

# STUDY PROTOCOL

## 1. Project Title:

Building capacity and promoting smoking cessation in the community via “Quit to Win” Contest 2015: a randomized controlled trial on brief intervention (AWARD model) and active referral to smoking cessation services.

## 2. Investigators

### Principal Investigator

Dr. Man Ping WANG, Assistant Professor, School of Nursing, HKU

### Co-investigator

Prof. Tai Hing LAM, Chai Professor, School of Public Health, HKU

Dr. William Ho Cheung LI, Associate Professor, School of Nursing, HKU

Dr. Yee Tak Derek CHEUNG, Post-doctoral fellow, School of Public Health, HKU

Dr. Yi Nam SUEN, Post-doctoral fellow, 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 two innovative and brief community-based smoking cessation interventions through the “Quit to Win” Contest organized in the 18 districts of Hong Kong. The specific objectives of the study are:

- (1) To build capacity in the community on smoking cessation through a training of trainer (TOT) programme;
- (2) To empower the community organizations at the district level to raise the awareness of smoking cessation and reach smokers in the community;
- (3) To evaluate the effectiveness of two innovative brief interventions (AWARD model and active referral) on assisting smokers to use existing smoking services and the smoking cessation hotline (1833183) and to quit, based on a brief advice with a leaflet using randomized controlled trial (RCT) design; and

(4) To evaluate the process and outcome of the recruitment of smokers through the recruitment activities.

## 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 outcome is self-reported smoking cessation in the past 7 days at 6 months follow-up. Secondary outcomes include smoking cessation services use; biochemical validated smoking cessation; and smoking reduction (50% or above reduction in cigarette consumption compared with baseline). Smoking cessation services use included several indicators: calling a hotline, booking an appointment, smoking cessation 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 2015
Proposed study completion date:	31 March 2016
Expected final report date:	30 September 2016

## 7. Scientific/historical background

### **Smoking and second-hand smoke in Hong Kong**

Although smoking prevalence is decreasing in Hong Kong, there are still 648,800 daily smokers 10.8% (Census and Statistics Department, 2013) and half will be killed by smoking (Lam, 2012) which accounts for over 7,000 deaths per year (Lam, Ho, Hedley, Mak, & Peto, 2001). 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) (Census & Statistics Department, 2001; McGhee et al., 2006) . 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 (Cahill & Perera, 2011). 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 (Cahill & Perera, 2008).

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 (Chan, 2011). 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 (Wong & Chan, 2012). 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) for the intervention group (Schwarzer, 2008) 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 ( $p = 0.93$ ) (Schwarzer, 2008).

The five Quit to Win Contests in Hong Kong recruited over 5,000 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 the above foreign studies, the forthcoming RCT on Quit to Win Contest will explore the effectiveness of short-term monetary incentives combined with two innovative brief interventions (AWARD model and active referral).

For the QW 2013, 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 (Quit rate=10.9%, 95% CI 8.1%-14.7%) and those who did not receive any incentive for abstinence (Quit rate=8.4%, 95% CI 5.9%-11.9%).

### **Community participatory model for smoking cessation**

Community-Based Participatory Research (CBPR) is a partnership approach in a scientific research that involves the collaboration among community partners and academic researchers throughout the research process (Israel, Schulz, Parker, & Becker, 1998). 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 (Andrews, Newman, Heath, Williams, & Tingen, 2012). Community partners have the capability of mobilizing local social resources and manpower, and utilizing their network within the community, which are 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 in order to understand how well the program does and to link the progress to outcomes (Centers for Disease Control and Prevention, 2008). 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 active referral approach**

Smoking cessation substantially increase quit rate and WHO has urged to promote smoking cessation services (World Health Organization, 2015). Smoking cessation services in Hong Kong are under-used with more than half (60.9%) adult daily smokers who had never used smoking cessation services (Census and Statistics Department, 2013). Among these smokers only 9.6% were willing to use the services. Existing services mostly require self-initiation to seek the services but smokers general lack the will power of initiation. Active referral will help overcome the barriers of self-initiation. There is preliminary evidence that active referral of smokers to smoking cessation hotline services may increase likelihood of smoking abstinence at 12-month follow-up compared with no active referrals (Borland et al., 2008). A recent study has also reported that individuals who used the community-based referral were also more likely to quit than those who did not (43.6% vs 15.3%,  $P < 0.001$ ) (Haas et al., 2015).

