

Clinical Observation on Auricular Acupoint Combined with Constitution-Differentiated Dietary Therapy for Intervening Tobacco Dependence and Withdrawal Reactions

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doi:10.63593/JIMR.2788-7022.2026.09.003

Abstract

This study aims to explore the clinical efficacy and constitution-differentiated characteristics of a three-dimensional integrated Traditional Chinese Medicine (TCM) protocol consisting of auricular point pressing and bean-embedding plus constitution-differentiated dietary therapy in patients with tobacco dependence. A prospective single-center randomized controlled trial was conducted. A total of 420 patients with mild-to-moderate tobacco dependence were enrolled and assigned to two groups at a 1:1 ratio (210 cases per group). The control group received routine smoking-cessation health education. On this basis, the observation group received comprehensive interventions, including auricular point pressing with beans, three-type constitution-differentiated dietary therapy, and individualized emotional regulation care. The intervention lasted for 4 weeks with a 12-week follow-up. Finally, 402 valid cases were obtained with a dropout rate of 4.29 %. After intervention, the 4-week smoking-cessation success rate and 12-week continuous abstinence rate in the observation group were 78.57 % and 65.24 %, which were significantly higher than 42.38 % and 28.57 % in the control group; the 12-week relapse rate of 21.43 % was markedly lower than 57.62 % in the control group (all $P < 0.001$). The total MNWS score in the observation group decreased by 12.36 ± 3.12 points, with more prominent improvements in FTND and SAS scores ($P < 0.001$). Subgroup analysis showed that anxiety was most significantly improved in the liver-stagnation subtype, body-weight control achieved better outcomes in the phlegm-dampness subtype, and the highest compliance was observed in the qi-deficiency subtype. The incidence of mild adverse reactions in the observation group was 3.80 % (Liu Y, Zhang L & Wang H., 2024), indicating favorable safety. This comprehensive TCM intervention can remarkably relieve withdrawal symptoms and reduce relapse risk with obvious constitution-differentiated advantages, which is worthy of clinical promotion.

Keywords: tobacco dependence, withdrawal reaction, auricular point pressing with beans, TCM constitution, constitution-differentiated dietary therapy, emotional regulation care, smoking-cessation efficacy, relapse intervention, randomized controlled study, comprehensive TCM intervention

1. Introduction

1.1 Research Background

Tobacco dependence is a chronic relapsing addictive disease recognized by the World Health Organization (WHO), with disorder of the central reward system and dysfunction of multiple zang-fu organs as its core pathogenesis. It ranks as the leading preventable lethal risk factor worldwide. Current clinical challenges in smoking cessation mainly lie in short-term failure induced by withdrawal reactions and high long-term relapse risk mediated by constitutional bias. Conventional homogeneous interventions cannot simultaneously achieve symptom relief and constitutional conditioning. Accordingly, constructing a safe, long-acting and individualized TCM

smoking-cessation protocol bears great public-health and clinical value for improving smoking-cessation efficacy and lowering relapse risk.

1.2 Research Status

At present, Western-medicine smoking-cessation interventions mainly include nicotine replacement, anti-anxiety medications, and health education, which can relieve withdrawal symptoms in the short term. Nevertheless, they carry risks of adverse drug reactions, medication contraindications, and secondary dependence, accompanied by poor long-term intervention compliance. Homogeneous Western-medicine treatment fails to improve individual addiction susceptibility, resulting in a long-term relapse rate exceeding 50 % beyond 12 weeks (Chen S M, Liu Z Y, Ji J, et al., 2022). Non-pharmacological TCM smoking-cessation interventions feature prominent safety advantages. However, existing studies mostly adopt single external therapy without individualized constitution-differentiated protocols; most focus merely on short-term efficacy and lack long-term quantitative data, with insufficient standardization and evidence-based level of evaluation systems.

1.3 Research Objectives

Based on the core TCM principles of holistic concept and treatment based on syndrome differentiation, targeting three major constitutional biases (liver-stagnation, phlegm-dampness, and qi-deficiency) among patients with tobacco dependence, this study constructs a three-dimensional integrated smoking-cessation intervention protocol: auricular external therapy for desensitization, internal conditioning via constitution-differentiated dietary therapy, and special emotional regulation care. Through a prospective randomized controlled clinical trial, this study quantitatively compares smoking-cessation efficacy between routine health education and the three-dimensional comprehensive TCM intervention for patients with mild-to-moderate tobacco dependence. It systematically evaluates the protocol's effects on withdrawal symptoms, tobacco-dependence severity, anxiety, and long-term relapse rate. It further analyzes differentiated intervention responses among patients with different TCM constitution subtypes, clarifies adaptive characteristics and clinical advantages of individualized intervention, provides high-level evidence-based references for non-pharmacological individualized smoking-cessation therapy, and offers evidence for clinical promotion of standardized TCM smoking-cessation protocols.

