

**SOUTH BAYLO UNIVERSITY**

**Effects of Electroacupuncture for Weight Loss in Obese Women:**

**A Randomized Controlled Trial**

**by**

**YOUNG CHUN YOU**

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***DISSERTATION OF YOUNG CHUN YOU***  
***APPROVED BY RESEARCH COMMITTEE***



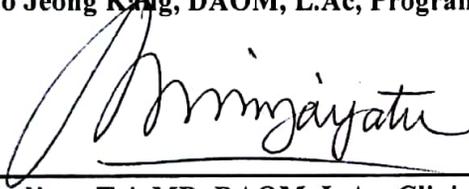
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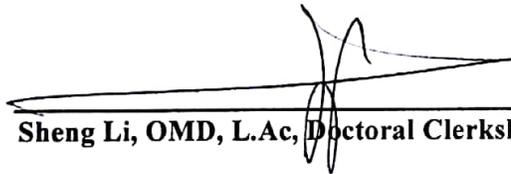
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# **Effects of Electroacupuncture for Weight Loss in Obese Women:**

## **A Randomized Controlled Trial**

**YOUNG CHUN YOU**

**SOUTH BAYLO UNIVERISTY AT ANAHEIM, 2018**

**Research Advisor: Eddie S. Hong, L.Ac., MS, OMD, QME.**

### **ABSTRACT**

Obesity, increasing the risk of diet-related disease has become a worldwide epidemic. The obese level has been constantly going high despite various therapeutic global efforts. For this reason, the eyes of global obesity treatment market turn to oriental medicine and other alternative treatment for obesity. Among current modalities of complementary and alternative medicine, Electroacupuncture(EA) is increasingly used to treat a range of clinical conditions, however the effect of EA for obesity has not yet known in Western. The aim was to examine the effects of EA treatment on weight reduction. Twenty participants were randomly divided into two groups. The treatment group (n=10) received abdomen acupressure, herbal formula plus EA at a frequency of 25 HZ to depth of approximately 15mm (perpendicular insertion) for 15minutes 2 times a week for a month. The control group (n=10) were treated with abdomen acupressure, herbal formula and did not receive EA. After 8 times of treatments, it was achieved to loss  $12.68 \pm 3.61$  (lb) in the treatment group and it was achieved  $10.03 \pm 1.84$  (lb) in the

control group. There were no significant differences for weight loss, BMI loss, and body fat loss treatment duration among the groups. These finding suggest that EA treatment under the condition of 25 HZ to depth of approximately 15mm (perpendicular insertion) for 15minutes may be not an effective intervention for decreasing body weight, visceral fat level reduction and BMI loss in obese women.

## TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	LITERATURE REVIEW	3
III.	MATERIALS AND METHODS	7
IV.	RESULTS	16
V.	DISCUSSION	20
VI.	CONCLUSION	29
VII.	REFERENCES	30
	APPENDIX	35

## LIST OF TABLES

<b>Table 1.</b> Inclusion Criteria and Exclusion Criteria	9
<b>Table 2.</b> Comparison of Baseline Data between the Two Groups	9
<b>Table 3.</b> Acupuncture Points Used for the Treatment of Overweight	11
<b>Table 4.</b> Homogeneity Test of Obesity Index and Self-Confidence between the Two Groups	15
<b>Table 5.</b> Effects of Electro Acupuncture on Obesity Index	17
<b>Table 6.</b> Effect of Weight Loss on Self-confidence and Quality of Life	18
<b>Table 7.</b> Statistics comparing before and after treatment in each group	19

## LIST OF FIGURES

<b>Figure 1.</b>	Trial Profile And Design.	8
<b>Figure 2.</b>	Donbang Needle, (Korea)	10
<b>Figure 3.</b>	ITO ES 160, 6ch device, Japan	10
<b>Figure 4.</b>	Tahara Herbal Formula, Japan	12
<b>Figure 5.</b>	Body Composition Machine InBody, Japan	13
<b>Figure 6.</b>	The Distribution Chart of Changed Body Weight of Two Groups	23
<b>Figure 7.</b>	The Distribution Chart of Changed BMI of Two Groups	23
<b>Figure 8.</b>	The Distribution Chart of Changed Visceral Fat Level of Two Groups	24
<b>Figure 9.</b>	Changes Body Weight in the Two Groups before and after the Intervention	25
<b>Figure 10.</b>	Changes BMI in the Two Groups before and after the Intervention	25
<b>Figure 11.</b>	Changes Visceral Fat Level in the Two Groups before and after the Intervention	26
<b>Figure 12.</b>	The Distribution Chart of Changed Self-confidence of Two Groups	27
<b>Figure 13.</b>	The Distribution Chart of Changed Quality of Life of Two Groups	27
<b>Figure 14.</b>	Changes Self-Confidence in the Two Groups before and after the Intervention	28
<b>Figure 15.</b>	Changes Quality of Life in the Two Groups before and after the Intervention	28

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I would like to thank Eddie S. Hong, L.Ac., MS, OMD, QME, a research advisor at the South Baylo University for acknowledgements. I, moreover, would like to thank Dr. Follick Edwin, Dr. Pia Melen, Dr. Wayne Cheng, Dr. Seng Li, Dr. Sandjaya Tri, Dr. Hyo Jeong Kang, and Dr. Joseph Suh as doctoral research committee members at the South Baylo University.

Finally, I could never have achieved this without the encouragement of parents. I love all my family.

July 2018

Young Chun You

## I. INTRODUCTION

Obesity is a serious health problem and is characterized by contribution of abdominal subcutaneous fat accumulation which has been associated with meal structure and diet composition like additional intake of processed foods and fewer physical activities. Obesity is associated with reduced quality of life and its rate is surprisingly increasing in either developed country or developing ones.<sup>1,2</sup>

Over 50% of Americans are overweight with 20% classified as obese (body mass index  $>30\text{kg/m}^2$ ).<sup>3,4</sup> In Korea, according to 2010 Korean Adults National Health and Nutrition Survey, 31% of Korean adults are obese.<sup>5</sup> Reasons for obesity vary and may include an unbalanced diet, genetics, social and economic factors, insufficient exercise, endocrine disorders, and a variety of mental and emotional disorders.<sup>6</sup> The problem caused by obesity is various chronic disease, such as diabetes, hypertension, arteriosclerosis, hypercholesterolemia, cardiac disease, and cerebrovascular disease. Furthermore, health concerns regarding obesity take into consideration the amount of fat and its distribution. Visceral fat tissue, placed within the peritoneum, peritoneum and encompassing organ, provides free fatty acids and leads to fat deposition within the liver.<sup>7,8</sup> In addition, obesity has been casually linked breast cancer, uterine cancer, and ovarian cancer in women.<sup>9</sup> In southeast Asia, obesity among women was more than double that of men. It is a fact that women are more likely to be obese than men are.<sup>10</sup> Obesity may be more vulnerable to women because of poor metabolism and diminishing hormone effects. In general, primary methods for resolving obesity are drugs, exercise, diet, and behavior modification therapy.<sup>11</sup> More recently the potential value of oriental

medicine approaches, such as herbal medicine, acupuncture, EA and acupressure has become apparent.<sup>12</sup> On these methods, acupuncture is one of the most popular alternative therapies, and it has been used to treat obesity for thousands of years. Besides, electro acupuncture is in which an electric wave is passed through acupuncture needles. The parameters of the EA can be precisely characteristic and the results are reproducible.<sup>13</sup> One study suggest that EA treatment is more effective than manual acupuncture.<sup>14</sup> However the effect of EA on obesity needs has not yet widely known in the west. The clinical trials have not been active for lack of research fund even mainstream of health fields and well-designed trials are in adequate. Thus, we conducted this randomized controlled trials to examine the effects of EA for achieving weight loss in obese women.

