

# Acupuncture combined with auricular acupressure for smoking cessation and its effects on tobacco dependence and smoking behavior among Hong Kong smokers: a prospective, multicenter clinical study

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## Research Article

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# Abstract

**Background:** Acupuncture combined with auricular acupressure has been used as a complementary and alternative treatment for smoking cessation in Hong Kong for over 10 years. This study aimed to verify its therapeutic effects and safety for smoking cessation and to evaluate its effects on tobacco dependence, smoking behavior, anxiety levels and sleep disturbances between successful and unsuccessful quit smokers in Hong Kong.

**Methods:** This prospective, multicenter clinical study conducted between September 2020 and February 2022 in Hong Kong was part of the Guangdong-Hong Kong-Macau Greater Bay Area project on smoking cessation. Thirty eligible current smokers (mean age: 47.10 years; 40% female) were recruited and received standardized acupuncture plus auricular acupressure treatment twice weekly for 8 weeks. The primary outcome was the success rate of smoking cessation at week 24. The secondary outcomes were the success rate of smoking cessation at weeks 8 and 16, exhaled carbon monoxide (CO) level, changes in scores on the Fagerström Test for Nicotine Dependence (FTND), Autonomy Over Smoking Scale (AUTOS), Hamilton Anxiety Rating Scale (HAM-A), Self-rating Anxiety Scale (SAS), and Pittsburgh Sleep Quality Index (PSQI). Adverse events were also recorded during the study period.

**Results:** Of 30, 28 participants completed 6 or more treatment sessions and all completed follow-up assessments. At week 24, the success rate of smoking cessation was 46.67%. The successful quit rates at weeks 8 and 16 were 36.67% and 43.33%, respectively. The overall change in mean FTND scores from baseline improved significantly from weeks 2 to 24 ( $P < 0.05$ ), with the successful quit group showing significantly greater improvement between weeks 8 and 24 ( $P < 0.01$ ). Compared with baseline, there were significant reductions in the mean AUTOS scores from weeks 6 to 24 ( $P < 0.001$ ), with the successful quit group showing greater improvement at weeks 16 ( $P = 0.04$ ) and 24 ( $P < 0.001$ ). No significant changes were detected in exhaled CO levels and HAM-A, SAS, and PSQI scores. No study-related adverse events were observed.

**Conclusions:** Acupuncture combined with auricular acupressure is an effective alternative treatment for smoking cessation and reducing tobacco dependence and cigarette consumption among Hong Kong smokers.

**Trial registration:** Chinese Clinical Trial Registry, No. ChiCTR2000033650. Registered on June 7, 2020, <http://www.chictr.org.cn/showproj.aspx?proj=54866>

## Background

Tobacco smoking is a challenging public health problem worldwide. The global prevalence of smoking among people aged over 15 years was 17.5% in 2019 [1]. In Hong Kong, the Census and Statistics Department survey report 2019 showed that cigarette smoking prevalence was 11.1% among those aged 15 years and older [2]. Smoking is a major cause of and associated with many preventable diseases and premature death globally [1]. According to the Global Burden of Diseases, Injuries, and Risk Factors Study 2019, smoking was the second leading risk factor for attributable deaths globally, which accounted for 8.71 million deaths [3].

Tobacco smoking increases the risk of contracting a wide range of diseases, including lung and heart diseases, chronic respiratory diseases, cancers, and diabetes, many of which are fatal. In general, there is a positive association between average daily cigarette consumption and the risk of most smoking-related diseases, and it can harm non-smokers who are exposed to environmental tobacco smoke [4].

Quitting tobacco smoking has a profound effect on improving health and quality of life and significantly reduces the risk of tobacco-related diseases and death. Stopping smoking at any age is more beneficial than continuing to smoke. Reducing tobacco use is critical for reducing the burden of noncommunicable diseases, which account for 71% of deaths globally [1]. Many countries have adopted different smoke-free legislative measures for tobacco control. In addition, various methods, including but not limited to pharmacotherapies, nicotine replacement therapy, and behavioral therapy, are available to help smokers achieve abstinence. Bupropion and varenicline are the most commonly used drugs for smoking cessation. Nicotine replacement therapy helps reduce motivation to smoke, and it is accepted as an essential treatment for people who want to stop smoking. Numerous trials have attempted to evaluate these treatments that have resulted in different levels of evidence; however, no single best method has been identified [5].

Over the years, acupuncture has been used for smoking cessation, with increasing acceptance and research investigating its effect on nicotine dependence. Previous clinical and experimental study has found that acupuncture alleviates cue-induced cravings during the initial abstinence phase of smoking cessation through the regulation of brain activation in areas involved in attention, motivation, and reward in smokers [6]. A study exploring the neural mechanisms of acupuncture indicated that the immediate effects of acupuncture on smoking craving were significant and identified the anterior cingulate cortex, insula, prefrontal cortex, visual cortex, and cerebellum as key brain areas, which might be related to decreasing salience of smoking and increasing the ability to resist the craving, respectively [7]. Previous clinical studies showed that acupuncture is effective for smoking cessation [8, 9] and its effect is noninferior to nicotine replacement therapy [9]. Its treatment effect may last for at least 5 years as confirmed in a previous study [10]. Acupuncture is safe and can relieve withdrawal symptoms [8] and reduce daily cigarette consumption [11, 12].