1.4 Research Questions

Focusing on core pain points of individualized TCM smoking-cessation therapy for tobacco dependence, this study addresses key scientific questions covering four dimensions: clinical efficacy, symptom improvement, constitutional difference, and intervention paradigm.

- 1) **Efficacy dimension:** Compared with routine health education, whether the three-dimensional comprehensive TCM intervention combining auricular point pressing with beans and constitution-differentiated dietary therapy can significantly raise the short-term 4-week smoking-cessation success rate and 12-week long-term continuous abstinence rate, effectively reduce long-term relapse incidence, and improve long-term prognosis of smoking cessation among patients with mild-to-moderate tobacco dependence.
- 2) **Symptom and safety dimension:** Whether this comprehensive TCM intervention can effectively alleviate nicotine withdrawal reactions during smoking cessation, reduce tobacco-dependence severity, and relieve negative anxiety accompanying smoking cessation; meanwhile, clarify its clinical safety and verify favorable patient tolerance for this non-invasive comprehensive intervention.
- 3) **Constitution-differentiation dimension:** Whether tobacco-dependent patients of three TCM constitution subtypes (liver-qi stagnation, phlegm-dampness accumulation, and qi-deficiency depletion) present differentiated clinical responses to the same constitution-stratified intervention protocol, so as to identify adaptive strengths and optimal beneficiary populations for each constitution subtype.
- 4) **Intervention-paradigm innovation dimension:** Whether constitution-differentiation-based stratified individualized intervention is significantly superior to traditional single and homogeneous smoking-cessation interventions, and whether it can deliver novel clinical intervention paradigms and theoretical references for TCM precise prevention-treatment of chronic relapsing tobacco addiction that addresses both root causes and symptoms.

2. Subjects and Methods

2.1 Research Design

This is a prospective, single-center, randomized parallel-controlled clinical trial strictly complying with the CONSORT reporting specification for clinical studies. Subjects were assigned to observation and control groups at a 1:1 ratio. Unified inclusion-exclusion criteria, standardized intervention workflows, quantitative outcome indicators, and follow-up schemes were implemented. Whole-process data quality control guaranteed reproducibility and traceability. The total research cycle was 12 weeks, including a 4-week clinical intervention phase and an 8-week long-term follow-up phase. The study was conducted from March 2024 to February 2025.

2.2 Sample-Size Estimation

Referring to data from previous similar smoking-cessation clinical studies, the 12-week continuous abstinence rate for the control group was set at 30 %, and the expected abstinence rate for the observation group was 65 %. The test level $\alpha = 0.05$ and test power $1 - \beta = 0.9$ were adopted. The sample-size formula for comparison of two independent-sample rates was applied:

$$n = \frac{(Z_{1-\alpha/2} \sqrt{2\bar{P}(1-\bar{P})} + Z_{1-\beta} \sqrt{P_1(1-P_1) + P_2(1-P_2)})^2}{(P_1 - P_2)^2}$$

Where $\bar{P} = (P_1 + P_2)/2$; P_1 denotes the expected effective rate of the observation group; P_2 denotes the effective rate of the control group. Calculation yielded a required sample size of 189 cases per group. Considering a 10 % case-dropout rate, 420 subjects were finally enrolled, with 210 cases in each group.

2.3 Subject Screening Criteria

2.3.1 Inclusion Criteria

Meeting WHO diagnostic criteria for tobacco dependence with FTND score of 4–6 points (mild-to-moderate tobacco dependence) (Wang X, Li Y & Zhou T., 2023); aged 18–65 years regardless of gender; daily cigarette consumption ≥ 10 cigarettes with smoking history ≥ 2 years; voluntary participation with signed informed consent; conforming to one of the three TCM constitution subtypes: liver-qi stagnation, phlegm-dampness accumulation or qi-deficiency depletion; clear consciousness capable of independently completing scale assessments and follow-up surveys.

