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Clinical guideline on acupuncture and moxibustion—
Smoking cessation

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Foreword

This guideline aims to provide a standardized set of recommendations and protocols for acupuncture and moxibustion interventions for tobacco dependence disorder.

This guideline is developed in accordance with the technical procedures and rules established by the Standardization Working Committee of the World Federation of Acupuncture-Moxibustion Societies.

This guideline is endorsed and published by the World Federation of Acupuncture-Moxibustion Societies.

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Please note that some of the contents of this guideline may involve patents. The issuing organization of this guideline does not assume the responsibility for identifying patents.

Clinical guideline on acupuncture and moxibustion—Smoking cessation

1 Introduction

1.1 Terminology

1.1.1
tobacco dependence

Smoking can be addictive, known as tobacco dependence. Generally, when contacting with the smoking at the beginning, smokers do not have many cigarettes and not smoke frequently. However, with the increasing duration of cigarette smoking, "smoking habits" results, the quantity and frequency of smoking gradually rise and "smoking addiction" is worsened. This kind of "tobacco addiction" is a chronic addictive disease in medicine, called tobacco dependence. Nicotine is the substance that causes tobacco addiction, encoded as 6C4A in the International Classification of Diseases (ICD-11, 6C4A).

1.1.2
tobacco withdrawal symptoms

Tobacco withdrawal symptoms are a series of symptoms that occur when smoking stopped or is reduced, including smoking cravings, anxiety, depression, difficulty concentrating and others. Tobacco withdrawal symptoms appear several hours after cessation of smoking, and are manifested the most strongly within the first 14 days of quitting smoking, which decreases thereafter until disappearing.

1.2 Aims and objectives

The WFAS *Clinical guideline on acupuncture and moxibustion—Smoking cessation* (hereinafter referred to as guideline) is formulated to provide clinicians with alternative regimens of acupuncture for smoking cessation with reliable clinical supported, focusing on the international demand and clinical questions of smoking cessation with acupuncture and moxibustion, with full consideration of the international applicability and combining with the values and preference of tobacco addicts. This guideline will be committed to improving the effectiveness, safety and specification of acupuncture for smoking cessation and boosting the clinical application of acupuncture and moxibustion for smoking cessation in the world.

1.3 Scope

This guideline is applicable for the smoking and scope of diseases applicable to smokers and tobacco addicts who are willing to quit smoking, and provide the treatments with acupuncture and moxibustion according for the smokers with different types of addiction and degrees.

1.4 Target audience

This guideline is applicable to professionals worldwide in the field of clinical practice, teaching and research, including ① acupuncture physicians, ② TCM physicians, ③ physicians for smoking cessation, ④ teachers and students of medical school or TCM education and training institutions and ⑤ relevant personnel of research institutions of Chinese medicine.

1.5 Settings

This guideline is applicable to hospitals worldwide, including hospitals specialized in acupuncture-moxibustion, primary hospitals or clinics engaged in clinical work of acupuncture and moxibustion, medical colleges with the discipline of acupuncture and moxibustion involved, and the institutions of researches and evaluation of acupuncture and moxibustion.

1.6 Summary of recommendations

No.	Recommendations	Grade of evidence
1	Brief interventions can help to quit smoking.	High, based solely on expert consensus
2	Setting up "quit day" could assist with smoking cessation.	Medium, based solely on expert consensus
3	The "5A" model of smoking cessation counseling can help quitting smoking.	High, based solely on expert consensus
4	The filiform needling therapy can help quit smoking.	High
	Lieque (LU7), Tianmei (Extra), Baihui (GV20), Hegu (LI4), Zusanli (ST36), Sanyinjiao (SP6), Taichong (LR3), and Zhongwan (CV12) are recommended.	Medium
	Even needling technique of reinforcing and reducing is applied to all of the acupoints.	Medium
	Acupuncture takes 20 to 30 minutes per session, ≥2 times per week, for a total of 8 to 12 weeks.	Medium

(*continued*)

No.	Recommendations	Grade of evidence
4	Acupuncture has the satisfactory clinical efficacy on smoking cessation when combined with electroacupuncture.	Medium
	Acupuncture has a certain of clinical efficacy on smoking cessation when combined with moxibustion.	Low
	Acupuncture has a certain clinical therapeutic effect on smoking cessation when combined with needle-embedding therapy.	Low
5	Auricular therapy can help quit smoking.	High
	Shenmen (TF4), Endocrine (CO18), Subcortex (AT4), Sympathetic (AH6a), Mouth (CO1), Lung (CO14) and Stomach (CO4) are recommended in auricular acupuncture.	Medium
	Seed-pressing and needling therapies of auricular acupuncture may effectively relieve the symptoms of tobacco dependence after smoking cessation.	High
6	Embedding needle therapy may assist with smoking cessation.	Low
	Acupoint application may assist with smoking cessation.	Low
	Fire needle therapy may assist with smoking cessation.	Low
7	Strengthening the management of smoking cessation management and follow-up can benefit tobacco-dependent patients and prevent from relapse.	High, based solely on expert consensus

1.7 Contacts

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2 Overview of the disease

2.1 Definition of tobacco dependence

In modern medicine, tobacco dependence is a chronic and highly recurrent disease, and nicotine dependence is essential. At present, there is no specific diagnostic standard for tobacco dependence in the world, and "drug dependence diagnostic standard" is adopted universally. Referring to the diagnostic criteria for drug dependence in ICD-11, combined with the behavioral characteristics of smoking, it is recommended that the clinical diagnostic criteria for tobacco dependence should be: having experienced or exhibited at least 3 of the following 6 items within the past one year: ① having strong craving for the need of tobacco; ② having difficulties to control smoking behaviors; ③ having nicotine withdrawal syndromes after smoking cessation; ④ manifesting as tobacco tolerance, i. e. needing to increase smoking to get the equal feeling by a small amount of smoking in the past; ⑤ giving up or reducing the other activities and hobbies due to smoking; and ⑥ insisting on smoking regardless of the dangers of it.

2.2 Epidemiology worldwide

According to the report of World Health Organization (WHO) in 2019, among the population aged 15 years and above, there are currently approximately 1.337 billion tobacco users[1]. Global tobacco epidemic monitoring report of WHO shows that from 2007 to 2017, the global smoking rate among people aged 15 and above decreased from 22.5% to 19.2%[2]. Tobacco kills more than 8 million people every year, among which, about 7 million people died of the diseases caused by smoking and 1.2 million people by passive smoking exposure[3].

Since the WHO *Framework convention on tobacco control* came into force in 2005, a global consensus had been made on tobacco harm. Currently, 181 countries have signed the convention and taken a series of tobacco control measures. In *China reported health hazards of smoking 2020*[4], the number of smokers in China exceeds 300 million, and the smoking rate among people aged 15 and above is 26.6%, of which, the smoking rate of adult men is as high as 50.5%. Annually, more than on million people in China die of tobacco, and it is expected to grow to 2 million per year by 2030 and 3 million by 2050 if without effective action.

2.3 Manifestations, assessment and measurements

2.3.1 Manifestations

Tobacco dependence is manifested by physical and psychological dependence. Physical dependence is manifested as a series of intolerable withdrawal symptoms after smokers stopping smoking or reducing smoking, e. g. smoking craving, anxiety, depression, restlessness, headache, increased salivary gland secretion, lack of concentration and sleep disorder. In general, withdrawal symptoms start in several hours after stopping smoking, and these symptoms are the worst within the first 14 days of quitting, and then gradually decrease until they disappear. Most withdrawal symptoms last for about a month, but some patients have a persistent desire of smoking for over a year. Psychological dependence is also called spiritual dependence, commonly known as "psychological addiction", which is manifested by a strong subjective desire of smoking. If tobacco addicts smoke again after experiencing withdrawal symptoms, these withdrawal symptoms will be alleviated or disappear, which disrupts the process of smoking cessation.

2.3.2 Assessment

Assessing tobacco use and tobacco dependence is an important step in intervention treatment. For smokers with tobacco dependence, the dependence severity is evaluated based on the following two scales (Tables 1 and 2). The Fagerstrom Test for Nicotine Dependence (FTND) includes six items, i.e. the first cigarette in the morning, smoking in public places, the cigarette hated most to give up, the number of cigarettes of smoking per day, frequency of smoking in the first hour after waking up, and smoking during illness. The total score varies from 1 to 10. The score 1 to 3 shows mild dependence, 4 to 6 medium dependence, and ≥7 severe dependence. The higher the FTND score, the more the dependence on tobacco. Heaviness of Smoking Index (HSI) is also applicable, the higher the cumulative score, the more severe the dependence on tobacco. This smoker is more likely to benefit from an intensive intervention of smoking cessation interventions, especially the treatment for it.

Table 1—The Fagerstrom Test for Nicotine Dependence (FTND)

No.	Question	Score
1	How soon after you wake up do you smoke your first cigarette?	
	Within 5 min	3
	6 to 30 min	2
	31 to 60 min	1
	After 60 min	0
2	Do you find it difficult to refrain from smoking in places where it is forbidden?	
	Yes	1
	No	0
3	Which cigarette would you hate most to give up?	
	The first in the morning	1
	Any other	0
4	How many cigarettes per day do you smoke?	
	≤10	0
	11 to 20	1
	21 to 30	2
	≥31	3
5	Do you smoke more frequently during the first hours after waking than during the rest of the day?	
	Yes	1
	No	0
6	Do you smoke even if you are so ill that you are in bed most of the day?	
	Yes	1
	No	0

Table 2—the Heaviness of Smoking Index (HSI)

NO.	0	1	2	3
1. How soon after you wake up do you smoke your first cigarette	>60 min	31 to 60 min	6 to 30 min	≤5 min
2. How many cigarettes per day do you smoke?	≤10	11 to 20	21 to 30	>30

2.3.3 Measurement

As the basic substance of tobacco dependence, nicotine can be detected accurately from blood or urine[5]. Cotinine is the main product after the primary metabolism of nicotine in the human body. After metabolized by cytochrome P2A6 (CYP2A6) in the body, nicotine in tobacco mainly presents in the blood, and is excreted from the urine with the metabolic process. Due to its long half-life (3 to 4 days) and relatively stable nature, cotinine has become the main biomarker for measuring the smoking quantity of smokers and passive smokers. Generally, nicotine concentration can be detected by measuring the concentration of cotinine in the serum, urine and saliva.

Carbon monoxide comes from incomplete combustion or oxidation of organic matter. When a smoker ignites a cigarette, the burnt cigarette produces carbon monoxide. Hence, detecting the carbon monoxide content can simply determine whether the smoker smokes or not. Compared with the high cost of nicotine test in the blood or urine and the complicated operation, the cost performance of the carbon monoxide detection by exhalation is higher, simpler and faster; and the accuracy of this test is guaranteed. Therefore, the carbon monoxide detection by exhalation has become a routine item in the clinics of smoking cessation.

2.4 Treatments of western medicine

2.4.1 Medicines for smoking cessation drugs

Medicines for smoking cessation can alleviate withdrawal symptoms and assist smokers with a desire to quit smoking so as to increase the successful rate. The medication has two categories, i. e. Nicotine Replacement Therapy (NRT) and non-Nicotine Replacement Therapy (non-NRT)[6]. Nowadays, nicotine patch, nicotine chewing gum (over-the-counter drug), bupropion hydrochloride sustained-release tablets (prescribed drug) and varenicline (prescribed drug) are approved in China. For heavy smokers who have failed to quit with multiple attempts and those with a high motivation to quit, the allied medication is used. For the populations with drug contraindications or unclear efficacy after medication for smoking quitting, such as users of non-burning tobacco products, a small number of cigarettes, pregnant/lactating women and juveniles, the medication is not recommended currently.

2.4.2 Brief smoking cessation interventions

14.8% of smokers experience a positive change in their willingness of quitting after one session of brief smoking cessation intervention[7]. This service technology is feasible in medical institutions. In the medical and health services, it is recommended to establish a system of questioning smoking history in the first visit and clearly advise smokers to quit smoking. For smokers who are willing to quit, the guidance and assistance should be enhanced for smoking cessation; and for those who have no intention of quitting smoking, they should be motivated for it. These interventions generally take no more than 3 minutes, but can encourage smokers to have an attempt and increase the successful rate of smoking cessation.

2.4.3 Smoking cessation clinic

Smoking cessation clinic is an effective way of providing the professional interventions of smoking cessation for smokers[8], especially for those who have unsatisfactory effect of brief interventions or voluntarily accept intensified interventions. It needs to publicize smoking cessation clinic through various means and instruct smokers to receive professional interventions for smoking cessation.

