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Study protocol of a pragmatic, randomised controlled pilot trial: clinical effectiveness on smoking cessation of traditional and complementary medicine interventions, including acupuncture and aromatherapy, in combination with nicotine replacement therapy

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ABSTRACT

Introduction Nicotine dependence is a disease, and tobacco use is related to 6 million deaths annually worldwide. Recently, in many countries, there has been growing interest in the use of traditional and complementary medicine (T&CM) methods, especially acupuncture, as therapeutic interventions for smoking cessation. The aim of this pilot study is to investigate the effectiveness of T&CM interventions on smoking cessation.

Methods and analysis The STOP (Stop Tobacco Programme using traditional Korean medicine) study is designed to be a pragmatic, open-label, randomised pilot trial. This trial will evaluate whether adding T&CM methods (ie, ear and body acupuncture, aromatherapy) to conventional cessation methods (ie, nicotine replacement therapy (NRT), counselling) increases smoking cessation rates. Forty participants over 19 years old who are capable of communicating in Korean will be recruited. They will be current smokers who meet one of the following criteria: (1) smoke more than 10 cigarettes a day, (2) smoke less than 10 cigarettes a day and previously failed to cease smoking, or (3) smoke fewer than 10 cigarettes a day and have a nicotine dependence score (Fagerstrom Test for Nicotine Dependence) of 4 points or more. The trial will consist of 4 weeks of treatment and a 20 week follow-up period. A statistician will perform the statistical analyses for both the intention-to-treat (all randomly assigned participants) and per-protocol (participants who completed the trial without any protocol deviations) data using SAS 9.1.3.

Ethics and dissemination This study has been approved by the Institutional Review Board (IRB) of the Dunsan Korean Medicine Hospital of Daejeon University (IRB reference no: DJDSKH-15-BM-11–1, Protocol No. version 4.1.).The protocol will be reapproved by IRB if it requires amendment. The trial will be conducted according to the Declaration of Helsinki, 7th version (2013). This study is designed to minimise the risk to participants, and the investigators will explain the study to the participants in detail. As an ethical clinical trial, the control group will also be given conventional cessation treatments, including NRT and counselling. Participants will be screened and provided with a registration number to protect their personal information. Informed consent will be obtained from the participants prior to enrolling them in the trial. Participants will be allowed to withdraw at anytime without penalty.

Trial registration number ClinicalTrials.gov (NCT02768025); pre-results.

Strengths and limitations of this study

- ► This article presents a protocol for implementing traditional and complementary medicine along with conventional therapy as a smoking cessation treatment.
- ► A randomisation process is used to maintain an equivalent number of heavy (10 cigarettes per day or more) and light smokers in the two groups.
- ► Our study protocol is designed as a pragmatic, randomised controlled trial designed to reflect the real world involving multidisciplinary collaborators.
- ► This is a pilot study; therefore, the sample size is small.

INTRODUCTION

Smoking is the main cause of preventable deaths worldwide, and 6 million deaths a year are related to tobacco use.[1] Smoking is associated with nearly every cancer and many types of chronic diseases, such as coronary artery

disease, stroke and asthma.[2] Tobacco-related deaths are expected to increase by 8 million by 2030 if effective smoking cessation policies are not implemented.[1]

Recently, traditional and complementary medicine (T&CM) methods, especially acupuncture, have gained attention in many countries as therapeutic interventions for smoking cessation. In an American trial,[3] 40% of smokers who had been treated with acupuncture successfully ceased smoking. In a Norwegian trial,[4] the experimental group received acupuncture treatment at the 'Shenmen', 'Mouth' and 'Liver' acupoints of the ear, and treating points LU6 (Kongzui) and LU7 (Leique) led to significant changes in the taste of cigarettes and desire to smoke compared with the control group, who had been treated at different acupoints.