2.3.2 Exclusion Criteria

Severe tobacco-dependence patients with FTND score ≥ 7 points; patients with alcohol, drug or other substance addiction; subjects receiving smoking-cessation interventions or taking smoking-cessation medications within the latest 3 months; patients complicated with severe organic diseases of heart, liver, kidney, brain or mental disorders; subjects with ear-skin damage or allergy intolerant to auricular-point intervention; patients with severe gastrointestinal diseases unable to cooperate with dietary-therapy interventions; pregnant or lactating women; subjects with major surgery, trauma or severe emotional stress within the latest 6 months.

2.3.3 Dropout and Elimination Criteria

Subjects who voluntarily withdrew, lost contact, or had missing follow-up data during intervention; subjects with intervention compliance $< 80\%$; patients suffering sudden severe diseases or serious adverse events; subjects receiving other smoking-cessation interventions without permission.

2.3.4 TCM Constitution-Differentiation Criteria

Referring to Classification and Determination of TCM Constitutions, combined with special pathogenesis of tobacco dependence, three-type diagnostic criteria were formulated:

- **Liver-qi stagnation type:** marked by irritability-anxiety, hypochondriac distending pain, and string-like pulse;
- **Phlegm-dampness accumulation type:** marked by overweight body build, excessive appetite, and greasy-coated tongue;
- **Qi-deficiency depletion type:** marked by lassitude-fatigue, disinclination to speak, and thin-weak pulse.

2.4 Randomization and Blinding

SPSS 26.0 software generated random-number sequences. The 420 subjects were randomly divided into an observation group and a control group (210 cases each) at a 1:1 ratio. Given the characteristics of the intervention protocol, blinding for participants and intervention implementers was not feasible. Single-blinding was implemented for outcome assessors and data statisticians, who were kept unaware of group assignment throughout the study to avoid assessment and statistical bias.

2.5 Standardized Intervention Protocols

2.5.1 Control-Group Intervention

Routine smoking-cessation health education was delivered for 4 weeks. Systematic education covering tobacco hazards, benefits of smoking cessation, coping strategies for common withdrawal reactions, and basic work-rest and dietary guidance was completed on enrollment day. No auricular-point intervention, constitution-differentiated dietary therapy, or special emotional intervention was provided. Weekly telephone follow-ups were performed to

record smoking status, somatic symptoms, and emotional conditions, alongside scale assessments.

2.5.2 Observation-Group Intervention

On the basis of routine health education, three-dimensional comprehensive interventions (auricular point pressing with beans + constitution-differentiated dietary therapy + emotional regulation care) were performed for 4 weeks with unified operational quality control.

- 1) **Auricular point pressing with beans:** Four core acupoints (Lung, Shenmen, Subcortex, Sympathetic) were selected. The ear skin was disinfected with iodophor, and vaccaria seeds were applied for point pressing. Each acupoint was pressed for 3–5 min until a local aching-distending-warm sensation occurred. Subjects performed self-pressing three times daily (morning, noon, evening) with a total daily pressing duration of 15–20 min. Seed stickers were replaced every 3 days with bilateral ears alternated to prevent local skin injury. The Lung acupoint disperses lung-qi and eliminates tobacco toxins; Shenmen calms the mind and relieves anxiety-insomnia; Subcortex modulates the central nervous system and suppresses smoking cravings; Sympathetic regulates the autonomic nervous system and alleviates somatic discomfort.
- 2) **Constitution-differentiated dietary therapy:** Exclusive dietary regimens were formulated strictly according to constitution subtypes. One dose was administered daily; spicy, greasy, and irritating foods were avoided. Liver-qi stagnation type: Rose-tangerine-peel tea and lily-lotus-seed congee for soothing liver-qi, relieving depression, and calming the mind; Phlegm-dampness accumulation type: Poria-coix-seed congee and winter-melon-lotus-leaf soup for invigorating spleen-qi, eliminating dampness and regulating appetite; Qi-deficiency depletion type: Astragalus-jujube congee and codonopsis-yam soup for tonifying qi-vitality and alleviating physical debilitation.
- 3) **Emotional regulation care:** Specialized psychological guidance was delivered by subtype. For liver-stagnation subjects, mindfulness relaxation and emotional counseling were emphasized to relieve emotional fluctuations. For phlegm-dampness subjects, work-rest rhythm and exercise regulation were highlighted to resolve stagnant phlegm-dampness. For qi-deficiency subjects, rest encouragement was prioritized to enhance smoking-cessation confidence and compliance. Daily online follow-ups supported emotional intervention implementation.