3 Guideline development process

The development of this guideline refers to the GRADE methodology and is based on the World Health Organization (WHO) guideline development manual, following the principle of "Evidence-based, Consensus-based, and Experience-based", and the best available evidence at present. The specific development process is described as follows.

3.1 Development of clinical questions

Firstly constructing the guideline clinical question is a key issue that needs to be urgently addressed before the development of clinical practice guidelines for smoking cessation. This guideline uses the PICOS model to construct the clinical question, which refers to the four key factors involved in the clinical question, including the Population (P), the Intervention (I), the Comparison (C), the Outcome (O), and Study type (S). We adopted the conclusions on the launching meeting held in Beijing in July 2018 to determine the most concerned clinical issues, and initially discussed the questions that may be encountered in the formulation process of the guideline so as to decide the direction of the future work. After discussions, based on the essential clinical problems for smoking cessation treated with acupuncture and moxibustion are determined, The Guideline Development Group (GDG), in terms of literature review [e.g. the existing guideline standard documents, pre-search system evaluation, clinical Randomized Controlled Trial (RCT) and other literature], designed the clinical questionnaire survey and drafted the clinical question items, in the form of a questionnaire survey, the opinions and suggestions were collected from clinical experts of Department of Respiratory Disease Prevention and Department of Acupuncture and Moxibustion. In following, the clinical questions were further screened. GDG conversed these questions to be the study questions with PICO model, and graded according to the four elements. After the final discussion by the writing group, the following clinical questions were determined (Table 3).

Table 3—Clinical questions in PICO

PICO project	PICO results
Population	Smokers and tobacco dependence who are willing to quit smoking
Intervention	Various therapies of acupuncture and moxibustion
Comparison	unlimited
Outcome	Abstinence rates, assessment indicators of withdrawal symptoms and signs scales, safety events

3.2 Searching, assessment and construction of evidence body

3.2.1 Evidence collection and sources

The web-based and manual searches were combined from six databases in English and Chinese versions, i.e. CNKI, Wanfang, VIP, PubMed, Web of Science and Embase.

3.2.2 Search strategy

The articles of Chinese databases were searched by the combination of title, keywords and subject words. The search terms in Chinese were: “戒烟”“烟草依赖”“戒断综合症”“戒断症状”“针刺”“针灸”“火针”“电针”“头针”“激光针”“耳针”“耳穴贴压”“耳穴压丸”“穴位贴敷”“埋针”“埋线”; and those in English included: “smoking cessation” “tobacco dependence” “tobacco withdrawal syndrome” “acupuncture”“acupuncture therapy” “fire needle” “electric acupuncture” “scalp acupuncture” “auricular therapy”“laser acupuncture”“acupoint application” and “acupoint catgut embedding”. The search time was from the inception to June 30, 2021.

According to the inclusion and exclusion criteria, the literature was screened to obtain the final target one, and the sheets of literature evidence records and literature feature extraction were formed.

3.2.3 Literature search

Inclusion criteria: The criteria were developed based on PICOS principles to clarify the diagnose of tobacco dependent. The therapies of acupuncture and moxibustion were used alone or in combination. Control measures were not restricted. Outcome indicators included at least one of the following items: ① key outcome indicators: abstinence rates (continuous abstinence rate and point abstinence rate); ② primary outcome indicators: FTND score, HSI score, Minnesota Nicotine Withdrawal Scale (MNWS) score, Brief Questionnaire of Smoking Urges (QSU-Brief), safety; ③ secondary outcome measures: cigarettes per day (CPD), content of exhaled carbon monoxide (CO), urinary cotinine concentration, shortened course of treatment, reduced pharmacoeconomics cost, etc. The research types included the clinical RCT with acupuncture and moxibustion as the main intervention measure for the assessment of the clinical efficacy. The languages in publication are English and Chinese.

Exclusion criteria:① the article title have been clearly defined RCT aiming to the effect the mechanism of acupuncture and moxibustion therapies on a certain biochemical index of human body for smoking cessation;② for the duplicate publications of the articles or data,the earliest published article would be included;③ failure to evaluate independently evaluate the effects of acupuncture and moxibustion on smoking cessation because of using the non-conventional treatments;④ data with repeated publication;and ⑤ lack of authentic data.

3.2.4 Literature feature extraction

Two researchers strictly followed the inclusion and exclusion criteria for literature selection and data extraction,and the cross-checking was performed. Any divergence could be resolved through discussion or consultation with a third party. Excel 2010 was used to extract data,including basic literature information,demographic baseline characteristics (age,gender,smoking history,etc.),sample size, intervention measures,whether to follow up,and all outcome indicators.

3.2.5 Analysis on risk of bias

The Cochrane Collaboration's tool for assessing risk of bias was used for RCT, including seven items,i.e. "random sequence generation""allocation concealment""blinding of subjects and experimenters""blinding of outcome evaluators""completeness of outcome data""selective reporting of research results" and "other sources of bias". Each item is judged as "low""high" or "uncertain". "Low risk" of bias indicates that the existence of bias is unlikely to seriously affect the research results,"high risk" refers that the existence of bias seriously weakens the credibility of the research results,and "uncertain" shows that the existence of bias raises doubts about the research results. For different research types,items/scales for the assessment of the risk of bias are used accordingly. ROB assessment is applicable to RCT,while,MINORS scale adopted for non-randomized controlled trials.

During assessing the risk of bias,"back-to-back assessment,unanimous approval,and third-party discussion and approval of doubts" are used to evaluate each literature and form the results of risk-to-bias assessment.

3.2.6 Comprehensive analysis of evidence

The software Review Manager 5.4.1 was used to synthesize and analyze the data of original studies such as RCT and observational study with the same study type,the same outcomes and the same data category,and then,the forest map and funnel map were obtained. For smoking cessation counseling management and follow-up visits,the method as expert consensus was used. For the questions failed to make consensus through questionnaire, the final agreement was reached after deepening analysis and discussion, and the recommendations were provided in association with patient interests ultimately.

3.2.7 Assessment of evidence quality

For the regimens of acupuncture and moxibustion with sufficient evidences supported, the Grading of Recommendations, Assessment, Development and Evaluations (GRADE)[9] is used to summarize the evidence bodies involving the effectiveness and safety of the included regimens of acupuncture and relevant therapies for smoking cessation, and to assess their quality. Provided the evidences are insufficient in quantity and meta-analysis is failed to be conducted, the secretary group will formulate a consensus questionnaire through Delphi method[10] to make recommendations based on expert consensus.

According to the GRADE method, the quality of evidence is divided into four levels: high, medium, low, and extremely low. In the process of evidence grading, five downgrade factors are considered—bias risk, imprecision, inconsistency, indirectness, and publication bias, and three upgrade factors—large effect size, dose-response relationship, and possible confounding factors (negative bias). Based on expert opinions and subsequent discussion, a consensus was reached, and a summary table of results was formed to present the evidence hierarchy. Finally, the evidences presented through the summary table of evidence, and the recommendations were classified by referring to the GRADE system. Eventually, in association with the experts' opinions, the preliminary recommendations of acupuncture and moxibustion were obtained for smoking cessation.

3.3 Development of recommendations

Panel voting was adopted to reach consensus on recommendations based on clinical evidence level, and the quality of evidence was evaluated based on the GRADE system to obtain the consensus on recommendations. Using Delphi method, the agreement on recommendations in this guideline was reached after two-round consensus meetings. The experts participated into and accomplished two rounds of questionnaire consultation. If the consensus degree of a recommended opinion exceeds 75% after the first round of survey, it is considered that the consensus is reached on this opinion, and then, minor revision and editing are required in response to the experts' suggestions. The degree less than 75% shows the failure of consensus, and the major revision is needed. Additionally, the second-round consultation should be followed. If the consensus degree is still lower than 75%, a face-to-face meeting is required to ensure the consensus on whether recommended or strongly recommended. A strong recommendation rather than a weak one is supported by at least 50% of participants/experts. For crucial clinical questions that are effective and safe in terms of smoking cessation assessment, counseling management and follow-up, and also indispensable for clinical use, but lack of the support of evidence-based medicine, the relevant international guidelines and experiences of expert panel should be considered in combination. Besides, one round of Delphi survey should be undertaken to form recommendations as "strong recommendation, only based on expert consensus".

4 Recommendations

Question 1:Can brief interventions (identification,admonition,encouragement,and assessment) help quit smoking?
(1) Recommendation
Brief interventions can help to quit smoking.(Strong recommendation,based solely on expert consensus)
(2) Summary of findings
The evidences were from the results of the preliminary research of working group,and research subjects were the practitioners for smoking cessation and acupuncture-moxibustion. Combined with the experience of GDG members,and the consensus reached by the ballot of the GDG expert panel,85% of experts voted to supplement brief interventions to assist with quitting smoking for tobacco dependents. By means of the expert consensus,the relevant structured methods were provided for assessment and management so that the the common challenges in clinical setting would be overcame practically. In association with the relevant smoking cessation guidelines,*Initiating pharmacologic treatment in tobacco-dependent adults: an official American Thoracic Society clinical practice guideline* (2020 edition)[11],and *the Chinese clinical guidelines for smoking cessation* (2015 edition)[12],because brief interventions are simple in operation and acceptable by tobacco-dependent patients and more feasible by doctors compared with the non-brief interventions,GDG agrees that brief interventions are recommended prior to the conventional treatment for smoking cessation.
(3) Explanation
• Subgroup Brief interventions work for three groups of people:smokers with the willingness to quit and are attempt to quit smoking at present;smokers with the willingness to quit but are not attempt to quit smoking at present;the former users of tobacco who are preparing to quit smoking recently[13]. Purpose:to ensure every smoker to be identified and provided one session of brief intervention prior to each clinical visit or formal treatment. • Implementation Before implementing this recommendation,it is suggested that patients should be in the clinic of smoking cessation to determine the diagnosis,condition and treatment plan.

(*continued*)

- **Monitoring and evaluation**

To monitor whether more smokers and tobacco dependents have received brief interventions rather than medical treatment after the release of this guideline.

- **Research priorities**

To conduct high-quality RCT of brief intervention in tobacco dependents and observe the efficacy of brief intervention treatment.

(4) Application of recommendation

- **Being conductive to smoking cessation.**

Clinicians should actively identify, counsel and encourage smokers to quit smoking, and adopt different interventions at different stages. See Table 4.

Table 4—Different stages of smoking cessation and countermeasures

Stages	Interventions
Pre-contemplation	• Apply the 5A's and 5R's models to encourage quitting; • Enhance the quitting motivation for using motivational interview method
Contemplation	Assisting smokers with balance choice table
Preparation	• Assist in assessing the postential barriers or challenges encountered; • Set up a smoking cessation plan and prepare various smoking cessation methods and supports
Action	Provide information on smoking cessation, e.g. various smoking cessation methods
Relapse	Develop a long-term plan for relapse prevention

- **Assessing the degree of tobacco dependence and the confidence of smokers is an important step of smoking cessation with acupuncture and moxibustion.**[14]

The willingness of smokers themselves to quit smoking is the precondition of successful cessation. For smokers who have suffered from tobacco dependence, the professional assessment and intervention are needed. The assessment of tobacco dependence includes the type of tobacco used, smoking quantity, the duration of smoking, the time of starting smoking, the degree of dependence on tobacco, previous attempts to quit smoking, exposure to passive smoking, and attitudes and knowledge about tobacco use. Commonly, FTND scale and HSI scale are adopted to evaluate the degree of tobacco dependence and smoking intensity.

(*continued*)

The confidence of smokers in quitting smoking plays an important role in the cessation, and the willingness to quit smoking of the smokers themselves is the foundation for successful quitting. By asking smokers the questions such as the importance of smoking quitting, confidence, preparation and the expected cost, evaluate the confidence and determination of the smokers are assessed, which is conductive to the regimen formulation for smoking cessation. Usually, Visual Analogue Score (VAS) is applied[15], which is sensitive and comparable. It involves drawing a 10 cm horizontal line on paper, one end of the line being 0 indicates none, the other end being 10 suggests the highest degree, and the middle part shows the different degrees of importance, confidence or preparation for smoking cessation.