This clinical trial aims to verify the effectiveness of acupuncture and aromatherapy in combination with nicotine replacement therapy (NRT) and counselling, which are standard regimens applied for smoking cessation. The intervention of this trial is referred to as the 'T&CM tobacco control programme', which involves a combination of ear and body acupuncture, aromatherapy, NRT and counselling. NRT and counselling have been widely used in conventional Western medicine in addition to such drugs as varenicline and bupropion.[5] In this T&CM tobacco control programme, ear acupuncture, body acupuncture and aromatherapy will be applied instead of Western interventions for smoking cessation. The primary objective of this trial is to evaluate whether the smoking cessation success rate increases with the application of the T&CM tobacco control programme. The secondary objective is to evaluate the satisfaction of the participants in the T&CM tobacco control programme. This study represents the second research result of our STOP (Stop Tobacco Programme using traditional Korean medicine) study series.

METHODS

Trial design

The STOP study design is a pragmatic, open-label, randomised pilot study. This trial will compare conventional cessation treatment methods (ie, NRT, counselling) alone and in combination with T&CM methods (ie, acupuncture, aromatherapy). The hypothesis of this trial is to investigate whether the smoking cessation rate increases by adding T&CM methods to conventional treatment. The trial will consist of 4 weeks of treatment with seven visits and a 20 week follow-up period. An overview of the trial process is shown in figure 1.

Participants and recruitment

Smokers who want to quit smoking will be recruited over 6 months at the Dunsan Korean Medicine Hospital of Daejeon University in Daejeon, Republic of Korea. Posters for recruiting participants will be posted publicly inside and outside of the hospital. They will also be recruited actively by posting leaflets on the bulletin boards of the offices near the hospital. Potential participants will contact our information centre via e-mail or telephone. Those who agree to participate in the study and provide written informed consent will be eligible to participate in the study.

Inclusion criteria

Participants will be more than 19 years old and able to communicate normally in Korean, and those who do not disinclined to use NRT will be enrolled. They will also be current smokers who meet one of the following criteria: (1) smoke more than 10 cigarettes a day, (2) smoke less than 10 cigarettes a day and previously failed to cease smoking, or (3) smoke fewer than 10 cigarettes a day and has a nicotine dependence score (Fagerstrom Test for Nicotine Dependence, FTND) of 4 points or more. The FTND is a representative questionnaire that evaluates nicotine dependence. It consists of six questions, and the score ranges from 0 to 10. Scores of 1–3, 4–6 and 7–10 indicate low, moderate and high levels of nicotine dependence, respectively. Questions 1 and 2 assess the heaviness of smoking index, and high nicotine dependence is indicated if the sum of these two scores is 4 or more.[6]

Exclusion criteria

Participants who correspond to one or more of the following will be excluded from this trial: (1) during the previous 2 weeks suffered from cardiovascular disease, severe arrhythmia or unstable angina pectoris; (2) currently suffering from severe arrhythmia; (3) currently suffering from otitis externa or any other condition that precludes ear acupuncture; (4) cannot be treated with a nicotine patch because of long-term dermatitis (eg, psoriasis); (5) diagnosed with and currently being treated for a mental illness (eg, dementia, delirium, depression); or (6) currently pregnant or breast feeding.

Participant withdrawal criteria

Participants who meet the following criteria will be discontinued from the trial: (1) voluntarily withdrawing of consent, (2) protocol violation such as not complying study schedule, (3) occurrence of a serious adverse event and (4) investigator's decision to terminate the study for the sake of the participant's health. Only the reason for withdrawal will be collected and no more follow-up will be progressed.

Sample size

There are no previous studies on which to base the sample size calculation. This trial is designed as a pilot study. According to previous research on sample size determination for pilot trials, approximately 30 patients or greater was recommended to estimate a primary outcome of cessation success rate.[7] Therefore, the total sample size was set at 40, considering a 20% dropout rate.[8] Participants will be assigned to either the intervention or control group at a ratio of 1:1.

