SOUTH BAYLO UNIVERSITY

Comparison between the Effect of Auricular Acupuncture and Body Acupuncture on Smoking Cessation or Reduction: a Randomized Controlled Trial

by

Mika Sugano-Isa

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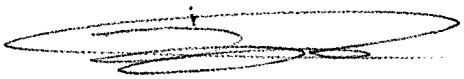
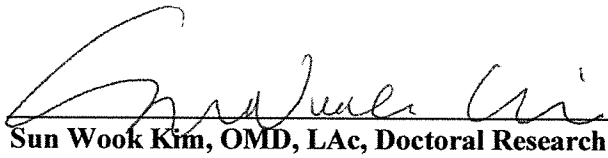
Yisung Lee, MD, PhD, Academic Dean



Shan Qin Cui, MD, OMD, LAc, Professor

Soo Gyung Kim, OMD, LAc, Doctoral Program Student Advisor



Sun Wook Kim, OMD, LAc, Doctoral Research Coordinator

Sung Hwan Yun, PhD, LAc, Doctoral Research Project Coordinator

South Baylo University

Los Angeles, California

March 14, 2015

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Mika Sugano-Isa

South Baylo University at Los Angeles, 2015

Research Advisor: Dr. Meredith Chunyi Qian, M.D. (China), L.Ac

ABSTRACT

Cigarette smoking is the leading cause of preventable death in the United States. Smoking cessation greatly improves life expectancy, reduces morbidity, and decreases health care costs associated with treating smoking-related conditions. Even though smokers may be well aware of these benefits, the addictiveness of nicotine may prevent many from achieving smoking cessation. Acupuncture and acupressure are used to help smokers, though the effectiveness is inconclusive based on the evidence of systematic review. Several trials have shown that acupuncture point stimulation decreases the desire to smoke and decreases tobacco consumption. The objective of this study was to compare the effectiveness between auricular and body acupuncture treatments for the purpose of the reduction of smoking habits via the randomized controlled trial design. This research concluded that four-week auricular or body acupuncture treatments with acupressure using intradermal seeds were significantly effective in decreasing daily cigarette consumption, craving to smoke, and taste of cigarettes. There was no significant difference in the effectiveness between the auricular and the body acupuncture treatment in daily cigarette consumption, craving to smoke, taste of cigarettes, and carbon monoxide level.

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	LITERATURE REVIEW	3
III.	METHODS	11
IV.	RESULTS	18
V.	DISCUSSION	30
VI.	REFERENCES	34
	APPENDICES	
	A. Informed Consent Form	40
	APPENDIX I: English	41
	APPENDIX II: Spanish	43
	APPENDIX III: Korean	45
	B. Questionnaire	47
	APPENDIX I: Initial smoking cessation trial questionnaire	48
	APPENDIX II: Smoking cessation trial questionnaire	49
	C. Research Data	50
	APPENDIX I: Auricular acupuncture treatment data	51
	APPENDIX II: Smoking cessation trial questionnaire	52
	D. IRB Meeting Summary	53

I. INTRODUCTION

Cigarette smoking remains the single largest preventable cause of death and disease in the United States. Even though the population of smokers has been decreasing for the past 50 years, a large number of people still keep smoking.[1, 2] The major problems caused by smoking include lung cancer, pulmonary disease, and heart disease; lung cancer is especially known to be the most serious problem.[3]

Smoking cessation is reported to remarkably increase life expectancy, reduce morbidity, and decrease health care costs associated with treating smoking-caused diseases.[4] Even though smokers want to reduce or quit smoking, it is difficult because they are addicted to the effects of nicotine. Nicotine is a major chemical compound found naturally in tobacco causing lasting addiction similar to heroin or cocaine.[5] Over time, a smoker may become physically and emotionally dependent on nicotine which causes unpleasant withdrawal symptoms when one attempts to quit.[5]

Many methods have been developed and applied in an attempt to treat smoking habits. The most commonly used formulation is nicotine replacement therapy (NRT), frequently available over the counter.[6] The U.S. Food and Drug Administration (FDA) approved five forms of NRTs, which include a skin patch, gum, nasal spray, inhaler (nicotine vapor), and lozenge.[5] However, some research has revealed that NRTs are associated with a variety of side effects.[6] Non-NRTs have been shown to be effective as second-line therapies for smoking cessation, but there is not enough evidence to prove that they improve the chance of quitting.[2, 5] Many other methods including hypnosis, acupuncture, ear magnet therapy, low-level laser therapy, cigarette filters, smoking deterrents, herbs, supplements, and mind-body practices such as yoga and meditation have been proposed and tested as alternative to reduce nicotine intake.[2] The

treatments using acupuncture and acupressure have been reported in literature to have practical effects on the reduction of smoking habits.[5] The advantage of acupuncture and acupressure for smoking cessation is that they exhibit fewer side effects than other methods including NRT.[7] To date, limited research data are available in literature for the reduction or cessation of smoking habits.

The objective of this study was to compare the effectiveness between auricular and body acupuncture treatments for the purpose of the reduction of smoking habits. Clinical experiments were conducted on the basis of the randomized controlled trial design.

In the experimental trials, a total of four unilateral acupuncture treatments were provided to each experimental group once a week over a period of four weeks. Collected date were analyzed using paired t-tests, independent t-tests, and correlation methods with the statistical software of Statistical Package of the Social Sciences (SPSS version 22.0).

Based on the results of this study, it could be concluded that a promising effect was obtained in decreasing smoking habits, craving to smoke, and taste of cigarette by using either auricular or body acupuncture treatments with acupressure using vaccaria seeds. No significant difference was observed in the effectiveness between auricular and body acupuncture treatments in reducing cigarette consumption, cigarette cravings, taste of cigarette, and carbon monoxide (CO) level.

II. LITERATURE RIVIEW

2.1. Smoking Statistics

Smoking rates of adults in the United States have dropped from 42.4% in 1965 to 17.8% in 2013, which is a 58% decline.[1, 2] However, approximately 42.1 million of U.S. adults still smoke cigarettes in 2013.[1] Cigarette smoking is the leading cause of preventable death in the United States.[8] From 2010 to 2014, smoking killed an average of approximately 80,000 people each year in the United States alone.[9] Causes of death attributed to smoking include lung cancer (127,700 people, 26.6%), pulmonary diseases (113,100 people, 23.5%), coronary heart disease (99,300 people, 20.7%), other cardiovascular disease (61,300 people, 12.8%), lung cancer and coronary heart disease from secondhand smoke (41,280 people, 8.6%), other cancer (36,000 people, 7.5%), and other diagnoses (1,640 people, 0.3%).[3] An estimated 158,040 deaths from lung cancer are expected to occur in 2015, accounting for about 26.8% of all cancer deaths.[3] Lung cancer causes more deaths than the next three most common cancers combined such as colorectal cancer (49,700 death, 8.4%), breast cancer (40,730 death, 6.9%), and pancreatic cancer (40,560 death, 6.9%).[3] Smoking is a contributing factor in 80 and 90 percent of lung cancer deaths in women and men, respectively.[10] Compared to non-smokers, men who smoke are 23 times more likely to develop lung cancer, while women are 13 times more likely.[10] The risk increases with both quantity and duration of smoking.[10]

2.2. Benefits of Smoking Cessation

Smoking cessation greatly improves life expectancy, reduces morbidity, and decreases health care costs associated with treating smoking-related conditions.[4] Health benefits over time of stopping smoking include:

- Within 20 minutes after quitting, blood pressure and heart rate decrease.[11]
- Within 12 hours after quitting, carbon monoxide (CO) levels in the blood decrease to normal.[12]
- Two weeks to three months after quitting, circulation and lung functions improve.[13]
- One to nine months after quitting, coughing and shortness of breath decrease.[13]
- One year after quitting, the risk of coronary heart disease is cut in half.[14]
- Five year after quitting, the risk of cancer of the oral cavity, esophagus, and bladder are cut in half.[13]
- Ten year after quitting, the risk of lung cancer decreases about 30 to 50%.[13]
- Fifteen year after quitting, the risk of coronary heart disease drops to the level of a non-smoker.[13]

2.3. Nicotine Addiction

Due to the addicting effects of nicotine, smokers find it difficult to reduce or quit from their habit. Nicotine is a major chemical compound found naturally in tobacco, which is as addictive as heroin or cocaine.[5] Over time, a smoker becomes physically and emotionally addicted to nicotine.[5] This physical dependence causes unpleasant withdrawal symptoms when one attempts to quit.[5] The emotional and mental dependence makes it difficult to stay away from nicotine.[5] When smoke is inhaled, nicotine is carried deep into the lungs where it is quickly absorbed into the bloodstream and carried along with carbon monoxide (CO) and other toxins to every part of the body.[5] High concentrations of CO are present in cigarette smoke.[13] In fact, nicotine inhaled from cigarette smoke reaches the brain faster than drugs that enter the body through a vein.[5]

2.4. Nicotine Withdrawal Effects

Symptoms of nicotine withdrawal usually begin within a few hours after the last cigarette and peak about two to three days later when most of the nicotine and its by-products are out of the body.[5] Symptoms of nicotine withdrawal can include any of the following: dizziness, depression, feeling of frustration, impatience, anger, anxiety, irritability, sleep disturbances, difficulty concentrating, restlessness, headaches, tiredness, increased appetite, weight gain, constipation, gas, cough, dry mouth, sore throat, nasal drip, chest tightness, and slower heart rate.[5]

2.5. Nicotine Replacement Therapy (NRT)

Many methods have been applied towards the treatment of smoking cessation. The most commonly used formulation is nicotine replacement therapy (NRT), frequently available over the counter.[6] The U.S. Food and Drug Administration (FDA) approved five forms of NRTs, which include a skin patch, gum, nasal spray, inhaler (nicotine vapor), and lozenge.[5] However, a meta-analysis identified that NRTs are associated with a variety of side effects, such as heart palpitations, chest pains, nausea and vomiting, gastrointestinal complaints, insomnia, skin irritations, mouth and throat soreness, mouth ulcers, hiccups, and coughing.[6] Prescription medications such as Bupropion, Varenicline, Nortriptyline, and Clonidine are also available to help smokers quit and some can be used along with NRT.[5]

Only about 4% to 7% of smokers are able to quit smoking on any given attempt without medications or other help.[5] Studies in medical journals have reported that 19 to 27% of smokers who use NRT can stay smoke-free for over 6 months and 23 to 33% of smokers who use

medications can stay smoke-free for over 6 months.[2] Combining counseling, other types of emotional support, or NRT can boost success rates higher than medications alone.[2, 5]

2.6. Non-Nicotine Replacement Therapy (Non-NRT)

Non-NRTs have been shown to be effective as second-line therapies for smoking cessation; however, there is not enough evidence to prove that they improve the chance of quitting.[5] Many other methods including hypnosis, acupuncture, ear magnet therapy, low-level (cold) laser therapy, cigarette filters, smoking deterrents, herbs, supplements, and mind-body practices such as yoga and meditation are used as other methods without nicotine for smoking cessation.[5] Counseling services such as telephone-based programs that link callers with trained counselors, a long-standing peer help program called Nicotine Anonymous®, and stop-smoking programs at some workplaces, hospitals and wellness centers are also available for smoking cessation.[5]

2.7. Acupuncture Treatment for Smoking Cessation in the United States

Acupuncture treatment originated from China, but the earliest documented report of acupuncture used for quitting smoking came from the United States.[15] In the U.S., Sacks, L, presented the earliest report on the effectiveness of ear needling for smoking cessation in the *American Journal of Acupuncture* in 1975.[15] Early acupuncture practices for smoking cessation also started about the same time in China when the Chinese medicine practitioners used ear acupuncture together with GV20 (Baihui).[15] Since then, acupuncture treatments for this purpose have commonly used ear acupuncture points as the major area of application, frequently supplemented by body points.[15]

Body acupuncture has also been investigated for smoking cessation effectiveness.[15] American doctor James S. Olms accidentally discovered an extra-meridian point on the wrist which reduced the nicotine addiction.[16] Olms published his findings in the *American Journal of Acupuncture* in 1981.[16] The point was named Tim Mee (Tian Wei or Tian Mi), derived from the Cantonese word for “sweet taste" because one can really taste food for the first time after losing the tobacco habit.[16] In Olms’s study, total of 535 patients were treated and 75% success for smoking cessation on the first treatment with this new point.[16]