Auricular acupressure, which works by continuously stimulating acupoints to regulate and relieve disease symptoms, has been adopted as a simple and effective noninvasive intervention to help quit smoking. It may be beneficial to relieve withdrawal symptoms and decrease the level of exhaled carbon monoxide (CO) [13]. The results from a previous systematic review and meta-analysis suggested that ear acupressure is beneficial in achieving smoking cessation and could be a clinical alternative to established smoking cessation interventions [14]. However, this result was based on data without biochemical confirmation.

In view of the above, acupuncture, auricular acupressure, or a combination of both could be effective in smoking cessation; however, their efficacy remains controversial and lacks high-quality scientific evidence [15]. A previous systematic review and Bayesian network meta-analysis showed that the probability rankings of auricular acupressure and acupuncture plus auricular acupressure were better than other interventions in smoking cessation [16]. Substantial uncertainty remains, as previous studies showed conflicting results and no firm conclusion can be made regarding the effectiveness of acupuncture as a single treatment for smoking cessation.

Therefore, we aimed to provide additional clinical research evidence and verify the efficacy and safety of acupuncture combined with auricular acupressure for smoking cessation. In addition, we evaluated the changes in tobacco dependence, smoking behavior, anxiety levels and sleep disturbances between successful and unsuccessful quit smokers in Hong Kong.

## Methods

### Study design and setting

This prospective, multicenter, open-label clinical study was conducted between September 24, 2020, and February 22, 2022. The trial sites included Pok Oi Hospital–The Chinese University of Hong Kong Chinese Medicine Clinic cum Training and Research Centre (Shatin District) and two community-based mobile clinics. The trial consisted of 8 weeks of treatment and 16 weeks of follow-up (an 8-week treatment period with follow-up at weeks 16 and 24). The trial was approved by the Joint Chinese University of Hong Kong–New Territories East Cluster Clinical Research Ethics Committee (No. 2020.116) and registered in the Chinese Clinical Trial Registry (No. ChiCTR2000033650). The trial adhered to the Declaration of Helsinki and Good Clinical Practice guidelines. The study was conducted in accordance with the STandards for Reporting Interventions in Clinical Trials of Acupuncture recommendations [17]. All participants provided written consent prior to participation. Treatments were provided free of charge, and no subjects were paid for participation.

### Participants

Current smokers who wanted to quit smoking were recruited and underwent eligibility assessment by cross-referral from all Chinese medicine service units under the management of Pok Oi Hospital (covering all districts in Hong Kong) between September 2020 and August 2021.

Eligible participants had to meet the following inclusion criteria: (1) voluntarily quit smoking; (2) aged between 18 and 65 years; (3) smoked for  $\geq 1$  year; (4) consumed  $\geq 20$  cigarettes per day in the previous year; (5) positive salivary cotinine test; (6) nicotine dependence score (Fagerström Test for Nicotine Dependence, FTND [18]) of  $\geq 4$  points; (7) provided written informed consent and volunteered to participate; and (8) undergone a washout period of more than 1 month if other smoking cessation treatments were previously conducted.

Participants were excluded if they (1) had severe and unstable cardiac, pulmonary, cerebral, or hematologic diseases, or diabetes with other complications; (2) had mental illness and drug abuse; (3) had apoplexy or nervous system diseases; (4) had unknown diseases; (5) had blood coagulation disturbances or current administration of anticoagulant drugs; (6) had moderate or severe liver and kidney impairment; (7) were pregnant; or (8) had a history of smoking cessation treatments, such as acupuncture, auricular acupressure, or nicotine replacement therapy, within the previous month.

After the eligibility assessment by the study team, the participants were enrolled and underwent baseline pretreatment evaluation. Routine biochemical and hematological tests and electrocardiography were performed before treatment administration.

### Intervention

All participants received standardized acupuncture and auricular acupressure treatments twice a week for 8 consecutive weeks. The treatments were performed by Hong Kong Registered Chinese Medicine Practitioners who had over 3 years of practice experience and received training to execute standard protocol procedures before study initiation. The treatment protocol was developed based on the neural mechanism of acupuncture [6, 7], previous clinical studies [19, 20], and clinical experience of acupuncture experts.

For acupuncture treatments, the acupoints used were Baihui (GV20), Yintang (GV29), bilateral Lieque (LU7), and bilateral Hegu (LI4) [21, 22]. These were frequently used acupoints for smoking cessation [20]. During each treatment session, the participants were in a supine position exposing the acupoints. After skin disinfection, sterile, single-use acupuncture needles (0.25 mm × 25/40 mm; Suzhou Medical Appliance Factory, Suzhou, China) were obliquely inserted into GV20 (depth, 0.8–1.0 cun) and bilateral LU7 (depth, 0.5–1.0 cun until it reached Yangxi [LI5]); transversely inserted into GV29 (depth, 0.8 cun); and perpendicularly inserted into bilateral LI4 (depth, 0.5–0.8 cun), manipulating the needles using the lifting and thrusting method [23] until deqi sensation [24] was achieved for each acupoint whenever possible, and retained in situ for 30 min before removal. During retention, the needles were manipulated by lifting and thrusting 20 times every 10 min.

