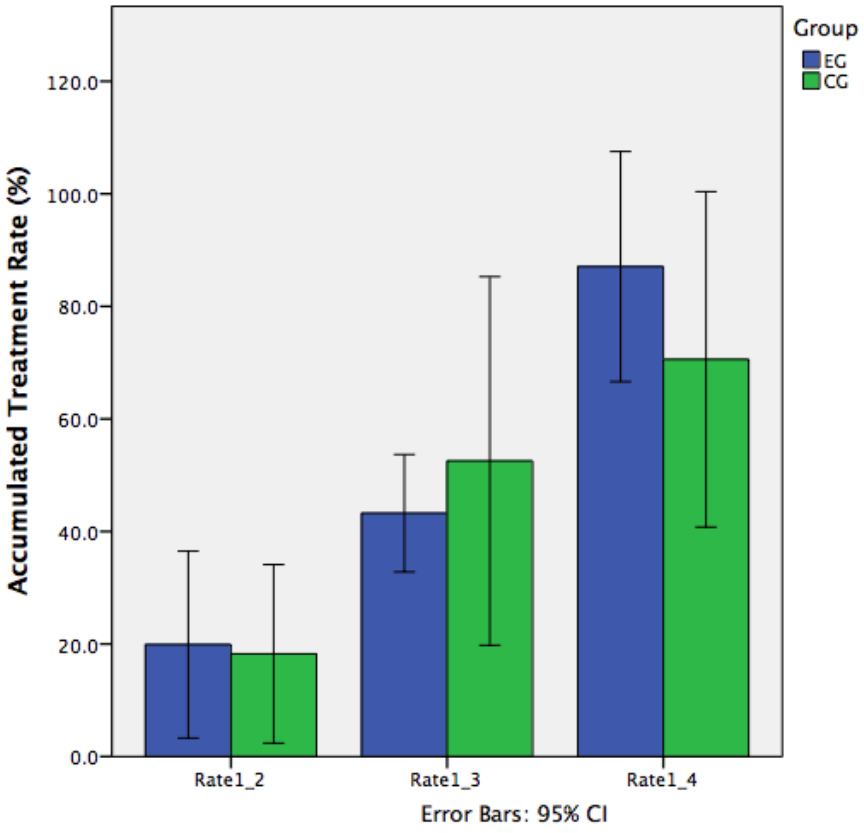

Figure 9. Comparison of Treatment Rates Between the Two Groups According to ICIQ Scores

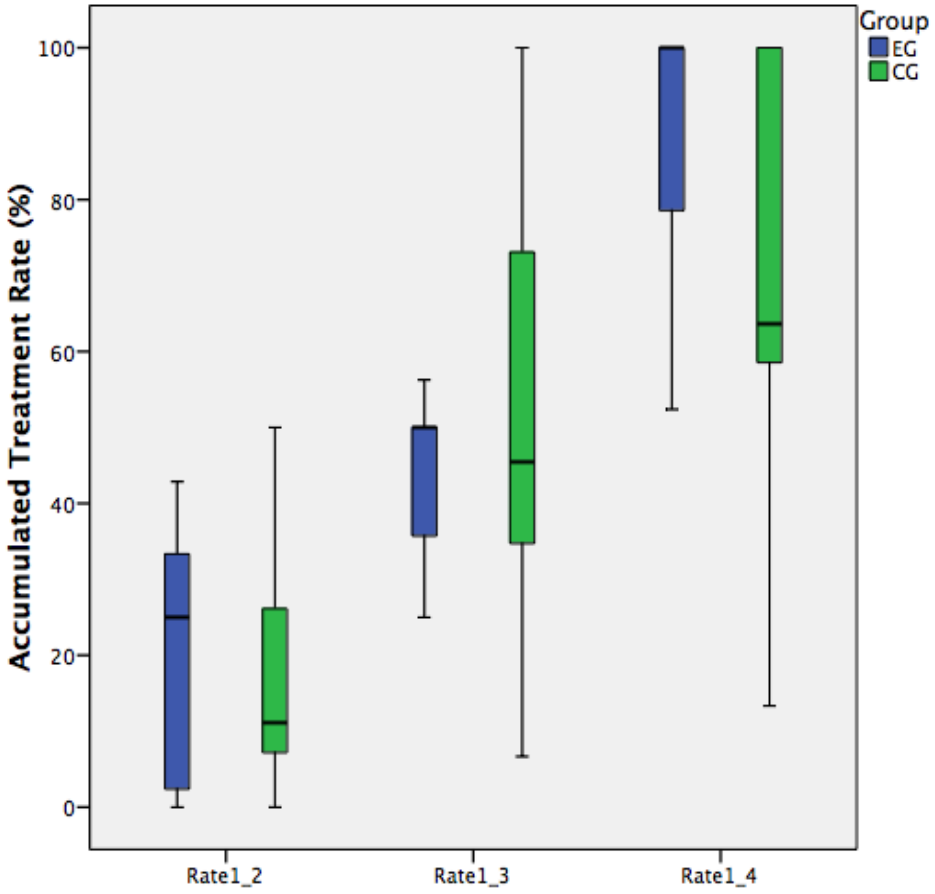

Figure 10. Box Plot of Treatment Rates Between the Two Groups According to ICIQ Scores