Question 2: Can set up "quit day" help quit smoking?
(1) Recommendation
Setting up "quit day"could assist with smoking cessation. (Medium, based solely on expert consensus)
(2) Summary of findings
The evidences were from the results of the group's preliminary research, and research subjects were the practitioners for smoking cessation and acupuncture-moxibustion. Combined with the experience of GDG core members, and the consensus reached by a vote of the GDG expert panel, 65% of experts agreed to set up "quit day" to help tobacco dependents quitting. The expert consensus provided the way for "quit day" and the relevant structural methods, as well as practical guidance for overcoming common the challenges in clinical settings. Besides, the relevant smoking cessation guidelines were combined such as *Initiating pharmacologic treatment in tobacco-dependent adults: an official American Thoracic Society clinical practice guideline* (2020 edition), *Chinese clinical guidelines for smoking cessation* (2015 edition) and *EPA guidance on tobacco dependence and strategies for smoking cessation in people with mental illness* (2014 edition)[16]. Because of the simplicity of the setting up "quit day", easy operation and acceptance by both tobacco-dependent patients and doctors, and satisfactory feasibility, GDG believes that compared to normal smoking cessation treatment, setting up "quit day" is recommendable to be conductive to the psychological adjustment for the smokers so as to make the preparation for smoking quitting.
(3) Explanation
• Subgroup Setting up "quit day" for ordinary smokers may be contributed to quitting smoking. A progressive cessation is recommended for medium to severe tobacco dependents with the symptoms such as anxiety and depression[17].

(*continued*)

The goal is to prepare for quitting smoking and setting up quitting date (preferably starting to quit within two weeks), and begin abstinence after "quit day". • Implementation Before implementation, it is recommended that patients should visit smoking cessation clinic to clarify the diagnosis, condition and treatment plan. When initiating the implementation, the degree of anxiety/depression should be evaluated first. If severe anxiety or depression is diagnosed by psychiatrist or psychologist, this recommendation is no longer suitable to be adopted alone, and relevant specialized treatment needs to be supplemented. • Monitoring and evaluation To monitor whether more smokers and tobacco dependents accept the setting up "quit day" and is benefited. • Research priorities To conduct high-quality RCT of setting up "quit day" on the base of routine treatment for smoking cessation so as to observe the efficacy of quitting smoking.
(4) Application of recommendation
Determining a specific quitting date (e.g. holiday, birthday or anniversary), rather than an unspecified period of time (such as within 2 weeks). No any cigarette is allowed since the "quit day"[18]. The cessation day should be not more than one week apart from the assessment day (The assessment date and smoking cessation date may be on the same day), which is marked the beginning of the formal smoking cessation plan.

Question 3: Can smoking cessation counseling assist in quitting smoking?
(1) Recommendation
The "5A" model of smoking cessation counseling can help quitting smoking. (Strong, based solely on expert consensus)
(2) Summary of findings
The evidences were from the results of the group's preliminary research, and research subjects were the practitioners for smoking cessation and acupuncture-moxibustion. Combined with the experience of GDG core members, and the consensus reached by a vote of the GDG expert panel, 98% of the experts voted to agree that smoking cessation counseling can help quit smoking, and 90% of the experts voted to add the "5A" model to the assistance, the expert consensus provides the decision approaches to the use of the "5A" model of smoking cessation counseling and relevant structured methodology, as well as practical guidance for overcoming common challenges in clinical settings.

(*continued*)

Besides, the relevant smoking cessation guidelines were combined such as *Initiating pharmacologic treatment in tobacco-dependent adults: an official American Thoracic Society clinical practice guideline* (2020 edition) and *the Chinese clinical guidelines for smoking cessation* (2015 edition). Because of the simplicity of "5A" model of smoking cessation counseling, easy operation and acceptance by both tobacco-dependent patients and doctors, and satisfactory feasibility, and the "5A" quit smoking counseling model, GDG believes that it is recommendable to add smoking cessation counseling in the treatment.
(3) Explanation
• Subgroup The "5A" model of smoking cessation intervention is available to all tobacco-dependent patients and smokers who are willing to quit. The specific regimen is based on smokers' intention and actual smoking status. • Implementation This recommendation is applicable to areas/communities that have undergone smoking cessation counseling training and have formal qualifications as physicians. The appropriate smoking cessation supports should be provided individually, the smoking cessation counseling program be communicated to give full consideration to the patient's willingness. Before implementing this recommendation, it is suggested that patients should be in the clinic of smoking cessation to determine the diagnosis, condition, and treatment plan. • Monitoring and evaluation To monitor whether more patients receive smoking cessation counseling to help quit smoking after the release of this guideline. • Research priorities To conduct high-quality systematic evaluation and meta-analysis of the "5A" smoking cessation counseling model to provide the evidences, and make the comparison among different smoking cessation counseling models so as to observe which is optimal.
(4) Application of recommendation
There are many types of smoking cessation counseling, and the "5A" model smoking cessation counseling is commonly used. Many other ways are also involved such as medical staff counseling, hotline counseling, individual and group counseling, and psychological and behavioral therapies. All of these are effective in increasing the rate of cessation, and can be used throughout the entire cessation treatment and help quit smoking and increase the success rate.

(*continued*)

Currently, the "5R" model is often used to enhance smokers' motivation to quit smoking, and the "5A" is to help smokers quit smoking through intervention programs. The "5A" model include: ① Ask: Ask and record the smoking status of all smokers when visiting. ② Assess: Assess each smoker's willingness to quit smoking. ③ Advise: Suggest to quit smoking. ④ Assist: Provide the assistance such as practical counseling for smoking cessation and hotline. It is suggested to develop appropriate smoking cessation assistance plan based on the individual situation and smoking habits. It is recommended that smokers and tobacco addicts who have the intention to quit smoking to accept acupuncture and moxibustion therapy for smoking cessation. ⑤ Arrange: After starting quitting smoking, it is recommended to arrange a follow-up for at least 6 months, by ways of the return visit to smoking cessation clinic or by phone so as to capture the quitting progress.

Question 4: Compared with conventional smoking cessation therapy, can tobacco dependents be benefited from conventional filiform needling therapy?
(1) Recommendation
The filiform needling therapy can help quit smoking. (Strong, based on medium quality evidence)
(2) Summary of findings
9 RCTs[19-27] were included, involving 5 outcomes. Among them, the abstinence rate is low-quality evidence, and the scores of the relevant scales with tobacco withdrawal symptoms are of medium quality. Compared with conventional smoking cessation therapy, the improvements of acupuncture in FTND score, HSI score, MNWS score, QSU score and abstinence rate were not significantly different ($P>0.05$). Based on this, GDG believes that compared to conventional smoking cessation therapy, the filiform needling therapy is recommendable.
(3) Explanation
• Subgroup Given the evidence body is from non-pregnant adult tobacco dependents in China and foreign countries, this recommendation is applicable to non-pregnant adult tobacco dependents, and adult smokers who have the intention to quit smoking can also refer to this recommendation.

(*continued*)

• Implementation This recommendation is applicable to areas/communities with formal qualifications of acupuncture doctors who have received smoking cessation counseling training. This recommendation is applicable to non-pregnant tobacco dependents who are willing to quit smoking. For smokers with severe tobacco dependence, it is recommended to increase the intensity and frequency of acupuncture, or combine with psychological counseling and drugs. Conditions when this recommendation cannot be used independently: ① acupuncture cannot be delivered immediately when the patients are hungry, over food intake, drunk, fatigue or mentally distressed; ② acupuncture is forbidden on the places with infection, scars, ulcer, soars and tumor areas, except for the need of specific treatment; ③ acupuncture is forbidden for the patients with disturbance of blood coagulation. • Monitoring and evaluation To monitor whether more smokers and tobacco dependents are willing to quit after acupuncture rather than conventional smoking cessation therapy after the release of this guideline. • Research priorities To conduct high-quality RCTs of acupuncture and conventional smoking cessation therapy to evaluate the efficacy and safety of acupuncture treatment.
(4) Recommended treatment protocol
• Selection of acupoints Ⅰ: Baihui (GV20), Lieque (LU7), Hegu (LI4), Zusanli (ST36), Sanyinjiao (SP6), Taichong (LR3). Ⅱ: Tianmei (N-UE-60), Lieque (LU7). Ⅲ: Tianmei (N-UE-60), Zusanli (ST36), Hegu (LI4), Lieque (LU7), Baihui (GV20), Shenmen (HT7), Zhongwan(CV12). For cough, running nose and dry eyes, Yintang (EX-HN3) is added; for dysphoria, melancholy and insomnia, Neiguan (PC6) is added; and for sleep disorders, Shenmen (HT7) is added.

(*continued*)

- **Operation**

Needling: Prior to acupuncture, the smokers are in a supine position to expose the sites where acupoints are located. After skin disinfection, the disposable sterile needles are obliquely inserted at Baihui (GV20) along the scalp downward and at Lieque (LU7) upward, 0.5 to 0.8 cun in depth. The needle may be inserted from LU7 and toward to Tianmei (N-UE-60). Other acupoints should be inserted vertically.

Reinforcing and reducing technique: The even-needling technique is applied to all the acupoints.

Needle retaining: 20 to 30 min. The duration of treatment depends on the illness and patient's acceptance.

- **Frequency and course of treatment**

Acupuncture is given one to two weeks prior to the date of quitting to improve the effects on smoking withdrawal.

Each acupuncture treatment takes 20 to 30 min, recommended frequency ≥2 times/week for a total of 8 to 12 weeks. The sessions of acupuncture treatment in the first month is proportional to the successful rate of withdrawal. The study shows that the completion of more than 6 sessions of treatment can significantly increase the effect of withdrawal[28].

For severe tobacco dependents, it is recommended to increase the intensity, frequency and duration of acupuncture treatment.

- **Adjuvant treatment of acupuncture**

① Electroacupuncture[29]

For those who are not sensitive to acupuncture, it is recommended to use electroacupuncture on the basis of acupuncture. Studies have shown that electroacupuncture can effectively enhance the arrival of *qi* (needle sensation) and relieve withdrawal symptoms.

Operation: The electrodes of electroacupuncture instrument are attached to the needle handles at bilateral Lieque (LU7) and Zusanli (ST36) on the same side respectively. Electric stimulation lasts for 30 min, with continuous wave, 15 Hz in frequency and 1 to 5 mA in current intensity.

② Moxibustion[30]

Moxibustion is recommended on the basis of acupuncture. The study results show that acupuncture combined with moxibustion can relieve the withdrawal symptoms and improve the successful rate of smoking cessation.

(*continued*)

Operation: After acupuncture, the smokers change to be a sitting position. A moxa stick is ignited and mild moxibustion technique is delivered at bilateral Lieque (LU7) and Zusanli (ST36), 15 minutes at each acupoint.

③ Intradermal needle therapy[31]

Intradermal needle therapy is recommended on the base of acupuncture. This therapy is applicable for those with obvious withdrawal symptoms. Studies have shown that the combination with intradermal needling may relieve withdrawal symptoms and obtain a persistent effect.

Selection of acupoints: Baihui (GV20), Shenmen (HT7), Tianmei (N-UE-60).

Operation: After acupuncture, held with a forceps, the thumbtack-type needles are inserted into inserted and then the needle handles are covered with medical tape. The needles were retained for 24 h each treatment.

- **Other issues**

① Before giving acupuncture and moxibustion treatment for smoking cessation, informing smokers the benefits of smoking cessation and the potential problems encountered during cessation, especially the withdrawal syndromes that may occur in the several weeks after cessation.

② Requiring the smokers stopping cigarettes after the date of quitting.

③ Informing the smokers the benefits of quitting smoking, the underlying problems and countermeasures.

④ As alcohol is associated with relapse, the smokers should be restricted or abstained from drinking alcohol during smoking cessation.

⑤ For the smokers who receive acupuncture treatment for the first time, the practitioner should communicate well with them and observe their reactions during treatment to prevent possible incidents. Disinfection should be done carefully to prevent from infection. During retaining needles, it is necessary to keep the body warm and the privacy of the patient protected. The practitioner should tell the patients to avoid cold and wind after treatment. The attention should be paid to whether fainting occurs and the timely management should be undertaken.

Question 5:Compared with conventional smoking cessation therapy,can tobacco dependents are benefited from auricular therapy?

(1) Recommendation

Auricular therapy can help quit smoking. (Strong,based on medium-quality evidence)

(2) Summary of findings

12 RCT studies are included[23-27,32-38],with 6 outcomes involved. Among them,the abstinence rate is low-quality evidence;FTND score is graded to be extremely low quality evidence,while HSI and QSU scores are assessed to be the mediumd quality evidence.

Compared to conventional smoking cessation therapy, auricular therapy showed no significant difference at improving HSI scale score and increasing abstinence rate ($P > 0.05$). The improvement of FTND score,MNWS score,and QSU score was superior to conventional smoking cessation therapy ($P<0.05$).

Compared to conventional smoking cessation therapy,auricular therapy has shown medium beneficial effects.