Auricular acupressure was administered unilaterally and alternated between the left and right ear in each treatment session. The auricular acupoints used were Shenmen (TF<sub>4</sub>), Fei (CO<sub>14</sub>), Wei (CO<sub>4</sub>), Neifenmi (CO<sub>18</sub>), Pizhixia (AT<sub>4</sub>), Jiaogan (AH<sub>6a</sub>), and Kou (CO<sub>1</sub>) [25]. After skin disinfection, Vaccariae seeds (Wang Bu Liu Xing) 2 mm in diameter were embedded on the surface of the 7 auricular acupoints within the adhesive tape and maintained for 3 days. Participants were instructed to press each auricular acupoint via the central plastered seed 3–5 times per day for 30–60 s.

During the study period, the study team advised each participant to avoid any other treatments for smoking cessation. However, medications should be continued for basic diseases such as hypertension, diabetes, hyperlipidemia, and coronary heart disease.

## Outcome measures

Evaluations in this study were performed at baseline and at weeks 2, 4, 6, and 8 after the start of treatment, as well as at weeks 16 and 24 when follow-up was performed.

The primary outcome measure was the success rate of smoking cessation at week 24, with success defined as self-reported quitting and verified by an exhaled CO level < 10 parts per million (ppm) within 24 h of self-reported abstinence, measured using CO Check Pro (MD Diagnostics Ltd, UK), and a negative test result for salivary cotinine, measured using the Oral Fluid Cotinine Test Mini Cube (TestCountry, USA).

Secondary outcomes were the success rate of smoking cessation at weeks 8 and 16, exhaled CO level at each evaluation time point, efficacy indicators of the FTND and Autonomy Over Smoking Scale (AUTOS) at each evaluation time point, and scale evaluations of the Hamilton Anxiety Rating Scale (HAM-A), Self-rating Anxiety Scale (SAS), and Pittsburgh Sleep Quality Index (PSQI) at each evaluation time point. The FTND (score, 0–10) is a 6-item valid measure devised to evaluate the number and strength of cigarettes smoked as well as smoking behavior, with a higher score indicating a higher level of nicotine dependence [18]. AUTOS (score, 0–

36) is a 12-item valid and highly reliable theory-based instrument with three subscales to assess withdrawal symptoms, psychological dependence, and cue-induced craving [26, 27]. HAM-A (score, 0–56) is a 14-item (symptom-defined elements) reliable and valid clinician-rated instrument for quantifying anxiety symptoms, with a higher score indicating greater symptom severity [28, 29]. The SAS (index, 25–100) is a 20-item rating instrument for anxiety disorders, with a higher score indicating greater anxiety [30]. PSQI (score, 0–21) is a 19-item reliable and valid self-rated questionnaire intended to assess sleep quality and disturbances, with a higher score indicating poorer sleep quality [31]. All adverse events or reactions were monitored, appropriately managed, and recorded throughout the study period.

## **Statistical analysis**

This study is part of the Guangdong-Hong Kong-Macau Greater Bay Area smoking cessation project, and the Hong Kong site was assigned to recruit 30 subjects. Therefore, no additional formal sample size calculations were performed. This sample size is similar to that in previous research on sample size determination for pilot trials [32].

We used the statistical package IBM SPSS Statistics version 27.0 (IBM Corp, Armonk, NY, USA) for conducting statistical analyses, and all participants' data were included in the analysis. They were performed by a statistician not involved in treatment provision or data collection. All statistical tests were two-sided, with a significance level of 0.05.

To analyze the data, appropriate parametric or nonparametric statistical tests were used in accordance with the nature of the data. Baseline characteristics of participants were reported as mean and standard deviation for continuous variables and count and percentage for categorical variables.

To investigate the changes in the mean scores for all continuous outcome variables from baseline to week 24, linear mixed-effects model (LMM) analyses were conducted. The fundamental assumptions of the LMM (including normality, validity of the model, and independence of data points) were tested to ensure accuracy of the test results.

The overall and individual group changes for each continuous outcome from baseline across all measurement points were analyzed using LMM analyses. In addition, LMM analyses were performed to compare the treatment effects between the successful and unsuccessful quit groups across all study time points from baseline to week 24 (group-by-time interaction effects). Post-hoc between-group and within-group differences were computed using Bonferroni adjustment for multiple comparisons (six time points). Any adverse events or additional information was descriptively analyzed and reported.

## **Results**

### **Participant flow and baseline characteristics**

From September 2020 to August 2021, a total of 33 current smokers who expressed interest in the study were screened. Of them, three declined before the start of treatment. The remaining 30 participants were enrolled and treated, and none were lost to follow-up. Of 30, 15 completed all 16 treatment sessions and only 2

received less than 6 treatment sessions. All pretreatment salivary cotinine test results were positive. The flow of the study is shown in Fig. 1.

[Insert Fig. 1 Here]

The demographic and clinical characteristics of the participants are presented in Table 1. All the participants were Chinese, 40.00% were female, and 76.67% were aged 40 years and above. The mean age was  $47.10 \pm 10.74$  years, and the majority of the participants were aged between 40 and 49 years (43.33%). The mean duration of smoking was  $24.10 \pm 11.43$  years, and 70.00% of the participants smoked at least 10 cigarettes per day. In addition, 46.67% of participants had tried to quit smoking in the past. The mean scores for FTND and AUTOS were  $5.06 \pm 1.87$  and  $19.33 \pm 7.99$ , respectively. Moreover, we presented the baseline data of participants by categorizing them into successful and unsuccessful quit smokers (based on smoking cessation at week 24). The baseline characteristics between the two groups were similar, except that those who successfully quit smoking had a lower level of exhaled CO before treatment.



