STUDY PROTOCOL

1. Project Title:

Building capacity and promoting smoking cessation in the community via "Quit to Win" Contest 2018: a single-blind cluster randomized controlled trial on brief intervention (AWARD), active referral and financial incentive for attending smoking cessation (SC) service to increase abstinence

2. Investigators

Principal Investigator

Dr. MP Wang, Assistant Professor, School of Nursing, HKU

Co-investigator

Prof. TH LAM, Chair Professor, School of Public Health, HKU

Dr. Snow Xue WENG, Post-doctoral fellow, School of Nursing, HKU

Dr. William HC LI, Associate Professor, School of Nursing, HKU

Dr. Derek YT CHEUNG, Research Assistant Professor, School of Nursing, HKU

3. Study sites

The study will be conducted in the community of all 18 District Council districts in Hong Kong.

4. Aims of the study

The aim of this project is to promote and evaluate an innovative community-based smoking cessation intervention through the "Quit to Win" Contest organized in all the 18 districts of Hong Kong. The specific objectives of the study are:

(1) To build capacity in the community on SC through a train the trainer (TTT) programme;

(2) To empower the community organizations at the district level to raise the awareness of the harms of smoking and the importance of SC and reach smokers in the community;

(3) To test, by a 2-arm RCT, the effectiveness of a combined intervention of face-to-face brief cessation advice (AWARD), active referral of SC service plus financial incentive on encouraging SC services use compared with control participants among current smokers who joined the contest;

(4) To evaluate the process and outcome of the recruitment of smokers through the recruitment activities and qualitative interview;

(5) To conduct qualitative interviews with quitters and non-quitters participated in the RCT to explore their experience on the interventions.

5. Outcome measure(s):

a) Building up the capacity of community-based smoking cessation intervention

The outcomes are to increase the knowledge, attitudes and competence of community workers in providing brief smoking cessation intervention.

b) To evaluate the process and outcome of the recruitment of smokers in the community

Recruitment input: (i) number of staff/helpers from non-government organizations (NGOs) and The University of Hong Kong (HKU) trained to participate in recruitment and providing community-based smoking cessation services; (ii) number of leaflets and self-help materials distributed in the recruitment activities.

Recruitment outcomes: (i) number of recruitment activities organized under the Quit to Win Contest; (ii) number of people, including smokers and non-smokers, reached in all the recruitment sessions; (iv) number of eligible participants enrolled into the Contest;

c) Testing the effectiveness of two innovative smoking cessation interventions

The **primary outcomes** are biochemically validated abstinence (exhaled carbon monoxide and saliva cotinine) at 3- and 6- month follow-ups. Secondary outcomes include self-reported tobacco abstinence in the past 7 days; prolong tobacco abstinence (3- month or 6-month), SC services use; and smoking reduction (50% or above reduction in cigarette consumption compared with baseline), intention to quit, quit attempt, self-efficacy on quitting. SC services use included several indicators: calling a hotline, booking an appointment, SC clinic attendance, counselling session attendance, and other indicators to be further specified after liaison with the existing services (e.g. services providers' records on services utilization).

6. Estimated duration and commencement date

Proposed starting date:	1 June 2018
Proposed study completion date:	31 May 2019
Expected final report date:	30 September 2019

7. Scientific/historical background

<u>Smoking and second-hand smoke in Hong Kong</u>

Although smoking prevalence is decreasing in Hong Kong, there are still 615,000 daily cigarette smokers in Hong Kong in 2017 [1] and half will be killed by smoking [2] which accounts for over 7,000 deaths per year [3]. Smoking also accounts for a large amount of medical cost, long-term care and productivity loss of US$688 million (0.6% Hong Kong GDP) [4, 5]. Smoking is a highly addictive behavior and it is difficult for smokers with strong nicotine dependence to quit without assistance. On the other hand, reaching and helping the many smokers who have no intention to quit is a challenge, because they are unlikely to seek professional help from smoking cessation services.

