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ORIGINAL RESEARCH

Effect of Acupoint Catgut Embedding for Abdominally Obese Female with Strong Appetite: Mixed Analysis of a Randomized Clinical Trial

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Background: Abdominal obesity (AO) is not only a health issue, but also a serious impact on women's work and life. The article of acupoint catgut embedding (ACE) on AO has already been accepted to be published and showed significant effect. However, whether ACE is effective for abdominally obese female with strong appetite is still unclear.

Methods: This is a mixed analysis of a multicenter, double-blind, randomized controlled trial.Which was conducted in China between July 2018 and March 2020 (n = 101), while with the supplementary samples (n = 22) between April 2020 and June 2022. According to the appetite and intervention methods, 123 abdominally obese female were divided into ACE group with strong appetite (n = 27) and moderate appetite (n = 31), control (non-acupoint catgut embedding) group with strong appetite (n = 37) and moderate appetite (n = 28). Four subgroups were given a 12-week actual intervention period and a 4-week follow-up. Waist circumference (WC), appetite, body weight and BMI were applied and assessed at baseline and after 6, 12 and 16 weeks.

Results: In this study, the mean onset age of abdominal obesity in females was 25.27 (8.19) years old. The longer duration of AO, the lower the appetite in females ($p<0.05$). At 12 and 16 weeks, ACE group with strong appetite showed significant decrease in WC and appetite than control group with strong appetite ($p<0.01$). However, ACE group with moderate appetite showed no significant decrease than control group with moderate appetite in WC, appetite, body weight and BMI ($p>0.05$). At 12 and 16 weeks, there was no significant difference in appetite between the ACE groups (strong and moderate appetite)($p>0.05$), while there was still a difference between the control groups ($p<0.05$).

Conclusion: Younger abdominally obese female had a stronger appetite. ACE own the remarkable therapeutic effects for younger abdominally obese female and showed the perfect effect on appetite-reduction.

Keywords: acupoint catgut embedding, abdominal obesity, obese female, appetite, waist circumference

Background

Obesity is a global health issue regardless of region, race and age. There are more than 1.9 billion adults (39%) overweight worldwide, and of which at least 650 million adults (13%) are obese.[1] As a major type of obesity, the abdominal obesity (AO) rate in adults is about 29.1% and the prevalence increased rapidly in China.[2–4] AO is not only associated with diseases, such as diabetes, hypertension, dyslipidemia, atherosclerosis, and colorectal cancer.[5–9] For females, it is more of a stumbling block for people's pursuit of beauty, job title and wage level.[10–12]

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Dietary control is considered as an effective treatment for obesity,[13] but is difficult for people with strong appetite to adhere to, as it is a painful thing for them. Acupoint catgut embedding (ACE) is a special acupuncture therapy which based on Traditional Chinese Medicine (TCM) theory and new needling instrument. ACE generate the long-term stimulation effect of acupoint by inserting gut into the acupoint. It has been used for the treatment of digestive tract and endocrine diseases since the mid-1960s.[14] Studies indicated that catgut embedding at acupoints is effective in the treatment of AO.[15,16] Nevertheless, there is no credible evidence that ACE could reduce appetite, waist circumference (WC), body mass index (BMI) in abdominally obese female with strong appetites. In this mixed analysis of a multicenter, randomized, double-blind, controlled study, we examined the efficacy of ACE in abdominally obese female with different appetites and set non-acupoints catgut embedding as the sham control.

Methods

Study Design

The foregone study was undertaken between July 2018 and March 2020, without the gender requirement (male 22, female 101). The foregone article has been accepted to be published in *Journal of Traditional Chinese Medicine*. In order to further explore the effect of ACE on abdominally obese female with strong appetite. Based on the analysis of the foregone study data, we supplemented female samples (n = 22) between April 2020 and June 2022. Every participant received a 12-week intervention period and a 4-week follow-up. Primary and secondary outcomes were measured at baseline, 6, 12, and 18 weeks after the intervention. Possible adverse events were carefully monitored from 1 to 16 weeks. The flow chart was shown in Figure 1.

The study was registered in Chinese Clinical Trial Registry (ChiCTR1800016947), and approved by the Hospital Ethics Committee of The Sports Trauma Specialist Hospital of Yunnan Province (2018CK-001). All participants were fully informed and signed written informed consent forms.