Table 1  
Baseline characteristics of the participants

Characteristic	Total (n = 30)	Successful Quit (n = 14)	Unsuccessful Quit (n = 16)	P value
Age	47.10 ± 10.74	49.50 ± 13.11	45.00 ± 8.01	0.26
Sex				0.76
Female	12 (40.00)	6 (42.86)	6 (37.50)	
Male	18 (60.00)	8 (57.14)	10 (62.50)	
Body mass index, kg/m <sup>2</sup>	25.10 ± 3.69	25.24 ± 3.08	24.98 ± 4.26	0.85
Marital status				0.76
Married	18 (60.00)	8 (57.14)	10 (62.50)	
Single or divorced	12 (40.00)	6 (42.86)	6 (37.50)	
Education level				0.35
Secondary	26 (86.67)	13 (92.86)	13 (81.25)	
Post-secondary or above	4 (13.33)	1 (7.14)	3 (18.75)	
Occupation				0.51
Currently employed	19 (63.33)	8 (57.14)	11 (68.75)	
Unemployed/retired/others	11 (36.67)	6 (42.86)	5 (31.25)	
Family type				0.58
Two-parent family	23 (76.67)	11 (78.57)	12 (75.00)	
Single-parent family	7 (23.33)	3 (21.43)	4 (25.00)	
Living condition				0.75
Living alone	3 (10.00)	2 (14.29)	1 (6.25)	
With family members	25 (83.33)	11 (78.57)	14 (87.50)	
With others	2 (6.67)	1 (7.14)	1 (6.25)	
Smoking duration, year	24.10 ± 11.43	22.85 ± 14.81	25.18 ± 7.73	0.60
Daily cigarette consumption*	14.41 ± 7.16	13.28 ± 8.18	15.46 ± 6.16	0.42
Previous quit attempts				0.06
None	16 (53.33)	10 (71.43)	6 (37.50)	
≥1	14 (46.67)	4 (28.57)	10 (62.50)	

Data are expressed as mean ± standard deviation or number (%).

Characteristic	Total (n = 30)	Successful Quit (n = 14)	Unsuccessful Quit (n = 16)	P value
Reason to quit smoking				0.26
Own health	21 (70.00)	9 (64.29)	12 (75.00)	
Family suggestion	3 (10.00)	1 (7.14)	2 (12.50)	
Medical suggestion	1 (3.33)	0 (0.00)	1 (6.25)	
Other reasons	5 (16.67)	4 (28.57)	1 (6.25)	
Exhaled CO Level (ppm)				0.001
<10 ppm	18 (60.00)	13 (92.86)	5 (31.25)	
≥10 ppm	12 (40.00)	1 (7.14)	11 (68.75)	
FTND	5.06 ± 1.87	5.14 ± 2.17	5.00 ± 1.63	0.83
AUTOS				
Withdrawal symptoms	6.33 ± 3.20	6.78 ± 2.75	5.93 ± 3.60	0.48
Psychological dependence	5.83 ± 3.20	6.35 ± 3.20	5.37 ± 3.24	0.41
Cue-induced craving	7.16 ± 2.50	7.85 ± 2.31	6.56 ± 2.58	0.16
Total	19.33 ± 7.99	21.00 ± 7.53	17.87 ± 8.34	0.29
HAM-A	16.06 ± 9.02	18.85 ± 9.33	13.62 ± 8.26	0.11
SAS	50.80 ± 7.82	50.92 ± 8.84	50.68 ± 7.10	0.93
PSQI	7.43 ± 4.05	7.35 ± 4.03	7.50 ± 4.21	0.92
Data are expressed as mean ± standard deviation or number (%).				

Abbreviations: CO, carbon monoxide; ppm, parts per million; FTND, Fagerström Test for Nicotine Dependence; AUTOS, Autonomy Over Smoking Scale; HAM-A, Hamilton Anxiety Rating Scale; SAS, Self-rating Anxiety Scale; PSQI, Pittsburgh Sleep Quality Index.

\*One participant in the unsuccessful quit group used electronic cigarettes.

### Primary outcome

Regarding the primary outcome, the success rate of smoking cessation at week 24 was 46.67%. Thirteen out of the 14 participants who successfully quit smoking attended 6 or more treatment sessions. Among those who did not quit smoking (n = 16), 11 (68.75%) reported a reduction in the number of cigarettes smoked per day at week 24.

### Secondary outcomes

The success rates for smoking cessation at weeks 8 and 16 were 36.67% and 43.33%, respectively. Among those who did not quit smoking, 63.16% and 70.59% reported a reduction in daily cigarette consumption at weeks 8 and 16, respectively.

Overall, the mean exhaled CO levels for all participants showed a gradual reduction over time; however, no significant changes were detected ( $P > 0.05$ ). The mean exhaled CO levels at each time point for the successful and unsuccessful quit groups are illustrated in Figure 2, and no significant changes over time were found in either group ( $P > 0.05$ ).