Previous Quit to Win Contest findings

The Quit and Win programme provides an opportunity to reach and encourage a large group of smokers to make quit attempt and maintain abstinence. The Quit and Win model posits that smokers participating in the contest will have higher motivation to quit with incentives and better social support [6]. Studies have found that such quitting contests or incentive programs appeared to reach a large number of smokers and demonstrated a significantly higher quit rate for the quit and win group than for the control group [7].

In 2009, we conducted a 3-arm RCT to compare the effectiveness of a 3-minute brief telephone advice, 8 mobile phone (SMS) messages and usual care of smoking cessation self-help booklet [8]. More than one thousand participants were successfully recruited in 1.5 months with an overall self-reported quit rate of 21.6% at 6 months. However, the 2 interventions groups did not show a higher quit rate than the control group. In the Quit to Win Contest 2010, we compared the effectiveness of an on-site face-to-face brief smoking cessation advice (intervention) with self-help booklet (control) on quit rate and changes in smoking behavior. Once again, we recruited over one thousand participants in 2.5 months. A marginally significant ($p = 0.08$) higher quit rate was observed in the intervention group (18.4%) compared with the control group (13.8%) at the 6-month follow-up [9]. The Quit to Win Contest 2012 studied on the effectiveness of the on-site counselling with telephone boosters and health education card was theoretically based on the Health Action Process Approach (HAPA) [10] for the intervention group and the SMS intervention group who received 16 SMS about cessation advice and motivation were compared with the control group. The HAPA suggests that one's intention of behavior change can be fostered by knowing that the new behavior has positive outcomes as opposed to the negative outcomes that accompany the current behavior; and

planning (action planning and coping planning) which serves as an operative mediator between intentions and behavior. The quit rates at 3 months were 9.4% (on-site counselling) and 11.5% (SMS) compared with 9.3% in the control group (p = 0.93) [11]. The Quit to Win Contest 2013 tested the effectiveness of combining competition and short-term monetary incentives to motivate smokers to quit smoking. The overall quit rate was 9.4% (95% CI 7.8%-11.4%). The quit rate for participants who were given prior notice about receiving the monetary incentive (HKD500) upon validated abstinence at the 3-month follow-up was 9.0% (95% CI 6.4-12.6%), which was similar to those who received a delayed notice (10.9%, 95% CI 8.1%-14.7%) and those who did not receive any incentive for abstinence (8.4%, 95% CI 5.9%-11.9%) [12]. In 2014, an RCT tested the effectiveness of the cut down to quit (CDTQ) and quit immediately (QI). CDTQ and QI groups showed similar self-reported quit-rate at 6-month (9.6% vs. 10.6%, p= 0.85)[13]. In Quit-to-Win Contest in 2015, a 3-armed RCT tested the effectiveness of the moderate active referral (MAR) of SC services and AWARD approaches. The results presented MAR intervention significantly increased smoking abstinence rate at 6 months when compared with brief general SC advice (17.2% vs. 11.5%, p=0.02) [14]. In QTW Contest 2016, we evaluated the effects of a higher intensity and personalized active referral (HAR) vs. low intensity text messaging (Text) vs. very brief SC advice (VBA; control group) on encouraging smoking cessation (SC) service use and increasing the quit rate. HAR group included onsite AR, brief advice using AWARD model with a warning leaflet plus a referral card provided, and instant messages as reminders. Text group included brief advice using AWARD model with the same warning leaflet plus the referral card provided and low intensity text messages as reminders. VBA group included onsite general brief advices and a 12-page booklet. Findings at 6-month follow-up of this RCT showed that the intervention group with HAR had a significantly higher self-reported quit rate than VBA (the control group) (17.0% vs. 11.2%, P = 0.02). Text group also had

significantly higher self-reported quit rate than the control group (17.1 % vs. 11.2%, P = 0.02) [15]. The latest QTW Contest 2017 evaluated the effectiveness of a combined intervention of brief cessation advice (AWARD), interactive instant SC messaging plus active referral to smoking cessation (SC) services to increase quitting. The preliminary result showed that the combined intervention resulted in higher smoking cessation rate compared with control group at 6-month follow-up (18.6% vs. 11.8%, P = 0.01).

