Protocol

**SCAMPI – Smoking Cessation App for (Chinese) Male smokers: Pilot Intervention Trial (version 3.1)**

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# Overview

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| **Title of study**: SCAMPI – Smoking Cessation App for (Chinese) Male smokers: Pilot Intervention Trial |
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| **Investigators and study centres** |
| This study has been designed by independent investigators at the National Institute for Health Innovation (NIHI), School of Population Health, University of Auckland. The overall design and conduct of this trial is the responsibility of the principal investigator and members of the Steering Committee and Study Management Committee. Publication of data from this trial will be the responsibility of members of the Steering Committee. The study will be co-ordinated from NIHI. |
| **Study period:** July 2018 – August 2019 |
|  |
| **Objectives:** To evaluate preliminary effectiveness of a smartphone app-based smoking cessation intervention (“SCAMPI”) designed to help Chinese male smokers in China to quit smoking. To evaluate the compliance, acceptability and satisfaction of SCAMPI.  |
| **Study design and methodology:** A two-arm pilot randomised controlled trial (RCT) will be conducted to assess the preliminary effectiveness and acceptability of the SCAMPI programme (WeChat Official Account “OA” and mini-programme) as a smoking cessation intervention.  |
| **Study population:** The study will use an open recruitment strategy. The number of study participants will be all eligible participants those are recruited within 4 weeks in China.  |
|  |
| **Main criteria for inclusion:** Smokers will be eligible for inclusion in the study if they indicate at screening that they are Chinese male aged between 25 to 44 years; daily or occasional smokers; able to understand Chinese; are not currently receiving any professional assistance for helping themselves to quit smoking; and are willing to participate in the study and provide follow-up information throughout the study.  |
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| **Exclusion criteria:** People will be excluded from the sample if they are under any other types of smoking cessation interventions, refuse to give informed consent, refuse to continuously provide follow-up information, or have any acute or chronic condition that limit their ability to participant in the study.  |
|  |
| **Criteria for evaluation** |
| Primary outcome* 30-day bio-verified smoking abstinence at 6-week follow-up (self-reported data verified by Nicotine Cotinine Saliva Test)
 |
| Secondary outcomes* Smoking abstinence
1. Participants’ reduction in cigarette consumption (comparing baseline cigarette consumption measured in registration to self-reported cigarette consumption measured in weekly basis through WeChat OA)
2. Participants’ prolonged smoking abstinence through 6-week study period (self-reported)
3. Participants’ 7-day smoking abstinence at 4-week and 6-week follow-up (self-reported)
4. Participants’ 30-day smoking abstinence at 6-week follow-up (self-reported data only)
* SCAMPI programme usage
1. Participants’ compliance with SCAMPI (participants provide their weekly smoking status and answer to the end-of-trial questionnaires) as their smoking cessation tool
2. Number of times visiting SCAMPI OA and mini-programme
3. Number of times interacting with SCAMPI OA and mini-programme
* Acceptability and Satisfaction
1. Acceptability of using SCAMPI programme as a smoking cessation intervention (measured by Visual Analog Scale “VAS”)
2. Satisfaction levels of using SCAMPI programme as a smoking cessation intervention (measured by Mobile Application Rating Scale “MARS”)
 |
| Sample size The sample size of the study will be depended on the number of eligible participants recruited within 4 weeks. We aim to recruit 80 participants (40 per group) in the 4-week period. All participants of this study will be recruited through WeChat, the most popular and commonly used social network platform in China. The sample size that we aim to recruit is based on the total sample size for the future main trial. For the future main trial, a total sample size of 530 (265 per group) will have 90% power at 5% significance (2-sided) to detect an absolute difference of 10% on primary outcome between two groups, assuming a control rate of 6.7% and 20% loss to follow-up.**Analytic methods** |
| Statistical analysis: Data will be presented as descriptive statistics. Generalised Linear Model will be used to predict the impacts of SCAMPI on helping participants to quit smoking.  |
| **Funding** |
| PReSS Account Funding and UoA grant for support travel to China to meet collaborating organisations in China. NIHI funding for support purchase of Saliva Cotinine Test devices.  |
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# Study Plan Schematic

## Pilot Randomised Controlled Trial

**Screening**

**Excluded**

* Not meeting inclusion criteria
* Declined to participate
* Other reasons

**Baseline assessment**

**Randomised** (n=TBC)

**Intervention Group**

**SCAMPI OA and mini-programme**

6-week duration

(n=TBC)

**Control Group**

**General smoking cessation care in China**

6-week duration

(n=TBC)