[Insert Figure 2 Here]

CO, carbon monoxide; ppm, parts per million; Wk, Week

The mean scores of the FTND for both the successful and unsuccessful quit groups at each time point are shown in Figure 3. LMM analysis indicated significant effects of group ( $P < 0.001$ ), time ( $P < 0.001$ ), and group-by-time interaction ( $P = 0.003$ ) for FTND. Significant between-group differences were identified between weeks 8 and 24, with the successful quit group having a significantly greater reduction in mean FTND scores. In the successful quit group, the FTND scores from weeks 4 to 24 were significantly lower than those at baseline (Table 2). However, these improvements were not observed in the unsuccessful quit group (Table 2).

[Insert Figure 3 Here]

FTND, Fagerström Test for Nicotine Dependence; Wk, Week

## **Table 2 Change from baseline for secondary outcome measures at different time points**

Outcome	Total	<i>P</i> value <sup>a</sup>	Successful Quit (n = 14)	Unsuccessful Quit (n = 16)	<i>P</i> value <sup>b</sup>
FTND					
Week 2	-1.80 (-3.51 to -0.08)	0.03	-2.57 (-5.44 to 0.30)	-1.12 (-3.27 to 1.02)	0.18
Week 4	-2.06 (-3.77 to -0.35)	0.006	-3.07 (-6.01 to -0.12)*	-1.18 (-3.17 to 0.79)	0.06
Week 6	-2.50 (-4.16 to -0.84)	<0.001	-3.35 (-6.21 to -0.50)*	-1.75 (-3.70 to 0.20)	0.08
Week 8	-2.73 (-4.49 to -0.97)	<0.001	-4.35 (-6.98 to -1.72)‡	-1.31 (-3.48 to 0.85)	0.006
Week 16	-2.73 (-4.51 to -0.95)	<0.001	-4.42 (-7.02 to -1.83)‡	-1.25 (-3.44 to 0.94)	0.004
Week 24	-2.76 (-4.48 to -1.05)	<0.001	-4.78 (-7.04 to -2.52)‡	-1.00 (-3.05 to 1.05)	<0.001
AUTOS					
Week 2	-3.30 (-9.83 to 3.23)	1.00	-4.85 (-14.43 to 4.72)	-1.93 (-11.18 to 7.31)	0.90
Week 4	-5.83 (-12.22 to 0.55)	0.11	-9.07 (-18.80 to 0.65)	-3.00 (-11.74 to 5.74)	0.10
Week 6	-8.93 (-14.82 to -3.04)	<0.001	-12.14 (-21.65 to -2.62) <sup>†</sup>	-6.12 (-13.62 to 1.37)	0.24
Week 8	-10.73 (-16.55 to -4.91)	<0.001	-14.00 (-23.48 to -4.51) <sup>†</sup>	-7.87 (-15.54 to -0.20)*	0.46
Week 16	-12.56 (-18.10 to -7.02)	<0.001	-17.50 (-25.99 to -9.00)‡	-8.25 (-15.71 to -0.78)*	0.04
Week 24	-13.03 (-19.10 to -6.96)	<0.001	-20.28 (-27.89 to -12.67)‡	-6.68 (-15.09 to 1.72)	<0.001
HAM-A					
Week 2	-0.86 (-8.64 to 6.91)	1.00	-2.00 (-13.48 to 9.48)	0.12 (-10.29 to 10.54)	0.40
Week 4	-4.13 (-11.69 to 3.42)	1.00	-5.78 (-17.48 to 5.91)	-2.68 (-12.35 to 6.97)	0.60
Week 6	-6.20 (-13.54 to 1.14)	0.20	-7.14 (-19.51 to 5.23)	-5.37 (-13.85 to 3.10)	0.55
Week 8	-6.53 (-13.82 to 0.75)	0.12	-8.14 (-20.17 to 3.89)	-5.12 (-14.00 to 3.75)	0.80
Week 16	-4.96 (-12.13 to 2.20)	0.66	-6.07 (-17.98 to 5.84)	-4.00 (-12.62 to 4.62)	0.36
Week 24	-5.80 (-13.08 to 1.48)	0.29	-9.14 (-20.44 to 2.15)	-2.87 (-12.80 to 7.05)	0.97
SAS					

Week 2	-2.40 (-8.61 to 3.81)	1.00	-1.00 (-11.45 to 9.45)	-3.62 (-11.52 to 4.27)	0.23
Week 4	-4.16 (-9.97 to 1.64)	0.55	-3.28 (-13.06 to 6.48)	-4.93 (-12.41 to 2.54)	0.26
Week 6	-3.60 (-8.82 to 1.62)	0.66	-3.21 (-12.43 to 6.01)	-3.93 (-10.54 to 2.67)	0.47
Week 8	-5.03 (-10.95 to 0.89)	0.19	-5.57 (-16.06 to 4.92)	-4.56 (-11.92 to 2.79)	0.86
Week 16	-3.66 (-8.99 to 1.65)	0.67	-3.00 (-12.28 to 6.28)	-4.25 (-11.06 to 2.56)	0.27
Week 24	-2.33 (-7.58 to 2.91)	1.00	-1.71 (-10.77 to 7.34)	-2.87 (-9.71 to 3.96)	0.37
PSQI					
Week 2	-0.80 (-3.79 to 2.19)	1.00	-1.00 (-5.66 to 3.66)	-0.62 (-4.70 to 3.45)	0.64

[Insert Table 2 Here]

The mean AUTOS scores at different time points for the successful and unsuccessful quit groups are shown in Figure 4. LMM analysis of changes in the mean AUTOS scores between both groups over time revealed significant effects of group ( $P = 0.012$ ), time ( $P < 0.001$ ), and group-by-time interaction ( $P = 0.002$ ). Post-hoc between-group comparisons showed significantly greater improvement in mean AUTOS scores in the successful quit group at weeks 16 ( $P = 0.04$ , Table 2) and 24 ( $P < 0.001$ , Table 2). Relative to the baseline score, the mean AUTOS scores at weeks 6 to 24 in the successful quit group and at weeks 8 and 16 in the unsuccessful quit group exhibited significant improvements (Table 2).