Overall the Quit to Win Contests in Hong Kong recruited over 9,000 smokers from the community. The competition probably helped in boosting up participants' confidence and motivation to quit but additional brief counselling and short messaging services did not significantly increase the quit rate. Lucky draws were included in the past contest for participants who successfully quit (validated by biochemical tests). In accordance with the research direction suggested by recent studies [6, 16, 17], the forthcoming RCT on Quit to Win Contest will examine the effectiveness of (1) moderate intensity personalized active referral to smoking cessation (SC) services, and (2) financial incentive on encouraging SC services use to increase quitting compared with control participants among current smokers who joined the contest.

Community participatory model for smoking cessation

Community-Based Participatory Research (CBPR) is a partnership approach in scientific research that involves the collaboration among community partners and academic researchers throughout the research process [18]. It has been found effective in enhancing community input, building community capacity, and addressing barriers to health in study participants who have historically been underrepresented in research [19]. Community partners have the capability of mobilizing local social resources and manpower and utilizing their network within the community, which is beneficial to a scientific research involving

population-based interventions. To effectively raise the awareness of the contest and recruit as many participants as we can from the community, working with NGOs in the 18 Hong Kong districts with a CBPR model should be one effective way of program implementation.

The challenge of applying the CBPR model in the smoking cessation program is to equip the staff from NGOs and HKU about the related skills and knowledge and maintain the quality of research process and intervention. Process evaluation is a systematic procedure during the delivery of public health interventions to understand how well the program does and to link the progress to outcomes [20]. In addition to the training programme and briefing session to be provided to the participating NGOs, monitoring and documentation are needed throughout the recruitment and research process so that the quality and integrity of the effort by the involved NGOs can be evaluated.

Rationale of using incentive to promote active referral

SC services utilization rates are markedly low in Hong Kong. The latest Thematic Household Survey reported that only 3.3% daily smokers had ever used SC services [1]. Among never-used smokers, only 3.1% of them were willing to try the SC services. Our previous trial in QTW Contest 2016 depicts a similar pattern. Despite over three quarters of participants (77.0%) in the HAR group had chosen an SC service. Among them, only a small percentage (34.9%) actually used the SC service. Most smokers (65.1%) failed to attend the SC service under the HAR intervention. Consequently, better interventions are needed to extend the reach of SC services and smokers who had chosen an SC service but fail to attend.

One approach to increase participation in SC service is to offer incentives. Despite the majority of SC services in Hong Kong is free of charge, SC and

counselling centres under the Hospital Authority (HA) charge HK$50 for a face-to-face counselling. Offering incentives enables smokers to overcome the service costs, transportation cost and perceived barriers and provides extrinsic motivation to access to SC services. Evidence has shown financial incentives do yield greater participation in SC programme [17]. A prior study in Hong Kong found provision of an incentive (HK$50) to offset the service fee of SC clinics increased booking and attendance rates in a clinical setting [16]. The effect of incentive on abstinence is less clear. Our previous trial in QTW Contest 2013 showed a small cash incentive with early notifications increased quit attempt by self-directed help, but it did not increase abstinence and the use of formal cessation aids [12]. Therefore, financial incentive-based SC programme focusing on promoting existing SC services use is warranted.

8. Study design

The present study consists of three phases: (I) provision of the training for SC ambassadors; (II) process evaluation of participant recruitment activities; and (III) a cluster RCT to test the effectiveness of a combined intervention using brief cessation advice, active referral and financial incentive for motivating smokers to attend SC services compared with smokers in the control group among current smokers who joined the contest.