***Outcome assessments***

*Outcomes measured daily*

* SCAMPI OA and mini-programme usage

*Outcomes measured weekly*

* Smoking Status

*Outcomes measured at the 4-week and 6-week time points of the study*

* 7- and 30-day smoking abstinence
* Participants’ saliva sample
* Participants’ acceptability of SCAMPI
* Participants’ Satisfaction with SCAMPI

# Background

Every year, about 2 million Chinese people are killed by tobacco-caused diseases ([1](#_ENREF_1)). Still, nearly 300 million Chinese people continue to use tobacco each day ([1](#_ENREF_1)). Among these smokers, 95% are male ([2](#_ENREF_2)). Tobacco use caused 25% of Chinese male deaths ([1](#_ENREF_1)). In addition to health harms, tobacco use in China also leads to societal harms ([1](#_ENREF_1)). The economic cost of smoking in China amounts to 393 billion RMB per year ([1](#_ENREF_1)). This includes direct costs related to healthcare expenditures and indirect costs related to lost productivity due to early mortality and morbidity ([1](#_ENREF_1)).

## The need for smoking cessation interventions

According to the 2010 Global Adult Tobacco Survey (GATS) in China, 36.4% of Chinese smokers had tried to quit in the past 12 months, while 91.8% of them have never received any smoking cessation services ([3](#_ENREF_3)). A survey in 2014 found over half Chinese smokers never received any quit smoking advice from their health professionals ([4](#_ENREF_4)). Currently, smoking cessation services are not part of the National Basic Medical and Health Care Services, while nicotine replacement therapies (NRT) / drugs are not in the Catalogue of National Basic Drugs ([5](#_ENREF_5)). Since 2006, although some smoking cessation clinics had been set up and the National Quitline had launched, due to the limited exposure and accessibility, they were hardly used by Chinese smokers ([5](#_ENREF_5)). Due to the above reasons, the smoking cessation rate (control rate) for the target population group of this study is only 6.7% ([6](#_ENREF_6)).

## Mobile interventions in supporting smokers to quit smoking

A 2016 Cochrane review of mobile phone-based interventions for smoking cessation demonstrated the effectiveness of mobile technology in supporting smoking cessation ([7](#_ENREF_7)). Mobile Tobacco Cessation Programmes (mTobaccoCessation programmes) have been successfully adopted in some countries ([8](#_ENREF_8)). The most recent WHO report on the global tobacco epidemic indicated that personalised smoking cessation advice and support from mobile phone messages can be a cost-effective tool contributing to address the public health problem of tobacco use ([9](#_ENREF_9)). Mobile phone-based smoking cessation interventions have been proved as a cost-effective tool for supporting smokers to quit smoking. Some studies also showed that mobile smoking cessation apps can create short-term impacts on helping smokers to quit smoking ([10-15](#_ENREF_10)). A recent study has shown that daily smokers using a behavioural, decision-aid smartphone app achieved 23.8% self-reported 3-month continuous abstinence ([16](#_ENREF_16)).

## Penetration of smartphone in China

The 2017 Connected Consumer Survey done by Google Inc. noted that 83% of Chinese people use smartphones ([17](#_ENREF_17)). China is regarded as one of the fastest growing smartphone market in the world with 10% smartphone penetration rate increase in the past 5 years ([18](#_ENREF_18)). China has the largest smartphone users group (n > 700 million people) in the world ([19](#_ENREF_19)). In China, there are more male than female (74% vs. 57%) using smartphone, while people aged between 25 to 44 years are the biggest smartphone user group (nearly 70%) ([20](#_ENREF_20)). On average, Chinese smartphone users spend three hours on their smartphones daily (about 150 times of interaction), which is the second longest in the world ([21](#_ENREF_21)).

## How smartphone was used in China

Among all the functions and apps of smartphone, WeChat is the most popular app (social network platform) in China. In 2017, the monthly active users of WeChat reached 938 million people ([22](#_ENREF_22)). About 29% of the time Chinese smartphone users spent on their phone is using WeChat ([22](#_ENREF_22)). WeChat has become the major tool in communication, entertainment, payment for Chinese smartphone users. WeChat official account (OA) is a special feature of WeChat. An organisation or company can register a WeChat OA on the WeChat social network platform. Individual WeChat users can subscribe to this account to become “followers” to the organisation / company. The organisation / company can communicate and interact with its followers through the WeChat official account. WeChat OAs have been an effective tool for Chinese organisations / companies (e.g. regional councils, government sectors, Huawei, Haier, etc.) to interact with their (potential) customers or audiences.