[Insert Figure 4 Here]

AUTOS, Autonomy Over Smoking Scale; Wk, Week

Improvements were detected in HAM-A, SAS, and PSQI scores for both successful and unsuccessful quit groups over time, but their changes were not significant (all  $P > 0.05$ , Table 2). Moreover, between-group comparisons showed no significant differences in HAM-A, SAS, and PSQI scores across all study time points (all  $P > 0.05$ , Table 2). Throughout the study period, no study-related adverse events were reported.

## Discussion

Smoking is an important global public health problem, and many countries have taken numerous measures to address it. Various therapeutic approaches, including acupuncture, have been used to help quit smoking. In Hong Kong, a pilot project was launched since 2010 to provide free acupuncture for smoking cessation with positive results [8, 12, 33]. The findings from the Hong Kong site in this Guangdong-Hong Kong-Macau Greater Bay Area Project gave an update and additional evidence on the efficacy and safety of acupuncture for smoking cessation in Hong Kong.

## Main findings

The 30 participants involved in this clinical trial were moderate to heavy smokers in Hong Kong. Our study showed that after acupuncture treatments, the success rates of smoking cessation achieved at weeks 8 (posttreatment) and 24 (follow-up period) were 36.67% and 46.67%, respectively. Among those who did not quit smoking, 63.16% and 68.75% reductions in cigarette consumption were recorded at weeks 8 and 24, respectively.

Regarding efficacy scales, the FTND scores from weeks 4 to 24 were significantly decreased compared to baseline in the successful quit group; however, these improvements were not observed in the unsuccessful quit group. As for AUTOS, the mean score at weeks 6–24 in the successful quit group and at weeks 8 and 16 in the unsuccessful quit group exhibited significant improvements relative to baseline.

No significant improvements were detected in exhaled CO level, HAM-A, SAS, and PSQI scores for both the successful and unsuccessful quit groups over time (all  $P > 0.05$ ). Finally, no study-related adverse events were observed.

### **Comparison with previous studies**

In general, our findings on abstinence rates were consistent with those of previous studies on acupuncture combined with auricular acupressure in Hong Kong (34.01% at week 8) [12] and China (43.00% at week 24) [9]. The higher abstinence rates recorded in our study may be due to the fact that most of our participants possessed lower exhaled CO levels. In a previous cohort study, successful quit smokers with 1-year abstinence exhibited lower levels of exhaled CO at an earlier stage of the intervention [34]. Besides, smoking cessation requires a strong will and a determined attempt to stop for most smokers. Our careful and intense follow-up schedule may provide continuous support to smokers on their roads to achieving smoking cessation.

With regards to FTND, a previous clinical trial has reported improvements in mean scores over time posttreatment (week 8) and at week 24 follow-up for both acupuncture and auricular point pressing [9]. Our results indicated a greater improvement in FTND scores over time, which revealed that acupuncture combined with acupressure may generate better therapeutic effects.

Similar to previous study findings, HAM-A scores did not show any significant changes over time after acupuncture treatment [35]. Moreover, SAS scores declined over time, as revealed in the previous trial [36]. However, our results did not detect any significant reduction.

### **Strengths and limitations of the study**

One of the strengths of our study was the careful design of the study intervention. Standardized acupuncture, including the choice of acupoints, retention, and treatment frequency, was based on literature [19, 20]. It has been reported that receiving sufficient and qualified acupuncture is the leading factor for short-term smoking cessation. The more acupuncture treatment received, the greater the possibility of quitting tobacco dependence with acupuncture [33]. A previous clinical trial in Norway reported that six acupuncture sessions may help motivate smokers to quit smoking completely, and the effect may last for five years [10]. In addition, another earlier study in Hong Kong demonstrated that 6 or more sessions of acupuncture were strongly associated with a higher chance of successful quitting [8]. In our study, over 90% of participants received 6 or

more treatments, which may be one of the contributing factors to a higher rate of successful smoking cessation.

Moreover, the measurement of exhaled CO levels may provide an immediate, noninvasive method for assessing smoking status [37], and cotinine is the best indicator of tobacco smoke exposure. The self-reported smoking cessation confirmed by exhaled CO level and cotinine test ensured objectivity and correctness and reduced the possibility of false claims.

Furthermore, the use of validated and reliable measurement tools increased the reliability of the outcomes. FTND is a convenient and valid self-report measure of nicotine dependency, and loss of autonomy is a good predictor of success in smoking cessation. Our results with improved FTND and AUTOS scores showed the positive therapeutic effects of acupuncture on tobacco dependence in smokers. On the other hand, HAM-A is a reliable and valid anxiety evaluation questionnaire, and SAS is a rating instrument for measuring anxiety disorders, whereas PSQI provides a standardized, quantitative measure of sleep quality [31]. Although no significant changes were found in these scales, we can still provide a preliminary insight into the effects of acupuncture on smokers' anxiety status and sleep quality.