Participants

We recruited participants from outpatients in 4 clinical centers: The Second Affiliated Hospital of Yunnan University of Chinese Medicine, The Sports Trauma Specialist Hospital of Yunnan Province, Kunming Hospital of Traditional Chinese Medicine and Shengai Hospital of Traditional Chinese Medicine.

According to the diagnostic criteria of AO by Chinese Medical Association, WC is used to diagnose AO. In this study, the main inclusion criteria was WC≥85 cm in female. The measurement method of WC: the measured person in the standing position, and the circumference of the body was measured at the horizontal position of the lower costal edge of the midaxillary line and the midpoint of the iliac crest line.[17] The second inclusion criteria included body mass index (BMI) ≥24 kg/m^2, aged between 18 and 60, simple overweight or obesity.[18]

The exclusion criteria were: WC<85 cm in females, BMI < 24 kg/m^2; secondary obesity caused by endocrine disease or medication; pregnancy, lactation and childbirth within the past 6 months; coronary heart disease, chronic obstructive pulmonary disease, liver cirrhosis, nephritis and other serious organ diseases; hypertension without effectively controlled; participants with severe mental and neurological diseases; allergic to alcohol or catgut; received other weight loss treatment within past 3 months.

Randomization and Blindness

The randomization sequence was computer generated by the Clinical Research Center of Yunnan University of Chinese Medicine. Stratified randomization was performed for 4 clinical centers. Opaque envelopes with random numbers were managed by the independent coordinator. Participants, inspector and analyst were blinded to group allocation. After the assistant lays the drapes, the acupuncturist performed the manipulations. Therefore, the acupuncturists were also blinded to group allocation.