8.1 Selection of subjects

Phase I

Around 100 staff/helpers from the district partners, COSH, HKU and other parties who will take part in the QTW 2018 will be invited to participate in a brief training programme. The TTT programme will (1) provide staff/ helpers with an overview of the QTW 2018 project; (2) equip them with the knowledge and new simple skills of helping smokers stop smoking in their respective communities; and (3) train them to give brief advice on smoking reduction and

use of existing SC services. The effect of the programme will be evaluated by pre- and post-tests. At least two half-day sessions of training will be held and the following topics will be covered in each session:

(1) Introduction of COSH;
(2) Objective and details of the QTW 2018 Campaign;
(3) Marketing and promotion of smoke-free messages;
(4) Global tobacco epidemic and control measures, including smoke-free policies and smoking cessation services in Hong Kong;
(5) Smoking hazards of active smoking, second-hand and third-hand smoke;
(6) Effectiveness of brief smoking cessation interventions and referral to and use of existing services;
(7) Brief smoking cessation and reduction advice and counselling skills with case study and sharing; and
(8) A brief introduction of evaluation using randomised controlled trial (RCT).

Phase II

About 70 sessions of recruitment and promotion activities will be organised with liaison with COSH aiming to recruit 1,200 participants. Well-trained smoking cessation ambassadors (about 6 per recruitment activity) will be deployed for onsite recruitment, brief intervention (e.g. brief SC advice), monitoring and evaluation. Each recruitment activity will be a study unit of the process evaluation and all the recruitment inputs and outcomes will be documented by a research staff for further analysis.

Phase III

We use the best study design possible under the constraints of the QTW to evaluate the effectiveness of new brief interventions. We follow the CONSORT (Schulz, 2010) in the design, implementation and reporting for the proposed

cluster RCT. Participants will be recruited in the community of all 18 districts during QTW recruitment activities in Hong Kong.

The cluster RCT (cRCT) will have 2 arms: intervention group (Group A) and control group (Group B). The participants will be randomly assigned to one of the 2 groups based on the randomization. Individual randomization at the recruitment site can have several participants being recruited together at the same time resulting in contamination as some participants may be exposed to the unintended interventions inadvertently. Based on the method of random assignment of recruitment session, participants will be allocated according to the randomly selected session to either group. The randomization for group assignment will be generated by the investigators of the project before participant's recruitment and allocation concealment will be ensured (please refer to "Randomization" for details). The intervention study will follow the CONSORT [21] in the design, implementation and reporting for the proposed cluster RCT.

We wish to conduct individual telephone or face-to-face interviews (subject to the availability of further funding) for quitters and non-quitters participated in the RCT after completion of 6-month follow-up to explore their perceptions on the intervention, comments of improvement and factors contributing to the quitting/ non-quitting.

Inclusion criteria

- Hong Kong residents aged 18 or above
- Smoke at least 1 cigarette per day in the past 3 months
- Able to communicate in Cantonese (including reading Chinese)
- Exhaled carbon monoxide (CO) 4 ppm or above, assessed by a validated CO Smokerlyzer.

- Intent to quit / reduce smoking

Exclusion criteria

- Smokers who have communication barrier (either physically or cognitively)
- Have participation in other smoking cessation programmes or services

8.2 Procedures

Phase I: Develop a smoking cessation training curriculum for the staff from NGOs and HKU

The smoking cessation training curriculum will be designed to illustrate the psychological and behavioral therapies in managing the care of the smokers. Throughout the training, participants will be taught a variety of topics by trained nurses and trained smoking cessation counsellors including: (1) Introduction of the Quit-to-Win Contest & the RCT; (2) Smoking trend and knowledge of health hazards from smoking; (3) COSH and social marketing on smoking cessation; (4) Recruitment strategies: How to approach smokers; (5) Experience sharing in communication with smokers; (6) Assessment of quitting readiness and individualized brief counselling; and (7) Technical skills such as conducting surveys and use of Smokerlyzers and advice on smoking reduction. At the end of the program, participants should be capable of delivering brief advice of smoking cessation for smokers. Upon completion of the training program, a certificate of attendance will be awarded to each participant. The outcomes of the training will be evaluated evaluated by pre- and post-tests through a self-administered survey, which includes knowledge, attitudes, and practice of smoking cessation intervention.