Therefore, the present study will examine (1) effectiveness of the active referral and AWARD approaches, (2) explore the use of CBPR model to build capacity and to engage community partners in taking on this important public health issue for sustainability in the community. In addition, process evaluation will be conducted to assess the effectiveness of the recruitment activity and how it is linked with the overall program outcomes.

## 8. Study design

The present study consists of three phases: (I) provision of the training for smoking cessation counsellors; (II) process evaluation of participant recruitment activities; and (III) a cluster RCT to evaluate the effectiveness of (a) a brief health warning and advice (AWARD) leaflet, and (b) an active referral intervention including a smoking cessation service leaflet and assisting smokers to book and use the existing smoking cessation services.

### 8.1 Selection of subjects

#### *Phase I*

Around 100 of staff/helpers from the district partners, COSH, HKU and other parties who will take part in the QTW 2015 will be invited to participate in a brief training programme. The TTT programme will (1) provide staff/ helpers with an overview of the QTW 2015 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 smoking cessation services. The effect of the programme will be evaluated by pre- and post-tests. At least two half-day sessions of programme will be held and the following topics will be covered in each session:

- (1) Introduction of COSH;
- (2) Objective and details of the QTW 2015 Campaign;
- (3) Marketing and promotion of smoke-free messages;
- (4) Tobacco epidemic and control measures in Hong Kong and the world;
- (5) Smoking hazards of active smoking, second-hand and third-hand smoke;
- (6) Effectiveness of brief smoking cessation interventions and existing services;
- (7) Brief smoking cessation and reduction advice and counselling skills with case study and sharing; and

#### *Phase II*

About 65 sessions of recruitment and promotion activities will be organised with liaison with COSH aiming to recruit 1,200 participants. Well-trained smoking cessation counsellors (about 6 per recruitment activity) will be deployed for onsite recruitment, counselling, 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 two 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 has 3 arms: intervention group A (Group A), intervention group B (Group B) and control group (Group C). The participants will be randomly assigned to one of the 3 groups based on the day they are being recruited (cluster randomization). Individual randomization is difficult at the recruitment site as several subjects may be recruited together at the same time and if individually randomized, would be exposed to the unintended interventions inadvertently. The randomization of 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).

**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 difficulties in communication (either physically or cognitively)
- Currently following other smoking cessation programmes

**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 advices 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 through a self-administered survey before, immediate after, and 6 months post training, which include knowledge, attitudes, and practice of smoking cessation intervention (Appendix 2 to Appendix 5).

### ***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 number of recruitment workers, posters and leaflets used. Recruitment outcome includes number of smokers and non-smokers approached and 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 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 (Appendix 6) 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 (Appendix 8) for voluntary participation to the trial will be obtained before administering the baseline questionnaire and delivery of the intervention for the participants.

### *Hypothesis*

The main hypothesis is that smokers in intervention groups (Group A + B) have higher smoking cessation rate than smokers in control group (Group C). The other hypotheses are: Group A vs. Group C; Group B vs. Group C and Group A vs. Group B have higher services use rate, validated smoking cessation rate and smoking reduction rate.

### *Quit to Win Contest*

In the Quit to Win study, three-arm RCT will be conducted to test the effectiveness of active referral and AWARD model approaches. A detailed flow chart of the RCT is attached (Appendix 1).

### **Intervention group**

Smokers in intervention groups will receive the following interventions.

#### *(1) Brief intervention using AWARD model (Group A & B)*

Smokers will receive AWARD intervention and a brief innovative leaflet on smoking harms and cessation.

#### AWARD model

AWARD will be delivered to smokers onsite and this includes: **A**sk about smoking history, **W**arn about the high risk, **A**dvice 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, 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. This is an innovative, simple and cheap intervention which is more feasible than more lengthy or intensive counseling and, if proven effective, can be delivered by lay or minimally trained persons in community settings.