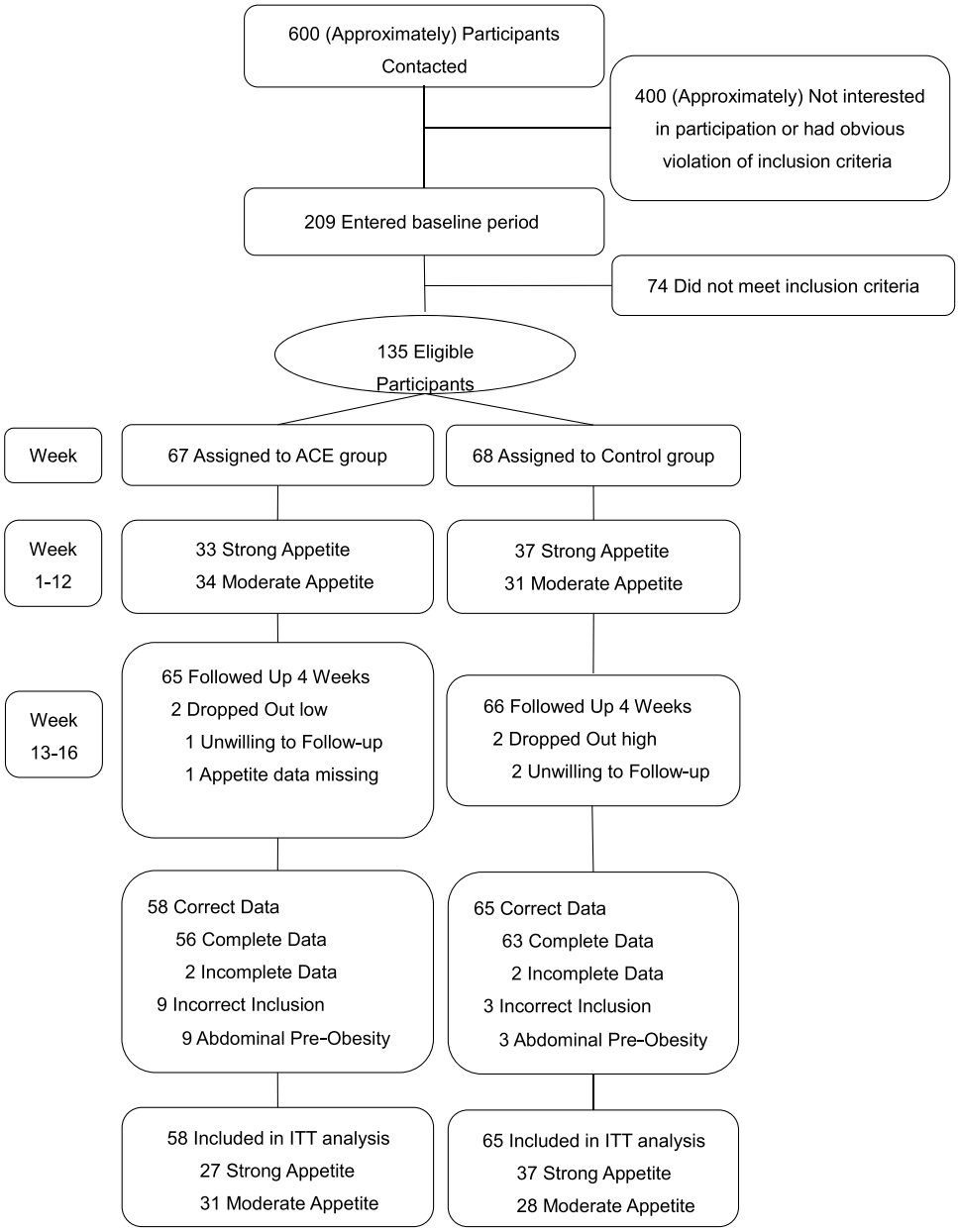

Figure 1 Flowchart of the screening, enrollment, randomization, and follow-up.

Interventions

Participants received catgut embedding treatment every 2 weeks for a total of 6 sessions. All catgut embedding manipulations were performed by an acupuncturist with national medical qualifications. The acupoints of the ACE group were Pishu (BL20), Weishu (BL21), Dachangshu (BL25), Zhongwan (CV12), Tianshu (ST25) and Zhangmen (LR13). The control group chose non-acupoints besides the acupoints, which were labeled NA1, NA2, NA3, NA4, NA5 and NA6. The location of these points and the operation of catgut embedding are shown in Figure 2.

The assistant marked the position of acupoints/non-acupoints, conventionally disinfected the skin of the operation area, and layed the sterile drapes. Took a sterile medical catgut with a length of 1–2cm (the length depends on the location of the acupoint), placed it on the front end of the trocar, then connected the needle core, lifted the partial skin with the thumb and forefinger of one hand, pierced the needle with the other hand. When the piercing reached the desired depth, we implanted the catgut in the subcutaneous tissue or muscle layer. After the needle was removed, pressed the