There was one study using Tim Mee written in English and two studies in Chinese in the Cochrane review for smoking cessation.[7] The study published in English concluded in 2009 and showed that an experimental group treated with electroacupuncture on Tim Mee plus five auricular points (Shenmen, lung, stomach, mouth, and endocrine) had a 13.3% quit rate.[17] The placebo group treated with electroacupuncture 5 mm apart from the real acupuncture point locations had a 13.7% quit rate.[17] The real points were not superior to the placebo points for smoking cessation, however the placebo points were inappropriate as a control since they likely had some physiological effects similar to the real acupuncture points.[17]

Acupuncture and acupressure has continually been used to help smokers even though the effectiveness is inconclusive by using the evidence of systematic review.[7] Acupuncture point stimulation includes needle acupuncture, auriculotherapy, electroacupuncture, laser acupuncture, massage, moxibution, and cupping.[17] Continuous stimulation may be provided by using indwelling needles or beads or seeds taped to the points.[7] Acupuncture point stimulation, a non-pharmacological therapy, is a convenient, economical, and safe treatment mode for smoking cessation with few side effects.[18] Acupuncture point stimulation is also known to alter the taste of cigarettes for smokers by stimulating peripheral nerves around acupuncture points and internal

organs through meridians.[17] After treatment, subjects report a less pleasant taste from cigarettes and effectively reducing their craving to smoke.[19] Other subjects who quit smoking also report that they have less desire to smoke or that tobacco no longer tastes as good as before treatment.[20] Several randomized trials have shown that acupuncture point stimulation decreases the desire to smoke, decreases daily tobacco consumption, and decreases the cotinine serum level in a short and longer term lasting up to five years.[19, 20, 21, 22, 23, 24, 25]

Evidence from uncontrolled studies suggests that acupuncture reduces the symptoms of nicotine withdrawal with some high rates of initial success.[7] Multimodality treatment, especially acupuncture combined with smoking cessation education or other interventions, have shown to help smokers resist smoking during treatment and avoid relapse afterwards.[18]

2.8. National Acupuncture Detoxification Association (NADA) Protocol

In 1985, the National Acupuncture Detoxification Association (NADA) was established to promote education and training of clinicians in the NADA ear acupuncture protocol.[26] NADA, a non-for-profit training and advocacy organization, encourages community wellness through the use of a standardized auricular acupuncture protocol for behavioral health, including addictions, mental health, and disaster and emotional trauma.[26] Auricular acupuncture treatments using this NADA protocol have become increasingly more popular among military and community settings. More than 1,500 clinical sites in the U.S., Africa, Europe, Asia, Canada, Australia, and the Caribbean currently use this protocol.[26] The NADA treatment has been shown to significantly decrease cravings for alcohol and drugs, withdrawal symptoms, relapse episodes, anxiety, insomnia, and agitation.[26]

For smoking cessation, the five points NADA protocol is the most widely adapted one.[27] The first NADA treatment report on smoking cessation with positive results appeared in *American Journal of Public Health* in 2002.[21] A randomized trial concluded that the combination of acupuncture using five NADA protocol points (Shen Men, Sympathetic, Kidney, Liver, and Lung) and LI4 (Hegu) with education demonstrated an effectiveness rate of 40% for smoking cessation.[21] In contrast, placebo acupuncture with education demonstrated an effectiveness rate of 22% of smoking cessation.[21] However, meta-analysis concluded that auricular acupuncture appears to be effective for smoking cessation, but the effect may not depend on point location.[28]

2.9. Chinese Medical View for Smoking

From a Chinese medical viewpoint, cigarettes are hot, drying, and toxic substances that damage Lung fluids.[29, 30] Long-term absorption into the body can cause the patient to have an imbalance of Yin and Yang, and Qi and blood dysfunction, which can cause deficiencies of the lung, liver, heart, spleen, and kidneys.[31]

There are three traditional Chinese medicine differential diagnosis for patients who smoke cigarettes.[31]

- **Heart and lung Qi deficiency:** Smoking cigarettes in combination with coughing, asthma, chest pain and fullness, sore throat, palpitations, shortness of breath, irritability, less sleep, disturbing dreams, pale tongue, and weak pulse.[31]
- **Liver and kidney Yin deficiency:** Smoking cigarettes with dizziness, vertigo, tinnitus, impotence, spermatorrhea, irregular menses, infertility, red tongue with little or no coating, and a thready pulse.[31]
- **Spleen and stomach deficiency:** Smoking cigarettes with chronic abdominal pain, mild

pain, distension and bloating of the abdomen, lack of appetite, diarrhea, heaviness in the body, heavy head, pale and swollen tongue with sticky coating, and soft moderate pulse.[31]

When acupuncture is used for smoking cessation, many patients state that they have a loss of interest in smoking, or a change in the taste of the cigarette where it becomes bitter, bland, glass-like, or strong tasting.[31] It is important to use Chinese medicine diagnosis and to use body points based on the differentiation.[31]

III. METHODS

3.1. Research Design

This research was conducted at South Baylo University, Los Angeles Clinic, California between 10/12/14 and 5/9/15. It was designed as a randomized controlled trial (RCT) with 34 participants, comparing two groups consisting of the following: 1. an auricular acupuncture with acupressure group (n = 17), 2. a body acupuncture with acupressure group (n = 17) (Figure 1).

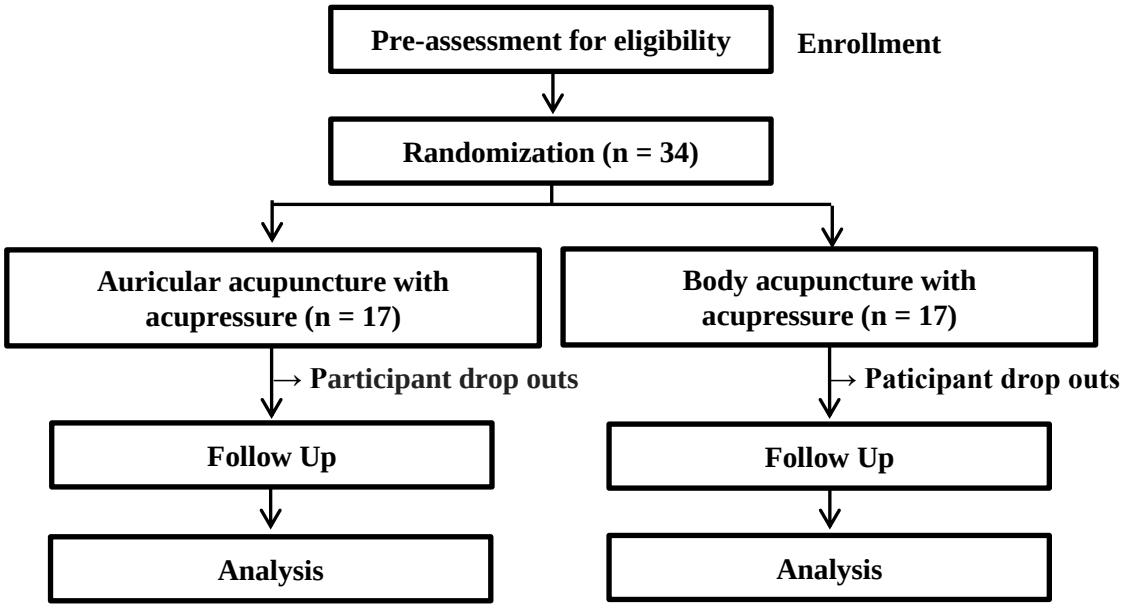

Figure 1. Schematic diagram of research flow.

3.2. Participants

Participants were recruited by means of posters at South Baylo University, Los Angeles clinic, advertisements on the internet, distribution of flyers on campus, and through word of mouth. All subjects gave informed consent to their participation in the research. The criteria for participants were to be 18 years of age or older, smoke at least 10 cigarettes per day, be under no other treatment for smoking cessation, not be currently treated with acupuncture, possess a desire to stop smoking, be able to come to treatment for four weeks, and be reachable by telephone.

3.3. Sample Size

Sample size was calculated with a two-tailed test based on the Cochrane systematic review and meta-analysis. The 16 studies which measured short-term outcomes of acupuncture compared with placebo acupuncture combine to give an overall positive result (RR 1.22, 95% CI 1.08 to 1.38) with moderate heterogeneity.[7]

$$n_C = \frac{\{Z_{\alpha/2}\sqrt{(1+\lambda)\bar{p}(1-\bar{p})} + Z_{\beta}\sqrt{\lambda p_c(1-p_C) + p_T(1-p_T)}\}^2}{\lambda d^2}$$

- p_c, p_t: success rate from control and treatment groups, respectively
- d: expected mean difference of success rate between two groups
- α, β: Type 1 error, Type 2 error α=5%, β= 20%
- n_C, n_T: no of participants in from control and treatment groups, respectively
- λ: the ratio of participants in treatment group over control group ($\lambda = n_T/n_C$)

Based on the sample size calculation, the number of participants needed to show statistical significance is over 3,672 (1,836 participants for each group). Therefore, this research was selected in order to conduct a pilot scale trial with total 34 participants, preliminarily to find out potential effects of acupuncture for smoking cessation. The participants were recruited and allocated into two groups randomly in this research.

3.4. Randomization and Blinding

The randomization was generated by computer program and concealed in envelopes. Randomization was in two groups: 1. an auricular acupuncture with acupressure group (n = 17), 2. a body acupuncture with acupressure group (n = 17). Participants were blind to their research group allocation.

3.5. Intervention

Each group received a total of four unilateral acupuncture treatments given as once a week over a period of four weeks. Single-use, sterile, stainless steel needles (DBC™ Spring Ten acupuncture needles, made in Korea) were used with guide tubes. Sizes used were 0.20 mm x 15 mm for auricular acupuncture treatment and 0.25 mm x 30 mm for body acupuncture treatment. Two mm vaccaria seeds (AcuZone ear vaccaria seeds, made in China) were used which are attached to 0.4" x 0.4", 3M surgical tape. Acupuncture treatment was administered by an acupuncturist without manual stimulation. The acupuncture needles were inserted for 30 minutes without conversation. Participants were seated in comfortable chairs. After removing the needles, intradermal seeds were placed on the same acupuncture points to maintain stimulation. The participants were advised to press intradermal seeds to stimulate the acupuncture points when a cigarette craving hits at least four times a day.[32] All treatments given for the research were provided to participants free of charge.

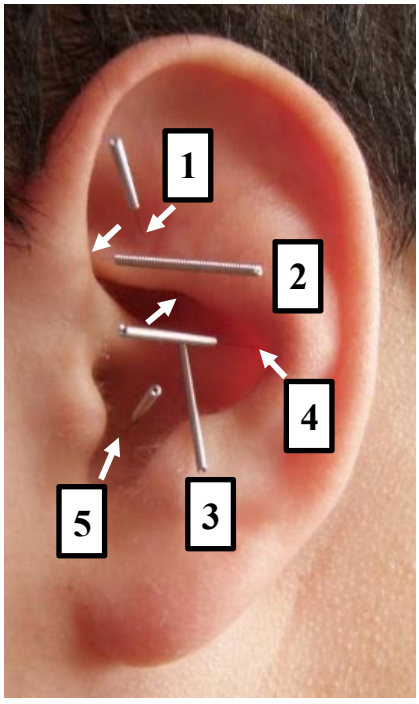

Figure 2. Auricular points. 1: Shen Men, 2: Sympathetic, 3: Kidney, 4: Liver, and 5: Lung 2

1) Auricular acupuncture treatment group

The auricular acupuncture group received five points: Shen Men, Sympathetic, Kidney, Liver, and Lung 2 based on the National Acupuncture Detoxification Association (NADA) protocol (Figure 2).[21, 26, 27] The five-points NADA protocol is the most widely adapted for smoking cessation.[27] The acupuncturist completed training with NADA protocol in Virginia. The practice of auricular acupuncture is based on the

theory that there are specific points on the auricle which correspond to major organs or systems of the human body and they can be manipulated by acupuncture or acupressure to exert a therapeutic effect upon the corresponding target organ or system.[27] Table 1 shows functions of auricular points that related smoking cessation.[32]

Table 1. Functions of auricular points (NADA protocol)

Auricular points	Functions[32]
Shen Men	Reduces stress, anxiety, and excessive sensitivity, enhances the functions of other acupuncture points.
Sympathetic	Balances sympathetic and parasympathetic nervous systems, improves blood circulation.
Kidney	Reinforces the function of kidneys.
Liver	Promotes smooth flow of Qi and blood, helps the body's detoxification, and relaxes the muscles and tendons.
Lung 2	Promotes smooth flow of Qi and blood, nourishes the skin and hair, and treats addiction related lung issues.