Brief innovative leaflet on health warning and smoking cessation

A 2-side color printed A4 leaflet will be designed to systematically cover the most important messages to motivate smoking cessation. The cost for this brief leaflet is much lower than the COSH 12-page booklet on smoking cessation and other existing printed booklets or leaflets. The design and content will be based on an existing leaflet currently being tested in a mega-RCT in Guangdong funded by TCO of DH. The content of the brief leaflet includes:

- (1) highlight the absolute risk of death due to smoking (1 of 2 smokers will die prematurely due to smoking, losing on average about 10 years of healthy life; and recent evidence that the risk could increase to 2/3 if smoking started at young age);
  - (2) the '1/2 deaths' is a World Health Organization (WHO) warning, which is the most authoritative, alarming and easily understood by everyone;
  - (3) the '2/3 deaths' should be the most alarming and is based on new evidence;
  - (4) the whole list of diseases caused by active and secondhand smoke (cancers, cardiovascular diseases, respiratory diseases and others) based on the 2014 US Surgeon General Report, which explains why the death risk is so high;
  - (5) about ten pictorial warnings in one page: adopting about 10 pictorial warnings from Hong Kong, China CDC and other places (if permission granted) to expose the smoker at the same time most of the most serious diseases due to smoking, to create the strongest threatening impact;
  - (6) benefit of smoking cessation: emphasizing various aspects of benefits including prevention of diseases; protecting family members and children; and saving money and building family happiness; and
  - (7) simple messages to encourage smokers to quit and refer the smokers to call 1833183.
- (2) *Smoking cessation services referral leaflet and active referral (Group A only):*  
Smoking cessation substantially increase quit rate and WHO has urged to promote smoking cessation services (World Health Organization, 2015). Smoking cessation services in Hong Kong are under-used with more than half (60.9%) adult daily smokers who had never used smoking cessation services

(Census & Statistics Department, 2013). Among these smokers only 9.6% were willing to use the services. Existing services mostly require self-initiation to seek the services but smokers general lack the will power of initiation. Active referral will help overcome the barriers of self-initiation. There is preliminary evidence that active referral of smokers to smoking cessation hotline services may increase likelihood of smoking abstinence at 12-month follow-up compared with no active referrals (Borland, 2008).

Smokers in this group will receive a strong referral leaflet and active assistance in booking smoking cessation services.

#### Referral leaflet

The current “Smoking Cessation Services” card developed by the Tobacco Control Office only describes the content of smoking cessation hotline (1833183) without details of other services and motivation messages. We shall design a more attractive and empowering new 2-side color printed A4 strong referral leaflet to motivate and assist the smokers to use the smoking cessation services. This will include 3 major parts:

- (1) An introduction on various existing smoking cessation services;
- (2) Practical information for facilitating accessing to the services including:
  - Cessation hotline (1833183): services content
  - Smoking cessation clinics: services content, address, hotline number and operation hours
  - Online smoking cessation services and URLs / 3D barcodes
- (3) Motivation information and messages to encourage use by emphasizing that the services are managed by experienced professional smoking cessation nurses and physicians, various cessation methods available to suit individual preferences (counselling, nicotine replacement therapy, cessation medication, acupuncture); free of charge, easy access and intensive support and follow-up; proven effectiveness in Hong Kong and elsewhere; many Hong Kong smokers have used the services and succeeded and some personal testimonies on successful local quitters by using the services.
- (4) Strong and supporting messages or slogans (based on COSH and others)

Active referral

We will introduce the smokers to various smoking cessation services in Hong Kong (using the referral leaflet) and motivate the smokers to use the smoking cessation services. Field research staff will assist the smokers to book their favorite/most convenient or preferred type of services: Department of Health hotline counseling; Tung Wah Integrated Smoking Cessation Centre services; Hospital Authority Clinics in 18 districts; and Pok Oi Hospital Chinese Medicine smoking cessation services. If the smokers are not ready to book the services onsite, we will encourage the smokers to set a day for booking within 7 days of baseline survey. We will call back the smokers in the designated day to assist booking for the services. Research staff will monitor smoking cessation services use of the participants at each follow-up (1, 2, 3, 6 months) and assist participants to book or re-book the appointments if necessary at 1, 2 and 3 months follow-ups. We shall liaise with the existing service providers and seek their assistance in helping our smokers as soon as possible.

Control Group (Group C)

Participants who are randomly allocated to the control group will receive minimal intervention, including: (1) the 12-page smoking cessation booklet (provided by COSH); (2) very brief, minimal and general smoking cessation advice include: “Please quit smoking for improving health and save money”, “Please refer to the booklet for the details about smoking cessation” and “Please call us if you have any enquiry”.