## II. LITERATURE REVIEW

### 2.1. Obesity

Obesity can be defined as a disease in which excess body fat has accumulated such that may be adversely affected.<sup>15</sup> Obesity can be occurred when food intake is greater than energy expended. In this situation, the surplus energy contributes the accumulation of fat in the body. Obesity is caused by combination of both genetic and environmental impact and it may proceed at any age as increasing health problem. The excess of fat in men tends to accumulate mainly in the upper abdomen. In the case of women, fat accumulation is considered a major factor for metabolic disorders of obesity.<sup>16</sup>

Obesity has been more exactly determined by the National Institutes of Health as a BMI of 30 and above and obesity becomes a worldwide communal health concerns. Obesity has an adverse effect on all aspects of human life in an unhealthy way and is connected with many diseases. Many research debate that BMI is associated with higher risk of morbidity and mortality. However reducing 10 kilogram can help decrease this risk significantly.<sup>17</sup>

On a literature review, more than 80% of people with diabetic are overweight. It shows that obesity is a major risk factor to develop type 2 diabetes mellitus (DM). The higher the obesity index, the higher the types 2 DM develop. Study of EZ, et, al. concluded weight loss can significantly improve the metabolic control and possibly life expectancy.<sup>18, 19</sup>

According to oriental medicine, obesity is a disease arising from qi and blood

stagnation and its source is phlegm-dampness. The mechanism of oriental medicine is a slow process of coordinating the human vitality, and that it happens with the combination of acupuncture and herbal medicine for two to three months period.

### **Oriental Medicine diagnoses overweight and obesity into four types**

1. Excessive Internal Phlegm and Dampness
2. Stagnation of Qi (vital energy) and Blood
3. Yang Deficiency of Spleen and Kidney
4. Liver Qi Stagnation

### **2.2. ACUPRESSURE - TUI NA**

Meridian is a combination of Jing and Luo channel, and it is a way of qi and blood flow. Within the body it communicates up and down, inside and outside, and carries the blood of the whole body and harmonizes the yin and yang to control the functional activity. Because the human body is a living organism, if the meridian is clogged, various diseases can be occurred. Acupressure-Tui na refers to the technique of applying constant and moderate pressure to the acupuncture points. It is a way to smooth the flow of body meridians, which is the passage of blood and the energy flowing through the human body. It also promotes the natural healing power of the physiological function and pathological changes of the human organ system. Acupressure-Tui na accelerates the flow of blood and lymph fluid to stimulate metabolism, moreover the constant acupressure treatment regulates autonomic nervous system failure. This increases immune function by enhancing natural healing power.

### **2.3. Electroacupuncture**

EA is the stimulation of acupuncture points by passing electricity between acupuncture needles and electric stimulation is applied for commonly 15~20 minutes. The study of EA for obesity has been actively carried out since 1992.<sup>20, 21, 22</sup>

EA is one of important modalities in oriental obesity therapy. In recent years, access to obesity information has become easier for medical consumer and evidence-based medical theory is strongly required.

For the attention of EA, when selecting acupuncture points, the two points should not be crossed the Ren meridian which is the center line of the body, and a patient with heart pacemaker is forbidden to have EA.

### **2.4. BMI**

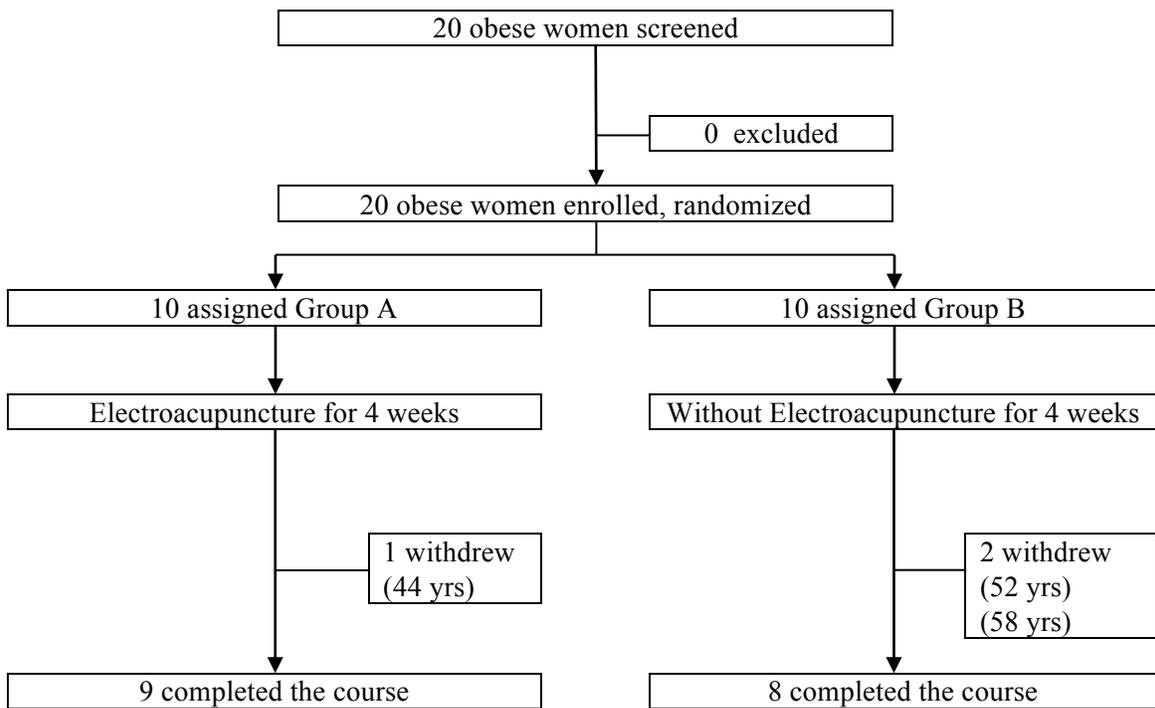
BMI is the calculation defined as the weight in kilograms divided by the square of the height in meters. This measurement has been used over 100 years for health professional to measure the degree of obesity and BMI was introduced in the 1830s by a Belgian astronomer, statistician, mathematician, Lambert Adolphe Jacques Quetelet. For a long time this measurement is used as an indicator of whether you are at risk for obesity. Therefore BMI provides the most useful and practical population-level indicator of overweight and obesity in adult. However obesity classification using BMI values are varied from Asian to Caucasian. Many researches shows that Asian population had more fat in the comparison of Caucasian and this means that for Asian BMI of 25 was considered to be severe obese. The Japanese have clarified obesity as above 25 of BMI<sup>23</sup> and for China great than 28 of BMI defined as obesity.<sup>24</sup>

In the view of Western, in the graded classification system developed by the World Health Organization, a BMI of  $30\text{kg/m}^2$  or above denotes obesity, and a BMI of  $25\text{kg/m}^2$  or above denotes overweight.<sup>25</sup> The criteria for obesity in Asia Pacific is BMI  $23\sim 24.9\text{kg/m}^2$  or more is considered high altitude obesity. In other words world obesity standard is more than  $30\text{kg/m}^2$ .