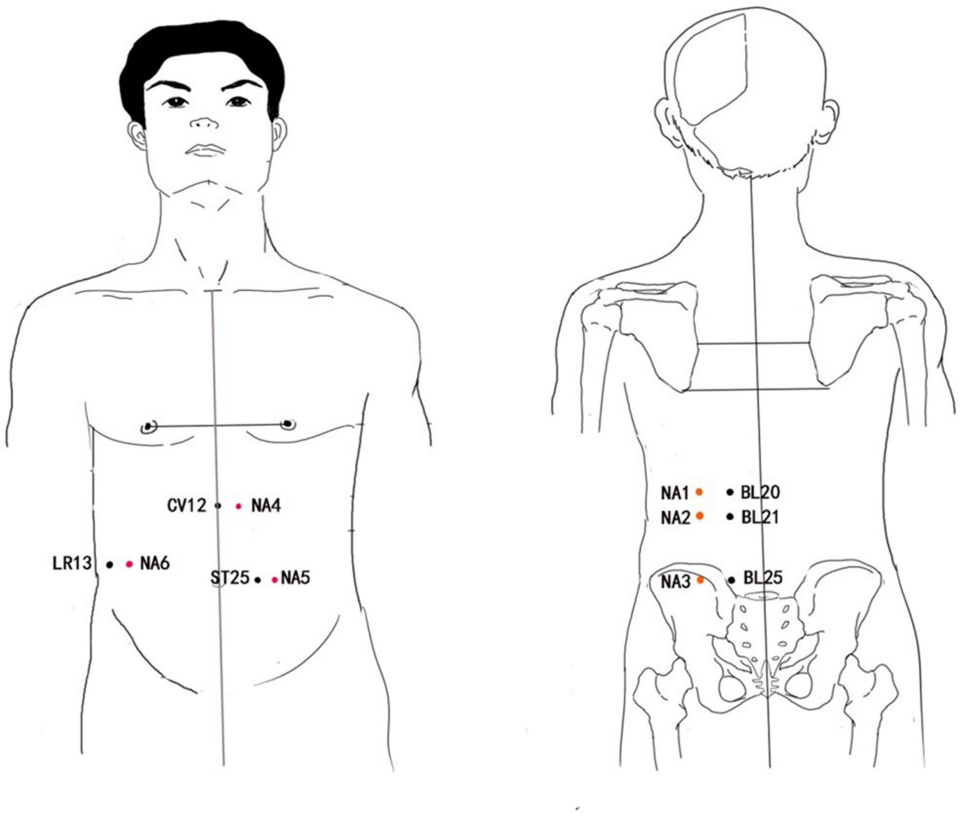

Figure 2 Location of the points. Acupoints of BL20(Pishu), BL21(Weishu), and BL25(Dachangshu) located in back waist. CV12(Zhongwan), ST25(Tianshu) and LR13 (Zhangmen) located in abdomen. The non-acupoints are next to the acupoints (in red).

needle hole with a dry cotton ball for half a minute to stop bleeding, and then pasted a bandage to protect the needle hole. Participants were recommended not to bathe for 24 hours and keep the embedding place dry.

The thread-embedded needle used in this study was $8^{\#}$ disposable needle (Jiangxi Glance Medical Equipment Co. Ltd. Production, Nanchang, China), and the medical catgut was an absorbable collagen line with the specification of 2–0, 2 cm*20 lengths (Jiangxi longteng biotechnology co., LTD, Nanchang, China).

Diet and physical activity were not restricted during treatment and follow-up, participants were asked to continue their routine.

Outcome Measures

Outcome measurements were performed at baseline, 6 and 12 weeks in the intervention period, and 16 weeks in follow-up phase. No eating or drinking for 2 hours before the indicators test. The primary outcomes were WC and visual analogue scale (VAS) of appetite. The secondary outcomes were body weight, and BMI.

Assessed appetite by VAS as reported in the article.[19] No appetite and minimal intake (0 score). Slight appetite and small amount of intake (1–3 score). Moderate appetite and moderate intake (4–6 score). Strong appetite and large intake (7–10 score). Possible adverse event was monitored and recorded as needed from 1 to 16 weeks. The body weight was in kilograms (Kg) and accurate to 10g. Body height in meters (m) and accurate to 1 cm. BMI was calculated by height and weight. At the end of the normal exhalation, measured round the abdomen and hip in the horizontal direction and without pressing skin. Circumference in centimeters (cm) and accurate to 1mm.

Statistical Analysis

All data were analyzed by SPSS (vers 19.0, SPSS Institute, Chicago, IL, USA) and GraphPad Prism (vers 7.0, GraphPad Software, San Diego, CA, USA). The clinical outcomes described and baseline characteristics are based on the intention-

to-treat (ITT) population, which included participants who have received one treatment. Continuous variables were presented as the mean and standard deviation (SD). While the nonnormally distributed variables were presented as the median and interquartile range (IQR). Categorical variables were described as numbers and percentages. The missing data were all in follow-up, expectation maximization and last observation carried forward method were not suitable. Therefore, when the missing data were involved, they were disposed by listwise deletion. The significance level used for the statistical analysis with 2-tailed testing was 5%.

Normality of continuous variables was determined by the Shapiro–Wilk test, Kolmogorov–Smirnov test, Skewness and Kurtosis. Homogeneity of continuous variables was determined by *F*-test, Brown-Forsythe and Bartlett's test. Independent-Sample *t*-test or nonparametric test (Mann–Whitney test) was used when compared between groups. One-way ANOVA or nonparametric (Friedman) test was used to compare the repeated measurements (≥3) within the group. Paired *t*-test or nonparametric test (Wilcoxon test) was performed to compare the two repeated measurements within the group.

Results

Participants Information

Approximately 600 potential participants were invited and 209 participants aged between 18 and 65 had entered the baseline period. After initial screening, 135 of 209 participants were submitted to the randomized process. During all intervention phases, 135 participants completed 6 treatments and 3 tests. Noted that three participants were unwilling to undergo follow-up (1 in the ACE group and 2 in the control group). During the follow-up test, 1 participant had an emergency and failed to complete the measure. Meanwhile, the recruiters mistakenly included 12 participants who were abdominal pre-obesity (WC 80–85 cm in females). Ultimately, a total of 123 participants (58 in the ACE group and 65 in the control group) were included in the ITT population (Figure 1).