Table 1. Summary of intervention in 3 groups

	<b>Intervention (Group A)</b>	<b>Intervention (Group B)</b>	<b>Control (Group C)</b>
<b>COSH booklet + general advices</b>			✓
<b>Brief leaflet + AWARD intervention</b>	✓	✓	
<b>Referral leaflet + active referral</b>	✓		

**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 QW Contest and will receive the same monetary incentive if he/she pass the biochemical validations at 3- and 6- month. This group will be analyzed separately from the RCT.

**Follow-up**

All participants in RCT will be followed-up after 1, 2, 3 and 6 months by telephone interview to assess their smoking status and quitting progress. Details of interventions at follow-ups are:

- 1) Intervention group A: brief AWARD intervention, enquiry and reinforce the use of smoking cessation services, assist in booking/re-booking smoking cessation services
- 2) Intervention group B: brief AWARD intervention
- 3) Control group C: Survey only, no intervention

Maximum 7 calls and 1 voice message at the end will be made to an unreachable participant for a follow-up. Self-reported quitters (no smoking in past 7 days) at 3- and 6- month follow-up will be validated with biochemical and non-biochemical methods. The former validation includes the measurement of the quitter's exhaled CO level and saliva cotinine level conducted by HKU. The latter 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 QW.

**8.3 Randomization**

By cluster randomization, all participants recruited in a particular day (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 days into the three RCT groups to ensure the number of recruitment activities for the three RCT groups is similar. One investigator will randomly generate blocks, with each block size equal to 3, 6 or 9, containing a random permutation of the 3 RCT groups. 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 to Appendix 5).

##### ***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 2014. 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 8); (2) a set of follow-up questionnaires 1 month & 2 month booster interventions (Appendix 9 to Appendix 14); and (3) a set of follow-up questionnaires for 3 & 6 months (Appendix 15 to Appendix 20) 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 65 recruitment sessions to be evaluated.

### ***Phase III***

#### ***Quit to Win***

The sample size calculation is based on the primary outcome of self-reported 7-day point prevalence quit rate at the 3-month follow-up. Based on the previous Quit to Win Contests, the 3-month quit rate for the control group was approximately 10.0% (previous QTW projects). According to the RCT of active referral conducted by Borland et al. (2008), the rate ratio of quit rate for the intervention and control group was 1.92 (Intervention group: 12.3%, Control group: 6.9%). Therefore, the effect size for the intervention in the present study is set conservatively at 1.60. The quit rate for Group A+B and Group C is 16.0% and 10.0%, respectively. To detect a significant difference of quit rate between Group A+B and Group C with a power of 80% and 5% significant level, we will need 284 subjects per group. We estimate that 65 recruitment activities will be organized. Assuming an intra-cluster correlation coefficient as 0.005 and a retention rate of 70% at the 3-month follow-up (Eldridge, Ashby, & Kerry, 2006; Sally & Bland, 1998), the total sample size taking into account the intra-cluster correlation within each recruitment day and attrition is 1,291 (i.e.  $1291 = 284 \times 3 \text{ Groups} \times 1.06 \text{ effect size} \times 70\% \text{ retention rate}$ ).

#### ***8.6 Statistical Analysis***

Data will be entered into SPSS for Windows (version 20). 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 of 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 failure to achieve any cessation outcome. Complete case analysis will also be conducted after excluding participants with missing data.

**8.7 Chronological outline of research plan**

Timeline	2015									2016		
	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
<u>Preparation</u>												
1. Preparation of IRB, training material, smoking cessation materials and research instruments	■	■										
<u>Intervention</u>												
Phase I												
2. Training of smoking cessation counsellors and logistics arrangement		■	■									
3. Evaluation survey (Pre-training, immediate post-training)		■	■									
4. Data analysis and report preparation for the Smoke-free Training				■	■							
Phase II												
5. Recruitment of subjects at the districts & NGOs			■	■	■	■						
6. 1 month telephone follow-up				■	■	■	■					
7. 2 month telephone follow-up					■	■	■	■				
8. 3 months telephone follow-up and biochemical validation of quitters						■	■	■	■	■		
9. 6 months telephone follow-up and biochemical validation of quitters								■	■	■	■	■
<u>Analysis and write up</u>												
10. Data collection and cleaning			■	■	■	■	■	■	■	■	■	■
11. Data analysis						■	■	■	■	■	■	■
12. Report preparation and result dissemination							■	■	■	■	■	■

**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 in 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 month 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**

Research Fund: The Hong Kong Council on Smoking and Health

Indemnity and compensation: Nil.

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