### **III. MATERIALS AND METHODS**

#### **3.1. Study design and participants**

This study was approved by the IRB of South Baylo University in Los Angeles, California and carried out between March 2018 and May 2018 at an acupuncture clinic in San Jose. All participants were female aged between 30 and 65 years old with a body mass index between 23 and 35. Table 1 show the inclusion criteria and exclusion criteria and table 2 indicate comparison of baseline data between the two groups. Total eight times of treatments were applied to all participants. All subjects had no history of a major medical or psychiatric illness and with prior experience of EA. Figure 1 show trial profile and design. They were required to give written informed consent before the trial started. All participants were informed about the purpose of the study and assured of their confidentiality; it was clearly indicated that this study's participation was voluntary and participants could withdraw at any time.



**Figure 1.** Trial Profile And Design.

**Table 1.** Inclusion Criteria and Exclusion Criteria

---

**Inclusion criteria**

1. Age between 30 and 65 years old
2. Body mass index <35 kg/m<sup>2</sup>

**Exclusion criteria**

1. Pregnant or lactating women
2. Childbirth within 6 months
3. Heart disease, for example, patient with pacemaker, myocardial infraction, cardiac failure
4. Endocrine disease, for example, thyroid disorder
5. Stroke or otherwise unable to exercise

**Table 2.** Comparison of Baseline Data Between The Two Groups

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	Treatment group	Control group	P
Age (years)	50.3±9.1	52.5±7.8	0.6
30≤BMI<35 (n)	2	1	—
23≤BMI<30 (n)	7	7	—

---

BMI, body mass index

### 3.2. Interventions and procedure

EA points were chosen based on oriental medicine theory for the obese. The EA treatment principles were invigorating qi, eliminating spleen dampness, and nourishing the kidney. The acupoints were St25 (Tianshu), St28 (Suidao), Sp14 (Fujie), Sp15 (Daheng), Kd14 (Siman) and Kd15 (Zhongzhu). The stainless-steel acupuncture needles (0.25\*40mm) were inserted to depth of approximately 15mm (perpendicular insertion) after using skin sterilization procedures (Figure 2). EA was applied for 15minute two times in a week to EA treatment group and were performed by using a ITO-ES 160 6CH device (ITO ELECTRO THERAPEUTIC DEVICE, JAPAN) (Figure 3) that conveyed an electrical stimulus at a frequency of 25HZ with positive and negative alternation. Acupressure was applied by hands to all participants for 15minutes and it was performed by an expert acupuncturist. Table 3 shows the names, locations and indication of acupuncture points for the EA treatment.



**Figure 2.** Donbang Needle(Korea)



**Figure 3.** ITO ES 160, 6ch device, Japan

**Table 3.** Acupuncture Points Used for the Treatment of Overweight

Acupoints	Location of Acupoints	Indications
ST25 (Tianshu)	On the middle of the abdomen, 2 cun lateral to the umbilicus.	Abdominal distention, borborygmus, pain around the umbilicus, constipation, diarrhea, dysentery  Irregular menstruation, mass and gathering in the abdomen, amenorrhea
ST28 (Suidao)	On the lower abdomen, 3 cun below the center of the umbilicus, 2 cun lateral to the anterior median line	Lower abdominal distention, dysuria Dysmenorrhea, infertility, hernia Constipation
Sp14 (Fujie)	On the lower abdomen, 1.3 cun below SP 15, 4 cun from the anterior midline of the body.	Pain around the umbilical region, abdominal distention, diarrhea, constipation Hernia
Sp15 (Daheng)	On the middle of the abdomen, 4 cun lateral to the center of the body.	Diarrhea, constipation, abdominal pain
Kd14 (Siman)	On the lower abdomen, 2 cun below the center of the umbilicus, 0.5 cun lateral to the anterior midline.	Abdominal pain and distention, diarrhea, edema  Irregular menstruation, dysmenorrhea
Kd15(Zhongzhu)	On the lower abdomen, 1 cun below the center of the umbilicus, 0.5 cun lateral to the anterior midline.	Irregular menstruation, dysmenorrhea  Abdominal pain, constipation, diarrhea

### 3.3. Diet and Exercise

A 1450kcal/day was the amount chosen to give a diet over their basal metabolism and all participants drank 100ml/day of fermented herbal formula (Tahara vegetable and fruits fermented juice, JAPAN)(Figure 4) after meals for 4 weeks. All participants were allowed to maintain their usual exercise levels. However intense or unusual workout not permitted.



100% organic ingredients which have undergone a 2-year fermentation process. Fermentation keeps all the beneficial micro-organisms present which help the digestive tract stay healthy and active, moving waste and optimizing the immune system.

**Figure 4.** Tahara Herbal Formula (JAPAN)

### 3.4. Outcome measures

In the study, a model Inbody-570 body composition analyzer (FDA class 2 registered, GSA certified, USA) that was a biological electric instrument was used to measure the obesity index: BMI, % Body Fat and Visceral Fat Level (VFL). Height (ft) was measured with a model HF-200 apparatus (Fanics, Korea). Level change of self-confidence and quality of life was evaluated using a 10cm Visual Analogue Scale(VAS; '0' representing the most negative rating and '10' representing the most positive rating) and participants were asked to mark their level at their first visit and last visit. (Figure 9, 10)



**Figure 5.** Body Composition Machine InBody 570/ 2017 (JAPAN)

### **3.5. Data analyses**

Data were analyzed using SPSS software, for windows (SPSS, Chicago, Illinois). For all the analyses, a value of  $p < 0.05$  was regarded as statistically significant. In this study, sample size for two each group were  $n=9$ (treatment group) and  $n=8$ (controlled group). Table 4 shows homogeneity test of obesity index and self-confidence between the two groups. Both of independent t-test as parametric test and Mann-Whitney test as non-parametric test were used for the mean of the independent sample, The effect of EA were evaluated with a paired t-test, independent samples t-test compared the means for two groups. Missing value in test score were considered missing at random.

**Table 4.** Homogeneity Test of Obesity Index And Self-Confidence Between The Two Groups (N=17)

Variable	Treatment group (n=9)	Control group (n=8)	t	p-Value
Body Weight (lb)	157.40±21.72	151.92±25.59	0.47	0.644
BMI(kg/m <sup>2</sup> )	27.01±3.79	26.67±3.72	0.18	0.856
Visceral Fat Level	12.33±4.00	12.62±4.50	-0.14	0.890
Self-confidence	4.11±0.78	4.25±0.70	-0.38	0.706

Values are expressed as mean ± standard deviation.