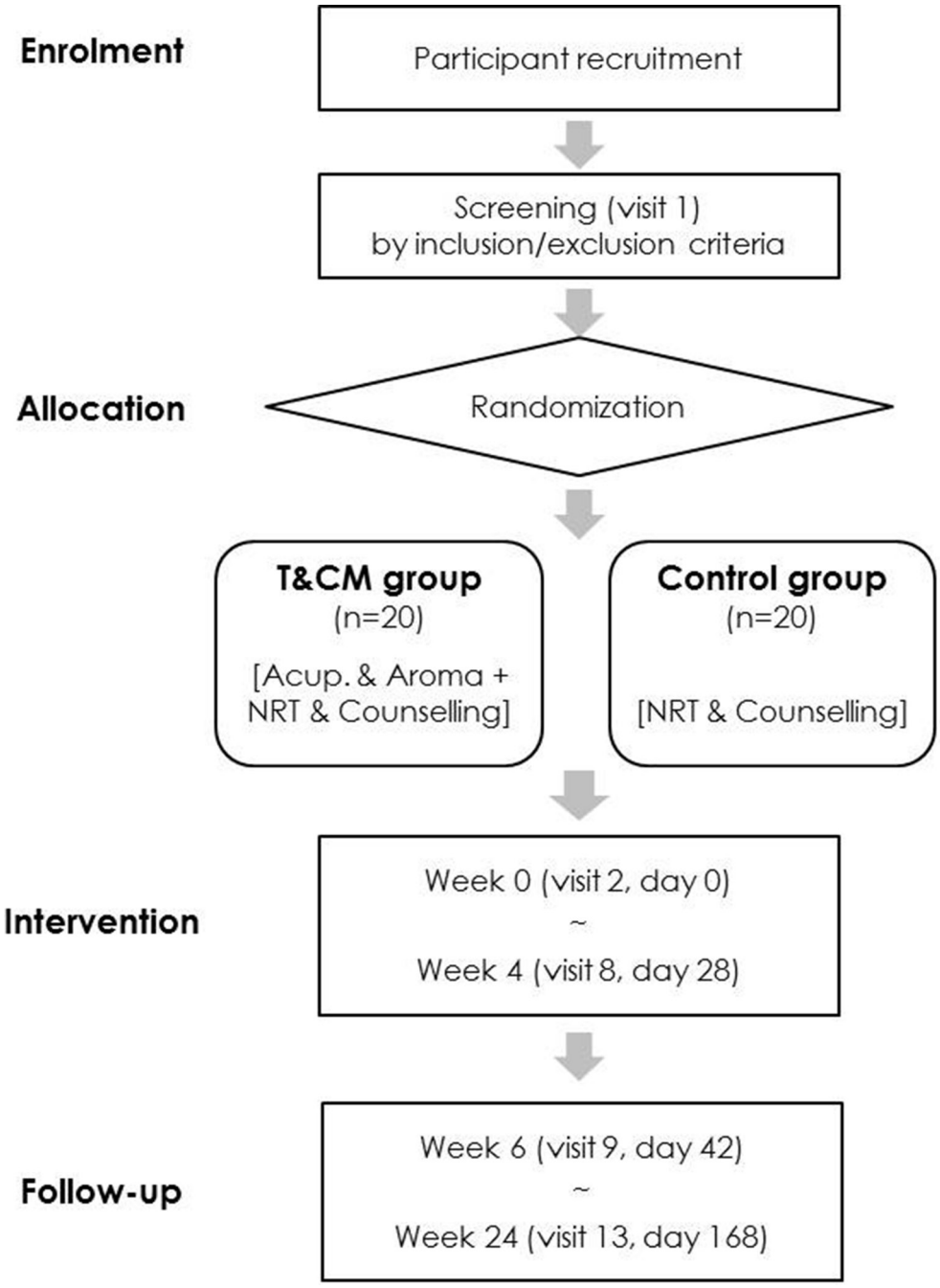

Figure 1 Flow chart of T&CM tobacco control programme. NRT, nicotine replacement therapy; T&CM, traditional and complementary medicine.