Phase II: Process evaluation of the recruitment activities

Quality assurance

Throughout the process evaluation, the trained staff from HKU and NGOs will be monitored on site. Spot checks will be conducted at every venue by an

investigator or a more senior research assistant to ensure a consistent delivery of the interventions proposed. They will also be responsible to monitor the whole process of each recruitment activities, and record necessary information related to the recruitment input, outcome and other environmental factors. Recruitment input includes the number of recruitment workers, posters and leaflets used. Recruitment outcome includes the number of smokers and non-smokers approached and the number of people who pay attention to the recruitment booth. The research staff will also assess the environmental factors including weather, date, time, location, facilities that may have an impact on the achievement of the recruitment sessions.

Phase III: Recruit and provide smoking reduction/cessation counselling

At the recruitment sessions, smoking cessation counsellor will measure the potential participant's level of carbon monoxide (CO) in exhaled air, screen their eligibility for entering the contest, and provide the self-help smoking cessation booklets developed by the Hong Kong Council on Smoking and Health (COSH). Then the counsellor will explain and invite the participants to join the RCT on smoking cessation intervention. Written consent for voluntary participation in the trial will be obtained before administering the baseline questionnaire and delivery of the intervention for the participants.

Hypothesis

The major research hypothesis is: combined brief advice, personalized active-referral plus financial incentive group (Group A) will have higher validated abstinence rate than the control group (Group B). The other hypotheses include higher SC services use rate, self-reported abstinence rate, smoking reduction rate, quit attempts, intention to quit, self-efficacy of quitting in the Group A compared with Group B.

Quit to Win Contest

In the Quit to Win study, 2-arm RCT will be conducted to test the effectiveness of combined intervention of brief cessation advice, active referral and financial

incentive brief advice in achieving smoking abstinence. A detailed flow chart of the RCT is attached (Appendix 1).

Intervention Group A

Participants in Group A will receive a combined intervention:

(1) Brief intervention using AWARD advice,

(2) Personalized active referral to SC services,

(3) Financial incentive for encouraging SC services use

(1) Brief intervention using AWARD model

Smokers will receive AWARD intervention delivered by the SC counsellors who completed the TTT programme and a brief warning leaflet emphasising on smoking harms (especially one out of two smokers will be killed by smoking, and the risk could be up to 2/3 for high risk smokers) and benefits of cessation.

AWARD model

AWARD will be delivered to smokers onsite and this includes: **A**sk about smoking history, **W**arn about the high risk *(with a brief health warning leaflet, see below for information)*, **A**dvise to quit as soon as possible and not later than a quit date (which will qualify them for the QTW prizes), **R**efer smokers to smoking cessation services *(with a referral card, see below for information),* and **D**o it again: to repeat the intervention; participants who fail to quit or relapse will be encouraged to quit again (and those who have quit will be encouraged to prevent relapse) during each telephone follow-up. The whole process of AWARD can be delivered within 30 seconds to 1 minute.

a) Brief leaflet on health warning and smoking cessation

The 2-side colour printed A4 leaflet, which systematically covers the most important messages to motivate SC and being used in QTW 2015, will be

disseminated to smokers during the counselling, with improvements if necessary. The content of the leaflet includes: (1) highlights of the absolute risk of death due to smoking; (2) the whole list of diseases caused by active and second-hand smoking; (3) ten horrible pictorial warnings of health consequences of smoking and second-hand smoking in one page to maximize the impacts; (4) benefits of SC and (5) simple messages to encourage participants to quit smoking and remind them to call the Department of Health SC hotline 183 3183.

b) Referral card

The 3-folded "Smoking Cessation Services" card which was developed and used since QTW Contest 2015 will be disseminated to smokers in this project, with improvements if necessary. The content consists of brief information and highlights of existing SC services, contact methods, motivation information and strong supporting messages or slogans.