5.2.5. GLM Repeated Measure

General linear model (GLM) repeated measure was used for pre-treatment results and for results after the first, second, and third treatments. Wilks' lambda distribution was used for multivariate test results, which were statistically highly significant ($p = 0.001$). However, the interaction of the treatment group was not statistically significant ($p = 0.188$). This suggests that the changes in ICIQ values after each successive treatment are significant, but the patterns in which the values change are similar in the control and experimental groups.

The between-subjects effect shows that the difference between the results of the control group and those of the experimental group is not significant ($p = 0.891$). Figure 11 shows the similar pattern in which the ICIQ values of both groups decrease after each treatment, although the experimental group shows a greater change.

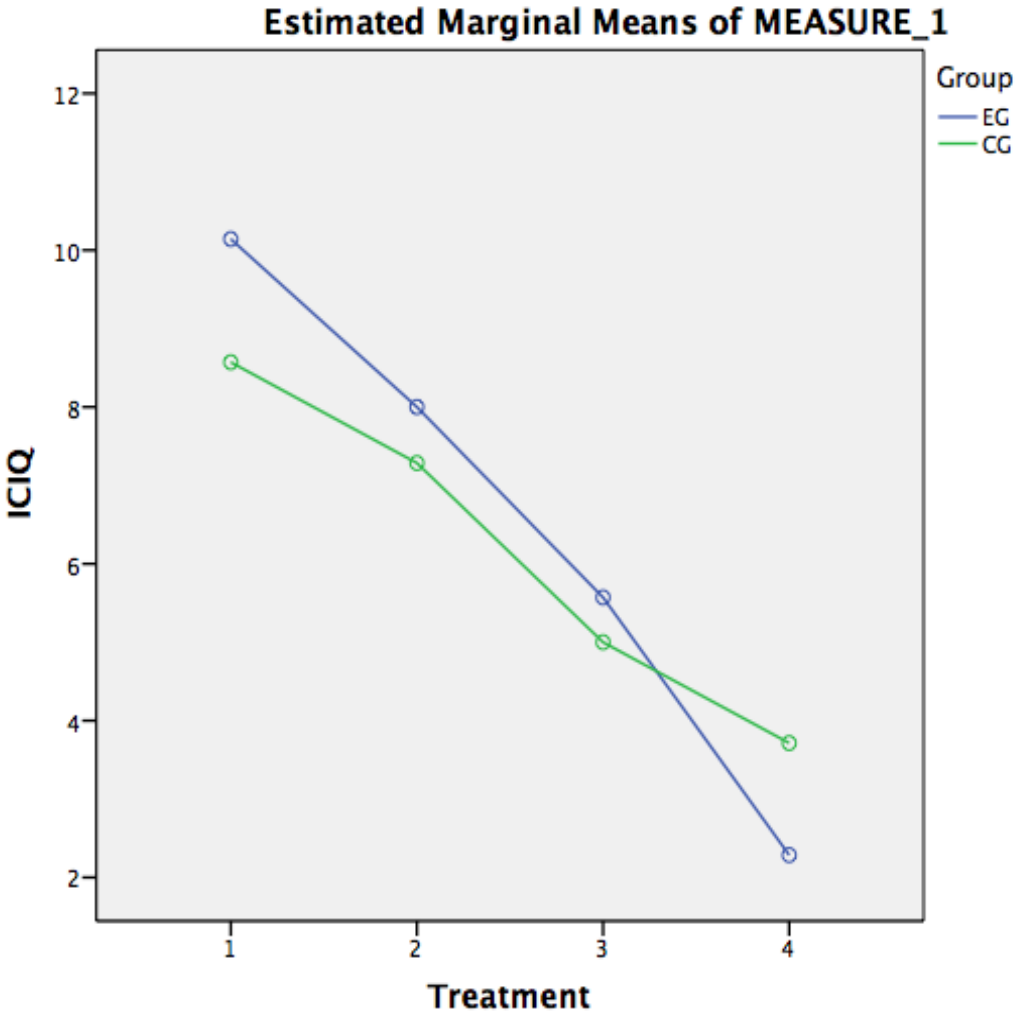

Figure 11. GLM Repeated Measure for Treatments According to ICIQ Scores

VI. CONCLUSION

The study examined 14 urinary incontinence patients who were treated either with only acupuncture or with both acupuncture and the herbal formula *Jiao Wei Suo Quan Wan*.