Randomisation

All of the participants will be assigned to either the intervention or control group, with equivalent numbers of heavy (10 cigarettes per day or more) and light smokers in the two groups. Block randomisation with a block size of four will be used for the allocation. The randomisation will be conducted via a web-based randomisation system by an independent investigator with no contact with the participants or researchers. In the event of website inaccessibility, the investigator will inform the researchers to which group a participant has been assigned. The randomisation process will be recorded by the web-based randomisation system.

Blinding

As an open-label trial, the T&CM programme will be applied only to the intervention group. Neither the participants nor the clinical practitioners will be blinded during the clinical trial. However, outcome assessors will be blinded for measuring the outcomes.

Interventions

The intervention group will receive NRT, counselling, body and ear acupuncture, and aromatherapy, whereas the control group will be provided with NRT and counselling only. The treatment period will be 4 weeks. The

treatments will be applied twice a week for the first 3 weeks and then once in the fourth week.

Nicotinereplacement therapy

At each visit, participants will be provided with nicotine patches (Nico-free patch, Daewoong, South Korea) and nicotine gum (Nicorette gum, Johnson & Johnson, USA). Each participant will apply one nicotine patch every morning, and the attachment site will be changed every day. Either the Nico-free patch 20 (38 mg) or Nico-free patch 10 (19 mg) will be selected depending on the dose as follows: (1) those who smoke 10 cigarettes per day or more will use the Nico-free patch 20 (38 mg), and (2) those who smoke fewer than 10 cigarettes per day or weigh less than 45 kg will use the Nico-free patch 10 (19 mg).[9] The nicotine gum contains 2 mg of nicotine (Nicorette gum, 2 mg), and participants can use up to 15 gum pieces per day.[10]

Counselling

Counselling will be performed by a Korean medical doctor who is qualified to administer smoking cessation counselling. Each counselling session will require 5–10 min once a week. The counsellor will teach the patient about the necessity of cessation, cessation methods and withdrawal symptoms with the 5A-type counselling (ie, 'ask', 'advise', 'assess', 'assist' and 'arrange'). The 5A counselling steps will be applied in the following order: 'asking about smoking status', 'advising to stop smoking', 'assessing the will to not smoke', 'assisting the smoker in cessation' and 'arranging a follow-up visit'.[11] Although all of the enrolled participants will have already resolved to quit smoking, 5A counselling will be performed to reinforce their willingness.

Acupuncture

The intervention group will receive acupuncture treatment on body acupoints and ear acupoints. The intervention group will be treated seven times during the treatment period on both sides of the HT7 (Shenmen), LI4 (Hegu), ST36 (Zusanli), LU7 (Lieque) and LU6 (Kongzui) acupoints. Acupoints may be added depending on each participant at the doctor's discretion. Acupoints will be needled after disinfection. Stimulation will be performed for 20 min by a qualified Korean medical doctor with 6 years of training in Korean medicine and more than 5 years of clinical experience. Sterile needles (Dongbang, South Korea), 0.20×30 mm in size, will be used for treatment. The intervention group will receive ear acupuncture treatment a total of seven times at the 'Shenmen', 'Lung', 'Pharynx', 'Trachea' and 'Endocrine' acupoints. Needle stimulation will alternate between the right and left sides. The ear acupuncture sites will be patched until the next visit. In the event that a visit is delayed for more than 3 days, the participant will be instructed to remove the intradermal ear acupuncture himself/herself. Participants will be instructed to self-stimulate the acupoints three to six times a day to reduce the desire to smoke. Intradermal needles (Dongbang), 0.2×1.5 mm in size, will be used for the treatment.

Aromatherapy

Participants in the intervention group will be provided with bottles containing 20 mL of mixed oil to aid control of their tobacco use. The composition of the blended oil will be four drops each of lavender, peppermint and rosemary (Tisserand, UK) in 15 mL of jojoba oil (Tisserand). Participants will be instructed to frequently self-massage one to two drops of the blended aroma oil behind their ears.

OUTCOME MEASURES

Primary outcome

The primary outcome of this trial is the continuous abstinence rate at the end of treatment (4 weeks). Participants will be considered to have successfully ceased smoking on smoking fewer than five cigarettes during the 4-week treatment period, which will be evaluated by exhaled carbon monoxide (CO) with a threshold of 6 ppm.