Therefore,GDG believes that auricular therapy can be recommended for smoking cessation compared with conventional smoking cessation therapy.

(3) Explanation

- Subgroup

Given the evidence body is from non-pregnant adult tobacco dependents in China and foreign countries,this recommendation is applicable to non-pregnant adult tobacco dependents,and adult smokers who have the intention to quit smoking can also refer to this recommendation.

- Implementation

This recommendation is applicable to areas/communities with formal qualifications of acupuncture doctors who have received smoking cessation counseling training.

This recommendation is applicable to non-pregnant tobacco dependents who are willing to quit smoking.

For smokers with severe tobacco dependence,it is recommended to increase the intensity and frequency of auricular therapy with either seed pressure or needling,or combine with psychological counseling and drugs.

Conditions when this recommendation cannot be used independently:① auricular acupuncture cannot be delivered immediately when the patients are hungry, over food intake, drunk, fatigue or mentally distressed; ② auricular acupuncture is forbidden on the places with abscess,ulceration and frostbite.

(*continued*)

- Monitoring and evaluation

To monitor whether more smokers and tobacco dependents are willing to quit after auricular therapy rather than conventional smoking cessation therapy after the release of this guideline.

- Research priorities

To conduct high-quality RCTs of auricular acupuncture and conventional smoking cessation therapy to evaluate the efficacy and safety of auricular acupuncture.

(4) Application of recommendation

Auricular acupuncture is recommended in consideration in the following conditions:

① poor compliance of tobacco dependents;

② tobacco dependents with long time on duty, high pressure on life and work.

(5) Recommended treatment protocol

- Selection of acupoints

Shenmen (TF4), Fei (CO14), Jiaogan (AH6), Neifenmi (CO18), Pizhixia (AT4), and Wei (CO4).

Kou (CO1) is added for nausea, whereas Zhiqiguan (CO16) added for cough.

- Operation

① Auricular point pressing method

After routine disinfection, the patch of acupressure bead (seed of cowherb) is pressed at different auricular acupoints. Each auricular point is pressed for at least 1 min. In addition, the smokers are instructed to press the patch of acupressure bead at each auricular point for 20 seconds every 1 to 2 h, or whenever they have a craving for smoking.

② Auricular needling

During the insertion of needle, the auricle is fixed with the pressure hand and the needle is inserted quickly with the puncture hand. The needling direction depends on the location of each auricular point. The depth of insertion is 0.1 to 0.3 cm, without the penetration the auricle. The needles are retained for 15 to 30 min, during which, the needles were manipulated intermittently for 1 or 2 times. While the ear is supported by the pressure hand, the needles are removed with the puncture hand swiftly, and the puncture sites were pressed with dry disinfected cotton ball immediately.

(*continued*)

- Frequency and course of treatment

One or two times per week, for 12 weeks.

For heavy nicotine-dependent smokers, the intensity, frequency and duration of treatment with seed pressure should be delivered.

Question 6: Compared with conventional smoking cessation therapy, can tobacco dependents be benefited from other acupuncture and moxibustion therapies?

(1) Recommendation

Embedding needle therapy may assist with smoking cessation.

Acupoint application may assist with smoking cessation.

Fire needle therapy may assist with smoking cessation.

(Low, based on low-quality evidence)

(2) Summary of findings

3 RCTs[38-40] were included, with 4 outcomes involved. Among them, the abstinence rate refers to the extremely low quality evidence, while the score for the relevant scales of tobacco withdrawal symptoms is low-quality evidence.

Compared with conventional smoking cessation therapy, other acupuncture and moxibustion therapies have no statistical difference in improving withdrawal symptoms and increasing withdrawal rate ($P>0.05$).

Therefore, GDG believes that compared to conventional smoking cessation therapy, other acupuncture and moxibustion therapies can be attempted.

(3) Explanation

- Subgroup

Given the evidence body is from non-pregnant adult tobacco dependents in China, this recommendation is applicable to non-pregnant adult tobacco dependents in China, and adult smokers who have the intention to quit smoking can also refer to this recommendation.

- Implementation

This recommendation is applicable to areas/communities with formal qualifications of acupuncture doctors who have received smoking cessation counseling training.

(*continued*)

This recommendation is applicable to non-pregnant tobacco dependents who are willing to quit smoking.

For smokers who are afraid of acupuncture, acupoint application at auricular points is recommended.

For those without obvious acupuncture effect, the embedding needle is recommended.

For those with strong constitution, fire needle is recommended.

The following conditions when this recommendation cannot be used independently:

① Acupoint application: a) contraindicated for long illness, weakness, emaciation, pregnancy and children, as well as people with severe heart, liver and kidney dysfunction; b) prohibited at the sites with trauma and ulcer.

② Embedding needle therapy: a) prohibited or use with caution in the conditions of mental tension, overwork or over hungry to avoid fainting; b) not applicable to the sites with skin infection or ulceration; c) not applicable if at active stage of tuberculosis, with bone tuberculosis, serious heart disease or pregnancy; d) use with caution for the patients with bleeding tendency; e) prohibited for the people with absorption and repair dysfunction of subcutaneous tissue due to diabetes or other diseases.

③ Fire needle: a) use carefully for women in pregnancy/lactation and infants; b) prohibited for the people with diabetes, hemophilia and coagulation disorder.

- Monitoring and evaluation

To monitor whether more smokers and tobacco dependents are willing to quit after the other acupuncture-moxibustion therapies rather than conventional acupuncture or smoking cessation therapy after the release of this guideline.

- Research priorities

To conduct high-quality RCTs of other acupuncture-moxibustion therapies in comparison with conventional acupuncture/smoking cessation therapy to evaluate the efficacy and safety.

(*continued*)

(4) Recommended treatment protocol
• **Acupoint application**[38] ① Selection of acupoints Tianmei (N-UE-60), Fenglong (ST40), Tiantu (CV22), Danzhong(CV17). ② Operation The circular acupoint herbal pastes with a diameter of 1.5 cm are made by the modern preparation process of Chinese medicine pastes, and fixed on the pressure sensitive tape, with a length of 3 cm. The acupoint herbal pastes are fixed on acupoints. ③ Frequency and course of treatment Once per day, retained for 6 h, and 24 h is the best option; lasting 6 weeks and follow up for 2 weeks. • **Fire needle**[39] ① Selection of acupoints Baihui (CV20), Lieque (LU7), Hegu (LI4). ② Operation After the needle tip is burnt by 30% red, the needle is pricked swiftly at Baihui (CV20), bilateral Lieque (LU7) and Hegu (LI4), 7 pricks at each acupoint, about 0.01 mm in depth. ③ Frequency and course of treatment Once every 3 days, twice a week for 3 weeks. • **Embedding needle**[40] ① Selection of acupoints Xinshu (BL15), Shenmen (HT7), Tianmei (N-UE-60), Taichong (LR3). ② Operation In a sitting or supine position, the absorbable surgical sutures are implanted at bilateral Zusanli (ST36) and Lieque (LU7), and fixed with band-aids for 24 h after needle withdrawal. ③ Frequency and course of treatment Once every two weeks, and four treatments required.

Question 7:Can strengthening smoking cessation management and follow-up benefit smokers and help prevent relapse?
(1) Recommendation
Strengthening the management of smoking cessation management and follow-up can benefit tobacco-dependent patients and prevent from relapse. (Strong,based solely on expert consensus)
(2) Summary of findings
The evidences were from the results of the group's preliminary research, and research subjects were the practitioners for smoking cessation and acupuncture-moxibustion. Combined with the experience of GDG core members, and the consensus reached by a vote of the GDG expert panel, the votes from 98% of the experts agreed that tobacco dependents are benefited by intensifying the management of smoking cessation and the followup visit of prevention from replapse. The expert consensus provides the decision approaches to intensifying the management and relevant structured methodology, as well as the practical guidance for relapse prevention. Based on the relevant smoking cessation guidelines such as *Initiating pharmacologic treatment in tobacco-dependent adults: an official American Thoracic Society clinical practice guideline* (2020 edition) and *the Chinese clinical guidelines for smoking cessation* (2015 edition), the relapse occurs mostly in a short period after smoking quitting and the smokers who quit recently may be high in the risk of relapse. Besides, the relapse may also happen in several months or even years after cessation. Smoking cessation management and follow-up is easily operated and acceptable by tobacco dependent patients and doctors, suggesting a satisfactory feasibility. Hence, GDG believes that smoking cessation management and follow-up bring the benefits to tobacco-dependent patients and are conductive to preventing from relapse.
(3) Explanation
• Subgroup For those who have already quit smoking, it is advisable to take measures to strengthen smoking cessation management and follow-up to prevent relapse. For those who are quitting smoking, it is advisable to strengthen smoking cessation management and follow-up to improve compliance. • Implementation Before implementation, it is suggested doctors to strengthen the relevant smoking cessation follow-up and management training.

(*continued*)

Smokers are noticed that given the relapse happens, they should report it to a doctor as soon as possible to obtain timely intervention. • **Monitoring and evaluation** To monitor whether more tobacco-dependent patients will have lower relapse rate after smoking cessation management and follow-up after the issue of this guideline. • **Research priorities** A large sample of high-quality clinical trials should be carried out, and the follow-up time should be over 6 months. The smokers' relapse should be intensively observed and followed up so as to precisely understand the time points and periods of relapse behavior, which may provide the references for subsequent acupuncture and moxibustion intervention programs.
(**4**) **Application of recommendation**
Smoking cessation management and follow-up are the powerful means of relapse prevention. Smoking cessation management should be applied to the whole process of smoking cessation treatment, including the application of brief intervention before quitting, strengthening management and counseling during treatment, and the persistent attention and follow-up after the successful cessation, by the ways of communication technology (App/WeChat) or telephone and face-to-face interview. Consequently, the feedback can be collected regularly. According to the responses to the interventions, the timely measures and assistance are provided to consolidate the state of quitting and prevent the relapse of smoking. The persistent attention is paid to the quitting progress during the smoking cessation and the management and the counselling are enhanced. It is suggested that acupuncture and moxibustion for smoking cessation should be delivered for no less than 3 months and the regular follow-up be at least 6 sessions. Besides, the relevant scales and biochemical indicators should be tested. Attention is also laid after treatment to assess the to the adverse reactions of treatment and the therapeutic effect of acupuncture and moxibustion on smoking cessation. For those who have successfully quit smoking, it is advisable to consolidate their smoking cessation status and forewarn them the potential inducing factors. Hence, the patients can be alerted to prevent from relapse. In case the relapse happens, the patients are informed to report timely and seek the assistance from doctors. In addition, smokers should be assisted to deal with the difficulties and obstacles that arise during the process of quitting, the successful countermeasures (especially risk avoidance, distraction, positive thinking) are intensified. They are assisted to maintain the confidence of smoking cessation, such as avoiding the temptation of smoking, establishing a healthy lifestyle, strengthening physical exercise, and adjusting their mental state.

(*continued*)

(5) Other issues
Smokers who successfully quit smoking are at risk of relapse. According to studies, the relapse rate among Chinese smokers is high and higher than the abstinence rate[41]. The relapse rate among Chinese smokers ⩾15 years of age is 66.05%, of which 66.59% are males and 55.79% females; the highest relapse rate is found in the age group of 15 to 24 years (82.63%)[42]. Overseas studies have shown that the relapse rate is higher among young people compared with the elderly, and it is higher among quitters who live in families where smoking is allowed indoors compared with those in smoke-free families; compared with the married population, the relapse rate is higher among those who are not married, widowed, divorced, and separated; the relapse rate is dropped significantly if smoking cessation is over 6 months consecutively or even longer[43]. Mostly the relapse occurs in the first several weeks of smoking cessation, but in some cases, it may occur several years after quitting. Most smokers experience relapse after quitting and require multiple attempts to the successful quitting. Relapse can be prevented by intervening with relevant influencing factors to reduce the relapse rate. Studies have shown[44] that relapse to smoking is influenced by various factors such as social status, cultural level, occupation, and family. Heavy tobacco dependence is one of the independent risk factors for relapse in young smokers[45]. It was found[46] that the relapse rate in the family support group was lower than that in the control group at 3 months of follow-up, but the difference was not statistically significant, and the difference showed statistical significance only at 6 months of follow-up, which emphasized the effectiveness of the family support method in reducing the relapse rate with the extension of time. Therefore, through publicizing and educating family members, teaching them knowledge of smoking cessation techniques, using the strength of the smoker's family, and carrying out the follow-up program regularly, as well as providing timely feedback, we can continue to support and supervise smoking cessation, reduce relapse, and improve the abstinence rate of quitting smoking.