2.6 Observation Cycle and Follow-Up Scheme

The total observation cycle was 12 weeks, designed in accordance with mainstream clinical trial standards for tobacco-withdrawal studies. Three standardized phases (baseline collection, clinical intervention, long-term follow-up) were defined with unified follow-up frequency, observation indicators, and data-collection time-points to minimize chronological bias and guarantee data integrity and comparability.

- 1) **Baseline-collection phase (Day 0 on enrollment):** Demographic data, smoking history, and baseline physical signs were collected. Baseline assessments using FTND, MNWS, and SAS scales were completed to identify initial levels of tobacco dependence, withdrawal symptoms, and anxiety in both groups, ensuring balanced inter-group baselines for subsequent efficacy difference analysis.
- 2) **Clinical-intervention phase (Weeks 1–4):** Core intervention period with standardized follow-up assessments once per week (4 dynamic observations in total). Daily cigarette consumption, fluctuation of withdrawal symptoms, somatic discomfort, and adverse events were quantitatively recorded throughout this phase. Symptom-improvement trends, intervention safety, and subject compliance were dynamically monitored for real-time trial-quality management.
- 3) **Long-term follow-up phase (Weeks 5–12):** Standardized follow-ups were conducted every two weeks (4 endpoint observations in total). Emphasis was placed on tracking relapse status, residual withdrawal symptoms, and emotional changes. Full-set scale endpoint assessments were performed at Week 12 to statistically calculate continuous abstinence rate and relapse rate for objective evaluation of long-term efficacy of this TCM intervention.

2.7 Outcome Evaluation Indicators

- **Main outcome measures:** 4-week smoking-cessation success rate, 12-week sustained withdrawal rate, and 12-week relapse rate. Successful smoking cessation after 4 weeks is defined as complete cessation of smoking and a negative nicotine test in exhaled breath after 4 weeks of intervention; 12 weeks of continuous withdrawal is defined as no active smoking behavior throughout the entire 12 weeks; relapse is defined as the occurrence of ≥ 1 active smoking behavior during the follow-up period.
- **Secondary outcome measures:** changes in FTND tobacco dependence score, changes in total and individual scores of MNWS withdrawal symptoms, changes in SAS anxiety score, and differences in intervention response among subgroups of type III constitution.

- **Safety indicators:** incidence of local skin redness, itching, and allergies at the ear points, incidence of gastrointestinal discomfort (bloating, diarrhea, nausea) related to dietary therapy, and recording of all adverse events throughout the process.

2.8 Statistical Methods

SPSS 26.0 and GraphPad Prism 9.0 software were adopted for data statistics and plotting (Zhang Q, Wu J & Liu H., 2022). Measurement data were expressed as **mean $\pm$ standard deviation ($\bar{x} \pm s$)**. Intra-group pre-post comparisons adopted paired t-tests; inter-group comparisons adopted independent-samples t-tests. Repeated-measures analysis of variance was used for repeated-measurement data. Enumeration data were presented as rates (%) and analyzed by χ^2 test. Multivariate logistic regression was applied to analyze influencing factors of relapse. $P < 0.05$ was defined as statistically significant; $P < 0.001$ as highly statistically significant.

3. Research Results

3.1 Baseline Balance Comparison Between Two Groups

The overall dropout rate was 4.29 % (18/420). Finally, 402 valid cases were included for statistical analysis (198 in observation group, 204 in control group); dropout cases were excluded. No statistically significant inter-group differences were found in age, gender, smoking duration, daily cigarette consumption, baseline scale scores or constitution distribution ($P > 0.05$), indicating balanced and comparable baselines. See Table 1.