(2) Personalized active referral to SC services

Similar to QTW Contests 2015, smokers in Group A will be introduced to various SC services in Hong Kong (using the referral card) and be motivated to use the services. Active referral intervention is designed to promote using the existing SC services to increase abstinence rate. Well-trained SC ambassadors will assist smoker to choose favorite/most convenient or preferred type of services: Tung Wah Group of Hospitals Integrated Smoking Cessation Centre (ISCC) services; Pok Oi Hospital Chinese Medicine smoking cessation services; Hospital Authority clinics in 18 districts; Department of Health hotline counseling; Youth Quitline; and Women Quitline. We then will send smokers' contact details to SC services provider within 7-day and SC services providers will contact the smokers within 1-2 weeks. If the smokers are not ready to

provide personal details for booking the services onsite, we will encourage the smokers to set a day for booking within 7 days of baseline survey. SMS messages will be sent to encourage them to book the SC appointment. Research staff will monitor SC services use of the participants at each follow-up (1-, 2-, 3- and 6-month) and assist participants to book or re-book the appointments if necessary at 1- and 2- month follow-up (after very brief questionnaire surveys). We shall liaise with the existing service provides and seek their assistance in helping our smokers in a timely manner.

(3) Incentive for promoting SC service use

Incentive on encouragement of using SC services will be provided in intervention group (Group A) in order to motivate participants to seek existing cessation assistance. Intervention participants are informed at baseline that they will receive financial incentive (supermarket coupon HK$300) if they attend or use any of the SC services within 3-month. Participants who are willing to book the SC services are required to sign a form stating that they are willing and will use the services. Participants who used the SC service within 3-month will receive incentive by post.

For some present-biased smokers, they pay less attention to the smoking hazards and have low levels of intrinsic motivation to quit [12]. Financial incentives have been shown to successfully promote SC, particularly among low-income smokers [22, 23]. Offering financial incentive such as cash and gift vouchers provide extrinsic motivation for smokers. Therefore, providing participants a small financial incentive for promoting SC services could be a feasible intervention to motivate more smokers to attend SC services and to increase abstinence.

Control Group: AWARD advice (Group B)

Participants in the control group will receive the AWARD advise and SC booklet as in the intervention group. Referral to SC service will be provided to participants in control group after 6-month survey.

Participants in both intervention and control groups will also receive a 12-page generic self-help SC booklet provided by COSH. It has been used since QTW Contest 2013 and will be disseminated to all smokers in this project. The content includes information about benefits of quitting, smoking and diseases, methods to quit, how to handle withdrawal symptoms, declaration of quitting, etc.

Table 1. Summary of intervention in 2 groups

	Intervention (Group A)	Control (Group B)
Personalized active referral + financial incentive	✓	
Referral card + warning leaflet	✓	
AWARD advice + COSH booklet	✓	✓

Non-trial Group

Those who are unable to read or communicate using Chinese, or those who refuse to participate in the RCT, can still participate in the QTW Contest and will receive the same monetary incentive if he/she passes the biochemical validations at 3- and 6- month. This group will be analysed separately from the RCT.

CSD Group

Invited by Correctional Services. Department (CSD), a group of prison smokers from Lo Wu Correctional Institution and Stanley Prison will participant the QTW contest. They will not be enrolled in the RCT but they can still participate in the QTW Contest and will receive the same monetary incentive if he/she

passes the biochemical validations at 3- and 6-month. This group will be analysed separately from the RCT.

Follow-up

All participants in the RCT will be followed-up at 1, 2, 3 and 6- month by telephone interview to assess their smoking status and quitting progress. At 1- and 2- month follow-up, booster interventions (see details below) will be given to participants. The follow-up at 3- and 6- month will be telephone survey only with no further intervention. Components of follow-up at 1- & 2- month in each group are:

(1) Intervention Group A: brief AWARD intervention, enquiry and reinforce the use of SC services, assist in booking/re-booking SC services and very brief survey (only asking smoking status, abstinence, SC services use).