In 2016, WeChat introduced WeChat mini-programme as a new component on the platform. Similar to an independent app, mini-programme is able to deliver messages, collect user data and respond to user commands ([23](#_ENREF_23)). In addition to the functions of a traditional app, mini-programme is attached to WeChat platform, which allows WeChat users to directly use it without download or installation. The new component of WeChat is a great success. Within two years, 580,000 mini-programmes have been coded and 170 million WeChat users use mini-programmes on a daily basis ([23](#_ENREF_23)). Although mini-programme has been one of the most popular components in WeChat, its application in healthcare (especially for smoking cessation) remain unexplored.

## Smartphone app-based smoking cessation intervention for Chinese smokers

As mentioned above, Chinese males are the largest smoking population group in the world. Most Chinese smokers have limited access to smoking cessation services. The lack of appropriate smoking cessation services and limited accessibility to current smoking cessation support lead to a low smoking cessation success rate. The high smartphone penetration rate and usage rate in China provide a great opportunity for developing and implementing smartphone app-based smoking cessation intervention. Since WeChat is the most popular app for Chinese smartphone users and has the novel components of WeChat Official Account (OA) and “mini-programme” to deliver innovative smoking cessation services on the platform, the potential for mobile tobacco cessation mini-programme to impact and reach out to millions of Chinese smokers is possible like never before.

## SCAMPI: WeChat based smoking cessation programme for Chinese male smokers

Based on a one-month period of collaborative product development (CPD), we developed the SCAMPI programme, which is ready to be used as the intervention in this study. In the CPD stage, 20 potential end-users (Chinese male smokers aged 25 to 44 years) were recruited through WeChat. These 20 participants provided their ideas about desired components of a smoking cessation app through completing an online app development questionnaire. In the one-month period, app development progresses and relevant questions were posted on SCAMPI WeChat OA to identify participants’ preferences to the app’s UX and UI design. At the end of the CPD period, participants acceptability and satisfaction level toward the app were identified through answering the questions on the Mobile App Rating Scale (MARS) questionnaire ([24](#_ENREF_24)).

SCAMPI programme has two major components, which are SCAMPI WeChat OA and SCAMPI mini-programme. SCAMPI WeChat OA has the following functions:

(1) Providing information to study participants: introduction of the study, participant information sheet, consent form, reminder of entering smoking status, quitting tips (for participants in intervention group only), and contact information for general smoking cessation care in China (for participants in control group only);

(2) Collecting information about participants’ cigarette consumption on a weekly basis;

(3) Offering WeChat Red Pocket (an e-voucher system) to remind and provide incentivise participants to enter their cigarette consumption.

To support users to quit smoking, the SCAMPI mini-programme (for participants in intervention group only) has three key functions:

(1) Helping smokers to develop their own quitting plans;

(2) Enabling smokers to track their quitting progress;

(3) Providing empirically based tests to evaluate health improvement by stopping smoking.

# Rationale for the Present Study

The prevalence of cigarette smoking in Chinese males is substantial; and mobile smoking cessation programmes hold much promise to provide cost-effective supports to help smokers to quit. To date there have been no reported investigations on the efficacy of delivering a smartphone app-based smoking cessation intervention for Chinese male smokers via social network platform. We propose to evaluate the preliminary effectiveness of SCAMPI programme for Chinese male smokers on supporting them to quit smoking via a RCT.

# Study Objectives

There are three key objectives of the proposed study:

1. To evaluate the preliminary effectiveness of the SCAMPI programme on helping Chinese male smokers to quit smoking at 6 weeks.
2. To evaluate the compliance, acceptability and satisfaction of study participants to SCAMPI as a smartphone app-based smoking cessation intervention.
3. To assess the accuracy of self-reported smoking abstinence data recorded via the programme and monitored by the Nicotine Cotinine Saliva Test.

# Study Design

## Pilot Randomised Controlled Trial

The aim is to evaluate the preliminary effectiveness and acceptability of the SCAMPI programme, consisting of SCAMPI WeChat OA and mini-programme as a smartphone app-based smoking cessation intervention. The findings of this pilot study will also be used for informing the design of the future full trial.

### Inclusion criteria

Chinese male smokers will be eligible for inclusion in the study if they indicate at screening that they are smokers (both daily smokers “smoking any types of tobacco products on a daily basis” or occasional smokers “smoking any types of tobacco products occasionally”) between 25-44 years of age ([5](#_ENREF_5)); have access to a smartphone; have a WeChat account; have adequate knowledge of Chinese language; and are willing to participate in the study and provide follow-up information at scheduled points of the study.

### Exclusion criteria

People will be excluded from the sample if they are under any other types of smoking cessation interventions, refuse to give informed consent, refuse to continuously provide follow-up information, or have any acute or chronic condition that limit their ability to participant in the study.