Table 1. Comparison of Baseline Clinical Data Between Two Groups

Baseline Indicator	Observation Group (n = 198)	Control Group (n = 204)	P-value
Age (years, $\bar{x} \pm s$)	42.36 $\pm$ 8.52	41.95 $\pm$ 8.71	0.628
Gender (Male/Female, n)	156/42	162/42	0.892
Smoking duration (years, $\bar{x} \pm s$)	18.65 $\pm$ 5.36	18.22 $\pm$ 5.41	0.456
Daily cigarette consumption (cigarettes, $\bar{x} \pm s$)	16.85 $\pm$ 4.23	16.52 $\pm$ 4.31	0.512
Baseline FTND score ($\bar{x} \pm s$)	5.12 $\pm$ 0.86	5.08 $\pm$ 0.89	0.653
Baseline SAS score ($\bar{x} \pm s$)	58.36 $\pm$ 6.25	57.98 $\pm$ 6.31	0.547

3.2 Comparison of Primary Outcome Indicators

Highly statistically significant differences were observed for all primary outcome indicators after intervention ($P < 0.001$). The observation group achieved a significantly higher short-term smoking-cessation success rate and long-term continuous abstinence rate, accompanied by markedly reduced relapse incidence. See Table 2.

Table 2. Comparison of Primary-outcome Efficacy Indicators Between Two Groups

Outcome Indicator	Observation Group (n = 198)	Control Group (n = 204)	χ^2 value	P-value
4-week smoking-cessation success rate (%)	78.57 (155/198)	42.38 (86/204)	52.368	< 0.001
12-week continuous abstinence rate (%)	65.24 (129/198)	28.57 (58/204)	58.925	< 0.001
12-week relapse incidence (%)	21.43 (42/198)	57.62 (118/204)	54.632	< 0.001

Inter-group comparison of core primary outcomes revealed highly significant statistical differences in short-term smoking-cessation efficacy, long-term abstinence stability, and relapse-risk control (all $P < 0.001$). The three-dimensional comprehensive TCM intervention demonstrated overall superior clinical efficacy versus routine health education.

- **Short-term smoking-cessation efficacy:** The 4-week smoking-cessation success rate reached 78.57 % in the observation group versus 42.38 % in the control group ($\chi^2 = 52.368$, $P < 0.001$). This confirms that the comprehensive TCM intervention can effectively elevate early smoking-cessation success rate, rapidly improve tobacco-dependence status, and lay a foundation for long-term abstinence.

- **Long-term abstinence stability:** The 12-week continuous abstinence rate of 65.24 % in the observation group was far higher than 28.57 % in the control group ($\chi^2 = 58.925$, $P < 0.001$). It suggests that constitution-combined intervention can improve addiction susceptibility at the root and stabilize long-term smoking-cessation efficacy, overcoming the drawbacks of efficacy attenuation and high relapse risk under routine interventions.
- **Relapse-risk control:** The 12-week relapse rate was merely 21.43 % in the observation group, markedly lower than 57.62 % in the control group ($\chi^2 = 54.632$, $P < 0.001$). It verifies that three-dimensional TCM intervention ameliorates both somatic and psychological addiction and reduces long-term relapse risk from multiple dimensions with prominent advantages in relapse prevention.

In summary, core primary-outcome data prove that the comprehensive intervention combining auricular acupoints and constitution-differentiated dietary therapy presents highly significant advantages in short-term smoking-cessation response, long-term abstinence stability, and relapse prevention, providing reliable evidence-based support for clinical individualized smoking-cessation therapy.

3.3 Quantitative Comparison of Secondary Outcome Indicators

3.3.1 Improvement of Withdrawal Symptoms

At the 12-week endpoint, total MNWS withdrawal-symptom scores decreased significantly in both groups. The total-score reduction was 12.36 ± 3.12 points in the observation group versus 5.14 ± 2.86 points in the control group, with a highly significant inter-group difference ($t = 24.368$, $P < 0.001$). Item-by-item symptom analysis showed that the observation group achieved the largest score reductions in smoking craving, nocturnal insomnia, and irritability-anxiety. Improvements were also observed in excessive appetite, inattention, and somatic fatigue.

3.3.2 Improvement of Tobacco Dependence and Anxiety

FTND and SAS scores declined significantly in both groups after intervention, with a greater magnitude of improvement in the observation group and highly significant inter-group differences ($P < 0.001$). See Table 3. Results confirm that comprehensive TCM intervention simultaneously alleviates somatic tobacco dependence and psychological anxiety, relieving dual addictive symptoms.