#### **IV. RESULTS**

We allocated randomly the participants into two groups by computer and 17 subjects completed the study (Figure1). Table 5 shows the comparison results between two group and indicated BW, BMI and VFL of the both group. Table 6 shows effect of weight loss on self-confidence and quality of life. Table 7 shows statistics comparing before and after treatment in each group. After 8 times of treatments, the BW ( $P=0.076$ ), BMI ( $P=0.049$ ) and VFL ( $P=0.935$ ) were achieved. Self-confidence and quality of life were improved in both groups. As can be seen, there were no significant difference in all the measurements between the control group and the treatment group.

**Table 5.** Effects of Electro Acupuncture on Obesity Index (N=17)

Variable	Pretest	Post-Test	Pre-Post	t	p-Value
Body Weight (lb)					
Treatment group	157.40±21.72	144.71±20.34	12.68±3.61	1.93	.076
Control group	151.92±25.59	141.88±24.25	10.03±1.84		
BMI(kg/m <sup>2</sup> )					
Treatment group	27.01±3.79	24.83±3.68	2.17±0.40	2.15	.049
Control group	26.67±3.72	24.93±3.44	1.73±0.43		
Visceral Fat Level					
Treatment group	12.33±4.00	9.66±4.38	2.66±1.00	0.08	.935
Control group	12.62±4.50	10.00±3.77	2.62±1.06		

Values are expressed as mean ± standard deviation.

**Table 6.** Effect of Weight Loss on Self-confidence And Quality of Life (N=17)

Variable	Pretest	Post-Test	Post-Pre	t	p-Value
Self-confidence					
Treatment group	4.11±0.78	6.11±0.60	2.00±0.86	0.65	.523
Control group	4.25±0.70	6.00±0.75	1.75±0.70		
Quality of life					
Treatment group	4.33±0.70	6.78±1.09	2.44±1.23	1.81	.096
Control group	4.63±0.51	6.25±0.46	1.63±0.51		

Values are expressed as mean ± standard deviation.

**Table 7.** Statistics comparing before and after treatment in each group

Variable	Pretest	Post-Test	Pre-Post	t	p-Value
Body Weight (lb)					
Treatment group	157.40±21.72	144.71±20.34	12.68±3.61	10.516	.000
Control group	151.92±25.59	141.88±24.25	10.03±1.84	15.397	.000
BMI(kg/m <sup>2</sup> )					
Treatment group	27.01±3.79	24.83±3.68	2.17±.40	16.235	.000
Control group	26.67±3.72	24.93±3.44	1.73±.43	11.237	.000
Visceral Fat Level					
Treatment group	12.33±4.00	9.66±4.38	2.66±1.00	8.000	.006*
Control group	12.62±4.50	10.00±3.77	2.62±1.06	7.000	.000
Self-confidence					
Treatment group	4.11±0.78	6.11±.60	-2.00±.86	-6.928	.006*
Control group	4.25±0.70	6.00±.75	-1.75±.707	-7.000	.000
Quality of life					
Treatment group	4.33±.70	6.77±1.09	-2.44±1.23	-5.933	.000
Control group	4.62±0.51	6.25±0.46	-1.62±0.51	-8.881	.009*

Values are expressed as mean ± standard deviation.

Paired Sample T test

\*Wilcoxon Signed Ranks Test

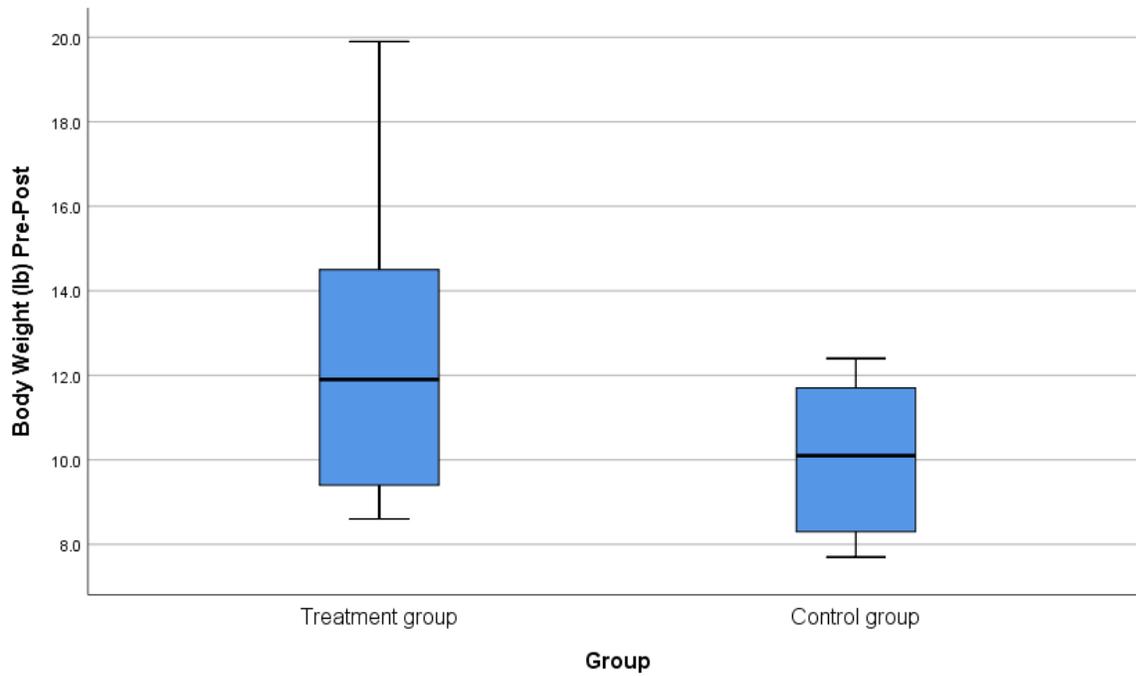
## V. DISCUSSION

According to a recent survey, over 40% of US adults use alternative medicine.<sup>26</sup> Due to the increasing prevalence of obesity; it is not surprising that safe and effective alternative treatments for weight control are very desirable. Many modern studies have reported on the beneficial effects of EA for obesity control.<sup>27, 28</sup> In addition, most of study reports indicated that body EA and abdominal acupuncture were effective for weight reduction in obese subjects.<sup>29, 30, 31</sup> There are some negative result of study also existed.<sup>32</sup> Excessive body fat, especially abdominal fat is affected by EA treatment.<sup>33</sup> Studies of fat cell reduction have actively been conducting in several ways for a long time. One is that the electric current passes into the muscle generating heat which is causing an increase of blood flow or circulation in affected area. Secondly catecholamines are released from the nerve endings stimulated by electricity. In addition, the lipolytic receptor; beta-2-adrenoreceptor in human fat cells is stimulated by electric current. All of these theories give an explanation how EA loosen up the breakdown of human fat cells and how EA reconstruct it. Moreover, other study found that with the plasma endorphin levels increased can give away the fat cells as well.<sup>34</sup> A diversity of mechanisms are proved with EA. On a recently conducted literature review draw to a closer that EA give rise to a significantly dominant amount of weight loss than sham through its regulatory effects on neurotransmitters.<sup>35</sup> The process that lead to this result is that electric currents can be passed through different frequency: low (2 ~ 4 Hz) or high frequency (100 ~ 120 Hz), and noteworthy, different frequencies have shown to selectively produce the release of various neuropeptides.<sup>36</sup>