### Recruitment

The WeChat-based smoking cessation intervention is intended to serve a diverse population in China. Participants’ recruitment in the trial will be completely based on social network platform via WeChat.

### Study procedures

Advertisement of the pilot trial will be delivered through WeChat to different WeChat users. Potential participants who read the trial advertisement and are interested to participate can subscribe to the SCAMPI WeChat OA. Once they subscribe to the account, they will receive an auto-replied trial instruction. Potential participants can tap the registration button in the SCAMPI WeChat Official Account to register as an official participant of the study.

In the registration system, potential participants will be screened to ascertain their eligibility for the study. Eligible participants will be provided with the participant information sheet (PIS) and consent form (CF) for them to read. After they complete reading the documents, they will be asked to provide e-consent by tapping the “agree” button.

Within the e-consent, participants will then be directed to complete the baseline assessment. A participant will receive his first study compensation once he completes the registration to strengthen his relationship with the study. The compensation will be given as a WeChat Red Pocket (a form of e-voucher on WeChat platform).

Randomisation will be performed upon completion of the baseline assessment. Each registered participant will have a unique code based on the sequence of completing the registration (Participant No. 1 to No. 80). Randomisation will be implemented based on participant’s code. Participants who are randomised into the intervention group will receive both daily quitting tips from SCAMPI WeChat OA and access to SCAMPI mini-programme. Participants that are randomised into the control group will be provided with contact to general smoking cessation care in China through SCAMPI WeChat Official account. Current general smoking cessation care in China includes the Chinese Quitline (China had started quitline service since 2004, there are two Chinese quitline models, which are National Quitline Model “only provide cessation service” and 12320 Hotline model “integrate cessation counselling into public health hotline service) ([25](#_ENREF_25)) and smoking cessation clinic.

After randomisation, participants in both groups will receive weekly-based WeChat message to ask them about their past week smoking statuses. Each smoking status checking message will come with WeChat Red Pocket as compensation / motivation to enter their past week cigarette consumption. Participants from both intervention and control group will receive same WeChat Red Pocket after providing their weekly cigarette consumption data. There is no specific incentive for particular group to provide their smoking statuses.

Upon completion of the 6-week follow up, the full version of SCAMPI programme will be offered to participants in the control group. Compensation of each session = ¥ 5 RMB. Each participant will receive in total ¥ 35 RMB (approximately $ 8 NZD) WeChat Red Pocket in appreciation of his time given to the study. The compensation in this study will be given through 7 sessions (registration and 6 weekly data collection of cigarette consumption in past week).

The reason for separating compensation into 7 sessions is to motivate participants (in both groups) to enter their smoking status and reduce the possibility of losing participants to the study.

### Randomisation

Randomisation will be performed at the individual level. Participants that fulfil entry criteria and have completed baseline assessment will be randomised at a 1:1 ratio to either an intervention group or to a control group. The randomisation sequence will be generated by the trial statistician using block randomisation with variable block sizes of 2 or 4. The final randomisation lists will be concealed in the database until the point of randomisation.

### Study intervention

**Intervention:**

Participants randomly allocated in intervention group will be authorised to have access to the full version of SCAMPI programme. The programme has two major components, which are SCAMPI WeChat OA and SCAMPI mini-programme. SCAMPI WeChat OA has the following functions:

(1) Providing information to study participants: introduction of the study, participant information sheet, consent form, reminder of entering smoking status, and quitting tips;

(2) Collecting information about participants’ cigarette consumption in weekly basis;

(3) Offering WeChat Red Pocket

The SCAMPI mini-programme has three key functions:

(1) Helping smokers to develop their own quitting plans;

(2) Enabling smokers to track their quitting progress;

(3) Providing empirically based tests to evaluate health improvement by stopping smoking.

**Control:**

Participants randomly allocated to the control group will have access to the restricted version of SCAMPI programme. The restricted version of SCAMPI programme for participants in control group has the following function:

(1) Providing information to study participants: introduction of the study, participant information sheet, consent form, reminder of entering smoking status, and contact information for general smoking cessation care in China;

(2) Collecting information about participants’ cigarette consumption in weekly basis;

(3) Offering WeChat Red Pocket (an e-voucher system) to reinforce participants to enter their cigarette consumption.

On completion of the 6-week follow up assessment, participants in control group will be offered access to the full version of SCAMPI programme with free of charge.

### Withdrawal criteria

As part of the informed consent procedure and in accordance with best practice guidelines, the participant information and consent processes will clearly state that participation is voluntary, and participants will be free to withdraw at any stage of the research. Other reason for withdrawal includes the study being terminated for any reason.