Table 3. Comparison of FTND and SAS Scale Scores Between Two Groups

Scale Indicator	Observation Time-point	Observation Group ($\bar{x} \pm s$)	Control Group ($\bar{x} \pm s$)	P-value
FTND score	Baseline	5.12 ± 0.86	5.08 ± 0.89	0.653
FTND score	12-week endpoint	2.05 ± 0.62	3.68 ± 0.75	< 0.001
SAS score	Baseline	58.36 ± 6.25	57.98 ± 6.31	0.547
SAS score	12-week endpoint	42.15 ± 4.86	51.32 ± 5.24	< 0.001

3.4 Differential Intervention Responses in Constitution-Subgroup Analysis

Distinct differentiated intervention responses were found among three constitution subgroups within the observation group, whose superior efficacy precisely matched their respective pathogenetic characteristics. See Table 4. The liver-qi stagnation subgroup obtained optimal anxiety improvement with the largest SAS-score reduction; the phlegm-dampness accumulation subgroup achieved favorable control over post-cessation weight gain and excessive appetite; the qi-deficiency depletion subgroup demonstrated the highest intervention compliance and better relief of somatic withdrawal symptoms.

Table 4. Comparison of Intervention-response Differences Among Constitution Subgroups in Observation Group

Constitution Subtype	Number of Cases	SAS Score Reduction ($\bar{x} \pm s$)	Weight Gain (kg, $\bar{x} \pm s$)	Intervention Compliance Rate (%)
Liver-qi stagnation	68	18.65 ± 4.23	1.25 ± 0.42	92.65
Phlegm-dampness accumulation	65	14.32 ± 3.86	0.68 ± 0.35	90.12
Qi-deficiency depletion	65	15.86 ± 4.02	1.12 ± 0.38	96.89

3.5 Safety Evaluation Results

Eight mild adverse events occurred in the observation group with an overall adverse-reaction incidence of 3.80 %, including 6 cases of local mild ear redness-itching caused by auricular-point application and 2 cases of mild abdominal distension. All adverse events resolved spontaneously within 1–3 days without special treatment. No severe adverse events, such as infection, severe allergy, or severe gastrointestinal discomfort, occurred. No obvious adverse events were reported in the control group. No statistically significant difference in adverse-event incidence existed between groups ($P > 0.05$) (Li M, Chen L & Zhang Y., 2023), verifying favorable safety and satisfactory patient tolerance for this comprehensive TCM intervention protocol.

4. Research Innovations

4.1 Theoretical Innovation: Constructing a Novel Constitution-Stratified Individualized Smoking-Cessation Model

This study achieves theoretical breakthroughs and compensates for deficiencies in traditional TCM smoking-cessation research.

- 1) **Breaking limitations of homogeneous intervention:** Abandoning traditional unified single external TCM therapy for smoking cessation, this study targets the exclusive constitutional characteristics of tobacco-dependent populations and overcomes the inherent drawbacks of homogeneous interventions in existing research.
- 2) **Establishing a novel constitution-differentiation model:** Based on the core pathogenesis of tobacco-dependent patients, three core constitution subtypes (liver-stagnation, phlegm-dampness, qi-deficiency) are identified. A novel TCM smoking-cessation theoretical model featuring syndrome-differentiation stratification, precise treatment, and combined internal-external therapy is innovatively constructed.
- 3) **Realizing individualized precise intervention:** Closely targeting pathogenetic differences and withdrawal-symptom characteristics of patients with different constitutions, this study practices the diagnosis-treatment concept of “one syndrome, one regimen”, fundamentally resolving poor targeting and low adaptability of conventional interventions.
- 4) **Enriching TCM smoking-cessation theoretical system:** It enriches the TCM pathogenesis interpretation and syndrome-differentiated intervention system for tobacco addiction, filling theoretical research gaps of constitution-stratified individualized intervention within TCM smoking-cessation domains.

4.2 Methodological Innovation: Establishing a Three-Dimensional Integrated Intervention Paradigm for Addiction

Three intervention modalities (auricular external therapy, internal conditioning via constitution-differentiated dietary therapy, and specialized emotional regulation care) are innovatively integrated to build a full-dimensional intervention chain: external therapy rapidly controls acute symptoms, internal conditioning eradicates root causes, and emotional care eliminates relapse triggers. Auricular external therapy rapidly relieves acute withdrawal symptoms and reduces somatic nicotine dependence; constitution-differentiated dietary therapy corrects zang-fu dysfunction and eliminates addiction-prone constitution; emotional regulation care ameliorates psychological dependence and removes emotional triggers for relapse. Synergistic effects achieve treatment addressing both root causes and symptoms, forming a replicable and promotable TCM intervention paradigm for chronic addictive diseases.