2) Body acupuncture treatment group

The body acupuncture group also received 5 points: LI4 (Hegu), Tim Mee (Tian Wei or Tian Mi, extra point), LU7 (Lieque), LV3 (Taichong), and KD3 (Taixi) (Figure 3).[18, 27] Tim Mee is a special point specifically used for smoking cessation discovered by accident by the American doctor James S. Olms.[16] The Chinese character for Tim Mee means "sweet taste," this is because the patient will be able to taste food again after stopping smoking.[16] This point is located on the wrist, in a depression between the tendons that make up the anatomical snuffbox, midway between LI5 (Yangxi) and LU7 (Lieque).[16] LI4 (Hegu), Tim Mee, and LU7 (Lieque) are used for

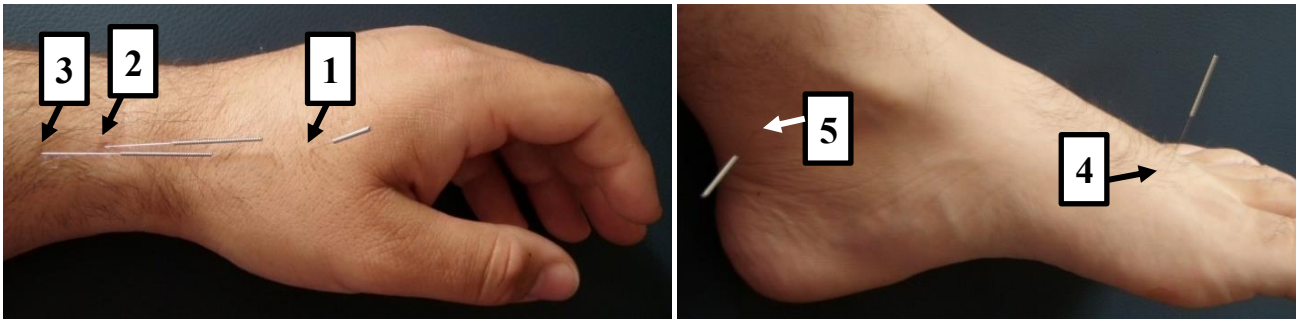

Figure 3. Body points. 1: LI4, 2: Tim Mee (extra), 3: LU7, 4: LV3, and 5: KD3

smoking cessation research.[7, 16, 17, 21] LV3 (Taichong) and KD3 (Taixi) are added for this research corresponded with the similar functions of auricular acupuncture from NADA protocol. Table 2 shows functions of body points that are related smoking cessation.[32, 33]

Table 2. Functions of body points

Body points	Functions [32, 33]
LI4 and LV3	This acupuncture combination is often called 'the Four Gate Points'. These points are used to circulate Qi throughout the body, regulate the nervous system, and calm the mind.
Tim Mee	An extra-meridian point specifically used for smoking cessation.
LU7	Promotes the dispersion and descent of lung Qi.
KD3	Strengthens the kidney, stabilizes the emotions and the mind.

From a Chinese medical viewpoint, cigarettes are hot, drying, and toxic substances that damage Lung fluids.[29, 30] Cigarettes are an important contributory factor to lung Yin deficiency.[30] Lung Yin deficiency is often associated with kidney Yin deficiency.[30] LU7 (Lieque) is the best point to tonify lung Qi and stimulate the descending of lung Qi.[30] This point is used for all types of cough or asthma.[30] KD3 (Taixi) is an extremely important point used to tonify the kidneys.[30]

This point is used to treat coughs because it strengthens the kidney's receiving of Qi from the lungs.[30] LI4 (Hegu) has a strong influence on the mind and can be used soothe the mind and relieve anxiety, particularly if combined with LV3 (Taichong).[30]

3.6. Evaluation

Participants completed the initial evaluation of demographic data including age, gender, ethnicity, education level, age at which they started smoking, smoking duration, daily cigarette consumption, previous smoking cessation experience, their level of craving smoking and taste of tobacco on numeric scale of 0-10 before the treatment. Exhaled carbon monoxide (CO) levels were measured by breath CO tester, piCO$^+$ Smokerlyzer® (Bedfont piCO$^+$ Smokerlyzer® carbon monoxide monitor, made in Kent, England) before each treatment.[34, 35] They completed the evaluation of daily cigarette consumption, number of pressing the intradermal seeds, their level of craving smoking and taste of tobacco on numeric scale of 0-10 at each visit and one week after the last treatment. Questions were minimized to reduce dropout rate. Successful cessation was measured by participant self-report and validated by two consecutive exhaled CO concentration readings of ≤10 ppm using the piCO$^+$ Smokerlyzer®.[35]

At any time, participants might voluntarily withdraw from the research if they developed severe nicotine withdrawal reactions or anxiety symptoms; if they had any adverse effects involving pain, discomfort, inflammation or infection at the local sites of the intradermal seeds; and as requested by the participants.

3.7. Statistical Analysis

The results are presented as means ± standard error of the mean (SEM). Paired t-tests were used to evaluate the differences within the groups between pre-treatment and post-treatment regarding daily cigarette consumption, craving to smoke, taste of cigarette, and CO level. Independent t-tests were used to evaluate the differences between the auricular acupuncture treatment group and the body acupuncture treatment group. Correlations between daily cigarette consumption and number of pressing the intradermal seeds, between daily cigarette consumption and craving to smoke, between daily cigarette consumption and taste of cigarette, between craving to smoke and taste of cigarette, and between daily cigarette consumption and CO level were analyzed by the Pearson correlation coefficient.

The Statistical Package of the Social Sciences (SPSS version 22.0) was used for statistical analysis. [36] A significant level was set to 0.05.[37]

3.8. Ethics

This proposal was submitted to the Institutional Review Board (IRB) of South Baylo University. The research started after getting approval from IRB about all the protocol and informed consent forms (ICF) in the three different languages of English, Spanish, and Korean.

IV. RESULTS

Thirty five smokers were screened for eligibility for this research. One did not meet the inclusion criteria because she smoked less than 10 cigarettes per day for a few days due to the common cold. Thirty-four participants were randomized into either the auricular acupuncture treatment group (n = 17) or the body acupuncture treatment group (n = 17). A total of 29 participants, 14 participants (82%) from the auricular acupuncture treatment group and 15 participants (88%) from the body acupuncture treatment group, remained in the research until the end of the follow up. Five participants dropped out from losing contact, becoming stressed with the situation, or changing their mind. The background characteristics of the two groups are given in Table 3.

4.1. Daily Cigarette Consumption

Before the first acupuncture treatment, the daily cigarette consumption for the auricular acupuncture treatment group and the body acupuncture treatment group was 13.3 $\pm$ 1.19 and 12.9 $\pm$ 0.99 cigarettes per day, respectively. One week after the fourth treatment, the daily cigarette consumption for the auricular acupuncture treatment group and the body acupuncture treatment group was 5.9 $\pm$ 1.11 and 6.0 $\pm$ 1.13 cigarettes per day, respectively.

The daily cigarette consumption decreased one week after the fourth treatment by 57.2% $\pm$ 6.63 for the auricular acupuncture treatment group ($P < 0.001$) and by 54.5% $\pm$ 7.26 for the body acupuncture treatment group ($P < 0.001$). Therefore, the daily cigarette consumption was significantly decreased by the auricular and the body acupuncture treatment groups using intradermal seeds (Figure 4).

Table 3. Background characteristics of auricular acupuncture treatment group and body acupuncture treatment group

	Auricular acupuncture treatment group	Body acupuncture treatment group
Age (years)	47.1	43.2
(range)	(25-62)	(23-63)
Gender		
Male	10	12
Female	4	3
Ethnicity		
Asian	11	6
African American	2	1
Caucasian	1	2
Hispanic	0	4
Indian	0	1
Persian	0	1
Education level (years)	15.2	13.5
High school diploma	2	5
Technical diploma	1	1
Associate's degree	2	2
Bachelor's degree	7	6
Master's degree	2	1
Age at the first cigarette	22.9	17.1
(range)	(14-45)	(13-27)
Smoking duration (years)	24.2	25.4
Daily cigarette consumption	13.3	12.9
Quit attempts (times)	4.0	4.0
Level of craving smoking (0-10)	6.3	6.7
Rate of tobacco taste (0-10)	6.2	6.0
Initial expired CO (ppm)	19.4	22.8

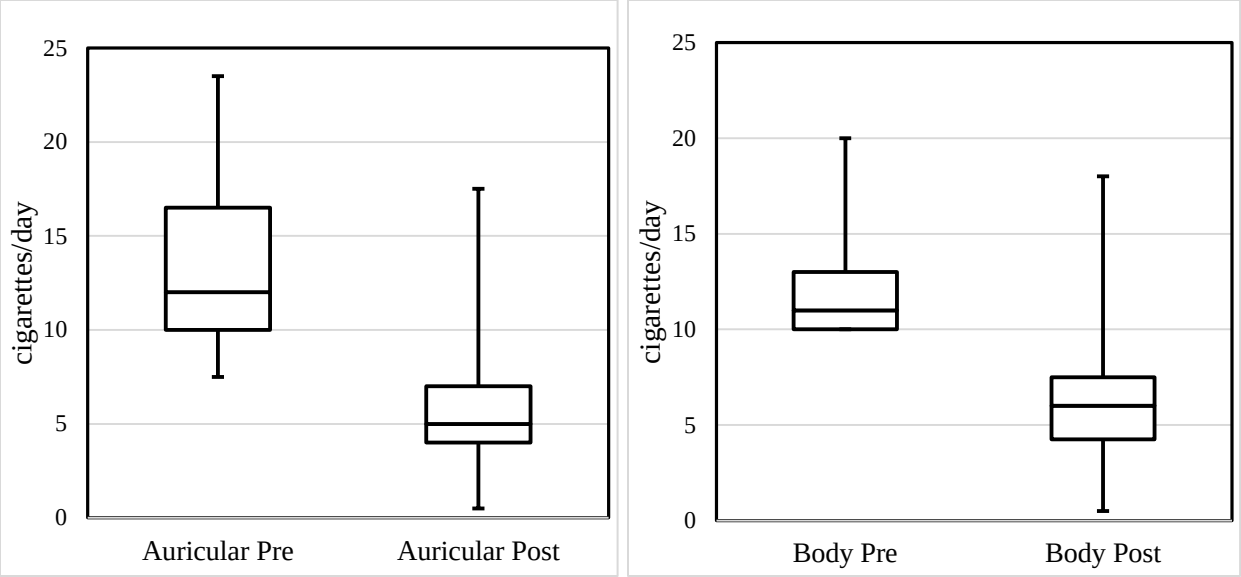

Figure 4. Daily cigarette consumption within group changes of the auricular acupuncture treatment group and the body acupuncture treatment group (Pre: before the first treatment and Post: one week after the fourth treatment)

Figure 5 shows daily cigarette consumption before the first treatment (1), before the second treatment (2), before the third treatment (3), before the fourth treatment (4), and one week after the fourth treatment (5) between the auricular acupuncture treatment group and the body

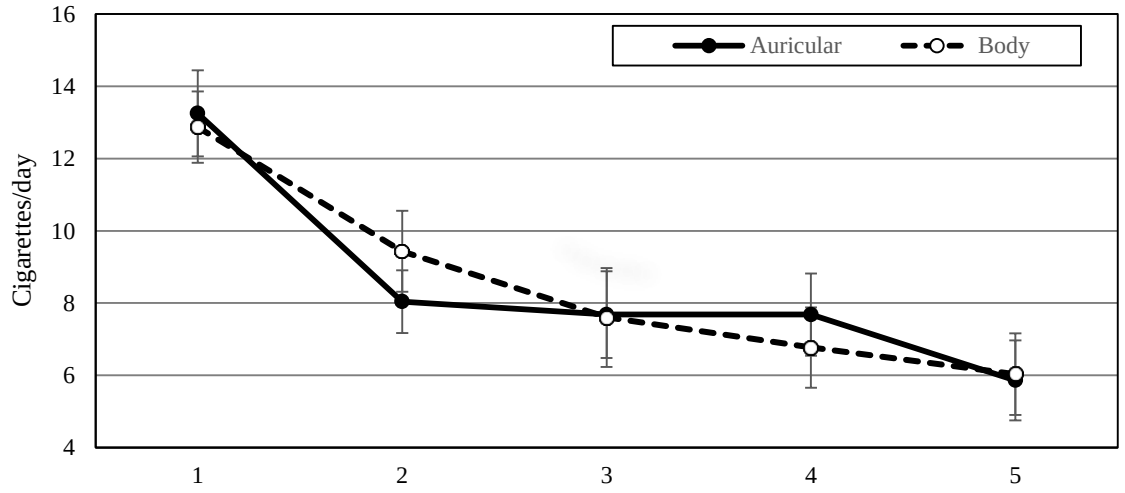

Figure 5. Daily cigarette consumption between the auricular acupuncture treatment group and the body acupuncture treatment group (1: before the first treatment, 2: before the second treatment, 3: before the third treatment, 4: before the fourth treatment, and 5: one week after the fourth treatment)

acupuncture treatment group. Daily cigarette consumption decreased significantly with the similar curves between both groups. One week after the fourth treatment, there was no significant difference between the auricular acupuncture treatment group (57.2% $\pm$ 6.63) and the body acupuncture treatment group (54.5% $\pm$ 7.26) in the reduction in daily cigarette consumption ($p = 0.788$).