Baseline Characteristics

Table 1 showed the statistical analysis of selected-participants' characteristics at baseline. The allocation of groups was based on the appetite and intervention methods. The statistical analysis also yields comparable statistics across the 4 groups at baseline ($p>0.05$). The mean age of abdominal obesity in females was 34.19 (8.57) years old in strong appetite, 37.34 (9.97) in moderate appetite. The mean onset age of abdominal obesity in females was 24.82 (6.89) in strong appetite, 25.75 (9.43) in moderate appetite. The median duration of abdominal obesity in females was 9.00 (6.75) in strong appetite, 10.00 (12.00) in moderate appetite. Compared with the moderate appetite, the female with strong appetite

Table 1 Baseline Characteristics of 123 Participants Included in the ITT Analysis

Baseline Characteristics	Strong Appetite (n=64)		Moderate Appetite (n=59)	
	ACE (n=27)	Control (n=37)	ACE (n=31)	Control (n=28)
Age, y	33.15 (7.53)	34.95 (9.29)	37.90 (10.96)	36.71 (8.93)
	34.19 (8.57)		37.34 (9.97)	
Duration, y	8.00 (9.00)	10.00 (6.00)	12.00 (9.00)	9.00 (6.75)
	9.00 (6.75)		10.00 (12.00)	
Onset Age, y	23.53 (6.62)	25.77 (7.03)	25.45 (9.34)	26.09 (9.70)
	24.82 (6.89)		25.75 (9.43)	
Appetite score	7.74 (0.66)	7.97 (0.89)	5.52 (0.83)	5.39 (0.83)
	7.85 (0.79)		5.47 (0.82)	

Notes: Age, onset age and appetite score were presented as mean (SD). Duration were presented as median (IQR). For age and onset age, *Independent-Sample t*-test were used between "Strong Appetite" and "Moderate Appetite". For duration, *Mann–Whitney* test were used between "Strong Appetite" and "Moderate Appetite". *Pearson Chi-Square* test was used to determine the correlations between appetite score and the duration.

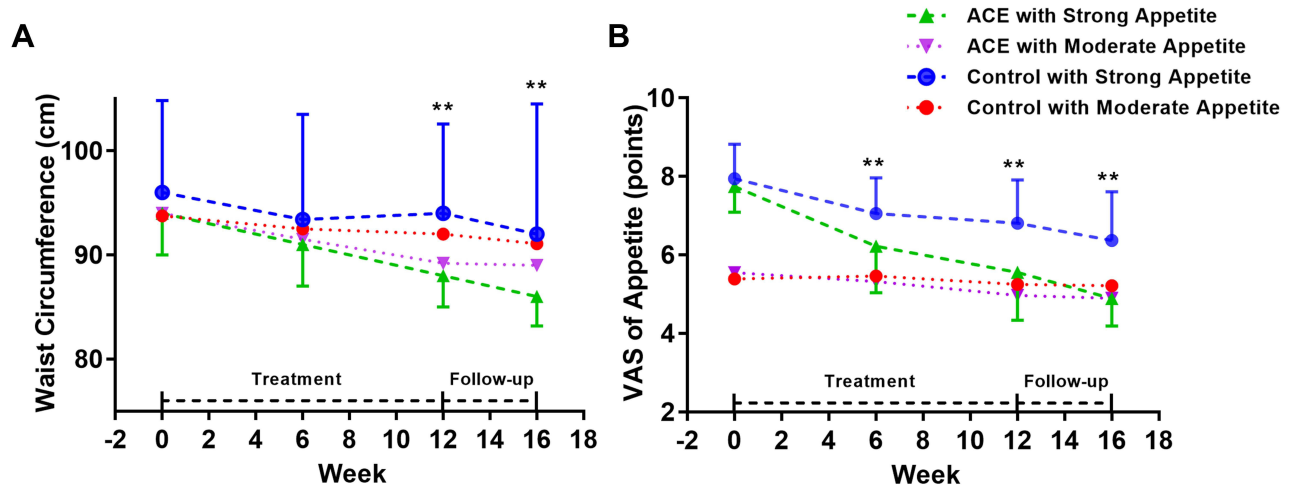

Figure 3 Waist circumference and appetite during the entire study.
Notes: (**A**) WC data were presented as median (IQR) in strong appetite groups, median in moderate appetite groups. *Mann–Whitney* test were used between every two groups. $^{**}p < 0.01$. (**B**) Appetite data were presented as mean (SD) in strong appetite groups, mean in moderate appetite groups. *Independent-Sample t*-test were used between every two groups. $^{**}p < 0.01$.

had no significant difference in the onset age (p=0.532). However, there are differences in age (p=0.062) and duration (p=0.078). Meanwhile, the appetite is correlated with the duration of AO (p<0.05).