4.3 Evidence Innovation: Compensating for Deficiencies in Long-Term Evidence and Subgroup Data

Existing TCM smoking-cessation studies generally prioritize short-term outcomes while neglecting long-term evidence. Through standardized 12-week long-term follow-up, this study quantitatively verifies the core role of constitution-differentiated dietary therapy in stabilizing smoking-cessation efficacy and lowering long-term relapse rate. Meanwhile, constitution-subgroup analysis accurately identifies adaptive advantages of interventions for different constitution populations, clarifying advantageous populations and action targets for individualized TCM smoking cessation. It provides high-level evidence-based support for precise and standardized clinical application of TCM smoking-cessation therapy.

5. Discussion and Academic Reflection

5.1 Core Mechanism of Comprehensive TCM Intervention for Alleviating Tobacco Withdrawal Symptoms

Combining quantitative study results with fundamental TCM theories, the core mechanisms by which this three-dimensional comprehensive intervention relieves tobacco withdrawal symptoms and reduces relapse rate are interpreted hierarchically:

- 1) **Core pathogenesis:** Tobacco is warm-dry in nature and consumes zang-fu qi-vitality after long-term smoking, easily inducing liver-stagnation, phlegm-dampness, and qi-deficiency constitutional biases. The proportional distribution of these three constitutions in this study was 34.34 %, 32.83%, and 32.83%, respectively. Constitutional imbalance constitutes the core TCM pathogenesis triggering severe withdrawal

reactions and contributing to long-term relapse rates exceeding 50 % beyond 12 weeks.

- 2) **Mechanism of auricular external therapy:** Targeted auricular acupoints (Lung, Shenmen, Subcortex, Sympathetic) dredge lung-meridian tobacco toxin, calm the mind, and modulate autonomic nerves and central reward functions. This study demonstrates that auricular-point intervention reduces MNWS scores by an average of 12.36 points, rapidly alleviating acute withdrawal symptoms such as insomnia and irritability and ameliorating somatic dependence.
- 3) **Mechanism of internal conditioning via differentiated dietary therapy:** Single auricular therapy only relieves symptoms rather than root causes. Subtype-specific dietary therapy precisely corrects constitutional biases: liver-stagnation dietary intervention achieves SAS-score reduction of 18.65 points (Gautam N, Shivalingesh K K, Swati S, et al., 2020); phlegm-dampness intervention limits weight gain to 0.68 kg; qi-deficiency intervention reaches a compliance rate of 96.89 %, eliminating the constitutional basis for addiction susceptibility at the root.
- 4) **Synergistic mechanism of emotional regulation care:** Subtype-specific emotional guidance relieves negative emotions for patients of different constitutions, removes triggers for psychological addiction, and avoids emotion-driven relapse behaviors. Synergistic three-dimensional intervention addresses both symptoms and root causes, finally yielding a high 12-week continuous abstinence rate of 65.24 % in the observation group, which is significantly superior to routine interventions.

5.2 Clinical Guiding Value of Constitution-Subgroup Differential Responses

Subgroup-analysis results fully demonstrate that tobacco-dependent patients exhibit significant constitutional differences in withdrawal-symptom phenotypes and intervention responses; homogeneous interventions cannot adapt to all populations. Patients with liver-qi stagnation suffer mainly from psychological-emotional dependence and respond best to liver-soothing mind-calming interventions. Phlegm-dampness patients are characterized by somatic metabolic disturbance and abnormal appetite, for which spleen-invigorating dampness-eliminating dietary therapy precisely relieves specific symptoms. Qi-deficiency patients have poor somatic tolerance and weak compliance; qi-tonifying interventions effectively enhance smoking-cessation tolerance and persistence. These findings define precise treatment principles for TCM syndrome-differentiated smoking cessation, provide a direct subtype-classification basis for clinical individualized smoking-cessation interventions, and resolve problems of vague targets and poor targeting in conventional TCM smoking-cessation therapy.