5 Access to the guideline

This guideline can be accessed through the website of World Federation of Acupuncture-Moxibustion Societies, and the paper version is published by Standards Press of China. The core content of this guideline will be published via journals of English version. Users can obtain this guide through the above channels.

6 Implication for future research

In the future more well-design studies on smoking cessation by acupuncture should be considered and high-quality RCTs of smoking cessation controlled by acupuncture therapy versus first-line cessation medications should be conduct to explore efficacy and non-inferiority; large-sample, multicenter studies be undertaken to explore the efficacy of acupuncture for smoking cessation with a follow-up greater than 6 months; and study on the economic burden of disease and health economic evaluations be considered.

7 Limitations

This guideline is based on the clinical needs of target users. Focusing on the most concerned intervention measures (acupuncture with filiform needle and auricular acupuncture), clinical questions and recommendations are developed. However, the evaluations are still limited in the treatment course and medical economics.

Annex A
Members of guideline working group

The guideline was drafted by the Institute of Acupuncture and Moxibustion of China Academy of Chinese Medical Sciences, Institute of Basic Theory of Chinese Medicine, Academy of Chinese Medical Sciences, Luohu Hospital of Traditional Chinese Medicine, Shenzhen.

A.1 Members of the expert group

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A.2 Member of the guide drafting group

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(*continued*)

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Annex B
Abbreviations

Full name	Abbreviation
The International Classification of Diseases 11th	ICD-11
Fagerstrom test for nicotine dependence	FTND
Heaviness of smoking index	HSI
Minnesota nicotine withdrawal scale	MNWS
Brief questionnaire of smoking urges	QSU-Brief
Visual Analogue Scale	VAS
Clinical Practice Guidelines	CPG
Evidence to decision	EtD
Grading of Recommendations，Assessment，Development and Evaluations	GRADE
Guide Development Group	GDG
Clinical randomized controlled trial	RCT
The European Psychiatric Association	EPA
World Health Organization	WHO
World Federation of Acupuncture-Moxibustion Societies	WFAS

Annex C
Summary of clinical questions

NO.	Clinical questions
1	Can brief interventions (identification,admonition,encouragement,and assessment) help quit smoking?
2	Can set up “quit day” help quit smoking?
3	Can smoking cessation counseling assist in quitting smoking?
4	Compared with conventional smoking cessation therapy,can tobacco dependents be benefited from conventional filiform needling therapy?
5	Compared with conventional smoking cessation therapy,can tobacco dependents are benefited from auricular therapy?
6	Compared with conventional smoking cessation therapy,can tobacco dependents be benefited from other acupuncture and moxibustion therapies?
7	Can strengthening smoking cessation management and follow-up benefit smokers and help prevent relapse?

前　言

本指南的制定旨在为烟草依赖疾病的针灸干预提供标准化的推荐方案。

本指南依据世界针灸学会联合会标准工作委员会制定的技术流程和规则研制。

本指南由世界针灸学会联合会(World Federation of Acupuncture-Moxibustion Societies,WFAS)归口并发布。

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针灸临床实践指南
戒烟

1 指南概要

1.1 名词术语

1.1.1

烟草依赖

吸烟可以成瘾,称为烟草依赖,吸烟者一般在开始吸烟时吸烟支数并不多,吸烟频率也不高,但随着吸烟时间的延长,“吸烟习惯”养成,吸烟量与吸烟频度会逐渐增加,“烟瘾”加大。这种“烟瘾”在医学上是一种慢性成瘾性疾病,称为烟草依赖。烟草中导致成瘾的物质是尼古丁,国际疾病分类(ICD-11)编码为 6C4A。

1.1.2

戒断症状

戒断症状是在停止吸烟或减少烟量的情况下出现的一系列症状,包括吸烟渴求、焦虑、抑郁、注意力难以集中等症状。戒断症状可在停止吸烟后数小时开始出现,在戒烟最初 14 d 内表现最强烈,之后逐渐减轻,直至消失。

1.2 目的

WFAS《针灸临床实践指南　戒烟》(以下简称本指南)的编写目的在于根据现有临床证据,针对目前针灸戒烟的国际需求及关注的临床问题,在充分考虑国际适用性的基础上,结合烟草依赖者的价值观和意愿,为临床医生提供可选择的、证据可靠的针灸戒烟治疗方案。本指南将致力于提高针灸戒烟的有效性、安全性与规范性,促进针灸戒烟在国际范围内的临床应用推广。

1.3 范围

本指南适用的疾病范围为具有戒烟意愿的吸烟者及烟草依赖者,各种类型、不同程度的吸烟者均可以酌情采用针灸治疗。

1.4 适用人群

本指南的适用人群为全球范围内临床、教学和科研相关的专业人员,包括:①针灸医师;②中医医师;③戒烟医师;④医学院或中医教育培训机构的教师和学生;⑤中医药科研机构相关人员。

1.5 适用场所

本指南的适用环境为全球范围内包含针灸专科的医院、从事针灸学临床工作的基层医院或诊所、包含针灸学专业的医学院校、针灸学相关的科研及评价机构。

1.6 推荐意见汇总

编号	推荐意见	推荐等级
1	简短干预可以帮助戒烟。	强推荐,仅依据专家共识
2	设定戒烟日可以帮助戒烟。	中推荐,仅依据专家共识
3	“5A”模式戒烟辅导可以帮助戒烟。	强推荐,仅依据专家共识
4	毫针刺法可以帮助戒烟。	强推荐
	列缺穴、甜美穴、百会穴、合谷穴、足三里穴、三阴交穴、太冲穴、中脘穴为推荐穴位。	中推荐
	所有穴位均采用平补平泻手法。	中推荐
	针刺治疗每次 20 min～30 min,频率≥2 次/周,一共治疗 8 周～12 周。	中推荐
	针刺法配合电针疗法对于戒烟具有良好的临床疗效。	中推荐
	针刺法配合艾灸疗法对于戒烟具有一定的临床疗效。	低推荐
	针刺法配合揿针疗法对于戒烟具有一定的临床疗效。	低推荐
5	耳穴疗法可以帮助戒烟。	强推荐
	神门、内分泌、皮质下、交感、口、肺和胃是耳穴疗法推荐用穴。	中推荐
	耳穴压丸法、耳针法可有效改善戒烟后烟草依赖的症状。	强推荐
6	穴位埋线对于戒烟具有一定的临床疗效。	低推荐
	穴位贴敷可以帮助戒烟。	低推荐
	火针疗法对于戒烟具有一定的临床疗效。	低推荐
7	加强戒烟管理与随访可以使烟草依赖者获益,有助于预防复吸。	强推荐,仅依据专家共识

1.7 联系人

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2 疾病概述

2.1 烟草依赖的现代医学定义

烟草依赖是一种慢性高复发性疾病,其本质是尼古丁依赖。目前,国际上尚无专门针对烟草依赖的诊断标准,一般采用通用的“药物依赖诊断标准”。参照 ICD-11 中关于药物依赖的诊断条件,结合吸烟

的行为特点，建议烟草依赖的临床诊断标准为：在过去1年内体验过或表现出下列6项中的至少3项：①强烈的戒烟欲望；②难以控制吸烟行为；③当停止吸烟耐受表现，戒烟后出现烟草戒断综合征；④出现烟草耐受表现，即需要增加吸烟量才能获得过去吸较少量烟即可获得的吸烟感受；⑤为吸烟而放弃或减少其他活动及喜好；⑥不顾吸烟的危害而坚持吸烟。

2.2 全球吸烟的流行情况

2019年世界卫生组织(World Health Organization，WHO)报告显示，全球15岁及以上人群中，现有烟草使用者(tobacco users)约13.37亿人[1]。世界卫生组织的全球烟草流行监测报告显示，2007—2017年，全球15岁及以上人群吸烟率从22.5%降至19.2%[2]。烟草每年使800多万人失去生命，其中约有700万人死于吸烟导致的疾病，120万人死于二手烟暴露导致的疾病[3]。

自2005年世界卫生组织《烟草控制框架公约》生效后，烟草危害成为全球共识，目前已有181个国家签署公约并采取了系列控烟措施。《中国吸烟危害健康报告2020》指出[4]，中国吸烟人数超过3亿，15岁及以上人群吸烟率为26.6%，其中成年男性吸烟率高达50.5%。烟草每年使中国100多万人失去生命，如不采取有效行动，预计到2030年将增至每年200万人，到2050年增至每年300万人。

2.3 烟草依赖的表现、评估和检测

2.3.1 表现

烟草依赖表现在躯体依赖和心理依赖两个方面。躯体依赖表现为，吸烟者在停止吸烟或减少吸烟量后，出现一系列难以忍受的戒断症状，包括吸烟渴求、焦虑、抑郁、不安、头痛、唾液腺分泌增加、注意力不集中、睡眠障碍等。一般情况下，戒断症状可在停止吸烟后数小时开始出现，在戒烟最初14 d内表现最强烈，之后逐渐减轻，直至消失。大多数戒断症状持续时间为1个月左右，但部分患者对吸烟的渴求会持续1年以上。心理依赖又称精神依赖，俗称“心瘾”，表现为主观上强烈渴求吸烟。烟草依赖者出现戒断症状后若再吸烟，会减轻或消除戒断症状，破坏戒烟进程。

2.3.2 评估

评估烟草使用和烟草依赖是干预治疗的重要步骤。对于存在烟草依赖的吸烟者，可根据以下两个量表(表1、表2)评估其严重程度。烟草依赖程度量表(Fagerstrom Test for Nicotine Dependence，FTND)包括晨起第一支烟、公共场所吸烟、最不愿意放弃的一支烟、每日吸烟量、晨起1 h吸烟量、生病时吸烟6个方面，总分为1分～10分，1分～3分为轻度依赖，4分～6分为中度依赖，≥7分为重度依赖。FTND得分越高，说明对烟草的依赖程度越高。还可以通过吸烟强度指数量表(Heaviness of Smoking Index，HSI)评估，其严重程度的累计分值越高，说明吸烟者的烟草依赖程度越严重，该吸烟者从强化戒烟干预，特别是戒烟治疗中获益的可能性越大。

表1 烟草依赖程度量表(FTND)

编号	问题	评分
1	您起床后多久才吸第一支烟?	
	5 min内	3
	6 min～30 min内	2
	31 min～60 min内	1
	60 min后	0

表 1 烟草依赖程度量表(FTND)(续)

编号	问题	评分
2	当您身处非吸烟区内(例如商场、地铁或升降机内),是否感到难于忍住不吸烟?	
	会	1
	不会	0
3	您觉得哪一支烟最难放弃?	
	早上第一支	1
	其他	0
4	您每日吸多少支烟?	
	⩽10 支	0
	11 支～20 支	1
	21 支～30 支	2
	⩾31 支	3
5	在起床后数小时内,您吸烟次数是否较在其他时间频密?	
	是	1
	否	0
6	当您患病导致大部分时间卧床时,您是否吸烟?	
	是	1
	否	0

表 2 吸烟强度指数量表(HSI)

评估内容	0 分	1 分	2 分	3 分
1. 您早晨醒来后多长时间吸第一支烟?	>60 min	31 min～60 min	6 min～30 min	⩽5 min
2. 您每天抽多少支烟卷?	⩽10 支	11 支～20 支	21 支～30 支	>30 支

2.3.3 检测

由于尼古丁是烟草依赖的物质基础,直接检测血液或尿液中的尼古丁相对比较准确[5]。可替宁是尼古丁在人体内进行初级代谢后的主要产物——烟草中的尼古丁在体内经细胞色素(Cytochrome P2A6,CYP2A6)代谢后,主要存在于血液中,随着代谢过程从尿液排出。由于可替宁的半衰期较长(3 d～4 d)且较稳定,因此成为测量吸烟者和被动吸烟者吸烟量的主要生物标志,一般情况下,可以通过检测血清中、尿液中以及唾液中的可替宁浓度来检测尼古丁浓度。

一氧化碳一般来自有机物不完全燃烧或氧化。当吸烟者点燃卷烟后,卷烟燃烧会产生一氧化碳,因而可以通过检测一氧化碳含量来简单判断吸烟者是否吸烟。相对检测血液或尿液中的尼古丁检测成本较高,操作复杂,呼出气一氧化碳检测的性价比更高,且检测方法更简便、快捷,检测结果的准确度也可以保证,故呼出气一氧化碳检测已成为戒烟门诊的常规项目。