Our study has some limitations. All the 30 smokers included in the Hong Kong site received acupuncture treatments and no controls for comparison. This small sample size may prevent the extrapolation of the findings and may not generate precise results. In addition, we investigated the therapeutic effects of acupuncture for smoking cessation in moderate and heavy smokers. Future studies focusing on light and intermittent smokers would be useful since light smoking also carries substantial health risks [38]. Moreover, our follow-up period was only up to week 24. A longer follow-up period will provide more insights into its therapeutic effects for long-term smoking cessation or helping smokers to maintain a longer-term or even life-long smoke-free life. Therefore, more research is required to verify the exact role of acupuncture treatment for smoking cessation and provide more robust and precise scientific evidence.

## Conclusions

The findings of this study indicated that acupuncture plus auricular acupressure may help smokers to quit smoking, especially those with lower exhaled CO levels in Hong Kong. The intervention is safe and may help unsuccessful quit smokers to reduce their smoking and tobacco dependence. Therefore, it may be a valuable complementary and alternative treatment option for smoking cessation.

## Abbreviations

**CO:** Carbon monoxide

**ppm:** Parts per million

**FTND:** Fagerström Test for Nicotine Dependence

**AUTOS:** Autonomy Over Smoking Scale

**HAM-A:** Hamilton Anxiety Rating Scale

**SAS:** Self-rating Anxiety Scale

**PSQI:** Pittsburgh Sleep Quality Index

**LMM:** Linear mixed-effects model

## Declarations

### Ethics approval and consent to participate

This study was reviewed and approved by the Joint Chinese University of Hong Kong–New Territories East Cluster Clinical Research Ethics Committee (CREC Ref. No. 2020.116) in April 2020. Written informed consent was obtained from all participants.

### Consent for publication

Not applicable.

### Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

### Competing interests

The authors declare that they have no competing interests.

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### Authors' contributions

LFH, WKH, GH, and ZXL conceived and contributed to the study design. LFH, WKH, and KLC obtained ethical approval. MC, GH, BN, and ZXL supervised the study. LFH and WKH contributed to the study collaboration. LLW, ZWC, SYT, CMW, KSC, and CLL participated in clinical treatment and data collection. LFH and WKH were responsible for data management and analysis. LFH drafted the manuscript. MC, KLC, BN, and ZXL reviewed the manuscript. All authors have read and approved the final manuscript.