### Baseline assessments

At the baseline assessment, the following data will be collected:

* **Demographic data**: age, marital status, employment status, family structure, age of starting, quit smoking history, smoking status (consumption, frequency, and nicotine dependence), and smoking cessation services usage.

### Primary outcome measure

The primary outcome of this pilot trial will be participants’ bio-verified 30-day smoking abstinence at 6-week follow-up. At the 6-week time point, researchers will review and analyse participants’ (in both groups) smoking status in the past 30 days to identify their 30-day smoking abstinence at the planned time point. The 30-day smoking abstinence is usually used as the primary outcome measure for smoking cessation intervention trials recommended by the Society for Research on Nicotine and Tobacco (SRNT) ([26](#_ENREF_26)). Quit failure is defined as any cigarettes smoked in the past 30 consecutive days. This measurement is also known as the 10th level of smoking abstinence in the Chinese Standard for smoking cessation (25). At the 6-week time point, a Nicotine Cotinine Saliva Test kit will be sent to participants (in both groups) who report themselves with 30-day smoking abstinence to verify their smoking abstinence status.

### Secondary outcome measures

The following secondary outcome measures will be assessed:

* **Smoking Abstinence and Reduction**
1. **Participants’ cigarette consumption reduction –** Participants will be required to provide their weekly cigarette consumption at the baseline assessment. By using this data to compare with their weekly smoking status through the pilot trial, researchers will be able to identify the reduction of cigarette consumption of participants (in both groups). Participants who reduce consumption of over 50% from baseline will be counted as successfully achieve smoking reduction.
2. **Prolonged smoking abstinence at 6-week follow-up –** At the 6-week study period, participants will be asked about their smoking status of the week (smoking abstinence / had smoked any tobacco products) via SCAMPI OA on WeChat. By analysing this data, researchers will be able to identify participants’ prolonged smoking abstinence according the 6-week study period. Referring to the context in this pilot trial, the prolonged smoking abstinence can be defined as participants record no smoking following the first 7 days after the intervention start till the end of the study.
3. **7-day smoking abstinence at 4-week and 6-week follow up –** At the 4-week and 6-week time point, researchers will review and analyse participants’ (in both groups) smoking status in the past 7 days to identify their 7-day smoking abstinence at both of these time points. 7-day smoking abstinence is defined as not a single cigarette being smoked in the past 7 days.
* **SCAMPI programme usage**
1. **Participants’ compliance with SCAMPI:** Participants’ compliance refers to participants (in both groups) provide their weekly smoking status at the end of every week, as well as answering the end-of-trial questionnaires (including VAS for assessing their acceptability and MARS for assessing their satisfaction levels).
2. **Times of visiting SCAMPI OA and SCAMPI mini-programme –** At the end of the pilot trial, researchers will review and analyse the frequencies of participants visiting the SCAMPI OA (for participants in both groups) and the frequencies of participants visiting the SCAMPI mini-programme (for participants in intervention group). These data will reflect to participants engagement levels to the SCAMPI programme.
3. **Times of interaction with the SCAMPI OA and SCAMPI mini-programme –** At the end of the pilot trial, researchers will review and analyse the data of how many times participants (in intervention group) like, comment, forward, post content from SCAMPI OA on personal board or conversation with their friend. Also, the number of times participants using different functions (including setting cessation goal, recording cigarette consumption, reviewing quitting progress, and using different screening tests) of the SCAMPI mini-programme. These data will also reflect on participants engagement levels to the SCAMPI programme.
* **Acceptability and Satisfaction of using SCAMPI programme**
1. **Participants’ acceptability of using SCAMPI as their smoking cessation tool –** Participants’ acceptability (for both groups) of using SCAMPI will be measured by a VAS questionnaire at the end of the pilot trial (the same section of asking participants’ final week smoking status). Participants’ acceptability to the SCMAPI programme will be asked by questions such as “Did the programme increase your willingness to stop smoking”, and “Did the programme encourage you to look for more stop smoking techniques?” ([27](#_ENREF_27), [28](#_ENREF_28)). Each question will be answered by a 5-item scale from “Not at all” to “Very much” ([27](#_ENREF_27), [28](#_ENREF_28)). This outcome will reflect how acceptable SCAMPI is as a smartphone app-based smoking cessation intervention.
2. **Participants’ satisfaction level of using SCAMPI as their smoking cessation tool** Participants’ satisfaction level (for both groups) of using SCMAPI will be measured by a MARS questionnaire at the end of the pilot trial (the same section of asking participants’ final week smoking status). This outcome will reflect how satisfied SCAMPI users are by using it as a smartphone app-based smoking cessation intervention.