Before the fourth treatment, four participants (29%) in the auricular acupuncture treatment group and five participants (33%) in the body acupuncture treatment group had two consecutive exhaled CO concentration reading of $\leq$10 ppm using the piCO$^+$ Smokerlyzer®. In previous studies, 10 ppm had been considered the threshold for proof of cigarette abstinence. Self-reported cigarette abstinence data were collected as well: once before the forth treatment and another one week after. However, self-reported claims of abstinence of only those who had CO concentration reading of $\leq$10 ppm were recorded as true smoking cessation successes. In spite of CO concentration readings that would have indicated that several participants had been abstaining from cigarettes, no participants (0%) in the auricular acupuncture treatment group and only two participants (13%) in the body acupuncture treatment group reported having completely abstained. The self-reported rate of cigarette abstinence increased one week after the fourth treatment, with one participant in the auricular acupuncture treatment group and three participants in the body acupuncture group reporting to have successfully abstained from cigarettes. The smoking cessation rates as measured one week after the fourth treatment were 7% (one out of 14 participants) in the auricular acupuncture treatment group and 20% (three out of 15 participants) in the body acupuncture treatment group.

4.2. Craving to Smoke

Figure 6 shows craving to smoke on numeric scale of 0 to 10 before the first treatment (1), before the second treatment (2), before the third treatment (3), before the fourth treatment (4), and one week after the fourth treatment (5) between the auricular acupuncture treatment group and the body acupuncture treatment group. Before the first acupuncture treatment, craving to smoke for the auricular acupuncture treatment group and the body acupuncture treatment group was 6.3 $\pm$ 0.45 and 6.7 $\pm$ 0.40, respectively. One week after the fourth treatment, craving to smoke for the auricular acupuncture treatment group and the body acupuncture treatment group was 3.9 $\pm$ 0.47 and 4.1 $\pm$ 0.65, respectively.

Craving to smoke decreased one week after the fourth treatment by 36.2% $\pm$ 7.58 for the auricular acupuncture treatment group (P = 0.001) and by 35.7% $\pm$ 11.40 for the body acupuncture treatment group (P = 0.003). Therefore, craving to smoke was significantly decreased by the auricular and the body acupuncture treatment groups using intradermal seeds.

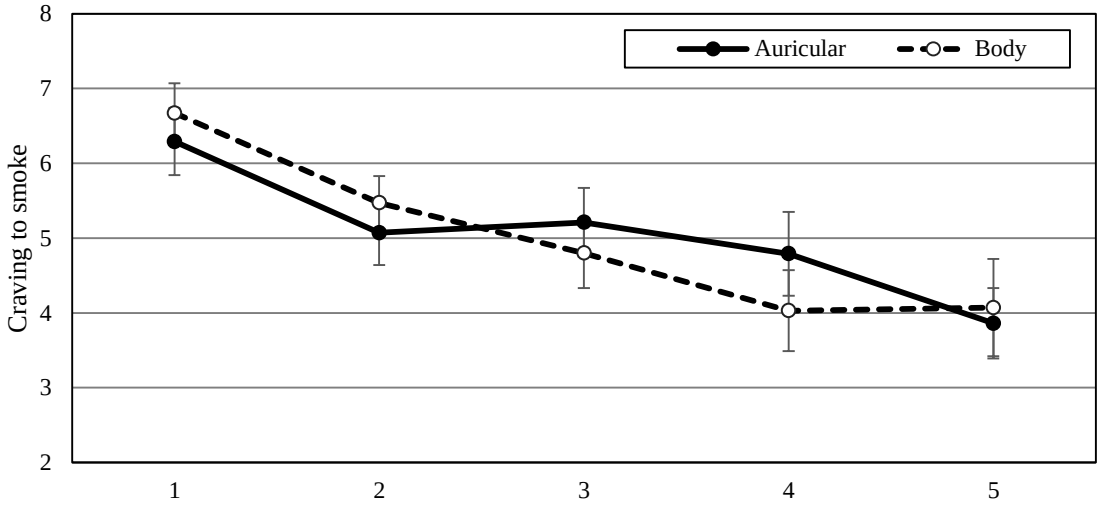

Figure 6. Craving to smoke between the auricular acupuncture treatment group and the body acupuncture treatment group (1: before the first treatment, 2: before the second treatment, 3: before the third treatment, 4: before the fourth treatment, and 5: one week after the fourth treatment)

Craving to smoke decreased significantly with the similar curves between both groups. One week after the fourth treatment, there was no significant difference between the auricular acupuncture treatment group (36.2% ± 7.58) and the body acupuncture treatment group (35.7% ± 11.40) in craving to smoke ($p = 0.972$).

4.3. Taste of Cigarettes

Figure 7 shows taste of cigarettes on numeric scale of 0 to 10 before the first treatment (1), before the second treatment (2), before the third treatment (3), before the fourth treatment (4), and one week after the fourth treatment (5) between the auricular acupuncture treatment group and the body acupuncture treatment group. Before the first acupuncture treatment, taste of cigarettes for the auricular acupuncture treatment group and the body acupuncture treatment group was 6.2 ± 0.54 and 5.9 ± 0.71, respectively. One week after the fourth treatment, taste of

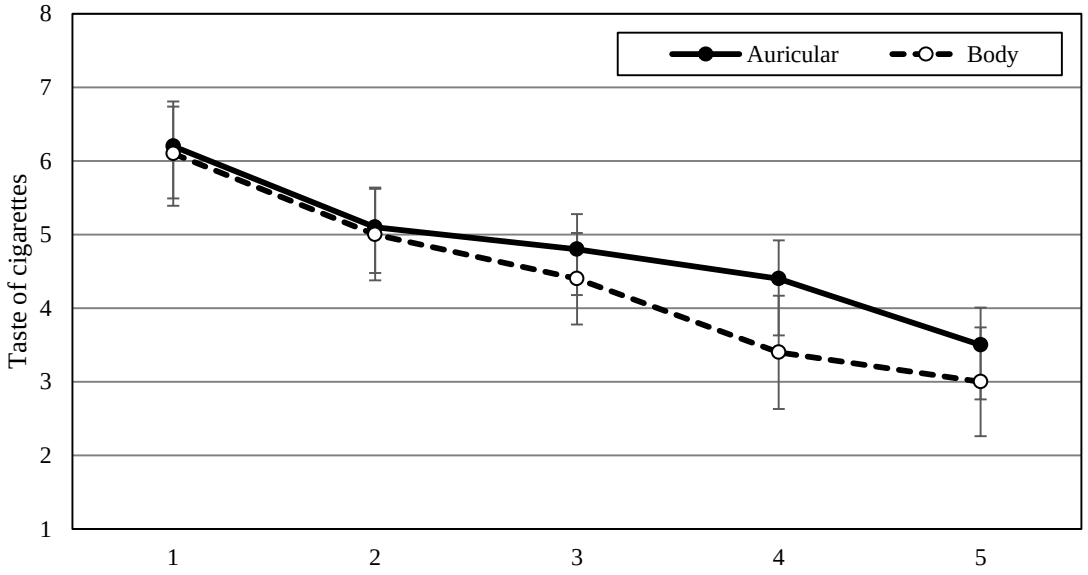

Figure 7. Taste of cigarettes between the auricular acupuncture treatment group and the body acupuncture treatment group (1: before the first treatment, 2: before the second treatment, 3: before the third treatment, 4: before the fourth treatment, and 5: one week after the fourth treatment)

cigarettes for the auricular acupuncture t reatment group and the body acupuncture treatment group was 4.0 ± 0.51 and 2.9 ± 0.74, respectively.

Taste of cigarettes decreased one week after the fourth treatment by 31.4% ± 10.49 for the auricular acupuncture treatment group (P = 0.005) and by 46.4% ± 9.57 for the body acupuncture treatment group (P = 0.001). Therefore, taste of cigarettes was significantly decreased by the auricular and the body acupuncture treatment groups using intradermal seeds.

One week after the fourth treatment, there was no significant difference between the auricular acupuncture treatment group (31.4% ± 10.49) and the body acupuncture group (46.4% ± 9.57) in taste of cigarettes (p = 0.297).

4.4. Carbon Monoxide (CO) Level

Figure 8 shows CO level (ppm) before the first treatment (1), before the second treatment (2), before the third treatment (3), and before the fourth treatment (4) between the auricular acupuncture treatment group and the body acupuncture treatment group. Before the first acupuncture treatment, CO level for the auricular acupuncture treatment group and the body acupuncture treatment group was 19.4 ppm ± 3.13 and 22.8 ppm ± 2.89, respectively. At the fourth treatment, CO level for the auricular acupuncture treatment group and the body acupuncture treatment group was 15.8 ppm ± 2.05 and 17.5 ppm ± 3.08, respectively.

CO level decreased in the fourth week by 8.6% ± 9.93 for the auricular acupuncture treatment group (P = 0.247) and by 22.7% ± 8.04 for the body acupuncture treatment group (P = 0.044). Therefore, CO level was not significantly decreased by auricular acupuncture treatments with acupressure using intradermal seeds, but it was significantly decreased by body acupuncture treatments with acupressure using intradermal seeds.

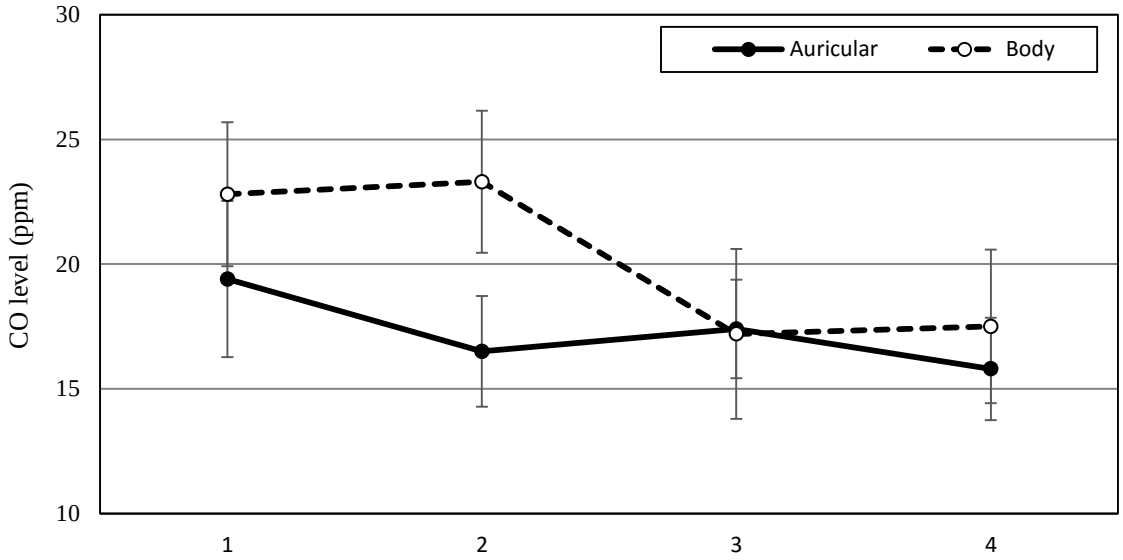

Figure 8. Carbon monoxide (CO) level (ppm) between the auricular acupuncture treatment group and the body acupuncture treatment group (1: before the first treatment, 2: before the second treatment, 3: before the third treatment, and 4: before the fourth treatment)

CO level for the body acupuncture treatment group decreased more than the auricular acupuncture treatment group. However, during the fourth week treatment, there was no significant difference between the auricular acupuncture treatment group (8.6% $\pm$ 9.93) and the body acupuncture treatment group (22.7% $\pm$ 8.04) in CO level ($p = 0.275$).