Foregone Study Outcomes

The effects of ACE on AO have already been accepted to be published. Results indicated that the WC, appetite, body weight, and BMI decreased significantly within ACE group and control group in 0–12 weeks (p<0.01) and follow-up (p<0.01). At 12 weeks and 16 weeks, the WC and appetite of ACE group were statistically different from control group (p<0.05). No serious adverse events were observed in totally 135 participants.

Mixed Outcomes

In this study, foregone outcomes (females only) and supplemented samples' outcomes were mixed for analysis. As shown in Figure 3A, at 12 weeks, the median WC of the ACE group with strong appetite was 88.00 (7.30), 94.00 (14.80) in the control group with strong appetite. At 16 weeks, 86.00 (6.91) in the ACE group (strong appetite), 92.00 (17.70) in control group (strong appetite). The WC of ACE group with strong appetite was significantly lower than the control at 12 and 16 weeks (p<0.01). However, there was no significant difference in WC within the moderate appetite groups (p>0.05).

As shown in Figure 3B, the appetite of ACE group with strong appetite was significantly lower than the control at 6, 12, and 16 weeks (p<0.01). At baseline and 6 weeks, the appetite within the ACE groups was significantly different (p<0.01). But at 12 and 16 weeks, the appetite of ACE group with strong appetite had decreased to the same level of ACE group with moderate appetite (p>0.05). While for the control groups, there were significant differences between strong appetite and moderate appetite during the total study period (p<0.01). The appetite of control group (strong appetite) had never decreased to the same level of moderate appetite.

As shown in Table 2, at 16 weeks, the body weight (p=0.058), and BMI (p<0.05) of ACE group with strong appetite were also significantly lower than control group with strong appetite. However, there were no significant differences in appetite, body weight, and BMI between the moderate appetite groups (p>0.05).

Another interesting result, within the ACE groups (strong and moderate appetite), there were no significant differences in WC, body weight and BMI during the total study period (p>0.05). The control groups (strong and moderate appetite) also showed similar results (p>0.05).

Table 2 Body Weight and BMI During the Entire Study

Secondary Outcomes	ACE (n=58)		Control (n=65)	
	Strong Appetite (n=27)	Moderate Appetite (n=31)	Strong Appetite (n=37)	Moderate Appetite (n=28)
Body Weight, kg				
Baseline	73.71 (5.79)	74.47 (10.36)	75.83 (9.38)	73.85 (10.25)
Treatment, wk				
1–6	72.06 (5.75)	73.81 (9.84)	75.01 (9.30)	73.07 (10.30)
7–12	70.63 (6.21)	72.56 (10.02)	74.58 (9.47)	72.42 (10.58)
Follow up, 13–16 wk	69.60 (7.32) (n = 27)	70.63 (9.65) (n = 30)	74.02 (9.96) (n = 35)	71.30 (11.11) (n = 28)
BMI, kg/m^2				
Baseline	28.79 (2.01)	29.00 (3.67)	29.67 (4.35)	28.60 (3.18)
Treatment, wk				
1–6	28.14 (2.05)	28.74 (3.40)	29.35 (4.34)	28.31 (3.25)
7–12	27.59 (2.29)	28.24 (3.41)	29.18 (4.38)	28.03 (3.26)
Follow up, 13–16 wk	27.15 (2.35) (n = 27)	27.51 (3.27) (n = 30)	28.97 (4.60) (n = 35)	27.61 (3.55) (n = 28)

Notes: Data were presented as mean (SD). *Independent-Sample t*-test were used between every two groups.

Discussion

In China, females' age of 25.27 (8.19) is the period to work and have children. However, the inequality in the labor market, especially the inequality caused by appearance characteristics, is more likely to be accepted by the general public. Meanwhile, the problem of appearance discrimination is seldom considered by academic researchers.[20] However, the discrimination may lead to losses of social welfare. If the problem of discrimination is not taken seriously in academia, the labor force may continue to suffer from more unequal treatment. Empirical evidence also demonstrates that there are strong correlations between appearance and social network, or human capital. Thereby, appearance discrimination (such as AO) probably indirectly determined employment and wages.[12,20] In terms of direct appearance discrimination, females may earn more from the "pretty appearance". What's more, the stress of work is rather a significant precipitating factor of obesity in female.[21] In addition to many diseases, obesity also has many adverse effects on pregnancy.[22]