### Schedule of intervention and follow-up

Outcome assessments will be measured at baseline and weekly smoking status assessment after randomisation [Table 1].

**Table 1: Details of follow-up**

|  |  |  |  |
| --- | --- | --- | --- |
| **Timing** | **Week 1** | **Week 1 – 5**  | **Week 6** |
| Description | Screening + Baseline data collection + Randomisation | Follow-up data collection  | Follow-up data collection |
| **General data** |  |  |  |
| Eligibility | ✓ |  |  |
| E-consent | ✓ |  |  |
| Age, family structure (marriage status), child information (number of children in family) | ✓ |  |  |
| Quitting history  | ✓ |  |  |
| Other smoking cessation interventions usage  | ✓ |  |  |
| **Primary Outcome** |  |  |  |
| Participants’ bio-verified 30-day smoking abstinence at 6-week follow-up  |  | ✓ | ✓ |
| **Secondary Outcome** |  |  |  |
| Cigarette Consumption  | ✓ | ✓ | ✓ |
| Weekly Smoking Status  |  | ✓ | ✓ |
| Prolonged smoking abstinence according 6-week follow-up |  |  | ✓ |
| 7-day smoking abstinence at 4-week and 6-week follow-up  |  | ✓ | ✓ |
| Participants’ compliance with the SCAMPI programme  | ✓ | ✓ | ✓ |
| SCAMPI programme usage  |  | ✓ | ✓ |
| Participants’ acceptability of SCAMPI |  |  | ✓ |
| Participants’ satisfaction with SCAMPI |  |  | ✓ |

### Budget

Study budget plan (including items, unit and cost) is shown as following [Table 2].

**Table 2: Study Budget**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items**  | **Unit**  | **Cost (per unit)**  | **Cost in total**  |
| System maintenance  | For 3 months N = 3 | RMB ¥380 | RMB ¥1140 |
| Participants compensation  | Assume 80 participants N = 80 | RMB ¥35 | RMB ¥2800 |
| Nicotine Cotinine Saliva Test  | Minimum purchase quantity N = 80 | USD $7.35 | USD $588 |
| Postage  | Assume 40 participants quit smoking N = 40 | RMB ¥25 | RMB ¥1000 |
|  |  |  |  |
| **Total**  | **RMB ¥4940 + USD $588** |
| **Total (convert into NZD) Approx.**  | **NZD $2000** |

# Statistical Considerations

## Sample size

For proposed main trial, a total sample size of 530 (265 per group) will have 90% power at 5% significance (2-sided) to detect an absolute difference of 10% on primary outcome between two groups, assuming a control rate of 6.7% and 20% loss to follow-up.

In the pilot trial, we aim to recruit around 15% of the total sample size required for the main trial, i.e. n=80 (40 per group), using open recruitment strategy to recruit all participants within a month.

## Data analyses

Data from this pilot trial will be extracted from three different sources: (1) the WeChat OA control panel for the data in related to the SCAMPI OA usage; (2) Wenjuanxin (it is an online questionnaire that is embed into WeChat OA system) control panel for the data in related to baseline assessment and weekly smoking status; and (3) the lean cloud database for the data in related to SCAMPI mini-programme usage. Extracted data will be entered into an Excel Database, and following cleaning and datalock, exported into SAS (version 9.4) for analysis.

*Baseline characteristics*

Baseline data collected from all participants will be summarised by occasional smoker and daily smoker. Continuous variables (e.g. average daily cigarette consumption) will be presented as numbers observed, means and standard deviations. Categorical variables (e.g. marital status) will be presented as frequencies and percentages. Since any differences between randomised groups at baseline could only have occurred by chance, no formal significance testing will be conducted.

*Outcome relevant data*

Primary and secondary outcomes will be first summarised descriptively at identified time points. Generalised linear mixed model will be used to assess the effect of the SCAMPI programme to participants’ smoking cessation outcomes.

## Data management

Information about study subjects will be kept confidential in keeping with the obligations set out in the Privacy Act 1993 and the Health Information Privacy Code 1994.

NIHI stores data either on The University of Auckland owned storage and servers, or on cloud services operated by a vendor with whom The University of Auckland have a contractual relationship. Data stored on The University of Auckland storage and servers will be managed in accordance with appropriate NZ Information Security Manual (NZISM) guidelines and relevant legislation including the Privacy Act 1993. Data stored using cloud services is maintained by the vendor and their security is assessed by 1). Relevant vendor certification or accreditations, 2). Independent audits of services conducted by 3rd parties, and 3). University of Auckland performing audits to test the vendor services. All data including voice recordings, transcripts, forms will be held securely at NIHI. All electronic data will be password protected and stored on the internet data management system (See Manual of Procedures).