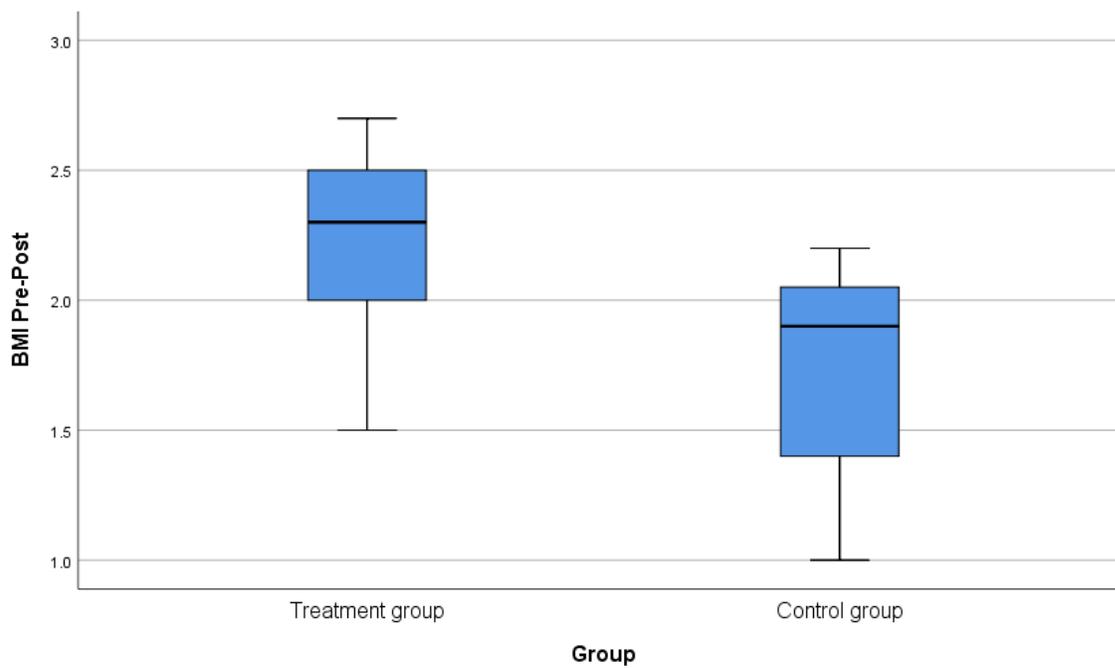
Low frequencies (2~4 Hz) release Met-enkephalins and beta-endorphins, however dynorphins (Dyn) are proven to be yielded in higher frequencies at 100 Hz.<sup>37</sup> Serotonins has also released as well with either low or high frequency and the combination of these all principal can suppress appetite, food craving, depression, and pain as well.<sup>38, 39, 40</sup> Interestingly there was also a study comparing EA and sit-up exercise in reducing weight. Study of CH et al., concluded that EA treatment is slightly effective than sit-up exercise reduction for weight reduction. Effects of EA in reducing weight and waist circumference in obese women: a randomized. This study attempted to identify the effect of EA in obese women, and found it is difficult to expect a superior effect even if the EA is added. Thus, adding EA treatment does not maximize the effect of body weight reduction. Table 5 analyzed Body weight, BMI, and Visceral Fat Level after the intervention and weight decreased by 12.68±3.61 (lb) in the treatment group and by 10.03±1.84 in the control group (Figure 6, 7, 8, 9, 10, 11). There was no statistically significant difference between the two groups in body weight change (t=1.93; p=0.076). In addition, BMI decreased by 2.17±0.40kg/m<sup>2</sup> in the treatment group and by 1.73±0.43kg/m<sup>2</sup> in the control group. BMI change did not differ between the two groups (t=2.15; p=0.049). Visceral fat level decreased by 2.66±1.00 and 2.62±1.06 in the experimental and control groups, respectively. Moreover the difference was not significant (t=0.08, p=0.935). In the study, participants were asked to mark their level self-confidence and quality of life and it was evaluated using a 10cm Visual Analogue Scale (VAS). The average score for total self-confidence increased by 2.00±0.86 and 1.75±0.70 in the experimental and control groups respectfully (Table 6, Figure 12, 13, 14, 15). There was no statistically significant difference between two groups in the total self-confidence score (t=0.65, p=0.523) (Table

6). In addition, change of life of quality in the treatment group was higher than in the control group; however there were no significant difference before and after intervention between the two groups( $t=1.818$ ,  $p=0.096$ ). In the study diet and exercise was self-administered and it was difficult to confirm whether or not they had the right amount of exercise and daily calories given to them for a month. It was hard to know the process was done accurately although each participant was encouraged by means of daily text messages and cell phone calls to exercise and eat properly. In addition, the sample size was small; this may have produced insignificant results in some of the study variables because of the lack of power.

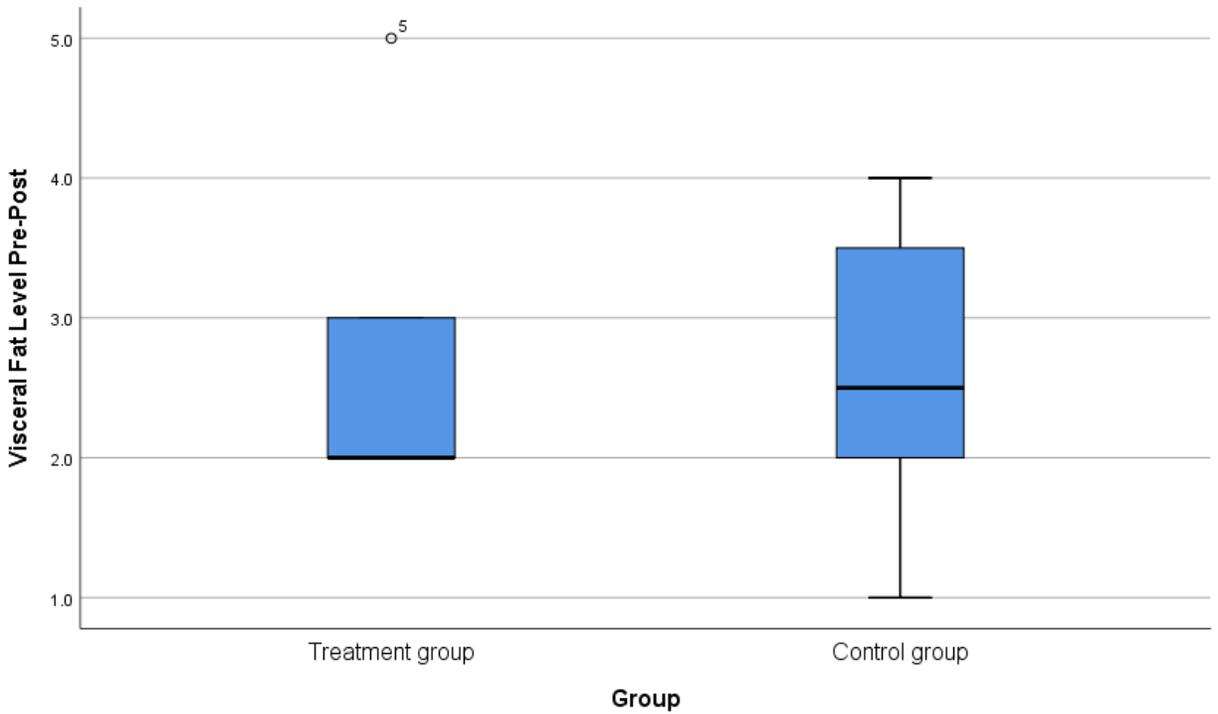
Despite the supporting results, this study met limitation, such as the difficulties of selecting suitable control or treatment group, the carry-over effect in the second stage and the short duration. Studies of a longer period of follow-up and various sets of electricity with other EA points should be considered in future study. Selected and other well designed protocols should be performed in the future as well.