(2) Control Group B: brief AWARD intervention and very brief survey.

For those unreachable participants at the schedule follow-up time, we shall make further calls, but limited to a maximum of 7 calls and 1 voice message as a reminder for their quitting. Self-reported quitters (no smoking in past 7 days) at 3- and 6- month follow-up will be invited for biochemical and non-biochemical validation. Biochemical validation includes the measurement of exhaled CO level and saliva cotinine level of the participants, which will be conducted by research assistants. The non-biochemical validation includes asking the quitter a few questions on the consequences of quitting, confirming quitter's quitting status by family members and assessment on the quitter by the interviewer. These are broadly similar to previous QTW Contests.

For CSD participants, self-administered questionnaire survey will be conducted at 1- and 2- month follow-up. The follow-ups at 3- and 6-month include self-administered questionnaire survey and face-to-face biochemical validation by

research staff. Qualitative interview to CSD participants will be conducted at 6-month to evaluate the process and outcome of the program.

8.3 Randomization

By cluster randomization, all participants recruited in a particular recruitment session (one day may have more than one activities) will be allocated to one of the RCT groups. Block randomization will be used to allocate the recruitment activity into the two RCT groups to ensure the number of recruitment activities for the two RCT groups is similar. The numbers for the permutation in the blocks will be generated with the website http://www.random.org (a website for generating random integers), and then merge with the list of all recruitment days.

8.4 Instruments

Phase I

A course evaluation form and a self-administered questionnaire including knowledge, attitude, and practice of smoking cessation will be completed by the participants of the training workshops (Appendix 2).

Phase II

A process evaluation form will be used to record the recruitment outcomes and observations including the number of people reached in the recruitment sessions of all recruitment sessions. It will be administered by the investigators or research staff.

Phase III

Quit to Win

Three sets of questionnaires will be adapted from our previous Quit to Win Contest conducted in 2015. These include: (1) a baseline questionnaire which collects demographic data, smoking behavior, quit attempts, smoking-related psychological factors and perceived social support when they participated the Contest (Appendix 9); (2) a set of follow-up questionnaires 1 month & 2 month booster interventions (Appendix 10a-b and 11a-b); and (3) a set of follow-up

questionnaires for 3- & 6-months (Appendix 12a-b and 13a-b) which collects information on smoking behavior, quit attempts, smoking-related psychological factors and perceived social support in the quitting process, as well as the impact of the Quit to Win Contest.

8.5 Sample size

Phase I

All staff/helpers from the participated NGOs and HKU who participate in the recruitment will be invited to attend the training program. A total of 100 participants (including a minimum of 36 NGO staff and HKU student helpers) can join the smoking cessation training program.

Phase II

COSH targeted to organize at least 2 recruitment sessions in each of the 18 districts in Hong Kong. There will be about 70 recruitment sessions to be evaluated.

Phase III

Quit to Win

The computer programme G*Power is used to calculate the sample size [24]. The proposed sample size is based on the primary outcome of validated quit rate at 6-month (Group A vs. Group B). Based on our previous QTW trials, the biochemically validated quit rate for the Control group was about 4.6% at 6-month follow-up [8, 12, 14]. In QTW 2015 trial, 6-month biochemically validated quit rate for the moderate intensity active referral was 9.0%. Cochrane review suggested the effect size of financial interventions aimed at encouraging the use of SC treatment is 1.48 [25]. Nevertheless, we conservatively assume a smaller effect size of 1.25 for the financial incentive in a combined SC intervention. It means that the validated quit rate at 6-month for Group A and Group B will be 11% and 4.6%, respectively. To achieve 80% power with a 5% false positive error rate to detect this effect size by a chi-square test, we will

need 275 participants per group. Assuming an intra-cluster correlation coefficient as 0.015 and a retention rate of 70% at the 6-month follow-up, the overall sample size of the study should be 1134 for the 2 groups (i.e. 974 = 275 x 2 Groups x 1.24 design effect / 70% retention rate).