5.3 Core Advantages of This Protocol Compared with Existing Interventions

Compared with conventional Western-medicine interventions, this comprehensive TCM protocol avoids drug toxic-side effects and secondary-dependence risks. It applies to diverse populations, including patients with mild-to-moderate tobacco dependence, those complicated by underlying diseases, and subjects intolerant to pharmacotherapy, with prominent advantages in safety and compliance. Nevertheless, Western-medicine interventions merely relieve symptoms without improving addiction-prone constitution, resulting in persistently high long-term relapse rates. By contrast, this protocol corrects addictive pathogenesis from constitutional origins and stabilizes long-term smoking-cessation efficacy. Compared with traditional single-modality external TCM therapy, this study integrates internal conditioning and emotional care to compensate for the limitation that single external therapy cannot address root causes. Meanwhile, international universal quantitative scales and long-term follow-up data elevate the evidence-based level of this study, rendering conclusions more clinically persuasive.

5.4 Clinical Application and Academic Value

This high-level prospective controlled trial confirms that three-dimensional comprehensive TCM intervention simultaneously ameliorates three pathological states of tobacco dependence: somatic addiction, psychological addiction, and constitutional addiction. It delivers a novel standardized TCM solution for non-pharmacological smoking cessation. Featuring simple operation, low cost, safety, and non-invasiveness, this intervention protocol can be widely applied in hospital smoking-cessation clinics, community health management, household self-intervention, and other scenarios with great clinical promotion value. Furthermore, the intervention paradigm of syndrome-differentiation stratification, combined with internal-external therapy, balancing short-term and long-term outcomes, breaks the limitations of mere symptomatic intervention. It delivers novel research ideas for TCM interventions targeting chronic relapsing addictive diseases, such as alcohol dependence and emotional addiction, and enriches the academic connotations of TCM individualized diagnosis-treatment and treating diseases by targeting root causes.

6. Research Limitations and Future Prospects

6.1 Research Limitations

This study still has certain limitations:

- 1) **Sample-source limitation:** As a single-center clinical trial, subjects are recruited from geographically

concentrated regions with limited population coverage, which partly reduces the universality and external validity of results. Multi-center large-sample clinical trials are required in follow-up research to further verify the promotion value of this protocol.

- 2) **Follow-up-duration limitation:** Only a 12-week short-term follow-up was arranged in this study. No medium-to-long-term (≥ 1 -year) smoking-cessation follow-up data are available, which cannot fully validate long-term abstinence stability and sustained relapse-prevention efficacy of this TCM intervention protocol.
- 3) **Evaluation-indicator limitation:** Outcome indicators mainly rely on subjective clinical scale scores. Objective laboratory quantitative indicators, including neurotransmitters, inflammatory factors, and metabolic levels, were not incorporated; thus, the molecular mechanism by which this intervention modulates tobacco dependence cannot be deeply interpreted.

6.2 Future Research Directions

Subsequent multi-center, large-sample clinical trials with long-term follow-up will be carried out to supplement medium- and long-term efficacy data and verify the universality and long-term stability of this protocol. Meanwhile, changes in dopamine, 5-hydroxytryptamine, inflammatory factors, and metabolic indicators of subjects will be detected to deeply explore molecular mechanisms of comprehensive TCM intervention. Dietary-therapy composition, frequency, and duration of auricular-point intervention for each constitution subtype will be further optimized to refine individualized intervention standards, build a standardized, normalized, and precise TCM smoking-cessation diagnosis-treatment system, and promote industrial standardization and clinical popularization of TCM smoking-cessation protocols.

7. Conclusions

The three-dimensional comprehensive TCM intervention protocol combining auricular point pressing with beans, constitution-differentiated dietary therapy, and emotional regulation care can significantly raise the 4-week short-term smoking-cessation success rate and 12-week long-term continuous abstinence rate among patients with mild-to-moderate tobacco dependence. It effectively reduces the severity of tobacco withdrawal symptoms, relieves anxiety during smoking cessation, and markedly lowers long-term relapse risk. Patients of different constitutions present differentiated intervention responses: liver-qi stagnation patients achieve optimal emotional improvement; phlegm-dampness accumulation patients obtain best control over metabolic disturbance; qi-deficiency depletion patients show highest intervention compliance. Constitution-differentiated stratified intervention realizes precise smoking-cessation therapy. This intervention protocol is safe, non-invasive, well-tolerated, associated with high compliance, and stable long-term efficacy. It possesses prominent clinical advantages over routine smoking-cessation health education and can serve as a preferred non-pharmacological smoking-cessation option for patients with mild-to-moderate tobacco dependence, worthy of extensive clinical promotion and application. This study provides high-level evidence-based data and innovative diagnosis-treatment paradigms for individualized and long-acting TCM interventions targeting chronic addictive diseases.

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