The effective treatments for obesity mainly include dietary control, physical activity, pharmacotherapy, behavioral intervention and bariatric surgery.[13,23–25] However, pharmacotherapy is usually associates with side effects, including abdominal pain, insomnia, headache, dysgeusia and insomnia.[23] On the other hand, dietary control and physical activity are difficult to stick,[24] as well as the effect of behavior intervention for obesity is typically limited.[24] What's more, bariatric surgery increases the risk of fractures.[25] ACE is the most widely used alternative therapy for AO in China with many successful trials.[15,16] The single treatment duration of ACE is less than 30mins, but it is effective for 2 weeks. Such time-saving advantage is well suited to the fast-paced modern society, and could reduce the time and financial burden of the weight loss process. However, whether ACE owns same the efficacy of abdominally obese female with different appetites is still uncertain.

In this mixed analysis, according to the appetite and intervention methods, we divided the participants into ACE group with strong appetite and moderate appetite, control group with strong appetite and moderate appetite. Non-acupoint catgut embedding was set as the control and many interesting results were observed. Results showed the longer duration of AO, the lower the appetite in females, which may have something to do with getting older. The decreases in several indicators (ie, WC, body weight, BMI) not only contribute to individual good health, but also help young obese females in reshaping their bodies, boosting self-confidence, enhancing their job competitiveness and increasing salary level.[12,20] The decrease of appetite in young abdominally obese female with strong appetite, which further reduces their dietary burden.

ACE showed better effect than non-acupoint catgut embedding in abdominally obese female with strong appetite. On the other side, ACE has similar effects on WC, body weight and BMI in abdominally obese female, whether with strong appetite or moderate appetite. Moreover, it could reduce the hyperactive appetite to normal levels. In recent years, some studies have questioned and challenged the specific effect of acupuncture at acupoints.[26,27] Therefore, in related studies, non-acupoints were usually used as sham control to verify the specificity of acupoints.[28,29] The non-acupoint area parallel to the acupoint and

meridians were usually selected as the contrast sites. Stimulating the non-acupoint sites generates definite effects, but not limited to the local nearby effects. Regarding the differences effects between the acupoints and non-acupoints stimulations, the acupoints attaches the importance on "Qi", which is abstract and dynamic and the non-acupoints on "shape", which is concrete and static.[26] This study is an evidence which verified the difference of acupoint specificity and the bidirectional regulation of acupoints. The outcomes' difference may be the result of the combined effect, which is local and targeted regulation of the acupoint and non-acupoint.[28] The anatomical structures of acupoint and non-acupoint are different in muscle fascia, blood vessels, nerves, lymph and other tissues. In the state of disease, there are differences in the sensitization of electricity, temperature and algesia between acupoint and non-acupoint. After the stimulation at acupoint, the *Qi* effect, degranulation of mast cells, adenosine release, and the regulation of brain network and target organ are also different.[27,29,30] Therefore, whether strong appetite or moderate appetite, the same acupoint stimulation plays the similar effect.

This trial has several limitations. To further expand the sample size, participants were recruited again. Therefore, it is not a standard secondary analysis. On the other hand, as the participants were divided into four groups based on appetite and intervention, the sample size of each group was still limited. Dietary and exercise limitations are more in line with scientific norms, which is easier to produce therapeutic effects. However, in not to burden the participants with dieting control, we did not restrict participants' diet and exercise. Therefore, the interesting results make more sense.

To sum up, ACE owns the perfect therapeutic effects on WC and appetite reduction for younger female with strong appetite. Which may also strengthen their self-confidence, job competitiveness, and salary level.

Abbreviations

ACE, acupoint catgut embedding; AO, abdominal obesity; BMI, body mass index; RCT, randomized controlled trial; VAS, visual analogue scale; WC, waist circumference.

Data Sharing Statement

Data can be obtained by contacting the corresponding author after publication of this article.

Ethics Approval and Consent to Participate

The study was conducted in accordance with the Declaration of Helsinki. The study was registered in Chinese Clinical Trial Registry (ChiCTR1800016947), and approved by the Hospital Ethics Committee of The Sports Trauma Specialist Hospital of Yunnan Province (2018CK-001). All participants were fully informed and signed written informed consent forms.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors declare no conflicts of interest in this work.

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