For the post-intervention qualitative study, a purposive sample of quitter and non-quitter will be interviewed with sample size determined by data saturation.

8.6 Statistical Analysis

Data will be entered into SPSS for Windows (version 23). A logic check program will be installed for entry validation. Descriptive statistics such as frequency, percentage, and mean will be used to summarize the outcomes and other variables. Chi-square tests and t-tests will be used to compare outcome variables between subgroups. Generalized Estimating Equation (GEE) models will be applied to test the intervention effect, to identify the baseline predictors of successful quitting and to assess the changes in smoking-related factors over time. The intention-to-treat (ITT) analysis will be used such that those lost to contact and refused cases at the follow-ups will be treated as a failure to achieve any cessation outcome. Multiple imputations will be used to compute missing data for outcome variables.

The **primary analyses** include: (1) Main effect: Intervention vs. Control on biochemically validated abstinence at 3-month and 6-month.

The **secondary analyses** include: (2) Main effect adjusting for baseline difference; (3) All secondary outcomes at 3-months and 6-months; (4) Mediation analysis of 3-month factors (psychosocial or resource effects) on biochemically validated abstinence at 6-month; (5) Subgroup analysis based on intention to quit at baseline, SC service at 3-month; (6) Cost-effectiveness

analysis over the 6-month trial period and long-term cost-effectiveness analysis over the lifetime horizon; (7) Qualitative study data analysis for understanding the effects of the intervention; (8) Network meta-analysis to combine the results of QTW 2015 and 2017 for comparing different level of active referral on quitting [26].

8.7 Chronological outline of research plan

Timeline	2018								2019					
	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun
Preparation														
1. Preparation of IRB, training material, smoking cessation materials and research instruments (1.5m)														
Intervention														
Phase I & II														
2. Training of smoking cessation counsellors and logistics arrangement (1.5m)														
3. Evaluation survey (Pre-training, immediate post-training) (2m)														
4. Data analysis and report preparation for the smoke-free Training (2m)														
Phase III														
5. Recruitment of subjects at the districts & NGOs (3.5m)														
6. 1 month telephone follow-up and booster (3.5m)														
7. 2 month telephone follow-up and booster (3.5m)														
8. 3 months telephone follow-up and biochemical validation of quitters (4m)														
9. 6 months telephone follow-up, biochemical validation of quitters and post-intervention qualitative study (subject to the availability of further funding) (5m)														

Analysis and write-up														
10. Data collection and cleaning (11m)														
11. Data analysis (8m)														
12. Report preparation and result dissemination (8m)														

9. Drug investigation: Nil

10. Describe any unusual or discomforting procedures to be used: Nil.

11. Are there any hazards associated with the investigation? No

12. Direct access to source data/documents

The raw data will be stored on an external hard-disk and locked in a cupboard with keys kept by the Principal Investigator. Only the Investigators and Research Assistant of the project will be permitted to access the raw data and/or study records. The data will be scanned and kept for 10 years or longer after the study is completed. Individual participants will not be directly identifiable from the dataset to be used for analysis.

13. Dissemination of study result

The research findings will be reported to the COSH for policy evaluation, disseminated in local and international conferences, and published in international peer-reviewed journals.

14. Consent

Participation in the study is totally voluntary. The smoking counselors at the study sites will explain to smokers who agree to join the Quit to Win Contest by COSH that we are carrying out a study on smoking cessation with more incentives than the lucky draw for the grand prizes, but the smokers will not be informed about the specifics of the incentives. The smoking counsellors will explain to the participants that they will receive telephone calls at 1-, 2-, 3- & 6-months for the follow-up of their smoking status. The participants will be assured that they can withdraw from the study anytime without any prejudice, and all the information will be kept confidential and results will be reported in

an aggregate format. Agreement to participate in the RCT will be considered as consent and participants are required to sign the written consent form.

15. Conflict of interest: None

16. Financing and insurance

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