Secondary outcomes

The secondary outcomes are the 7-day point prevalence abstinence, prolonged abstinence rate, participation rate, amount of smoking, tobacco craving, exhaled CO, pulmonary function (forced expiratory volume in 1 s (FEV_1), forced vital capacity (FVC), FEV_1/FVC), quality of life (EuroQol five dimension questionnaire (EQ-5D), EuroQol visual analogue scale (EQ-VAS)), FTND nicotine dependence score and withdrawal symptoms (Minnesota Nicotine Withdrawal Scale (MNWS)). The time points of the evaluations are shown in table 1.

Assessment of adverse events

All adverse events from the NRT, acupuncture and aromatherapy will be reported in detail, and the affected participants will be treated by doctors. The most common adverse events are expected to be skin erythema and pruritus at the sites of patch attachment. According to a previous study, mild local skin reactions were observed in approximately 54% of patients.[12] Adverse events will be distinguished from withdrawal symptoms, such as hunger, anxiety, depression, constipation, cough and insomnia.

Data management and monitoring

All collected data will be entered using a double entry method and encrypted. The data will be monitored by the Institute of Safety and Effectiveness Evaluation for Korean Medicine of Kyung Hee University. This will strengthen the data accuracy and maintain data quality.

Statistical analyses

A statistician who is not affiliated with this study will perform the statistical analyses for both the intention-to-treat (all randomly assigned participants) and per-protocol (participants who completed the trial without any protocol deviations) data using SAS 9.1.3.

Table 1 Study schedule of the T&CM tobacco control programme

Enrolment		Treatment period							Follow-up period				
Day	**−10**	**0**	**7**	**10**	**14**	**17**	**21**	**28**	**42**	**56**	**84**	**112**	**168**
Time point	Visit	Visit	Visit	Visit	Visit	Visit	Visit	Visit	Tele	Tele	Visit	Tele	Visit
Informed consent	✘												
Eligibility screening	✘												
Allocation		✘											
T&CM + NRT		◆—	—	—	—	—	—	—◆					
NRT		◆—	—	—	—	—	—	—◆					
Demographic characteristics	✘												
Physical examination		✘	✘	✘	✘	✘	✘	✘					
Smoking-related variables		✘											
Amount of smoking		✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘
Tobacco craving		✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘
FTND	✘			✘		✘		✘	✘	✘	✘	✘	✘
Exhaled CO		✘	✘	✘	✘	✘	✘	✘			✘		✘
MNWS			✘		✘		✘	✘	✘	✘	✘	✘	✘
EQ-5D, EQ-VAS		✘						✘		✘	✘	✘	✘
Pulmonary function test		✘			✘			✘					
Compliance			✘	✘	✘	✘	✘	✘					
Adverse events			✘	✘	✘	✘	✘	✘					
Concomitant medication			✘	✘	✘	✘	✘	✘					
Satisfaction								✘					
Non-smoking efforts									✘	✘	✘	✘	✘
Treatment history									✘	✘	✘	✘	✘

CO, carbon monoxide; EQ-5D, EuroQol five dimension questionnaire; EQ-VAS, EuroQol visual analogue scale; FTND, Fagerstrom Test for Nicotine Dependence; MNWS, Minnesota Nicotine Withdrawal Scale; NRT, nicotine replacement therapy; T&CM, traditional and complementary medicine; tele, telephone.

In the event of dropouts or withdrawals, the reasons for each missing value will be recorded. Missing values will be substituted using the multiple imputation method. Continuous abstinence rate, 7-day point prevalence abstinence, daily quantity of smoking, tobacco craving, exhaled CO, quality of life (EQ-5D, EQ-VAS), FTND nicotine dependence score, MNWS withdrawal symptoms, satisfaction, age, and drinking and exercise frequency are continuous variables that will be displayed as the mean, SD, and minimum and maximum values. Smoking status, cigarette taste, methods of attempted cessation, reason of cessation failure, sex, education level, occupation and marital status are categorical variables that will be displayed as frequencies. Independent t-tests for continuous variables and χ^2 tests for categorical variables will be used to examine significant differences between the two groups. Two-sided p values less than 0.05 will be considered significant. Fisher's exact test will be used instead of the χ^2 test when the expected value is less than 5. All analyses will be conducted after study completion, and interim tests are not planned.