The findings were as follows:

1. Both the treatment administered to the control group and that of the experimental group yielded results that were statistically significant. In comparing the ICIQ scores between the two groups, the experimental group had a greater treatment effect, indicating higher effectiveness in the treatment plan that combined acupuncture and the herbal formula, but the results did not show them to be statistically significant.
2. The study concludes that treatment with only acupuncture yields high treatment success rates, but the addition of *Jia Wei Suo Quan Wan* may enhance the effectiveness of the treatment.

This study contributes to preexisting findings about the effectiveness of acupuncture in improving symptoms of urinary incontinence. Improvements in patients of both groups after treatment that included acupuncture was statistically significant. Although the addition of herbs to the treatment proved to enhance the effectiveness of the treatment plan that included acupuncture, further study is necessary to determine whether the herbal formula *Jiao Wei Suo Quan Wan* can be used on its own as an effective treatment for urinary incontinence.

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APPENDIX A

Informed Consent Form

We invite you to take part in a research study that seeks to identify an effective means of treating urinary incontinence. Taking part in this research is entirely voluntary. If you decide to participate, you must sign this form to declare your intent to join the study as a participant.

The purpose of this research is to compare the effectiveness of treatment that consists of both acupuncture and herbal medicine to the effectiveness of treatment with only acupuncture. This research aims to improve existing treatment protocols and develop systemic treatment plans for middle-aged and elderly patients with urinary incontinence.

Participants will be required to complete a 72-hour bladder diary every week and to fill out the ICIQ-SF (International Consultation on Incontinence Questionnaire) at the beginning of each treatment session.

All participants will receive acupuncture treatment twice a week. A randomly assigned control group will receive in addition to acupuncture a prescription of herbal pills (*Jiao Wei Suo Quan Wan*) that will be taken daily. The pills contain only natural, plant-based products.

The study will be conducted between July and December 2017. If you agree to take part in this study, your involvement will last approximately three weeks. You will be asked to return to the clinic four times, and each clinic visit will take approximately 45 minutes.

Acupuncture involves the insertion of a thin needle at the surface of the body and manipulation of the needle to induce a mild to moderate sensation of tingling, heaviness, numbness, distention, or electric shock. These sensations may still be present after removal of the needles. Bruising and/or tenderness may occur at the site of needle insertion.

If you participate in the study and feel discomfort during acupuncture, you are urged to communicate with the clinician. The treatment can be modified to reduce intensity.

The possible benefits you may experience include reduced frequency and severity of urinary incontinence. Existing studies have demonstrated that acupuncture and the herbs prescribed in this study may have a positive effect on patients who experience urinary incontinence. However, there is no guarantee that you will benefit from being in this research.

Your research records that are reviewed, stored, and analyzed at South Baylo University will be kept confidential and secure. The records will only be accessed for research purposes.

If you have questions or about this study, you are encouraged to contact Soojeong Kim at atk5389@gmail.com or (213) 220-2050. If you have questions about your rights as a participant or have concerns about privacy, you may contact Dr. Edwin D. Follick, Chair of the South Baylo University Institutional Review Board, at edfollick@southbaylo.edu or (714) 533-6077.

Certificate of Consent

I have had an opportunity to discuss the study, including its possible benefits and risks, and to ask any questions I may have about the study. I have reviewed the information on this form and voluntarily give consent to be included as a participant in the research.

I agree that my signature below means that I have received this information, have asked the questions I currently have about the research, and those questions have been answered.

Participant: By signing below, I am voluntarily choosing to take part in this research.

_____	_____	_____
Printed Name	Signature of Participant	Date

Participant's Legally Authorized Representative: By signing below, I am giving permission for the participant to take part in this research.

_____	_____	_____
Printed Name	Signature of Participant's Legally Authorized Representative	Date

APPENDIX B

International Consultation on Incontinence Questionnaire – Short Form (ICIQ-SF)

☐☐☐☐☐☐☐☐ Initial number

ICIQ-UI Short Form

CONFIDENTIAL

☐☐ ☐☐ ☐☐ DAY MONTH YEAR

Today's date

Many people leak urine some of the time. We are trying to find out how many people leak urine, and how much this bothers them. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the PAST FOUR WEEKS.