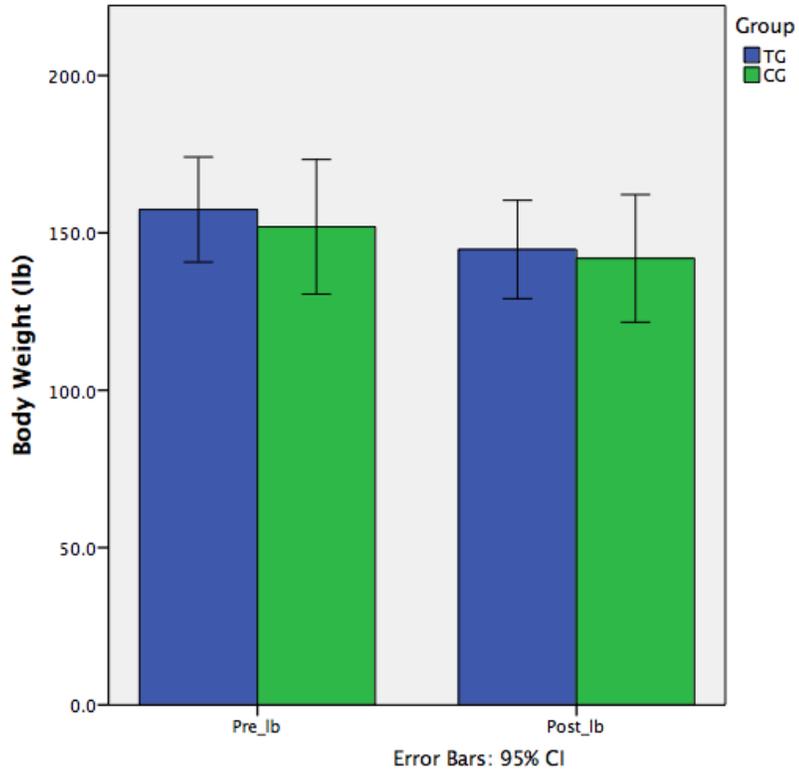
**Figure 6.** The Distribution Chart of Changed Body Weight of Two Groups



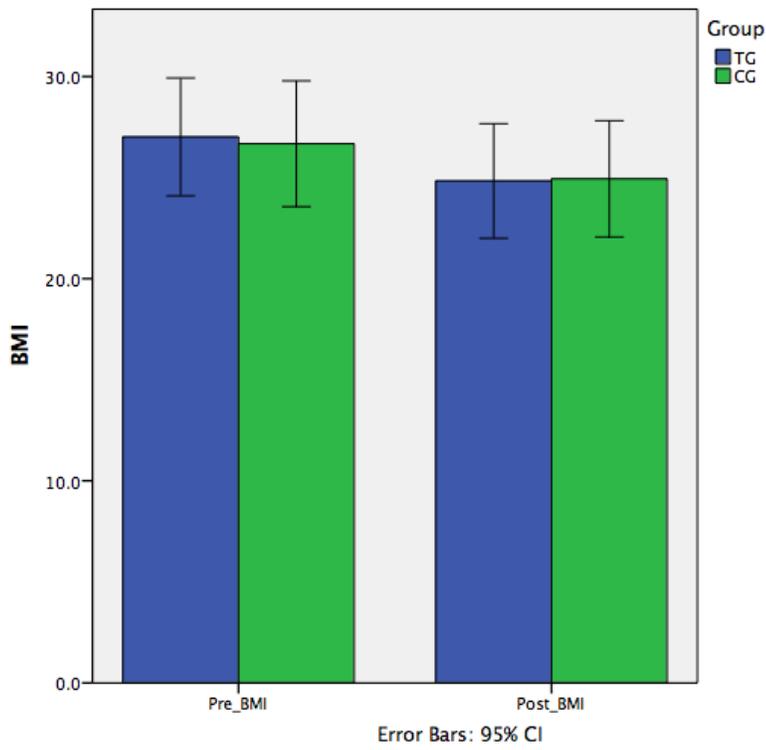
**Figure 7.** The Distribution Chart of Changed BMI of Two Groups



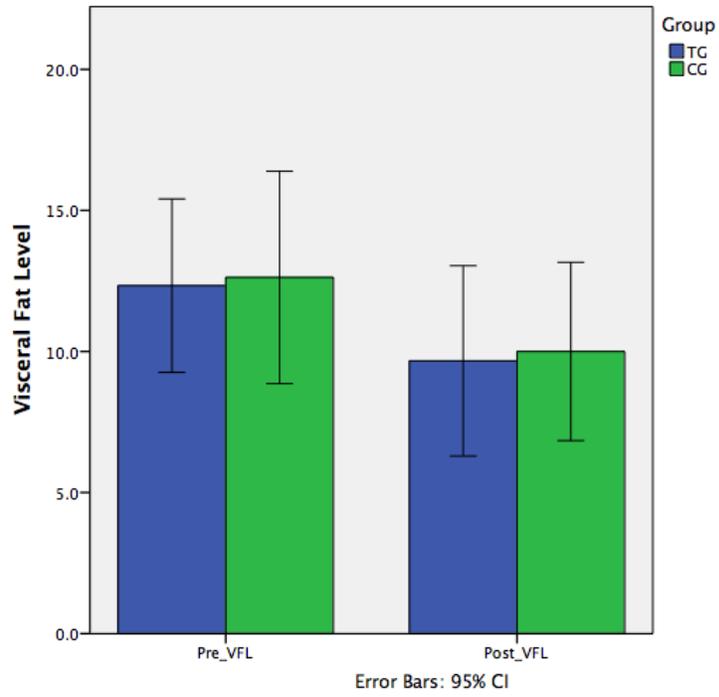
**Figure 8.** The Distribution Chart of Changed Visceral Fat Level of Two Groups