2.4 常用戒烟方法介绍

2.4.1 戒烟药物

戒烟药物可以缓解戒断症状,辅助有戒烟意愿的吸烟者提高戒烟成功率。戒烟药物分为尼古丁替

代疗法(Nicotine Replacement Therapy,NRT)和非尼古丁替代疗法(non-Nicotine Replacement Therapy,non-NRT)两类[6]。目前中国已被批准使用的戒烟药物有尼古丁贴片、尼古丁咀嚼胶(非处方药)、盐酸安非他酮缓释片(处方药)、伐尼克兰(处方药)。对于多次尝试使用不同方法戒烟失败的重度吸烟者以及有高度戒烟动机的吸烟者可以采取药物联合用法,对于存在药物禁忌或使用戒烟药物后疗效尚不明确的人群(如非燃吸烟草制品使用者、少量吸烟者、孕妇、哺乳期妇女以及未成年人等),目前尚不推荐使用戒烟药物。

2.4.2 简短戒烟干预

14.8%的吸烟者因 1 次简短戒烟干预发生戒烟意愿的正向改变[7],在医疗机构中实施简短戒烟干预技术服务具有可行性。在提供医疗卫生服务过程中,推荐建立首诊询问吸烟史制度,明确建议吸烟者戒烟。对于有戒烟意愿的吸烟者,宜提供进一步戒烟指导和帮助;对于尚无戒烟意愿的吸烟者,宜激发其戒烟动机。这些干预一般耗时不超过 3 min,但可促进吸烟者尝试戒烟并提高戒烟成功率。

2.4.3 戒烟门诊

戒烟门诊是对吸烟者进行专业化戒烟干预的一种有效途径与方式[8],其对象主要是简短干预效果不佳或自愿接受强化戒烟干预的吸烟者。可通过多种方式宣传戒烟门诊,引导吸烟者到戒烟门诊接受专业化戒烟干预。

3 指南制定过程

本指南遵照 GRADE 方法,并依据世界卫生组织(WHO)指南制定手册,遵循“循证为主、共识为辅、经验为鉴”原则,参考当前最佳证据制定。具体制定过程如下。

3.1 临床问题的确定

首先构建指南临床问题是针灸戒烟临床实践指南制定前亟待解决的关键问题,本指南采用 PICOS 模型构建临床问题,PICOS 是指临床问题中涉及的四项关键因素,包括:研究对象(Population,P),干预措施(Intervention,I),对照措施结局指标(Comparison,C),结局指标(Outcome,O),研究类型(Study,S)。本次指南首先通过于 2018 年 07 月在北京召开的启动会以确定临床最关心的问题,并针对指南制定过程中可能遇到的疑问、困惑进行前期探讨,以指明指南今后编写的工作方向。经过踊跃的发言和激烈的讨论,根据实际针灸戒烟临床问题,指南发展小组(Guideline Development Group,GDG)根据已有指南标准文件、预检索系统评价、临床随机对照试验(Randomized Controlled Trial,RCT)等文献,设计临床问卷调研,草拟临床问题条目,以问卷调查的形式,向呼吸科疾病预防科、针灸科等临床专家收集其看法和建议,然后根据调查结果,进一步对临床问题进行筛选,GDG 以 PICO 模式结构化进而转化研究问题,按照 4 个要素进行分级,最终经编写委员会讨论,确定临床关键问题(见表 3)。

表 3 PICO 临床问题

PICO 项目	PICO 结果
研究对象	具有戒烟意愿的吸烟者及烟草依赖者
干预措施	各种针灸疗法
对照措施	不限
结局指标	戒断率、各戒断症状和体征量表、安全事件

3.2 证据体的检索、评价与综合

3.2.1 证据收集与来源

本指南运用网络和手工检索相结合的方式对6个中英文数据库[中国知网(CNKI)、万方数据(Wan Fang)、维普数据库(VIP)、PubMed、Web of Science 和 Embase]进行检索。

3.2.2 确定检索策略

中文采用题名、关键词与主题词相结合的方式进行检索,中文检索词为:"戒烟""烟草依赖""戒断综合症""戒断症状""针刺""针灸""火针""电针""头针""激光针""耳针""耳穴贴压""耳穴压丸""穴位贴敷""埋针""埋线"。英文检索词为:"smoking cessation""tobacco dependence""tobacco withdrawal syndrome""acupuncture""acupuncture therapy""fire needle""electric acupuncture""scalp acupuncture""auricular therapy""laser acupuncture""acupoint application""acupoint catgut embedding"。检索时限为建库至2021年06月30日。

根据纳入和排除标准对文献进行筛查,获得最终目标文献,并形成文献证据登记表和文献特征提取表。

3.2.3 文献检索

纳入标准:根据PICOS原则制定纳入标准,明确诊断为烟草依赖患者;针灸疗法单独使用或联合其他疗法;对照措施不限;结局指标,至少包括以下一项:①关键结局指标:戒断率(持续戒断率以及点戒断率),②重要结局指标:FTND量表评分、HSI量表评分、明尼苏达尼古丁戒断量表(Minnesota Nicotine Withdrawal Scale,MNWS)评分、吸烟渴求问卷简短量表(Brief Questionnaire of Smoking Urges,QSU-Brief)、安全性,③次要结局指标:吸烟量数量、呼出一氧化碳(CO)、尿液可替宁浓度、缩短疗程、降低药物经济学成本等;研究类型为以针灸疗法作为主要干预措施评价临床疗效的临床随机对照试验(RCT);语种限制为英文和中文。

排除标准:①标题中明确说明仅研究针灸戒烟对人体某一生化指标的作用机制为目的的RCT;②重复发表或数据重复的文章仅纳入最早发表的一篇;③采用非常规治疗方法导致无法独立评价针灸戒烟的文献;④重复发表研究数据者;⑤发表数据存在明显欠真实者。

3.2.4 文献特征提取

由两位研究者严格根据文献纳入与排除标准进行文献筛选与资料提取,并交叉核对,如有分歧,经讨论解决或咨询第三方协商解决。使用Excel 2010提取资料,提取内容包括文献基本信息、人口学基线特征(年龄、性别、烟龄等)、样本量、干预措施、是否随访、所有结局指标等。

3.2.5 偏移风险分析

应用Cochrane偏倚风险评价工具对RCT进行偏倚风险评估,包括"随机序列产生""分配隐藏""对受试者、试验者实施盲法""对结局评估者实施盲法""结局数据的完整性""选择性报告研究结果"及"其他偏倚来源"7个条目。针对每个条目作出"低风险""高风险"或"不确定"判断。低风险偏倚表明存在的偏倚不可能严重影响研究结果,高风险偏倚提示存在的偏倚严重减弱研究结果的可信度,不确定偏倚则提示存在的偏倚引起对研究结果的怀疑。对于不同的研究类型应用不同的条目/量表进行偏倚风险评估;对于RCT予ROB风险偏倚评估,对非随机同期对照试验研究予MINORS量表评估。

偏倚风险评估采取"背对背评价、一致通过、存疑由第三方讨论通过"的方法对每篇文献评估,形成证据偏倚评估结果。

3.2.6 证据综合分析

应用 Review Manager 5.4.1 软件对研究类型相同、结局指标相同、数据类别相同的 RCT、观察性研究等原始研究的数据进行整合分析，获得相应森林图及漏斗图。对于戒烟辅导管理及随访等方面采用专家共识的方法，对通过问卷仍无法达成共识的问题再进行分析、讨论，最终达成一致，并综合患者利益作出最终推荐。

3.2.7 证据质量评价

对于证据数量充足的针灸方案，采用推荐分级的评估、制订与评价体系(Grading of Recommendations，Assessment，Development and Evaluations，GRADE)[9]，对纳入的针刺及相关疗法戒烟方案的有效性和安全性的证据体进行汇总和质量评价。证据数量不足、无法进行 Meta 分析的针刺及相关疗法戒烟，秘书组制作共识意见表通过德尔菲法(Delphi)[10]进行问卷调查，形成基于专家共识的推荐意见。

根据 GRADE 方法，将证据质量分为高、中、低、极低 4 个等级。在证据分级过程中，考虑 5 个降级因素——偏倚风险、不精确性、不一致性、不直接性以及发表偏倚，和 3 个升级因素——效应量大、剂量反应关系以及可能的混杂因素(负偏)。基于专家意见和后续的讨论达成共识，形成结果总结表，以呈现证据等级分级，最后通过证据总结表呈现证据，并参照 GRADE 系统对推荐级别的分级，结合专家意见，得到初步的针灸戒烟推荐意见。

3.3 推荐意见的形成

对基于临床证据水平的推荐意见采取小组投票方式取得共识，根据 GRADE 系统进行证据质量评估并取得推荐共识。利用德尔菲法，通过两轮共识会议达成本指南推荐意见共识。共识专家参与并完成两轮问卷咨询，第一轮问卷收齐后，若某条推荐意见的共识度超过 75%，则认为该条意见已达成共识，只需要根据专家的意见进行小范围的修改和语言表达；若未达到 75%，则这条推荐意见未取得共识，则需要根据专家的意见进行大范围的修改，并进行第二轮的专家调研。若第二轮的共识度仍未达到 75%，则经过一次面对面的共识会议对该条意见是否推荐及推荐强度达成共识。一条推荐意见被列为强推荐而非弱推荐，则需要得到至少 50%的参与者认可。对于戒烟评估、辅导管理及随访等方面有一定有效性和安全性、为临床不可或缺、但缺乏循证医学证据的重要临床问题，则结合相关国际指南及指南共识小组专家的经验，采用德尔菲通过 1 轮调查，形成推荐意见共识采用“强推荐，仅依据专家共识”方式表达推荐意见。

4 推荐意见

临床问题 1：简短干预(识别、告诫、鼓励与评估)是否可以帮助戒烟？
(1) 推荐意见
简短干预可以帮助戒烟。(强推荐，仅依据专家共识)
(2) 证据概述
证据来源于工作组的前期调研结果，调研对象主要为戒烟及针灸相关从业人员，结合 GDG 成员的经验，经 GDG 专家组投票达成共识，85%投票同意增加简短干预来帮助烟草依赖者戒烟，专家共识决策路径提供了评估和处理烟草相关性的结构化方法，并为克服临床环境中常见的挑战提供了实用指导。 结合相关指南，《成人烟草依赖的药物治疗：美国胸科学会官方临床实践指南》(2020 年版)[11]、《中国临床戒烟指南》(2015 年版)[12]，GDG 认为：因简短干预简单，易操作，易被烟草依赖患者和医生接受，且具有良好的可行性，相比于无简短干预，可以推荐常规戒烟治疗前增加简短干预。

（续）

（3）推荐说明

● **亚组考虑**

简短干预对三类人群有效：有意愿且现在愿意尝试的戒烟者；有意愿但在此时不愿意尝试的戒烟者；最近准备戒烟的前烟草使用者[13]。

其目标是确保每一位吸烟者都得到识别，在每次临床就诊时或正式治疗前，提供一次简短的干预。

● **实施考虑**

实施该推荐意见前，建议患者在戒烟门诊就诊，明确诊断、病情及治疗方案。

● **监察与评估**

监察该指南发布后，是否有更多的有意愿的戒烟者和烟草依赖者接受简短干预而非不治疗。

● **科研的优先考虑**

开展烟草依赖者简短干预的高质量 RCT，进行观察简短干预治疗的疗效。

（4）推荐意见使用说明

● **简短干预可以帮助戒烟。**

临床医生应积极识别、告诫吸烟者并鼓励其戒烟，并对处在不同阶段的吸烟者采取不同的干预措施，见表 4。

表 4　不同戒烟阶段及应对措施

不同时期	干预措施
思考前期(懵懂期)	● 主要采用 5A's 和 5R's 技巧鼓励戒烟； ● 以动机式访谈法提升戒烟动机
思考期	以平衡抉择表协助吸烟者
准备期	● 协助评估可能遇到的戒烟障碍或挑战； ● 设定戒烟计划，准备各项戒烟方法和支援
行动期	提供戒烟信息，如介绍各种戒烟方法
复吸期	制定长远预防复吸计划

● **评估吸烟者的烟草依赖程度和戒烟信心是针刺戒烟的重要步骤。**[14]

戒烟意愿是吸烟者本人成功戒烟的基础，对于已罹患烟草依赖的吸烟者，需要医生进行专业化戒烟评估与干预，烟草依赖的评估主要包括所用烟草的类型、吸烟量、吸烟持续时间、开始吸烟的时间、对烟草的依赖程度、以前的戒烟尝试以及接触二手烟、对烟草使用的态度和知识。常用 FTND 量表和 HSI 量表评估烟草依赖程度与吸烟强度。

吸烟者的戒烟信心对戒烟具有重要作用，戒烟意愿是吸烟者本人成功戒烟的基础。通过询问吸烟者对此次戒烟的重要性、信心，以及准备程度、预计为此付出的戒烟花费等问题，评估吸烟者的戒烟信心和决心，协助吸烟者后续制定合适的戒烟方法。通常采用视觉类比评分量表（Visual Analogue Score，VAS）[15]，该法比较灵敏，具有可比性，即在纸上面划一条 10 cm 的横线，横线的一端为 0，表示无，另一端为 10，表示强烈，中间部分表示不同程度的重要性、信心或准备程度。

临床问题2:设定戒烟日是否可以帮助戒烟?