4.5. Correlations between Daily Cigarette Consumption and Pressing Frequency of Intradermal Seeds

The participants were advised to gently press the vaccaria seeds at least four times a day to stimulate the acupuncture points when a cigarette craving hits. However, 37.5% of participants from the auricular acupuncture treatment group and 45.0% of participants from the body acupuncture treatment group pressed less than four times a day.

Figure 9 shows correlations between daily cigarette consumption and pressing frequency of intradermal seeds regarding the auricular acupuncture treatment group and the body

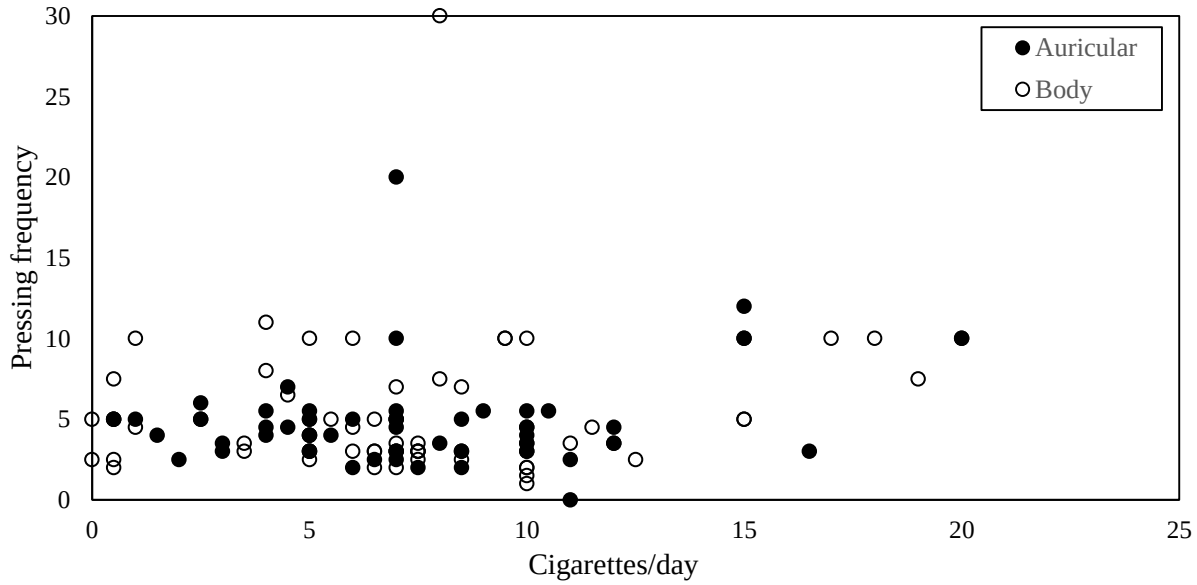

Figure 9. Correlations between daily cigarette consumption and pressing frequency of intradermal seeds regarding the auricular acupuncture treatment group and the body acupuncture treatment group

acupuncture treatment group. Pressing times of intradermal seeds weakly correlated with daily cigarette consumption for the articular acupuncture treatment group ($r = 0.24$, $p = 0.07$). Pressing times of intradermal seeds very weakly correlated with daily cigarette consumption for the body acupuncture treatment group ($r = 0.14$, $p = 0.29$).

4.6. Correlations between Daily Cigarette Consumption and Craving to Smoke

Some participants reported that they use smoking to cope with stress and smoking helps reduce stress. Figure 10 shows correlations between daily cigarette consumption and craving to smoke regarding the auricular acupuncture treatment group and the body acupuncture treatment group. Craving to smoke weakly correlated with daily cigarette consumption for the articular acupuncture treatment group ($r = 0.38$, $p = 0.001$). Craving to smoke strongly correlated with daily cigarette consumption for the body acupuncture treatment group ($r = 0.69$, $p < 0.001$).

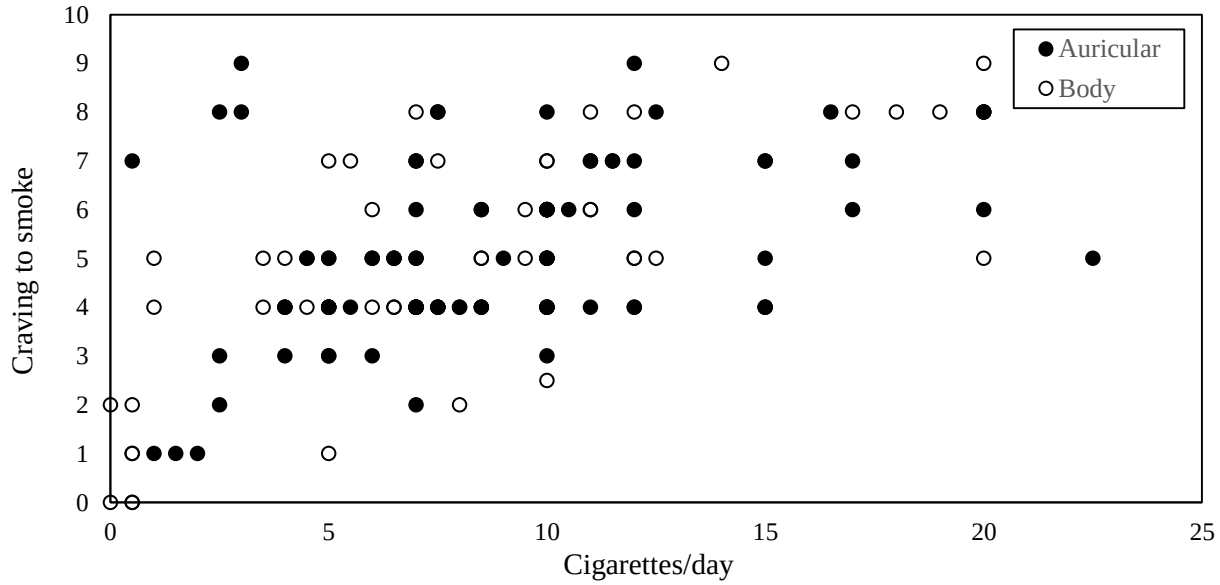

Figure 10. Correlations between daily cigarette consumption and craving to smoke regarding the auricular acupuncture treatment group and the body acupuncture treatment group

4.7. Correlations between Daily Cigarette Consumption and Taste of Cigarettes

Some participants reported that they smoke as an unconscious habit even though the taste of their cigarettes is terrible. Figure 11 shows correlations between daily cigarette consumption

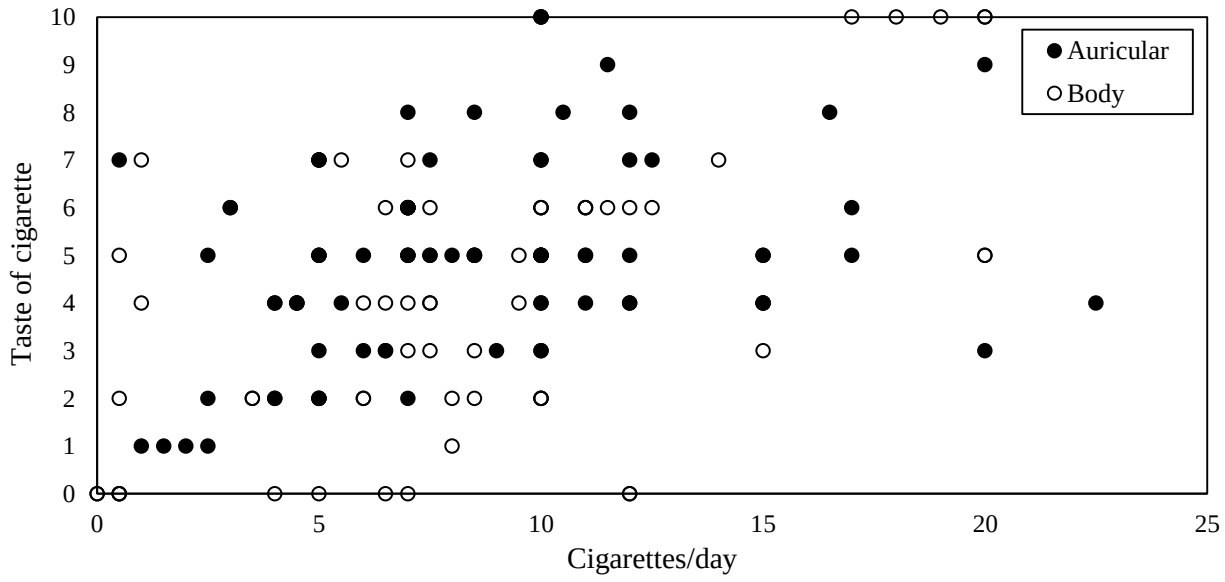

Figure 11. Correlations between daily cigarette consumption and taste of cigarettes regarding the auricular acupuncture treatment group and the body acupuncture treatment group

and taste of cigarettes regarding the auricular acupuncture treatment group and the body acupuncture treatment group. Taste of cigarettes weakly correlated with daily cigarette consumption for the articular acupuncture treatment group ($r = 0.32$, $p = 0.008$). Taste of cigarettes moderately correlated with daily cigarette consumption for the body acupuncture treatment group ($r = 0.57$, $p < 0.001$).

4.8. Correlations between Craving to Smoke and Taste of Cigarettes

Figure 12 shows correlations between craving to smoke and the taste of cigarettes regarding the auricular acupuncture treatment group and the body acupuncture treatment group. Craving to smoke strongly correlated with the taste of cigarettes for the articular acupuncture treatment group ($r = 0.64$, $p < 0.001$) and for the body acupuncture treatment group ($r = 0.54$, $p < 0.001$).

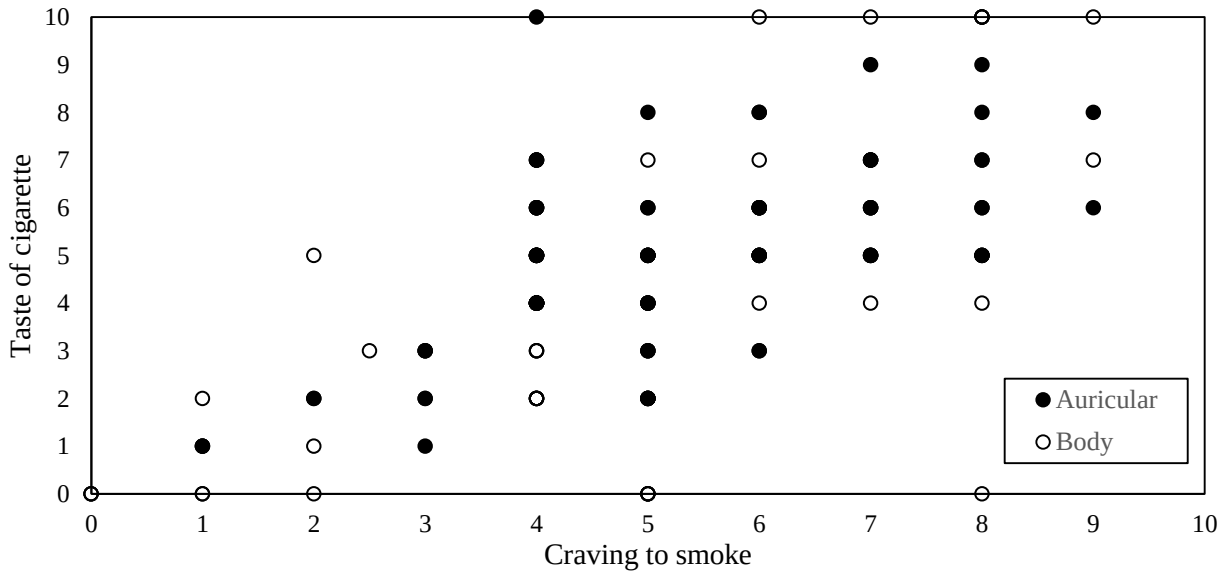

Figure 12. Correlations between craving to smoke and taste of cigarettes regarding the auricular acupuncture treatment group and the body acupuncture treatment group

4.9. Correlations between Daily Cigarette Consumption and CO Level

Some participants had higher CO levels with less cigarette consumption because they changed the brands and types or they asked their friends to provide them with cigarettes that were different from their original brands and types. Figure 13 shows correlations between daily cigarette consumption and CO level (ppm) regarding the auricular acupuncture treatment group and the body acupuncture treatment group. CO level weakly correlated with daily cigarette consumption for the articular acupuncture treatment group ($r = 0.36$, $p = 0.006$). CO level strongly correlated with daily cigarette consumption for the body acupuncture treatment group ($r = 0.72$, $p < 0.001$).