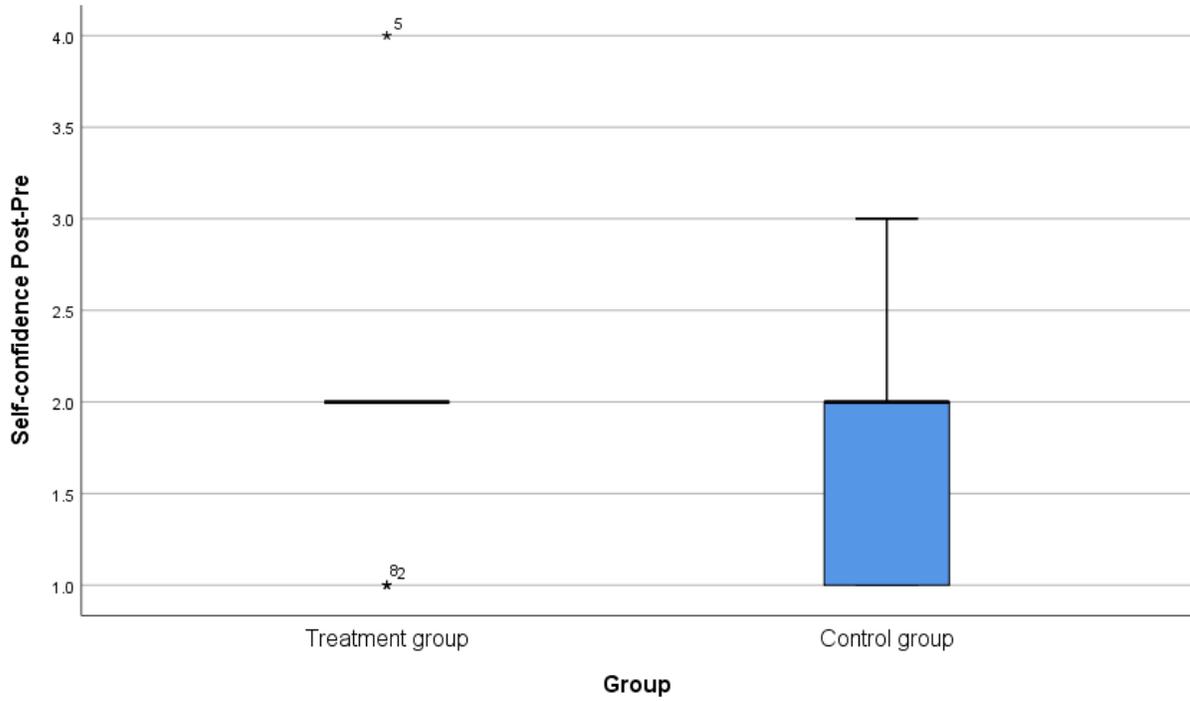
**Figure 9.** Changes Body Weight in the Two Groups before and after the Intervention



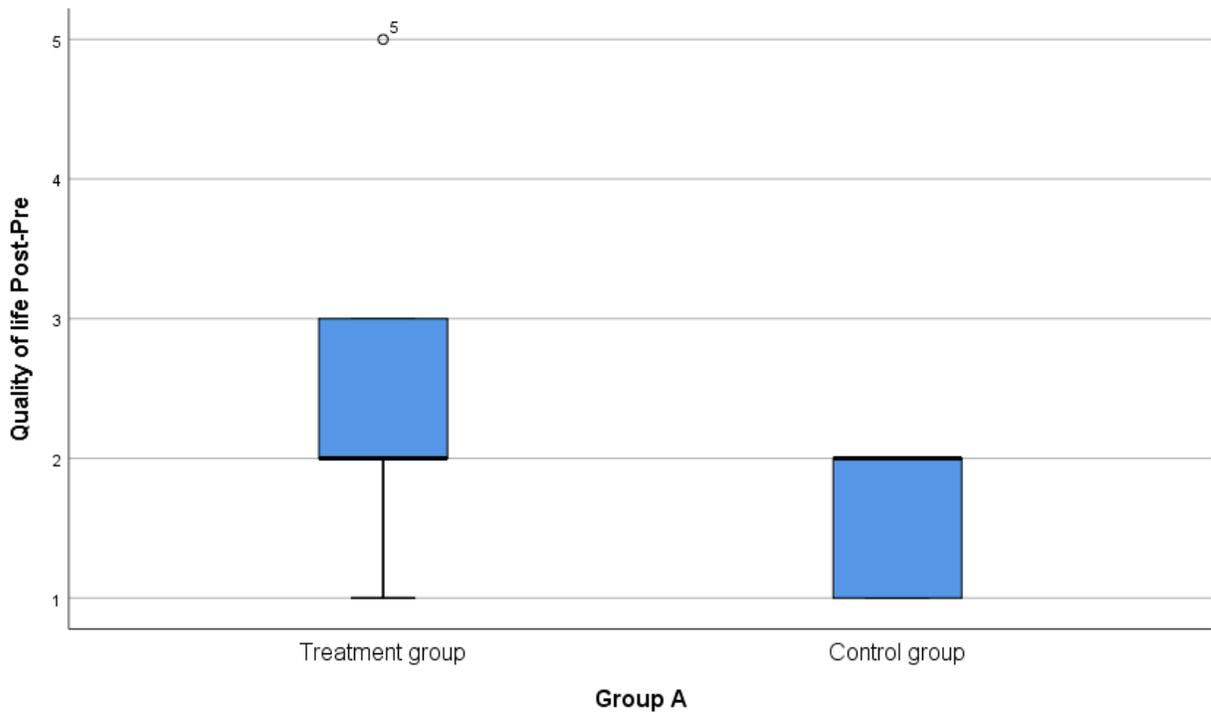
**Figure 10.** Changes BMI in the Two Groups before and after the Intervention



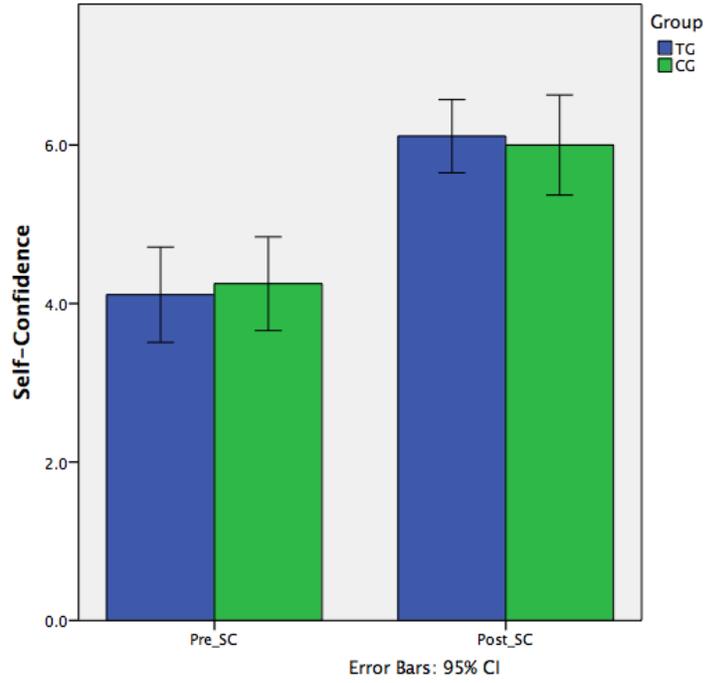
**Figure 11.** Changes Visceral Fat Level in the Two Groups before and after the Intervention