(1)推荐意见

设立戒烟日可以帮助戒烟。(中推荐,仅依据专家共识)

(2)证据概述

证据来源于工作组的前期调研结果,调研对象主要为戒烟及针灸相关从业人员,结合GDG专家组内核心成员的个人经验,经GDG专家组投票达成共识,65%投票同意设立戒烟日来帮助烟草依赖者戒烟,专家共识决策路径提供了如何设立戒烟日,以及相关性的结构化方法,并为克服临床环境中常见的挑战提供了实用指导。

结合相关指南,《成人烟草依赖的药物治疗:美国胸科学会官方临床实践指南》(2020年版),《中国临床戒烟指南》(2015年版),欧洲精神病学协会(European Psychiatric Association,EPA)《EPA精神疾病患者戒烟指导》(2014年版)[16],且因设立戒烟日简单,易操作,易被烟草依赖患者和医生接受,具有良好的可行性,基于此,GDG认为:相比于正常戒烟治疗,可以推荐设立戒烟日以帮助吸烟者调整心理,为戒烟做好准备。

(3)推荐说明

- **亚组考虑**

对于普通吸烟者,建立戒烟日可以帮助促进戒烟。

对于伴有焦虑、抑郁等症状中重度烟草依赖者建议采取递减戒烟法[17]。

其目标是为戒烟做好准备,制定戒烟日期(建议最好于两星期内开始戒烟),戒烟日后开始戒断。

- **实施考虑**

实施该推荐意见前,建议患者在戒烟门诊就诊,明确诊断、病情及治疗方案。

应用本推荐意见时,应首先评估患者焦虑/抑郁程度,如果精神医生或心理医生诊断患者属于重度焦虑或抑郁等情况出现,不再适合单独应用本方案,需要配合相关专科治疗。

- **监察与评估**

监察该指南发布后,是否有更多的烟草依赖患者接受戒烟日的设定以帮助戒烟。

- **科研的优先考虑**

在基础戒烟治疗中增加戒烟日设立的高质量RCT,观察其戒烟的真实疗效。

(4)推荐意见使用说明

设定一个明确的戒烟日期(例如节日、生日、纪念日等),而非不明确的时间段(如在2周内),从戒烟日开始,不再吸任何一支烟[18]。戒烟日的设定与评估日相距不多于1周时间(评估日及戒烟日可为同一日),为正式戒烟计划的开始。

临床问题3:戒烟辅导是否可以帮助戒烟?
(1) 推荐意见
“5A”模式戒烟辅导可以帮助戒烟。(强推荐,仅依据专家共识)
(2) 证据概述
证据来源于工作组的前期调研结果,调研对象主要为戒烟及针灸相关从业人员,结合GDG专家组内核心成员的个人经验,经GDG专家组投票达成共识,98%专家投票同意戒烟辅导可以帮助戒烟,90%专家投票同意增加“5A”模式干预戒烟辅导来帮助烟草依赖者戒烟,专家共识决策路径提供了如何设立使用“5A”模式戒烟辅导,以及相关性的结构化方法,并为戒烟门诊临床环境中如何应用提供了实用指导。 结合相关指南,《成人烟草依赖的药物治疗:美国胸科学会官方临床实践指南》(2020年版),《中国临床戒烟指南》(2015年版),此外,因“5A”戒烟辅导模式易操作,易被烟草依赖患者和医生接受,且具有良好的可行性。基于此,GDG认为:可以在戒烟治疗中增加戒烟辅导。
(3) 推荐说明
• **亚组考虑** 对于所有愿意戒烟的烟草依赖者及吸烟者均可采用“5A”戒烟干预方案,具体根据吸烟者的意愿与实际吸烟情况。 • **实施考虑** 本推荐意见适用于经过戒烟辅导培训,具有正规资质医师的地区/社区。 根据患者的具体情况提供恰当的戒烟辅助方法,宜与患者提前沟通戒烟辅导计划,充分考虑患者意愿。 实施该推荐意见前,建议患者在戒烟门诊就诊,明确诊断、病情及治疗方案。 • **监察与评估** 监察该指南发布后,是否有更多的戒烟患者接受戒烟辅导。 • **科研的优先考虑** 进一步对“5A”戒烟辅导模式开展高质量系统评价与meta分析,提供循证依据,并对不同戒烟辅导模式进行对比,观察哪种戒烟辅导疗效更优。
(4) 推荐意见使用说明
戒烟辅导种类较多,“5A”戒烟辅导模式是戒烟辅导中常用的一种模式,戒烟辅导中还有医务人员劝导、热线咨询、个人及团体咨询、心理及行为疗法等戒烟辅导手段,均可以有效提高戒断率,可以贯穿运用于整个戒烟治疗中,以帮助戒烟,提高戒烟成功率。 目前常以“5R”法增强吸烟者的戒烟动机,用“5A”法戒烟干预方案帮助吸烟者戒烟。“5A”包括: ① 询问(Ask):询问并记录所有就医者的吸烟情况。 ② 评估(Assess):评估每位吸烟者的戒烟意愿。 ③ 建议(Advise):建议所有吸烟者必须戒烟。 ④ 协助(Assist):提供戒烟帮助。向吸烟者提供实用的戒烟咨询,戒烟热线等。建议根据戒烟者实际情况与吸烟习惯制定合适的戒烟辅助。推荐有戒烟意愿的吸烟者及烟草依赖者使用针灸疗法戒烟。 ⑤ 安排随访(Arrange):吸烟者开始戒烟后,推荐安排随访至少6个月,随访的形式可以是要求戒烟者到戒烟门诊复诊或通过电话以了解其戒烟情况。

临床问题 4:相比于常规戒烟疗法,针刺是否可以使戒烟患者获益?
(1)推荐意见
毫针刺法可以帮助戒烟。(强推荐,基于中等质量证据)
(2)证据概述
本临床问题共纳入 9 项 RCT 研究[19-27],涉及 5 项结局指标。其中,戒断率为低质量证据;戒断症状相关量表评分为中等质量证据。 相比于常规戒烟疗法,针刺在改善 FTND 评分、HSI 评分、MNWS 评分、QSU 评分及提高戒断率方面差异无统计学意义($P>0.05$)。 基于此,GDG 认为:相比于常规戒烟治疗,可以推荐毫针刺法以帮助戒烟。
(3)推荐说明
● **亚组考虑** 制定该推荐意见的证据体的患者来源于国内外非孕期的成年烟草依赖者,故该推荐意见适用于非孕期的成年烟草依赖者,对于具有戒烟意愿的成年吸烟者亦可参考本推荐意见。 ● **实施考虑** 本推荐意见适用于经过戒烟辅导培训,具有正规资质针灸医师的地区/社区。 本推荐意见适用于具有戒烟意愿的非孕期烟草依赖患者。 对于重度烟草依赖的戒烟者,建议增加针刺治疗的强度和频次,或结合心理咨询和药物干预。 非单独适用本推荐方案的条件:①饥饿、饱食、醉酒、大怒、大惊、过度疲劳、精神紧张者,不宜立即进行针刺;②皮肤有感染、溃疡、瘢痕或肿瘤部位,除特殊治疗需要外,均不应在患部直接针刺;③有凝血机制障碍的患者,应禁用针刺。 ● **监察与评估** 监察该指南发布后,是否有更多的有意愿的戒烟者和烟草依赖者接受针刺治疗而非常规戒烟疗法。 ● **科研的优先考虑** 开展针刺与常规戒烟疗法的高质量 RCT,进行针刺治疗的疗效和安全性评价。
(4)治疗方案
● **取穴** 选穴一:百会穴、列缺穴、合谷穴、足三里穴、三阴交穴、太冲穴。 选穴二:甜美穴、列缺穴。 选穴三:甜美穴、足三里穴、合谷穴、列缺穴、百会穴、神门穴、中脘穴。 如有咳嗽、流鼻涕、眼睛干燥的症状,加用印堂穴;有烦躁、忧郁、失眠等症状,则加用内关穴;伴随睡眠障碍者加神门穴等。 ● **操作方法** 针刺方法:针刺之前,吸烟者取仰卧位,暴露穴位。皮肤消毒后,将一次性无菌针,沿皮下向后斜刺入百会穴,沿皮下向上斜刺列缺穴 0.5 寸～0.8 寸。可从列缺穴透刺甜美穴。余穴均直刺。

（续）

补泻手法：所有穴位均采用平补平泻手法。

留针时间：20 min～30 min，可依据患者病情及可接受度等因素，酌情确定治疗时间。

- **治疗频率及疗程**

建议针刺治疗从戒烟日前 1 到 2 周开始，可提高戒断效果。

针刺治疗每次 20 min～30 min，建议频率≥2 次/周，一共治疗 8 周～12 周。首月针刺次数与戒断成功率成正比，研究表明完成 6 次以上治疗可明显提高戒断效果[28]。

对于重度烟草依赖的戒烟者，建议增加针刺治疗的强度、频率和持续时间。

- **毫针刺法的辅助治疗**

① 电针疗法[29]

对针刺不敏感者，推荐在针刺的基础上采用电针辅助治疗。研究表明，电针疗法可以有效增强针刺得气感，对缓解戒断症状有明显作用。

操作方法：将电针仪的电极连接到双侧列缺穴和足三里穴的针柄上。电针刺激 30 min，连续波 15 Hz，电流强度 1 mA～5 mA。

② 艾灸疗法[30]

推荐在针刺的基础上采用艾灸治疗。研究表明，针刺配合艾灸可缓解戒断症状，提高戒烟率。

操作方法：针刺后患者取坐位姿势，取艾条一根将其点燃，采用温和灸手法，对双侧列缺、足三里两个穴位进行温和灸，每穴灸 15 min。

③ 揿针疗法[31]

推荐在针刺的基础上结合揿针治疗。戒断症状较明显者，可采用揿针疗法。研究表明，结合揿针可改善戒断症状，使疗效更持久。

选穴：百会穴、神门穴、甜美穴。

操作方法：针刺后，在穴位处予镊子夹持揿钉型皮内针垂直刺入，再用医用胶布覆盖针柄，每次留针 24 h。

- **其他注意事项**

① 针刺戒烟前，应告知吸烟者戒烟的好处，在戒烟过程中可能遇到的问题，特别是戒烟后数周内可能出现的戒断症状。

② 要求吸烟者在戒烟日后不要吸烟。

③ 告知吸烟者戒烟的好处、将会遇到的问题和有效的解决办法。

④ 由于酒精与复吸有关，因此吸烟者在戒烟时应限制饮酒或戒酒。

⑤ 对于首次接受针刺治疗的戒烟者，应在治疗期间保持良好的沟通，观察针刺反应，预防针刺不良反应；针刺时应仔细消毒，防止感染；留针时，应注意保暖，保护患者隐私，并告知治疗后要避寒避风；注意是否出现晕针并及时处理。