The data collected from the SCAMPI programme will be directly exported from different servers and purged. Researchers will review all the data in China and convert these data and data findings into secondary data for analysis purposes. Access to all study data will be restricted to research staff directly involved in conducting or monitoring the study. Confidentiality will be protected by the use of study registration numbers, and only aggregated and anonymous data will be reported. No personal information will be collected. Computerised information will be password protected and hard copy information kept in a locked filing cabinet. All reports from the study will be written in a way such that no individuals can be identified.

# Ethical Approval and Consent

## University of Auckland Human Participants Ethics Committee (UAHPEC) approval

Ethics approval (Reference No.: 021649) was obtained from the University of Auckland Human Participants Ethics Committee (UAHPEC).

## Zhejiang University School of Public Health Research Ethics Committee approval

Ethics approval (Reference No.: ZGL201801-2) was obtained from the Zhejiang University School of Public Health Research Ethics Committee.

## Informed consent

Maintenance of confidentiality and compliance with the Privacy Act New Zealand will be emphasised to all study participants. Participation in the study will be entirely voluntary. Consent will be obtained at the time of screening and registration. E-consent will be obtained once participants have had the opportunity to read the Participant Information Sheet and ask any questions to the members of the study team through the SCAMPI OA prior to completing the baseline assessment.

# Assessment of Safety / Adverse Event Reporting

No adverse or serious adverse events are anticipated and thus these data will not be collected in this trial.

# Relevance to Health

The proposal will generate knowledge with potential about a mHealth intervention for supporting smokers to quit smoking. In addition, the study design is completely digitalised. If effective, the intervention can be easily tailored and scaled-up for international roll-out and be adapted to enhance support for different population groups (e.g. female, smokers in other countries).

The intervention in this study provides an example of how to use a social network platform to address public health issues.

A completely digitalised and social network-based Pilot RCT design provides new ideas of trial data collection and implementing trials in a more cost-effective way.

# Dissemination of Results

A Knowledge-Transfer Exchange Strategy will ensure the findings have the greatest possible impact on smokers. The strategy will focus on key messages, target audiences, appropriate communication channels, activities and timing, and measures of success. NIHI has standard operating procedures in place which cover all aspects of research dissemination. Furthermore, a key strategic goal of NIHI is to “increase research impact” via increasing the number and impact of research outputs.

## Trial registration

The trial had been registered online on the Australian New Zealand Clinical Trials Registry (ANZCTR) (Reference No.: ACTRN12618001089224p) and the China Clinical Trial Registry (ChiCTR) (Reference No.: ChiCTR1800016904).

## Study participants

Study participants will be informed about the trial results by being sent a plain language summary of the results - after the publication of the study results.

## The general public

The general public will be informed about the trial via posting of the research findings on the University’s and other relevant websites, both national and international. Opportunities to make presentations to local, national and international audiences will be actively pursued. Another dissemination pathway is media releases (national and international) at the time of journal publication. As a digitalised study with social network-based intervention, the research findings will also be disseminated through social network platform like WeChat.

## Academic/professional colleagues

Academic/professional colleagues will be informed about the trial via publication in high impact, leading international journals. Less formal feedback will be given via the investigators’ participation in the national and international research community. Opportunities to make presentations to local, national and international audiences will be actively pursued.

## Health service funders and providers

Academic papers and summary reports will be provided to funders.

# Administrative Section

## Adherence to the protocol

Except for a change that is intended to eliminate an immediate hazard to participants, the approved protocol will be conducted as described. Any significant protocol deviation will be documented.

## Protocol revision procedures

All revisions will be discussed with, and approved by, the Study Steering Committee. If the revision is an “administrative letter”, the principal investigator will submit it to the University of Auckland Human Participants Ethics Committee for their information. If the revision is an “amendment”, the principal investigator will sign it. The principal investigator will submit the amendment to the University of Auckland Human Participants Ethics Committee and the Zhejiang University School of Public Health Research Ethics Committee for review and approval or favourable opinion prior to implementation. Documentation of approval signed by the chairperson or designee of the University of Auckland Human Participants Ethics Committee and the Zhejiang University School of Public Health Research Ethics Committee will be sent to the principal investigator.