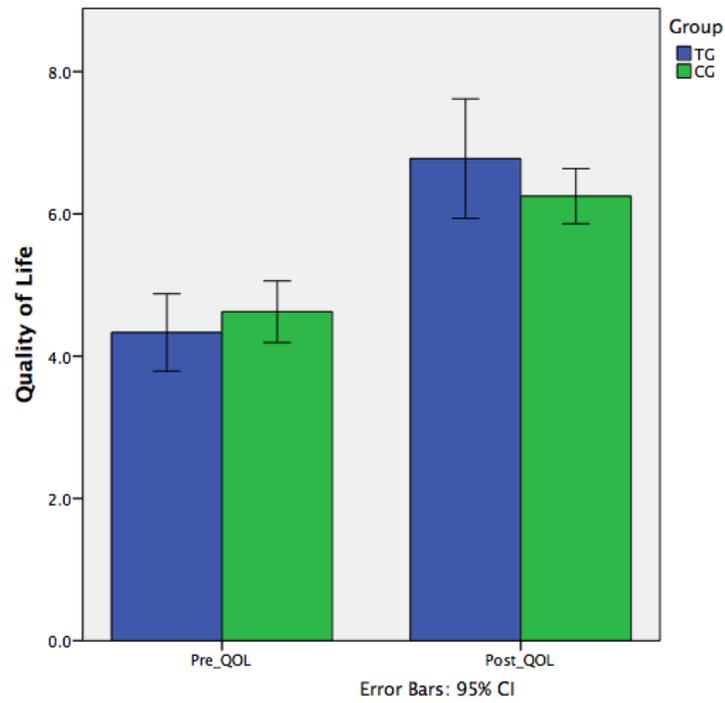
**Figure 12.** The Distribution Chart of Changed Self-confidence of Two Groups



**Figure 13.** The Distribution Chart of Changed Quality of Life of Two Groups



**Figure 14.** Changes Self-Confidence in the Two Groups before and after the Intervention



**Figure 15.** Changes Quality of Life in the Two Groups before and after the Intervention

## **VI. CONCLUSION**

We found the results of the treatment group receiving diet, herbal formula, abdominal acupressure, and electrical stimulation at a frequency of 25 HZ to depth of approximately 15mm (perpendicular insertion) for 15minutes did not make a difference in the result of the control group with diet, herbal formula and abdominal acupressure. Therefore this randomized controlled study demonstrates that EA treatment under the condition of 25 HZ to depth of approximately 15mm (perpendicular insertion) for 15minutes does not play a big role in reducing BW, BMI and VFL.

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## APPENDICES

### **Informed Consent Form**

**You are being asked to take part in a research study about Effects of Electroacupuncture for Weight Loss in Obese Women.**

Before you decide to participate in this study, it is important that you understand why the research is being done and what it will involve. Please read the following information carefully. Please ask the researcher if there is anything that is not clear or if you need more information

**The purpose of this study** is to examine the effects of EA for achieving weight loss in obese women.

**The study design.** This case study aims to observe the Effects of Electroacupuncture and Herbal Enzyme for Weight Loss in Obese Women. This study will use a design with 30 participants. Fifteen out of Thirty participants will be treated with acupuncture, abdomen acupressure, and fermented herbal formula. Fifteen participants will be treated with only herbal formula. The study period will be 4 weeks and participants will have a total of eight visits. The outcomes will be measured every time they visit.

**This study is being conducted by** YOUNG CHUN YOU, 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. At the completion of treatment plans, participants who are treated with oriental medicine weight reduction program in oriental medicine will show a significant weight loss compared to the subject who are treated with herbal formula only.

**By Participating in this research it is possible that you will be at greater risk than you would otherwise be.**

I understand that acupuncture is performed by the insertion of needles through the skin or by the application of heat to the skin (or both) at certain points on or near the surface of the body in an attempt to treat bodily dysfunction or diseases, to modify or prevent pain perception, and to normalize the body's physiological functions. I am aware that certain adverse side effects may result. These could include, but are not limited to: local bruising, minor bleeding, fainting, pain or discomfort, and the possible aggravation of symptoms existing prior to acupuncture treatment. I understand that no guarantees concerning its use and effects are given to me and that I am free to stop acupuncture treatment at any time.

You may decline to answer any or all questions and you may terminate your involvement at any time if you choose.

**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.** Your responses to this Effects of Electroacupuncture and Herbal Enzyme for Weight Loss in Obese Women will be anonymous. Please do not write any identifying information on your Effects of Electroacupuncture and Herbal Enzyme for Weight Loss in Obese Women. OR For the purposes of this research study, your comments will not be anonymous. Every effort will be made by the researcher to preserve your confidentiality including the following:

[State measures taken to ensure confidentiality, such as those listed below:

- Assigning code names/numbers for participants that will be used on all research notes and documents
- Keeping notes, interview transcriptions, and any other identifying participant information in a locked file cabinet in the personal possession of the researcher.

Participant data will be kept confidential except in cases where the researcher is legally obligated to report specific incidents. These incidents include, but may not be limited to, incidents of abuse and suicide risk. It will not be shared with or given to anyone except YOUNG CHUN YOU , L.Ac.

**Voluntary Participation** Your participation in this study is voluntary. It is up to you to decide whether or not to take part in this study. If you decide to take part in this study, you will be asked to sign a consent form. After you sign the consent form, you are still free to withdraw at any time and without giving a reason. Withdrawing from this study will not affect the relationship you have, if any, with the researcher. If you withdraw from

the study before data collection is completed, your data will be returned to you or destroyed.

**If you have any questions about this study, please contact** YOUNG CHUN YOU, L.Ac. at 1-831-295-0916 and [thankyoucm@gmail.com](mailto:thankyoucm@gmail.com). If you have any questions or concerns regarding your rights as a subject in this study, you may contact Dr. Jae Jong Kim, Chair of the South Baylo University. Institutional Review Board (IRB) at 213-738-0712 or [jaejongkim621@gmail.com](mailto:jaejongkim621@gmail.com).

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

## Certificate of Consent:

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

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Name of Participant (Print)

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Name of Witness (Print)

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Signature of Participant

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Signature of Witness

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Date: Day/Month/Year

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Date: Day/Month/Year

**Statement by the researcher/person taking consent:**

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

A copy of this ICF has been provided to the participant

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Print Name Researcher (Print)

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Signature of Researcher

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Date: Day/Month/Year