临床问题 5:相比于常规戒烟疗法,耳穴疗法是否可以使戒烟患者获益?
(1) 推荐意见
耳穴疗法可以帮助戒烟。(强推荐,基于中等质量证据)
(2) 证据概述
本临床问题共纳入 12 项 RCT 研究[23-27,32-38],涉及 6 项结局。其中,戒断率为低质量证据;FTND 量表评分为极低质量证据,HSI、QSU 量表评分为中等质量证据。 相比于常规戒烟疗法,耳穴疗法在改善 HSI 量表评分及提高戒断率方面差异无统计学意义($P>0.05$)。在改善 FTND 评分、MNWS 评分、QSU 评分优于常规戒烟疗法($P<0.05$)。 相比于常规戒烟疗法,耳穴疗法展示出中等程度的有利效果。 基于此,GDG 认为:相比于常规戒烟治疗,可以推荐耳穴疗法戒烟。
(3) 推荐说明
• 亚组考虑 制定该推荐意见的证据体的患者来源于国内外非孕期的成年烟草依赖者,故该推荐意见适用于非孕期的成年烟草依赖者,对于具有戒烟意愿的成年吸烟者亦可参考本推荐意见。 • 实施考虑 本推荐意见适用于经过戒烟辅导培训,具有正规资质针灸医师的地区/社区。 本推荐适用于具有戒烟意愿的非孕期成年烟草依赖患者。 对于重度烟草依赖的戒烟者,建议增加耳穴压丸、耳针等耳穴疗法的强度和频次,或结合心理咨询和药物干预。 非单独适用本推荐方案的条件:①紧张、疲劳、虚弱者不宜立即进行耳穴治疗;②脓肿、溃破、冻疮局部的耳穴禁用。 • 监察与评估 监察该指南发布后,是否有更多有意愿的吸烟者和烟草依赖者接受耳穴疗法而非常规戒烟疗法。 • 科研的优先考虑 开展耳穴疗法与常规戒烟疗法的高质量 RCT,进行耳穴疗法戒烟的疗效和安全性评价。
(4) 推荐意见使用说明
在以下情况,可考虑推荐耳穴疗法治疗: ① 依从性较差的烟草依赖者; ② 在岗时间长、生活节奏紧张、工作压力大的烟草依赖者。
(5) 治疗方案
• 取穴 神门、内分泌、皮质下、交感、肺、胃。 如果有恶心的症状加用"口"穴,如果有咳嗽的表现则加用"支气管"穴。 • 操作方法 常用的耳穴疗法主要包括耳穴压丸法、耳针法。 ① 耳穴压丸法 常规消毒后,用直径为 2 mm 的王不留行籽贴片贴在耳穴上。每个耳穴按压 1 min。此外,吸烟者应当每隔 1 h~2 h 按压每个耳穴穴位 20 s,或每当他们想吸烟时按压每个耳穴穴位 20 s。 ② 耳针法 进针时,押手固定耳郭,刺手持针速刺进针;针刺方向视耳穴所在部位灵活掌握,针刺深度宜 0.1~0.3 cm,以不穿透对侧皮肤为度;一般留针 15 min~30 min,可间歇行针 1 次~2 次。出针时,押手托住耳背,刺手持针速出,同时用消毒干棉球压迫针孔片刻。 • 治疗频率及疗程 每周 1 次~2 次,共治疗 12 周。 对于重度烟草依赖患者,应当加强耳穴贴压的强度、频次和治疗时间。

临床问题6:相比于常规戒烟疗法,其他针灸疗法是否可以使戒烟患者获益?
(1)推荐意见
其他针灸疗法可以帮助戒烟。(低推荐,基于低质量证据)
(2)证据概述
本临床问题共纳入3项RCT研究[38-40],涉及4项结局。其中,戒断率为极低质量证据,戒断症状相关量表评分为低质量证据。 相比于常规戒烟疗法,其他针灸疗法在改善戒断症状及提升戒断率方面与常规戒烟疗法无统计学差异($P>0.05$)。 基于此,GDG认为:相比于常规戒烟治疗,可以尝试其他疗法戒烟。
(3)推荐说明
● 亚组考虑 制定该推荐意见的证据体的患者来源于中国非孕期的成年烟草依赖者,故该推荐意见适用于中国非孕期的成年烟草依赖者,对于具有戒烟意愿的成年吸烟者亦可参考本推荐意见。 ● 实施考虑 本推荐意见适用于经过戒烟辅导培训,具有正规资质针灸医师的地区/社区。 本推荐意见适用于具有戒烟意愿的非孕期成年烟草依赖患者。 对于畏针的吸烟者,可尝试采用穴位贴敷的方法治疗。 对于针刺效果不明显者,可尝试采用穴位埋线治疗。 体质强壮者,可尝试采用火针治疗。 非单独适用本推荐方案的条件: ① 穴位贴敷:a)久病、体弱、消瘦、孕妇、幼儿,以及有严重心、肝、肾功能障碍者慎用;b)贴敷部位有创伤、溃疡者禁用。 ② 穴位埋线:a)精神紧张、过劳或者过饥者,禁用或慎用埋线,避免晕针现象发生;b)皮肤局部有感染或有溃疡时不宜埋线;c)肺结核活动期、骨结核、严重心脏病或妊娠期等均不宜使用本法;d)有出血倾向的患者慎用埋线疗法;e)由糖尿病及其他各种疾病导致皮肤和皮下组织吸收和修复功能障碍者忌用埋线疗法。 ③ 火针:a)孕妇、产妇及婴幼儿慎用;b)糖尿病、血友病、凝血机制障碍者禁用火针。 ● 监察与评估 监察该指南发布后,是否有更多有意愿戒烟者和烟草依赖者接受其他针灸疗法而非常规针刺或戒烟疗法。 ● 科研的优先考虑 开展其他针灸疗法与常规针刺/戒烟疗法的高质量RCT,进行其疗效和安全性评价。
(4)治疗方案
● 穴位贴敷[38] ① 取穴 甜美穴、丰隆穴、天突穴、膻中穴。 ② 操作方法 以现代中药贴剂制备工艺制成直径为1.5 cm圆形药贴,固定于边长3 cm压敏胶布上,将穴位药贴敷固定在穴位上。

（续）

③ 治疗频率及疗程

6 h/d，保持 24 h 最佳，治疗维持 6 周，随访 2 周。

- **火针**[39]

① 取穴

百会穴、列缺穴及合谷穴。

② 操作方法

针下 3 分烧至通红后，快速点刺百会穴、双侧的列缺穴及双侧的合谷穴各 7 下，深度约 0.01 mm。

③ 治疗频率及疗程

3 d 1 次，每周治疗 2 次，连续治疗 3 周。

- **穴位埋线**[40]

① 取穴

心俞穴、神门穴、甜美穴、太冲穴。

② 操作方法

患者取坐位或仰卧位，在双侧足三里穴、列缺穴两个穴位置入可吸收性外科缝线，出针后，用创可贴固定 24 h。

③ 治疗频率及疗程

每 2 周治疗 1 次，共治疗 4 次。

临床问题 7：加强戒烟管理与随访是否可以使戒烟患者获益，有助于预防复吸？

（1）推荐意见

加强戒烟管理与随访可以使烟草依赖者获益，有助于预防复吸。（强推荐，仅依据专家共识）

（2）证据概述

证据来源于工作组的前期调研结果，调研对象主要为戒烟及针灸相关从业人员，以及相关成功戒烟的患者代表，结合 GDG 专家组内核心成员的个人经验，经 GDG 专家组投票达成共识，98%同意加强戒烟管理和随访来帮助烟草依赖者预防复吸，专家共识决策路径提供了如何加强戒烟管理，以及相关性的结构化方法，并为预防复吸提供了实用指导。

结合相关指南，《成人烟草依赖的药物治疗：美国胸科学会官方临床实践指南》（2020 年版），《中国临床戒烟指南》（2015 年版），复吸多发生在戒烟后较短的时间内，新近戒烟者面临较高的复吸风险，但戒烟数月后甚至数年后仍可发生复吸，戒烟管理与随访操作简单，易行，易被烟草依赖患者和医生接受，且具有良好的可行性。

基于此，GDG 认为：加强戒烟管理与随访可以使烟草依赖患者获益，有助于预防复吸。

（3）推荐说明

- **亚组考虑**

对于已戒烟者，宜采取加强戒烟管理和随访相关措施以防止复吸。

对于正在戒烟者，宜采取加强戒烟管理与随访以提高依从性。

- **实施考虑**

实施该推荐意见前，建议医者加强相关戒烟随访与管理培训。

告知戒烟者如有复吸发生，应尽早报告医生以获得及时干预。

（续）

● 监察与评估 监察该指南发布后，是否有更多的烟草依赖患者在加强戒烟管理与随访后，复吸率降低。 ● 科研的优先考虑 开展大样本高质量临床试验，随访时间大于6个月，加强对吸烟者复吸情况的观察与随访，以准确了解复吸行为发生的时间节点与周期，为后续针灸干预方案提供参考。
（4）推荐意见使用说明
戒烟管理与随访是预防复吸强有力的手段，戒烟管理宜运用于戒烟治疗的全过程，从戒烟前的简短干预，戒烟治疗中的加强管理与辅导，到戒烟成功后持续关注与随访，包含以信息通信技术（App/微信）或电话、面对面访谈等形式进行管理与追踪，定期反馈结果，根据患者的戒烟干预情况，给予及时干预与帮助，以巩固戒烟状态，预防复吸。 戒烟过程中应持续关注戒烟者的戒烟进程，加强戒烟管理与戒烟辅导，建议针灸戒烟安排不少于3个月且次数不少于6次的定期随访，并进行相关量表与生化指标检测。关注患者接受针灸治疗后的情况，评估针灸治疗的不良反应，评估针灸戒烟的治疗疗效。 对戒烟成功者，宜巩固戒烟状态，告诫戒烟成功者可能还会遇到诱导因素，宜有所戒备，预防复吸；并要告知其如有复吸发生，应尽早报告医师，寻求协助。此外，应帮助吸烟者处理戒烟过程中出现的难题与障碍，强化成功的应对策略（特别是规避风险、分散注意力、正向的思维），帮助其保持戒烟斗志，例如避免吸烟的诱惑，建立健康的生活方式，加强锻炼身体，调整精神状态等。
（5）其他注意事项
成功戒烟的吸烟者面临复吸风险。根据研究，中国吸烟者的复吸率较高，且高于戒烟率[41]；中国≥15岁吸烟者中复吸率为66.05％，其中男性66.59％，女性55.79％；15岁～24岁年龄组复吸率最高（82.63％）[42]。国外研究显示，与老年人相比，年轻人复吸率更高；与无烟家庭的戒烟者相比，生活在家中室内允许吸烟的戒烟者复吸率更高；与已婚人群相比，从未结婚、丧偶、离婚和分居的人群复吸率更高；连续戒烟6个月或以上可显著降低复吸率[43]。大多数复吸发生在戒烟的前几周，但在某些情况下，复吸可能会发生在戒烟几年后。大多数吸烟者都有戒烟后复吸的经历，需要多次尝试才能成功戒烟。 可以通过干预相关的影响因素以降低复吸率，预防复吸。研究表明[44]，复吸受到社会地位、文化层次、职业、家庭等多方面的影响。重度烟草依赖是年轻吸烟者复吸的独立危险因素之一[45]。研究发现[46]，随访3个月时，家庭支持组的复吸率虽然较对照组低，但差异无统计学意义，到随访6个月时差异才显示出统计学意义，更突显随着时间的延长，家庭支持方法对降低复吸率的有效性。所以可通过对家属的宣传教育，传授其戒烟技巧知识，借助吸烟者家庭力量，定时执行随访计划、及时反馈，从而持续支持和监督戒烟行动，减少复吸，提高戒烟成功率。

5 获取途径

本指南在世界针灸学会联合会网站发布，纸质版由中国标准出版社出版。此外，指南的核心内容将于英文期刊发布。用户可通过上述途径获取本指南。

6 未来可开展的研究

开展针灸疗法与一线戒烟药物对照的戒烟高质量 RCT，进行有效性及非劣性研究；进行大样本、多中心，随访大于 6 个月的针灸戒烟疗效研究；并进行对于疾病经济负担的研究和卫生经济学评价。

7 局限和不足

本指南基于目标用户的临床需求调研，围绕最受关注的干预措施（毫针刺法和耳穴疗法）进行了临床问题和推荐意见的研制，对于治疗疗程和卫生经济学评价仍不足。

附　录　A
指南工作组成员

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附　录　B
缩略语表

全称	缩写
国际疾病分类第十一版	ICD-11
烟草依赖程度量表	FTND
吸烟强度指数量表	HSI
明尼苏达尼古丁戒断量表	MNWS
吸烟渴求问卷简短量表	QSU-Brief
视觉类比评分量表	VAS
临床实践指南	CPG
证据决策表	EtD
推荐分级的评估、制订与评价体系	GRADE
指南发展小组	GDG
临床随机对照试验	RCT
欧洲精神病学协会	EPA
世界卫生组织	WHO
世界针灸学会联合会	WFAS

附　录　C
临床问题汇总

编号	临床问题
1	简短干预(识别、告诫、鼓励与评估)是否可以帮助戒烟?
2	设定戒烟日是否可以帮助戒烟?
3	戒烟辅导是否可以帮助戒烟?
4	相比于常规戒烟疗法,针刺是否可以使戒烟患者获益?
5	相比于常规戒烟疗法,耳穴疗法是否可以使戒烟患者获益?
6	相比于常规戒烟疗法,其他针灸疗法是否可以使戒烟患者获益?
7	加强戒烟管理与随访是否可以使戒烟患者获益,有助于预防复吸?

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