DISCUSSION

Nicotine dependence is recognised as a disease, and smoking behaviour falls under the category of 'mental and behavioural disorders due to psychoactive substance use' according to the International Classification of Diseases 10th revision.[13] It is necessary to access to smoking cessation in terms of medical treatment. The US Preventive Services Task Force strongly recommends that doctors should intervene to help patients cease smoking by prescribing treatments approved by the Food and Drug Administration, such as NRT and bupropion, if needed.[14]

This study will investigate the effectiveness of T&CM for smoking cessation. The study is designed to be a pragmatic, randomised controlled trial because excessively controlling other conditions does not reflect real clinical conditions.[15] The control group will be provided conventional treatments, including NRT and counselling, because not treating the control group would cause ethical issues and increase the dropout rate. As it is difficult to cease smoking successfully with a single intervention, multiple interventions will be administered to the participants.[16] This will help increase the effects of the interventions as well as promote participant compliance. As successful smoking cessation typically does not last long, we will evaluate success rates by performing five follow-up assessments.

The main intervention of this trial is acupuncture.[17] Frequently used body acupoints for cessation treatment in the literature include HT7 (Shenmen),[18–20] LI4 (Hegu),[3 21] ST36 (Zusanli),[21–23] LU7 (Lieque)[4 21] and LU6 (Kongzui).[24] According to the guidelines on acupuncture treatment and counselling for smoking cessation, the 'Shenmun', 'Lung', 'Endocrine', 'Pharynx', 'Trachea', 'Mouth' and 'Inner-nose' ear acupoints are recommended for cessation treatment.[25] In addition, some clinical trials have demonstrated the effects of auricular acupuncture treatment for smoking cessation.[26–28] Aromatherapy can also play a role in relieving withdrawal symptoms. Lavender oil[29 30] and rosemary oil[30 31] help reduce anxiety after cessation, and peppermint oil[31] can relieve symptoms of respiratory discomfort, such as phlegm and cough. NRT and counselling will be applied to both the intervention and control groups as conventional treatments. This trial is designed such that the T&CM tobacco control programme, including acupuncture, aromatherapy, NRT and counselling, will be provided to the intervention group to raise the cessation rate.

There are several limitations to this proposed study. First, although NRT, which will be applied to both groups, is a proven method of cessation treatment, there is the possibility of bias due to the unblinded design of the study. To minimise the potential bias, the researchers will explain about that enough at the initial stage. Second, the proposed study is a pilot study with a small sample size, and a large-scale clinical trial will be necessary later.

Smoking is a habitual behaviour, and smoking cessation requires a strong will. Thus, participant satisfaction is as important as intervention effectiveness. T&CM is expected to be an effective method for helping individuals quit smoking with emotional comfort, which will be assessed by evaluating participant satisfaction and quality of life (SF-36). This article presents the first protocol of implementing T&CM in combination with conventional therapy as a smoking cessation treatment in Korea. This study will evaluate the effectiveness and safety of several T&CM interventions and will provide useful evidence for future studies.

TRIAL STATUS

As of October 2016, 10 participants have been enrolled in this study, and 3 of them have completed the 4-week treatment. This trial is ongoing.

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Contributors SP and SJ drafted the manuscript. YLP, BHJ and CSC designed the study. JAL and HYG edited the first manuscript. YCS and SGK supervised this protocol. All authors read and approved the final manuscript.

Competing interests None declared.

Patient consent Obtained.

Ethics approval This survey was approved by Institutional Review Board of Dunsan Korean Medicine Hospital of Daejeon University (IRB No. DJDSKH-15-BM-11-1).

Provenance and peer review Not commissioned; externally peer reviewed.

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