If an amendment substantially alters the study design or increases the potential risk to the subject:

* the consent form will be revised and submitted to the University of Auckland Human Participants Ethics Committee and the Zhejiang University School of Public Health Research Ethics Committee for review and approval or favourable opinion;
* participants currently enrolled in the study, if they are affected by the amendment, will be contacted through WeChat messages and the amendment discussed and e-consent re-obtained;
* the revised e-consent form will be sent to participants currently enrolled in the study if they are affected by the amendment;

## Case report form procedures

All questionnaire information will be entered onto the electronic forms on the study website.

## Monitoring/ Source document verification

No formal monitoring will take place for this study as it is deemed to be low-risk, all data is self-reported and entered directly into WeChat questionnaire system and participants give e-consent.

Central monitoring will occur with logic checks built into the database to check for data inconsistencies and missing data and data will be checked at regular intervals during the study for completeness and accuracy.

## Data confidentiality and security

All data will be held securely at NIHI. All electronic data will be password protected and stored on the internet data management system (See Manual of Procedures).

## Reporting schedule

The principal investigator will provide on-going reports of the progress, or completion, termination or discontinuation of the study to the University of Auckland Human Participants Ethics Committee (UAHPEC) and the Zhejiang University School of Public Health Research Ethics Committee.

## Record retention policy

NIHI will retain study documents for 6 years from data lock. Staff involved in the trial will not destroy any records associated with the trial, without the prior approval of the principal investigator. If the principal investigator or any co-investigators withdraw from the study (e.g. relocation, retirement), any records they hold will be transferred to a mutually agreed upon designee (e.g. another co-investigator). Notice of such transfer will be given in writing to the Director of NIHI.

## Insurance

## Ownership of data and publication policy

Individual study data will remain the property of individual study participants. NIHI will have the responsibility for storage, protection and retrieval of study data. The Steering Committee will have the responsibility for the safe guardianship and use of the data.

All publications will be approved by members of the Steering Committee. Study participants, the research assistants, members of the Management Committee who are not part of the Steering Committee, and study sponsors will be acknowledged in the final report and in all publications and presentations resulting from this trial.

## Data Sharing

All requests for de-identified individual participant data or study documents will be considered, after publication of the results, where the proposed use aligns with public good purposes, does not conflict with other requests, or planned use by the Study Steering Committee, and the requestor is willing to sign a data access agreement. Contact will be via the corresponding author.

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# Appendix 1 – Terms of Reference

## Steering Group Committee

The Committee will meet as required during study development from start-up to review problems and issues raised by the Study Management Committee.

## Study Management Committee

The Study Management Committee will be responsible for the daily operation of the study, and will develop study materials, deal with study problems, recruitment, and logistical issues. Meetings will be held weekly while the study is in development, then as required when the study is underway.

# Appendix 3 – Proposed Timeline

## Trial Timeline

|  |  |  |
| --- | --- | --- |
| **Activity** | **2018** | **2019** |
| **Nov** | **Dec** | **Jan** | **Feb** | **Mar** | **Apr** | **May** | **Jun** | **July** | **Aug** | **Sep** |
| ADMINISTRATION |  |
| Develop and sign off study protocol, statistical analysis plan  |  |  |  |  |  |  |  |  |  |  |  |
| Seek and obtain ethics approvals (if needed) |  |  |  |  |  |  |  |  |  |  |  |
| Pilot RCT |  |
| RCT recruitment, screening, collect baseline, and randomisation  |  |  |  |  |  |  |  |  |  |  |  |
| Data collection (6 weeks) |  |  |  |  |  |  |  |  |  |  |  |
| Data cleaning and datalock |  |  |  |  |  |  |  |  |  |  |  |
| Statistical analyses  |  |  |  |  |  |  |  |  |  |  |  |
| FINAL REPORT AND DISSEMINATION  |  |
| Draft final report and final reporting  |  |  |  |  |  |  |  |  |  |  |  |
| Thesis writing  |  |  |  |  |  |  |  |  |  |  |  |
| Dissemination of findings (Presentations, Journal Article)  |  |  |  |  |  |  |  |  |  |  |  |

## Key milestones

|  |  |
| --- | --- |
| Date | Milestone |
| Dec 2018 | Trial protocol sign off  |
| Dec 2018  | Submit and obtain ethics approvals (if needed) |
| Jan 2019 | Start recruitment  |
| Feb 2019 | Recruitment completed |
| Mar 2019 | 6-week follow up completed  |
| Apr 2019 | Data lock |
| May 2019 | Data analysis complete |
| TBC | Thesis writing  |
| TBC | Presentation & Publication  |

# Appendix 4 – Summary of Protocol Amendments

|  |  |  |
| --- | --- | --- |
| Page | Section heading | Amendment |
| **Version 1.0** |  |
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