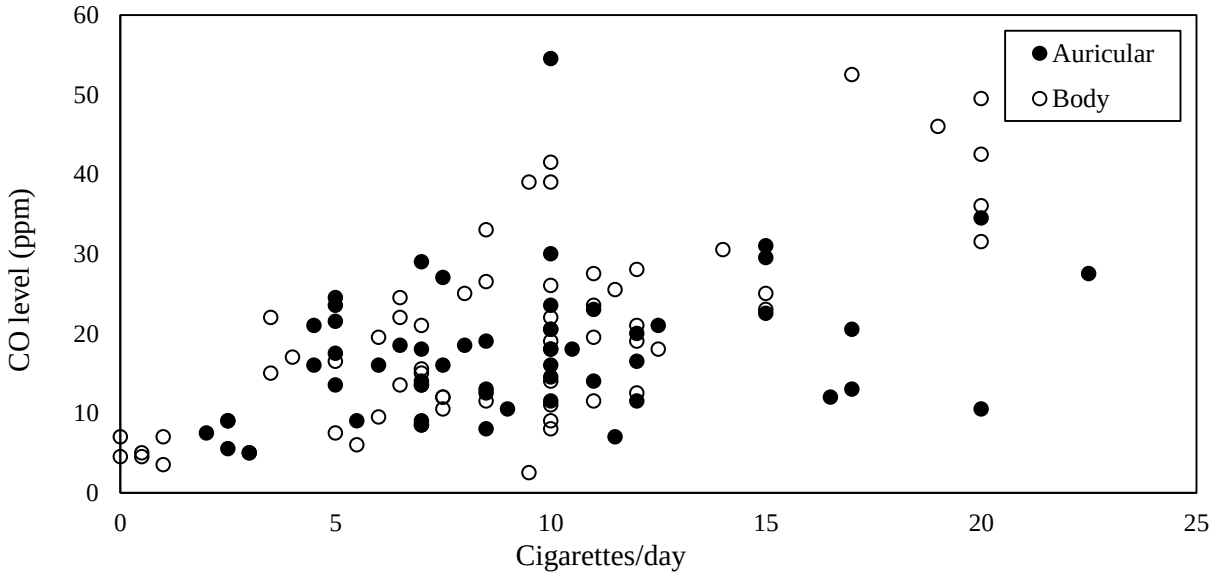

Figure 13. Correlations between daily cigarette consumption and CO level (ppm) regarding the auricular acupuncture treatment group and the body acupuncture treatment group

V. DISCUSSION

Cigarette smoking is the leading cause of preventable death in the United States.[8] Smoking cessation greatly improves life expectancy, reduces morbidity, and decreases health care costs associated with treating smoking-related conditions.[4]

This research indicates that four-week auricular or body acupuncture treatments with acupressure using intradermal seeds were significantly effective in decreasing daily cigarette consumption, $p < 0.001$, $p < 0.001$; craving to smoke, $p = 0.001$, $p = 0.003$; and taste of cigarettes, $p = 0.005$, $p = 0.001$, respectively; however, only body acupuncture treatments were significantly effective for decreasing CO levels ($P = 0.044$). Auricular acupuncture treatments were not as effective ($p = 0.247$). There was no significant difference in the effectiveness between the auricular acupuncture treatment and the body acupuncture in daily cigarette consumption ($p = 0.788$), craving to smoke ($p = 0.972$), taste of cigarettes ($p = 0.297$), and CO level ($p = 0.275$).

Pressing frequencies of intradermal seeds weakly correlated with daily cigarette consumption when used in conjunction with auricular or body acupuncture treatments ($r = 0.24$, $r = 0.14$, respectively). The participants were advised to gently press the vaccaria seeds at least four times a day to stimulate the acupuncture points when a cigarette craving hits. However, 37.5% to 45% of participants from both groups pressed less than four times a day, even though they were encouraged to press after each treatment.

Craving to smoke correlated with daily cigarette consumption more for the body acupuncture treatment group($r = 0.69$) than for the auricular acupuncture treatment group ($r = 0.38$). Taste of cigarettes correlated with daily cigarette consumption more for the body acupuncture treatment group ($r = 0.57$) than for the auricular acupuncture treatment group ($r =$

0.32). CO levels correlated with daily cigarette consumption more for the body acupuncture treatment group (r = 0.72) than for the auricular acupuncture treatment group (r = 0.36). Craving to smoke strongly correlated with the taste of cigarettes for both the auricular acupuncture treatment group and body acupuncture treatment group (r = 0.64, r = 0.54, respectively). Some participants reported that they smoke as an unconscious habit even though the taste of their cigarettes is terrible. They feel the need to break their unconscious habit, especially while under stress. Most participants reported the 30 minute treatments felt irritatingly long at the beginning of the study, but gradually became tolerable and calmed down as the study progressed.

Successful smoking cessation was measured by participant self-reported cigarette consumption and exhaled CO concentration readings of ≤10 ppm using the piCO^{+} Smokerlyzer®; however, the daily cigarette consumption was not always zero, even though exhaled CO levels were ≤10 ppm. Exhaled CO level of 10 ppm is usually taken as the cutoff between smokers and nonsmokers.[38] Some research reported that 6 ppm would be more appropriate as the cutoff between smokers and nonsmokers.[39] These studies suggest that an exhaled CO level of 10 ppm may be relatively high for a nonsmoker.[39]

In this research, the smoking cessation rates were 7% (one out of 14 participants) in the auricular acupuncture group and 20% (three out of 15 participants) in the body acupuncture treatment group. Reported by the American Cancer Society states that only 4% to 7% of smokers are able to quit smoking on any given attempt without medications or other help.[5] Therefore, this research indicates that acupuncture treatments with acupressure using intradermal seeds have higher smoking cessation rate than any given attempt without medications or other help. The participants were advised to gently press the vaccaria seeds at least four times a day to stimulate the acupuncture points when a cigarette craving hits. However, many participants from the both

auricular and body acupuncture treatment group pressed fewer than four times a day. If the participants pressed at least four times a day as instructed, the results could be better.

High dropout rates are not unusual in trials of addiction.[40] In this research, dropout rates were 18% (three out of 17 participants) from the auricular acupuncture treatment group and 12% (two out of 17 participants) from the body acupuncture treatment group. The dropout rate was lower compared with other smoking cessation research. Possible reasons are the short period of research (four week treatments), short treatment sessions (30 minute acupuncture treatment including a short questionnaire), and no-cost treatment.

Acupuncture and acupressure are becoming more popular in the United States; however, most Americans are unaware of it as an option for smoking cessation because there is not enough scientific evidence about acupuncture and acupressure for this purpose. The National Acupuncture Detoxification Association (NADA) encourages community wellness through the use of a standardized auricular acupuncture protocol for behavioral health, including addictions, mental health, and disaster and emotional trauma.[17] Auricular acupuncture treatments are becoming more popular among military and community settings using this NADA protocol. Body acupuncture treatments are also very effective according this research; however, there is no established the standard body acupuncture protocol yet.

In conclusion, this research indicates that four-week auricular or body acupuncture treatments with acupressure using intradermal seeds were significantly effective in decreasing daily cigarette consumption, craving to smoke, and taste of cigarettes; however, only body acupuncture treatments were significantly effective for decreasing CO levels. There was no significant difference in the effectiveness between the auricular acupuncture treatment and the

body acupuncture treatment in daily cigarette consumption, craving to smoke, taste of cigarettes, and CO level.

This research was a good opportunity and enlightening experience for the 29 participants. It is recommended that future researchers examine effective methods of acupuncture for smoking cessation with larger sample size for long periods of time such as one to five years. It is also recommended that future researchers use 6 ppm as the cutoff between smokers and nonsmokers. Some participants had higher CO levels even with reduced cigarette consumption because they changed the brands and types or they asked their friends to provide them with cigarettes that were different from their original brands and types. Therefore, participants who change the brand and types should be excluded in any future research.

If future research corroborates the finding of this study, the proposed methods of acupuncture or acupressure should be considered as options to supplement NRT or other established smoking cessation programs.

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APPENDICES

APPENDIX A

INFORMED CONSENT FORM

APPENDIX I: English

South Baylo University

Informed Consent Form

You are invited to participate in a research study about the comparison of the effect between auricular acupuncture and body acupuncture on smoking cessation: a pilot randomized controlled trial.

The goal of this research study is to determine the effect of auricular acupuncture treatment on smoking cessation in comparison to body acupuncture treatment.

This study is being conducted by Mika Sugano-Isa, L.Ac. There are 7 qualifications to participate in this study: (1) be 18 years of age or older; (2) smoke at least 10 cigarettes per day; (3) currently under no other treatment for smoking cessation; (4) not currently being treated with acupuncture treatment; (5) possess a desire to stop smoking; (6) be able to commit to treatment for four weeks; and (7) be able to be reached by telephone.

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 still be offered the same treatment that is routinely offered in this clinic. You may change your mind later and stop participating in this research even if you agreed earlier.

Participating in this study may not benefit you directly, but it will help to enrich the knowledge on smoking cessation.

By participating in this research it is possible that you may be at greater risk than you would otherwise be. There is, for example, a risk that your condition will not get better and the new treatment will not work as well as previous treatment. If the treatment is not working, we will provide treatment routinely offered to make you more comfortable. While the possibility of this occurrence is very low, you should still be aware of the possibility. Acupuncture treatment may cause local pain from needling and slight bleeding or hematoma. Ear seeds may cause discomfort of the ear. At any time, participants may voluntarily withdraw from the research if they develop severe nicotine withdrawal reactions or anxiety symptoms; if they have any adverse effects involving pain, discomfort, inflammation or infection at the local sites of the ear seeds; and as requested by the participants.

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 is collected from this research project will be kept confidential. Information about you that will be collected during the research will be safely stored and only the researchers will have access to it. Any information about you will be referenced by a number rather than your name. Only the researchers will know

what your number is and we will secure that information under lock and key. Your name will not be shared with or provided to anyone except research advisor: Dr. Meredith Chunyi Qian, M.D. (China), L.Ac.

If you have any questions about this study, please contact Mika Sugano-Isa at (562)243-3690 and mikap924@gmail.com. If you have any questions or concerns regarding your rights as a subject in this study, you may contact Dr. Edwin D Follick, Chair of the South Baylo University Institutional Review Board (IRB) at (714)533-6077 or edfollick@southbaylo.edu.

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

Certificate of Consent:
I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions regarding this study and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to act as a participant in this research.

Print name of participant_____ Print name of witness_____

Signature of participant_____ Signature of witness _____

Date _____ Date _____

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 questions asked by the participant have been answered correctly and to the best of my ability. I affirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily by the potential participant.

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

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____

APPENDIX II: Spanish

Universidad de South Baylo

Formulario de Consentimiento Sobre Aviso

Usted está invitado a participar en un estudio de investigación acerca de la comparación del efecto entre la acupuntura auricular y la acupuntura del cuerpo para dejar de fumar: un piloto de ensayo controlado aleatorio.

El objetivo de este estudio de investigación es determinar el efecto del tratamiento con acupuntura auricular para dejar de fumar en comparación con el tratamiento de acupuntura del cuerpo.

Este estudio está siendo realizado por Mika Sugano-Isa, L.Ac. Hay 7 requisitos para poder participar en este estudio: (1) tener 18 años de edad o más; (2) fumar al menos 10 cigarrillos por día; (3), actualmente ningún otro tratamiento para dejar de fumar; (4) No está siendo atendida con el tratamiento de acupuntura; (5) tener el deseo de dejar de fumar; (6) ser capaz de comprometerse con el tratamiento durante cuatro semanas; y (7) poder ser contactado por teléfono.

Su participación en esta investigación es completamente voluntaria. Es su decisión si desea participar o no. Si usted decide participar o no, todos los servicios que reciben en esta clínica continuará y nada va a cambiar. Si usted decide no participar en este proyecto de investigación, que todavía se le ofrecerá el mismo tratamiento que se ofrece habitualmente en esta clínica. Usted puede cambiar de opinión más tarde y dejar de participar en esta investigación, incluso si usted estuvo de acuerdo antes.

Su participación en este estudio puede no beneficiarse directamente, pero ayudará a enriquecer el conocimiento sobre el abandono del hábito de fumar.