1 Please write in your date of birth: ☐☐ ☐☐ ☐☐ DAY MONTH YEAR

2 Are you *(tick one)*: Female ☐ Male ☐

3 How often do you leak urine? *(Tick one box)*

never ☐	0
about once a week or less often ☐	1
two or three times a week ☐	2
about once a day ☐	3
several times a day ☐	4
all the time ☐	5

4 We would like to know how much urine <u>you think</u> leaks.
How much urine do you <u>usually</u> leak (whether you wear protection or not)?
(Tick one box)

none ☐	0
a small amount ☐	2
a moderate amount ☐	4
a large amount ☐	6

5 Overall, how much does leaking urine interfere with your everyday life?
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**
not at all — a great deal

ICIQ score: sum scores 3+4+5 ☐☐

6 When does urine leak? *(Please tick all that apply to you)*

never – urine does not leak	☐
leaks before you can get to the toilet	☐
leaks when you cough or sneeze	☐
leaks when you are asleep	☐
leaks when you are physically active/exercising	☐
leaks when you have finished urinating and are dressed	☐
leaks for no obvious reason	☐
leaks all the time	☐

Thank you very much for answering these questions.

ICIQ (배뇨 설문지)

많은 사람들이 가끔 소변증상을 경험합니다. 저희는 얼마나 많은 사람들이 소변증상을 겪고 있으며 이 소변증상이 **사람들을** 얼마나 성가시게 하는지 알아보려고 합니다. 귀하께서 **지난 4주 동안** 대개 어떻게 지내셨는지 생각하면서 다음의 질문 사항에 답변해 주시면 감사하겠습니다.

1. 귀하는 얼마나 자주 소변을 지립니까? (하나만 표시하십시오)

전혀 지리지 않는다 □ 0
일주일에 한번 정도나 그보다 덜 한 정도 □ 1
일주일에 두세 번 정도 □ 2
하루에 한 번 정도 □ 3
하루에 여러 번 □ 4
매번 □ 5

저희는 귀하가 소변을 얼마나 지린다고 생각하는지 알고 싶습니다.

2. 귀하는 평소에 지리는 소변이 얼마나 됩니까 (요실금 패드를 사용하든 안 하든 상관없이)?
(하나만 표시하십시오)

전혀 없다 □ 0
적은 양이다 □ 2
보통 양이다 □ 4
많은 양이다 □ 6

3. 귀하는 전반적으로 소변을 지리는 것이 귀하의 일상 생활에 얼마나 지장을 줍니까?
0 (전혀 그렇지 않다)에서 10 (매우 그렇다)까지의 숫자에 동그라미 표시하십시오

0 1 2 3 4 5 6 7 8 9 **10**
전혀 그렇지 않다 **매우 그렇다**

ICIQ 점수: 점수합계 1+2+3 □□

4. 귀하는 언제 소변을 지립니까? (해당되는 사항 모두 표시하십시오)

전혀 지리지 않는다 □
변기에 도착하기 전에 지린다 □
기침이나 재채기를 할 때 지린다 □
자는 동안에 지린다 □
과격한 운동을 할 때 지린다 □
소변을 보고 나서 옷을 입을 때 지린다 □
확실한 이유 없이 소변을 지린다 □
매번 지린다 □

ICIQ-UI Short Form (Spanish)

Nº del participante Iniciales del participante **CONFIDENCIAL**

D D M M M A A
Fecha de hoy

Hay mucha gente que en un momento determinado pierde orina. Estamos intentando determinar el número de personas que presentan este problema y hasta que punto les preocupa esta situación. Le estariamos muy agradecidos si nos contestase las siguientes preguntas, pensando en como se ha encontrado en las ÚLTIMAS CUATRO SEMANAS.

1 Por favor escriba la fecha de su nacimiento:

DIA MES AÑO

2 Usted es *(señale cual)*: Mujer ☐ Varon ☐

3 ¿Con que frecuencia pierde orina? *(Marque una)*

nunca ☐	0
una vez a la semana o menos ☐	1
dos o tres veces a la semana ☐	2
una vez al dia ☐	3
varias veces al dia ☐	4
continuamente ☐	5

4 No gustaría saber su impresión acerca de la cantidad de orina que usted cree que se le escapa.

Cantidad de orina que pierde habitualmente (tanto si lleva protección como si no) *(Marque uno)*

no se me escapa nada ☐	0
muy poca cantidad ☐	2
una cantidad moderada ☐	4
mucha cantidad ☐	6

5 Estos escapes de orina que tiene cuanto afectan su vida diaria?

Por favor marque un círculo en un número entre 0 (no me afectan nada) y 10 (me afectan mucho)

0 1 2 3 4 5 6 7 8 9 **10**

nada mucho

Puntuación de ICI-Q: sume las puntuaciones de las preguntas 3+4+5 ☐ ☐

6 ¿Cuando pierde orina? *(Señale todo lo que le pasa a usted)*

nunca pierde orina ☐
pierde orina antes de llegar al WC ☐
pierde orina cuando tose o estornuda ☐
pierde cuando duerme ☐
pierde orina cuando hace esfuerzos fisicos /ejercicio ☐
pierde orina al acabar de orinar y ya se ha vestido ☐
pierde orina sin un motivo evidente ☐
pierde orina de forma continua ☐

Muchas gracias por contestar esta preguntas.