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Chinese herbal tea to enhance stopping smoking

Submission date	Recruitment status	[X] Prospectively registered
18/12/2021	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/12/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
31/01/2025	Other	

Plain English summary of protocol

Background and study aims
It is known that stopping smoking can help prevent many diseases and save lives. It's difficult to stop smoking and resist nicotine dependence. Traditional Chinese herbal can help relieve cough and tea, as the routine behaviour can remind of stopping smoking. Thus, this study aims to find whether Chinese herbal tea can help smoking cessation and strengthen the faith in stopping smoking.

Who can participate?
Patients are willing to seek treatment to stop smoking in a smoking cessation clinic in China.

What does the study involve?
Participants will be randomly allocated to one of two groups as conventional treatment or combination with Chinese herbal tea for 4 weeks. After 4 weeks, participants will have the right to choose whether receive Chinese herbal tea for 8 weeks.
Participants will be asked to give blood samples at the beginning of the study and at the 4th week to ensure basic safety. Participants will get about 12-week treatment for smoking cessation and will complete the online questionnaires and assessments on the first day and every week to ensure the effectiveness of abstinence.

What are the possible benefits and risks of participating?
Participants will get 12-week treatment for smoking cessation and free Chinese herbal tea.
Participants may suffer from nicotine withdrawal symptoms such as sick, dizziness.

Where is the study run from?
Beijing University of Chinese medicine and smoking cessation clinic of Beijing Chaoyang Hospital (China)

When is the study starting and how long is it expected to run for?
June 2021 to June 2022

Who is funding the study?
Beijing University of Chinese medicine (China)

Who is the main contact?
1. PhD. Chun-li Lu
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2. Prof. Jian-ping Liu
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effectiveness of Chinese herbal tea combined with conventional therapy for patients to stopping smoking in smoking cessation clinic: a randomized controlled trial

Acronym
CHESS

Study objectives
Chinese herbal tea can relieve the cough and heat syndrome (based on traditional Chinese medicine theory), thus Chinese herbal tea combined with conventional therapy may have superior effect for smoking cessation and increase the compliance of smokers to stop smoking.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/06/2021, Ethics Committee of Beijing Chaoyang Hospital, Capital Medical University (8 Nan lu Workers Stadium, Chaoyang district, Beijing, China; +86 010-85231484; cyylunli2019@163.com), ref:2021--622

Study design
Single-centre interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Treatment for patients who are willing to stop smoking in smoking cessation clinic

Interventions

Experimental group: Chinese herbal tea combined with conventional therapy (based on physician prescription) for 4 weeks.
Control group: conventional therapy (based on physician prescription) for 4 weeks.
After 4-week treatment, all participants can choose by their own will to receive which treatment for 8 weeks, we conduct the follow-up for these 8 weeks.
Participants are randomly allocated to groups using the sealed envelope method.

Intervention Type
Mixed

Primary outcome measure
1. Carbon monoxide expiratory volume is measured using Carbon monoxide detector at baseline, 1day, 4 weeks.
2. Abstinence rate is measured using patients' self-report at baseline, 1 day, 1 week, 2 weeks, 3 weeks, 4 weeks, 8 weeks, 12 weeks.
3. Nicotine dependence is measured using Fagerstrom test for nicotine dependence (FTND) at baseline, 1 day, 1 week, 2 weeks, 3 weeks, 4 weeks, 8 weeks, 12 weeks.
4. Implementation outcomes of combined Chinese herbal tea during smoking cessation treatment is measured using questionnaire and interview (containing acceptability, appropriateness, feasibility, adoption, fidelity, and sustainability) at baseline, 1 week, 2 weeks, 3 weeks, 4 weeks, 8 weeks, 12 weeks.

Secondary outcome measures
1. Nicotine withdrawal symptoms are measured using Minnesota Nicotine Withdrawal Scale (MNWS) at baseline, 1 day, 1 week, 2 weeks, 3 weeks, 4 weeks, 8 weeks, 12 weeks.
2. Traditional Chinese medicine (TCM) syndrome is measured using TCM scale at baseline, 1 week, 4 weeks, 8 weeks, 12 weeks.
3. Safety outcomes are measured using blood examination (ALT, AST, GGT, BUN, Cr, UA, biochemical electrolyte) at baseline and 4 weeks.
4. Adverse events are measured using patients' self-report at 1 day, 1 week, 2 weeks, 3 weeks, 4 weeks, 8 weeks, 12 weeks during the whole course of study.

Overall study start date
12/06/2021

Completion date
30/06/2022

Eligibility

Key inclusion criteria
1. Patients in smoking cessation clinic seeking treatment.
2. Patients eligible for conventional medication.
3. The patients voluntarily sign the informed consent.

Participant type(s)
Other

Age group
Adult

Sex
Both

Target number of participants
25 in each group

Key exclusion criteria
1. Patients with serious diseases of the heart, lung, kidney and hematopoietic system.
2. Pregnant or lactating women.
3. Patients who are participating in other clinical trials.
4. Patients allergic to licorice and platycodon grandiflorum.
5. Patients with allergies to smoking cessation medications or similar ingredients.
6. Patients who are receiving other TCM treatments and whose TCM prescriptions include Gansui, Jingdaji, Haizao, and Yuanhua.

Date of first enrolment
01/02/2022

Date of final enrolment
30/03/2022

Locations

Countries of recruitment
China

Study participating centre
Beijing Chaoyang Hospital, Capital Medical University
8 Nan lu Workers Stadium
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Sponsor information

Organisation
Beijing University of Chinese Medicine

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Sponsor type
University/education

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ROR
https://ror.org/05damtm70

Funder(s)

Funder type
University/education

Funder Name
Beijng University of Chinese medicine

Results and Publications

Publication and dissemination plan
We planned to publish the results in high-impact peer-review international journal

Intention to publish date
30/07/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request (Jennylu@bucme.edu.cn)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	P15.06LB	25/04/2024	31/01/2025	No	No