Al participar en esta investigación, es posible que usted pueda estar en mayor riesgo de lo que de otra manera. Hay, por ejemplo, el riesgo de que su condición no va a mejorar y el nuevo tratamiento no funcionará tan bien como tratamiento previo. Si el tratamiento no está funcionando, vamos a ofrecer el tratamiento ofrecido rutinariamente para que se sienta más cómodo. Si bien la posibilidad de que esto ocurra es muy baja, aún debe ser consciente de la posibilidad. El tratamiento con acupuntura puede causar dolor local de la punción y un ligero sangrado o hematoma. Semillas de oído pueden causar molestias de la oreja. En cualquier momento, los participantes pueden retirarse voluntariamente de la investigación ante la aparición de reacciones de abstinencia de nicotina graves o síntomas de ansiedad; si tienen efectos adversos relacionados con el dolor, la incomodidad, inflamación o infección en los sitios locales de las semillas para los oídos; y conforme a lo solicitado por los participantes.

La información que usted comparta con nosotros si usted participa en este estudio se mantendrá completamente confidencial con todo el rigor de la ley. La información que se recoge de este proyecto de investigación se mantendrá confidencial. La información sobre usted

que se recogerán durante la investigación será almacenada de manera segura y sólo los investigadores tendrán acceso a la misma. Cualquier información sobre usted será referenciado por un número en lugar de su nombre. Sólo los investigadores sabrán lo que su número es y vamos a asegurar que la información bajo llave. Su nombre no será compartida con o proporcionada a nadie, excepto consejero de investigación: Dr. Meredith Chunyi Qian, MD (China), L.Ac.

Si usted tiene alguna pregunta acerca de este estudio, por favor póngase en contacto con Mika Sugano-Isa en (562)243-3690 y mikap924@gmail.com. Si usted tiene alguna pregunta o inquietud con respecto a sus derechos como sujeto en este estudio, puede comunicarse con el Dr. Edwin D Follick, Presidente de la Junta de Revisión Institucional de la Universidad del Sur Baylo (IRB) al (714)533-6077 o edfollick@southbaylo.edu .

SE LE DARA UNA COPIA DE ESTA FORMA O NO SE COMPROMETE A PARTICIPAR.

Certificado de Consentimiento:
He leído la información anterior, o me lo han leído a mí. He tenido la oportunidad de hacer preguntas con respecto a este estudio y las preguntas que he pedido han sido respondidas satisfactoriamente. Doy mi consentimiento voluntariamente para actuar como participante en esta investigación.

Nombre de participante_____ Nombre de testigo_____

Firma del participante_____ Firma de testigo _____

Fecha _____ Fecha _____

Declaración del investigador / persona dando su consentimiento:

He explicado con precisión la hoja de información al potencial participante. Confirmo que el participante se le dio la oportunidad de hacer preguntas sobre el estudio, y todas las preguntas formuladas por los participantes han sido contestadas correctamente y al mejor de mi capacidad. Yo afirmo que el individuo no ha sido obligado a dar su consentimiento, y el consentimiento ha sido dado libremente y voluntariamente por el posible participante.

Una copia de este formulario de consentimiento informado ha sido proporcionada al participante.

Nombre del Investigador / persona dando su concentimiento_____

Firma del Investigador / persona dando su concentimiento_____

Fecha _____

APPENDIX III: Korean

South Baylo University
환자치료 및 연구 동의서

귀하는 금연치료에 대하여 이침과 체침의 효과를 비교하는 연구활동에 참여 및 초청되었음을 알려드립니다. 이 연구는 무작위 배정방법으로 진행됨을 알려드립니다. 이 연구의 목적은 금연치료에 대하여 이침과 체침 치료 중 어떤 치료가 더욱 효과가 있는 지에 관한 것 입니다. 이 연구는 한의사이자 사우스베일로 대학의 박사과정중인 Mika Sugano-Isa L.Ac 에 의하여 진행되며, 7 가지의 자격기준에 부합한 사람이 참여할 수 있습니다. 첫째, 18 세 이상; 둘째, 하루 평균 10 개피이상 흡연; 셋째, 현재 금연에 관한 어떠한 치료도 받지 않는 자; 넷째, 현재 어떠한 침 치료도 받지 않는 자; 다섯째, 금연희망자; 여섯째, 4 주간 치료를 받을 수 있는 자; 일곱째, 전화로 연락이 가능한 자.

이 연구에 관한 귀하의 참여는 스스로 자원한 것입니다. 이 것은 귀하의 선택에 의한 것임을 알려드립니다. 귀하의 참여 여부에 상관없이 이 클리닉에서 진행되는 치료와 연구는 변하지 않고 지속될 것임을 알려드립니다. 귀하의 참여 여부와 무관하게 이 연구 프로젝트를 통해 지속적인 치료를 받게 됨을 알려드립니다. 또한, 이 연구에 대한 참여에 동의했더라도, 원하지 않는 경우엔 취소할 수 있음을 알려드립니다.

이 연구에 참여하는 것이 귀하에게 직접적으로는 다른 어떠한 이익이 없으나 금연에 도움을 드릴 수는 있습니다.

이 연구에 참여시 위험 요소가 다소 있을 수 있습니다. 예를 들어, 귀하의 건강이 호전되지 않거나, 혹은 새로운 치료 방법이 이 전의 치료 방법에 비해 비효율적일 수 있습니다. 만약 치료에 대하여 효과가 없다면, 우리는 다른 치료방법을 제의함으로써 더욱 편하게 치료를 받을 수 있도록 도울 것입니다. 가능성이 없다고 생각이 될지라도, 귀하는 가능할 수 있다는 마음으로 임하여 주시길 바랍니다. 침 치료를 통해 국소적 통증, 약간의 출혈 혹은 출혈증세가 발생 할 수 있음을 알려드립니다. 이침 사용시 귀에 불편한 증상이 있을 수 있습니다. 참여자 중 심한 금단현상으로 못 견딜 정도로 불편하신 경우; 혹은, 귀에 부착하는 압혈 스티커로 인해 통증이 있거나, 염증이 생기거나, 불편하거나, 혹은 감염의 증상이 있는 경우, 참여자가 원하는 경우에 한해서 언제든지 치료를 멈출 수 있음을 알려드립니다.

귀하가 이 연구에 참여함과 동시에 우리와 나눈 정보는 사적인 것으로 법에 의하여 보호됨을 알려드립니다. 이 연구에 관한 모든 수집된 정보는 사적인 것으로 법적으로 보호됩니다. 연구 중 귀하게 관한 모든 정보는 연구자에 의해 보관되며, 오직 연구원만 접근 할 수 있음을

알려드립니다. 연구에 사용되는 자료는 귀하의 성명대신 숫자 혹은, 기호로 표시될 것임을 알려드립니다. 오직 연구자들만 기호와 숫자에 대하여 알 것이며, 귀하에 관한 정보는 유출되지 못하도록 안전보관 될 것입니다. 귀하의 성명은 연구 지도자인 Dr. meredith Chunyi Qian. M.D. (China)L.Ac 에게 제한하여 제공될 것이며. 그 이외의 다른 누구에게도 제공되지 않음을 알려드립니다.

이 연구에 관하여 궁금한 점이 있으시다면, Mika Sugano-Isa L.Ac 에게 연락 주시길 바랍니다. 전화번호는 (562)243-3690 이며, 이메일은 mikap924@gmail.com 입니다. 만약, 이 연구에 따른 귀하의 개인정보관리보호방침 에 관하여 궁금한 점이 있는 경우 사우스베일로 한의학대학교의 Chair of the South Baylo Institutional Review Board (IRB)을 담당하고 계신 Dr. Edwin D Follick 에게 (714)533-6077 혹은 edfollick@southbaylo.edu 으로 연락 주시면 됩니다.

귀하는 이 연구에 참여여부와 관계 없이 이 서류의작성과 함께 복사본을 제공 받으실 것을 알려드립니다.

동의서에 관한 증명:

본인은 상기된 정보를 읽었으며 혹은, 설명을 상세히 들었습니다. 본인은 이 연구에 관련한 질문을 할 수 있는 기회가 있었으며, 질문에 관한 대답에 만족했습니다. 본인은 이 연구에 참여함을 동의합니다.

참여자 성명: _____ 증인성명: _____

참여자 서명: _____ 증인서명: _____

날짜: _____ 날짜: _____

동의서에 대한 연구자의 성명

본인은 연구자로서 정확한 정보를 서술 하였으며, 참여자에게 연구에 관한 질문을 할 수 있는 기회를 주었습니다. 그리고 본인이 할 수 있는 한에서 모든 질문에 답변하였음을 알려드립니다. 본인은 개인에게 강제적인 동의를 요구하지 않았으며, 동의서는 참여자의 자유의지에 의하여 작성되었음을 알려드립니다.

이 동의서의 복사본이 참여자에게 제공 되었음을 알려드립니다.

연구자/ 동의서 작성자 성명: _____

연구자 / 동의서 작성자 서명: _____

날짜: _____

APPENDIX B

QUESTIONNAIRE

APPENDIX I

Initial Smoking Cessation Trial Questionnaire

Participant's name:_____ Date:___/___/___File No:_____

1. Age group: ☐ 18-20, ☐ 21-30, ☐ 31-40, ☐ 41-50, ☐ 51-60, ☐ 61-70, ☐ 71-80, ☐ over 80

2. Gender: Female Male

3. What is your ethnic group?

Caucasian	African American	Asian
Hispanic	American Indian	Pacific Islander
Other (specify) :_____		

4. What is your education?

High school diploma/GED (12 years)	Bachelor's degree (16 years)
Technical diploma (13 years)	Master's degree (18 years)
Associate's degree/college diploma (14 years)	Doctorate degree (over 18 years)

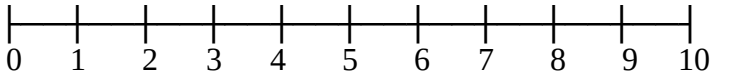
5. How old were you when you start smoking? _____ years old

6. How many years have you been smoking? _____ years

7. How many cigarettes do you currently smoke per day? _____

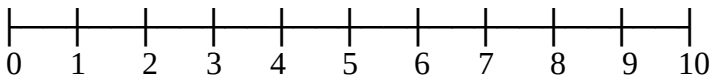
8. How often have you tried to quit smoking? _____

9. How much do you crave smoking?



No craving — Great craving

10. How does tobacco taste to you?



Bad taste — Great taste

11. The exhaled carbon monoxide (CO) level:_____ ppm _____ ppm

APPENDIX II

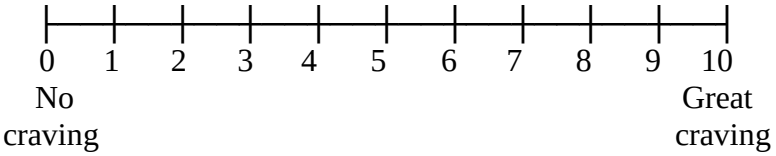
Smoking Cessation Trial Questionnaire

Participant's name:_____ Date:___/___/___File No:

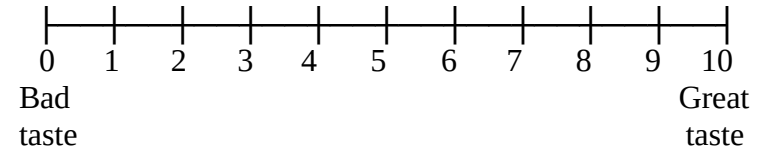
1. How many cigarettes did you smoke per day last week? _____