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## Figures

### Figure 1

#### Study flowchart

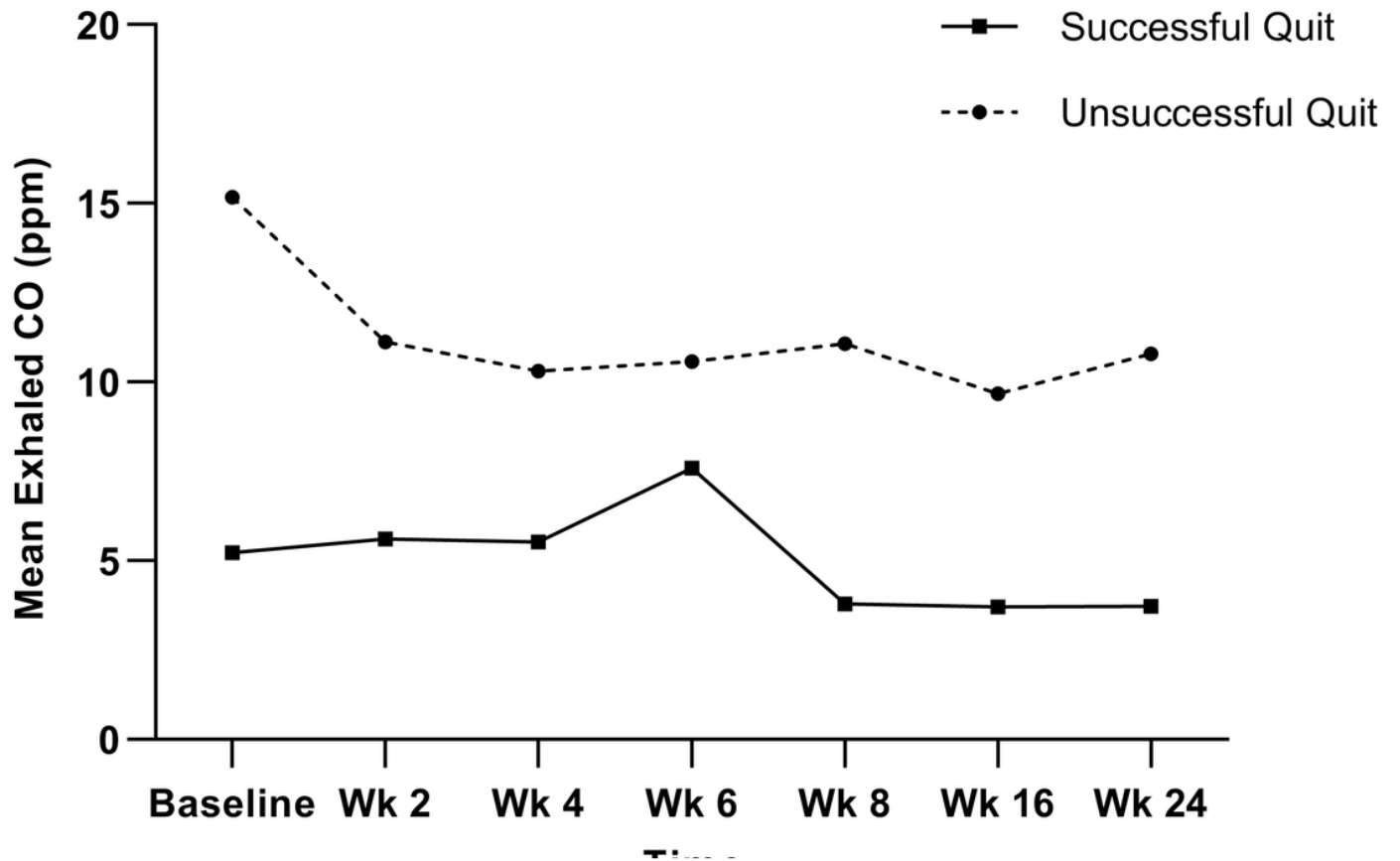


Figure 2

Changes in mean exhaled CO level over time

CO, carbon monoxide; ppm, parts per million; Wk, Week

Figure 3

Changes in mean FTND score over time

FTND, Fagerström Test for Nicotine Dependence; Wk, Week

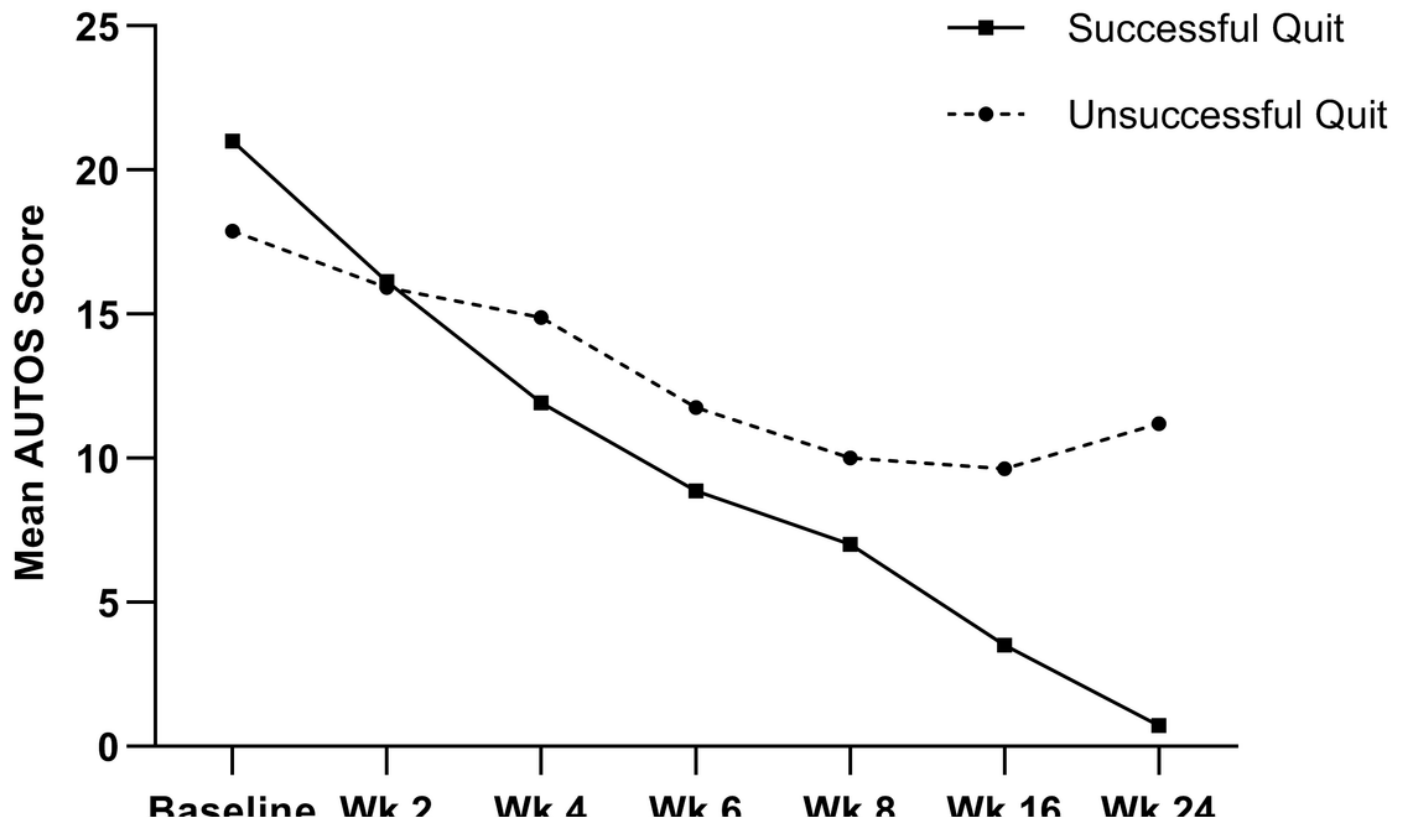


Figure 4

Changes in mean AUTOS score over time

AUTOS, Autonomy Over Smoking Scale; Wk, Week