2. How many times did you press the seeds per day? _____

3. How much do you crave smoking?



4. How does tobacco taste to you?



5. The exhaled carbon monoxide (CO) level:_____ppm _____ppm

6. Blood pressure:_____/_____

Name of Practitioner:_____ Signature of Practitioner:_____

APPENDIX C

RESEARCH DATA

APPENDIX I: Auricular acupuncture treatment data

		1	2	3	4	5	6	7	8	9	10	11	12	13	14
	Age	62	54	55	60	40	48	25	40	58	61	43	39	32	42
	Gender	M	M	M	M	F	M	M	F	M	F	M	F	M	M
	Ethnicity	Asian	Asian	Asian	Asian	Asian	Asian	Asian	Asian	White	AA	AA	Asian	Asian	Asian
	Education (years)	16	16	12	14	12	18	16	16	16	18	13	16	14	16
	Start smoke (age)	20	18	15	24	20	16	14	18	33	45	34	20	23	20
1	Years smoking	42	45	35	36	20	32	11	22	25	15	9	18	9	20
	Cigarettes/day	22.5	12	12	17	11.5	12.5	20	10	17	10	15	7.5	10	8.5
	Quit attempts	10	1	10	5	2.5	2	2	3	1	2	4	0	9	5
	Craving rate	5	9	4	7	7	8	8	4	6	6	7	8	5	4
	Taste rate	4	8	4	5	9	7	9	10	6	5	5	5	5	5
	CO level (ppm)	27.5	20	11.5	20.5	7	21	10.5	54.5	13	23.5	22.5	16	11.5	13
	Cigarettes/day	15	10	10	10	8.5	7	7	7.5	9	5	10	2.5	2.5	8.5
	Pressing frequency	10	5.5	4.5	3.5	2	3	10	2	5.5	3	4	5	5	3
2	Craving rate	5	8	3	6	6	6	5	4	5	4	4	8	3	4
	Taste rate	4	7	3	5	8	6	8	7	3	5	4	5	1	5
	CO level (ppm)	31	14.5	16	18	12.5	18	9	27	10.5	21.5	30	5.5	9	8
	Cigarettes/day	20	7	12	10	7	6	10.5	5	6.5	4.5	5	3	2.5	8.5
	Pressing frequency	10	5.5	4.5	3	2.5	5	5.5	4	2.5	4.5	5	3.5	6	5
3	Craving rate	6	7	6	6	5	5	6	4	5	5	3	9	2	4
	Taste rate	3	6	5	5	6	5	8	7	3	4	2	6	2	5
	CO level (ppm)	34.5	14	16.5	20.5	8.5	16	18	24.5	18.5	16	23.5	5	9	19
	Cigarettes/day	15	7	11	11	7	5.5	16.5	5	5	4.5	7	3	2	8
	Pressing frequency	10	4.5	2.5	0	5	4	3	4	3	7	3	3	2.5	3.5
4	Craving rate	4	7	4	7	4	4	8	4	5	5	2	8	1	4
	Taste rate	4	5	4	5	6	4	8	7	2	4	2	6	1	5
	CO level (ppm)	29.5	13.5	14	23	8.5	9	12	17.5	13.5	21	29	5	7.5	18.5
	Cigarettes/day	15	5	10	12	7	5	7	4	4	4	1.5	0.5	1	6
F/U	Pressing frequency	12	5.5	3.5	3.5	5	4	20	4	5.5	4.5	4	5	5	2
	Craving rate	4	5	4	7	4	3	4	4	3	4	1	7	1	3
	Taste rate	4	5	4	7	5	3	6	4	2	4	1	7	1	3

APPENDIX II: Body acupuncture treatment data

		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
	Age	50	38	23	41	54	51	31	47	63	57	47	52	40	28	26
	Gender	M	M	M	M	M	F	M	M	F	M	M	F	M	M	M
	Ethnicity	Hisp	Hisp	White	Asian	Asian	AA	Asian	Asian	Indian	White	Asian	Hisp	Persian	Asian	Hisp
	Education (years)	16	<12	12	18	14	16	16	16	12	12	13	12	16	16	14
	Start smoke (age)	17	13	16	16	20	27	16	20	12	14	19	13	21	15	18
1	Years smoking	33	25	7	25	30	22	15	27	51	43	25	39	19	13	8
	Cigarettes/day	12	10	11	11	10	11	10	20	20	10	20	10	12	12	14
	Quit attempts	5	0	3	3.5	0	10	0	10	8	3	10	2	3	1	2
	Craving rate	8	6	7	6	6	8	7	5	9	5	8	7	5	4	9
	Taste rate	4	6	6	6	10	6	6	5	10	2	5	10	0	6	7
	CO level (ppm)	28	8	23.5	19.5	14	11.5	18	31.5	42.5	39	36	9	19	12.5	30.5
	Cigarettes/day	8.5	5	11	10	7	7.5	15	10	20	8.5	10	1	12	6.5	9.5
	Pressing frequency	3	2.5	3.5	3	2	3.5	5	2	10	2.5	10	10	3.5	2	10
2	Craving rate	6	4	6	4	4	8	7	4	8	5	6	5	5	4	6
	Taste rate	3	5	5	5	7	5	5	2	10	2	6	7	0	6	5
	CO level (ppm)	26.5	16.5	27.5	26	15	12	23	20.5	49.5	33	19	7	21	13.5	39
	Cigarettes/day	3.5	0.5	0.5	6.5	10	7.5	8.5	15	19	10	11.5	1	4	7	9.5
	Pressing frequency	3.5	2.5	5	3	1	2.5	7	5	7.5	1.5	4.5	4.5	11	3	10
3	Craving rate	5	1	2	4	6	7	5	4	8	5	7	4	5	4	5
	Taste rate	2	2	5	4	7	4	5	3	10	2	6	4	0	5	4
	CO level (ppm)	15	4.5	5	24.5	11	12	11.5	25	46	41.5	25.5	3.5	17	13.5	2.5
	Cigarettes/day	6	0	0	3.5	5.5	6	12.5	10	17	7	7.5	5	6.5	7	8
	Pressing frequency	3	2.5	5	3	5	4.5	2.5	4.5	10	3.5	3	5	5	7	30
4	Craving rate	4	0	2	4	7	6	5	2.5	8	4	4	1	5	4	4
	Taste rate	2	0	0	2	7	4	6	3	10	3	6	0	0	4	2
	CO level (ppm)	19.5	4.5	7	22	6	9.5	18	22	52.5	21	10.5	7.5	22	15.5	25
	Cigarettes/day	6.5	0.5	0.5	5	5	4.5	10	8	18	6	7.5	0.5	7	7.5	4
F/U	Pressing frequency	3	2	5	3	10	6.5	2	7.5	10	10	3	7.5	5	3	8
	Craving rate	5	0	0	4	7	4	5	2	8	5	4	1	8	4	4
	Taste rate	3	0	0	2	7	4	5	1	10	2	3	0	0	4	2

APPENDIX D

IRB METTING SUMMARY

SOUTH BAYLO UNIVERSITY

Main Campus: 1126 North Brookhurst Street, Anaheim, CA 92801 Tel: 714.533.1495, Fax: 714.533.6040
L. A. Campus: 2727 West 6th Street, Los Angeles, CA 90057 Tel: 213.738.0712, Fax: 213.480.1332
Virginia Campus: 7535 Little River Turnpike, Unit 325-A, Annandale, VA 22003 Tel: 703.642.7518, Fax: 703.642.7519

www.southbaylo.edu

September 16th 2015

RE: Mika Sugano-Isa
Doctoral Research Project

Dear Mentor,

This letter will certify that the Institutional Review Board approved the Doctoral Research Project of Mika Sugano-Isa on September 25th 2014 with appropriate stipulations.

This document has become necessary in that the Doctoral Research Coordinator in 2014 has left the university, and the present coordinator, Sunghoon Yoon, PhD, OMD, LAc, will now be the final authority guiding the doctoral research process on the Los Angeles Campus.

Sincerely,

Pia Melen OMD LAc
Academic Dean

Wayne Cheng OMD LAc
Director Doctoral Program

Edwin D Follick PhD DTheol JD DC
Chair Institutional Review Board

South Baylo University
Institutional Review Board [IRB]

IRB Committee Revised 2014
Ed Follick Chair DTheol St Andrews Theological Intercollegiate London
Ki Haeng Cho BS MS Seoul National Korea PhD Korea Advanced Institute MS AOM South Baylo LAc
Jeefry Beasca BS Benedictine Philippines MBA Ateneo De Manila [Non-Affiliate]
Anne Ahn BS Korea MS AOM OMD South Baylo LAc
Sheng Li BMed Nanjing China MS AOM OMD South Baylo LAc
Sohila Mohiyeddini PhD Germany Personnel Director
Sunghoon Yoon BS Chungnam National Korea MS Seoul National Korea PhD Penn State MS Cand South Baylo

Of Counsel Consultants Attending
Wayne Cheng MS AOM OMD South Baylo LAc
Pia Melen BS Technical University Romania MS AOM OMD South Baylo LAc
Chul Hahn MS AOM OMD South Baylo LAc

Alternates and Special Subjects
Seong H Hue MS AOM OMD South Baylo LAc
Lionnel Yamentou BSc Open University London Africa MS CIS [Cand] California Mgt & Science [Non-Affiliate]
Michelle Jang [Alternate Non-Scientist]
Soo Gyung Kim BS Seowon Korea MS AOM OMD South Baylo LAc [Alternate]
Hong Joon Ahn BS MBA Korea MBA California Mgt & Science [Non-Affiliate]
Rak Wan Choi MS AOM OMD South Baylo LAc
David Shou Dao Feng MD MS Shanghai 2nd Medical MS OMD South Baylo LAc
Han Jik Kim MS OMD South Balyo LAc
Hong Feng BMed MS Nanjing PhD Tokyo OMD South Baylo LAc
Mai Layyous MB BS MD Alexandria MS OMD South Baylo LAc
Ryul Hyung Lee MD PhD Pusan National MS OMD South Baylo LAc
Henry Choi BA Western Ontario Canada MS AOM DAOM South Baylo LAc

IRB/NIH Format

Minutes of the South Baylo University IRB Meetings Held in [Date] 2012 Previously Distributed in University Conference Room 201 Anaheim Main Campus

Members Present
Ed Follick Chair
Ki Haeng Cho
Sung Hwan Yun
Sunghoon Yoon
Lionnel Yamentou

Members Absent
None with presently reappointment and new

The meeting convened at 10:33 a.m. September 25th, 2014 with a quorum present

Minutes of the Meeting Held on:
Revised committee for 2014

Principal Investigator: Sugano-Isa, Mika

Co-Investigators: None

Protocol Title: Comparison of the Effects between Auricular Acupuncture and Body Acupuncture on Smoking Cessation: a Pilot Randomized Controlled Trial

Protocol précis or summary:
In order to develop an effective method of acupuncture for smoking cessation by comparing auricular and body acupuncture, a randomized controlled trial with 50 participants consisting of an auricular acupuncture with acupressure group (n=25) and a body acupuncture with acupressure group (n=25) will be conducted. The success rate between the two groups will be analyzed and discussed by using chi square tests.

General Discussion: The Chair of IRB explained the concept and purpose of IRB hearing to the PI. He also guided the procedures of completing the documentation.

Specific Discussions:

Scientific design: a pilot randomized controlled trial (RCT) with 50 participants

Risks/benefits:
By participating in this research it is possible that participants may be at greater risk than they would otherwise be. There is, for example, a risk that their condition will not get better and the new treatment will not work as well as previous treatment. If the treatment is not working, PI will provide treatment routinely offered to make them more comfortable. While the possibility of this occurrence is very low, participants should still be aware of the possibility. Acupuncture treatment may cause local pain from needling and slight bleeding or hematoma. Ear seeds may cause discomfort of the ear. At any time, participants may voluntarily withdraw from the research if they develop severe nicotine withdrawal reactions or anxiety symptoms; if they have any adverse effects involving pain, discomfort, inflammation or infection at the local sites of the ear seeds; and as requested by the participants. Meanwhile, participating in this study will help to enrich the knowledge on smoking cessation

Subject selection:
Volunteers meet the selection criteria of (1) to be aged 18 years or over, (2) smoking at least 10 cigarettes per day, (3) to have no other treatment for smoking cessation, (4) no current acupuncture, (5) a desire to stop smoking, (6) to be able to come to treatment for four weeks, and (7) to be able to be reached by telephone. will be selected.

Additional safeguards: None

Minimization of risks to subjects:
If any side effects develop problems on participants, PI will stop using acupuncture treatment and will provide other treatment to decrease symptoms of the side effects or reactions. This case of side effect will be discussed together with participants and participants will always be consulted before PI move to the next step and will be referred to dermatologist.

Privacy & confidentiality:
The information collected from this research project will be kept confidential. Information about participants collected during the research will be put away and no-one but the researcher will be able to see it. Any information about participants will have a number on it instead of participants' name. Only the researcher will know the identification number of participants. Information will not be shared with or given to anyone except researcher and mentor.

Consent document: as attached

Additional considerations: None

Stipulations: None

Recommendations:
1. To prepare Korean and Spanish version of Informed Consent Form additionally.

IRB Decision and Vote:

Yes votes: 5
Abstained votes: 0
No votes: 0
Total votes: 5

Reasons for majority and minority opinion: Not applicable

Amendments: Not applicable.

Report of adverse events: If the auricular acupuncture, body acupuncture or acupressure treatment causes any adverse problems like discomfort, nausea, vomiting, dizziness, vertigo, allergy reactions such as scarring, rash, redness, itching, and swelling, the researcher will examine the case, and report to IRB without delay.

Information items: Not applicable