BMJ Open

# Effect of active referral combined with a small financial incentive on smoking cessation: study protocol for a cluster-randomized controlled trial



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|---|---|
| Journal: | *BMJ Open* |
| Manuscript ID | bmjopen-2020-038351 |
| Article Type: | Protocol |
| Date Submitted by the Author: | 07-Mar-2020 |
| Complete List of Authors: | Weng, Xue; University of Hong Kong, School of Nursing<br>Wang, Man Ping; University of Hong Kong, School of Nursing<br>LI, Ho Cheung William; The University of Hong Kong<br>Cheung, Yee Tak Derek; The University of Hong Kong, School of Nursing<br>Lau, Ching Yin; The University of Hong Kong, School of Nursing<br>Kwong, Antonio Cho Shing ; Hong Kong Council on Smoking and Health<br>Lai, Vienna; Hong Kong Council on Smoking and Health<br>Chan, Sophia; The University of Hong Kong, School of Nursing<br>Lam, Tai Hing; The University of Hong Kong, School of Public Health |
| Keywords: | Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PUBLIC HEALTH, Clinical trials < THERAPEUTICS |
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# Effect of active referral combined with a small financial incentive on smoking cessation: study protocol for a cluster-randomized controlled trial

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**Word count:** 2797 (main text only)

## Abstract

### Introduction

Evidence-based smoking cessation treatments are effective but underutilized, accentuating the need for novel approaches to prompt the use. This trial investigates the effects of active referral plus financial incentives to use smoking cessation services on smoking abstinence among community smokers.

### Methods and analysis

This ongoing study is a two-arm, accessor-blinded, pragmatic, cluster randomized controlled trial with follow-ups at 1, 2, 3 and 6 months after randomization. We aim to enroll 1026 daily smokers from 68 community sites (cluster) in Hong Kong. All participants receive AWARD model-guided advice (Ask, Warn, Advise, Refer, Do-it-again) and a self-help booklet at baseline. Additionally, participants in the intervention group receive an offer of referral to smoking cessation services at baseline and a small financial incentive (HK$300 ≈ US$38) for encouraging to use any of the smoking cessation services within 3 months. The primary outcome is bio-verified abstinence (exhaled carbon monoxide < 4 ppm and salivary cotinine < 10 ng/mL) at 6 months. Secondary outcomes include bio-verified abstinence at 3 months, and smoking reduction rate, self-reported 7-day point prevalence of abstinence and the use of smoking cessation services at 3 and 6 months. Intention-to-treat and logistic regressions will be used for primary analysis.

### Ethics and dissemination

This protocol has been approved by the Institutional Review Board of the University of Hong Kong/ Hospital Authority Hong Kong West Cluster (IRB reference number: UW 18–318). The results of this trial will be submitted for publication in peer-reviewed journals and the key findings will be presented at national and international conferences.

### Trial registration

ClinicalTrials.gov, NCT03565796.


### Strengths and limitations of this study

- This is the first trial to examine the effectiveness of active referral plus financial incentives to increase the use of smoking cessation service in promoting abstinence in the community.
- Using proactive approach to recruit smokers from a broader, community-based population, who are mostly undetermined to quit.
- Using biochemically verified abstinence as the primary outcome to increase scientific rigor and decrease misreporting
- The findings of this trial may be less generalizable to other countries lacking accessible and affordable smoking cessation services.

**Introduction**

Smoking cessation counselling and medications are cost-effective in reducing tobacco-related morbidity and mortality [1-3]. Effective smoking cessation treatments are readily available, yet the service utilization are low as 70% of the world's population does not have access to cessation services [4]. Publicly funded services on smoking cessation is widely available in Hong Kong [5-7]; while very few daily smokers (2.4%) used existing effective treatments which are proven to be effective [8].

To increase the use of smoking cessation service, we designed sequential trials on active referral that proactively connects community smokers with smoking cessation service providers yielding promising results. Call-back referral (CBR) that assisting smokers to book their preferred service providers who called back smokers to arrange an appointment for smoking cessation treatment showed a significantly higher self-reported abstinence at 6 months than that of a control condition receiving AWARD model-guided advice (Ask, Warn, Advise, Refer, Do-it-again) (17.2% vs. 9.4%, $P = 0.001$) [9]. We sequentially proposed two approaches of active referral by different intensities: onsite referral (OSR) that assisted smokers to book preferred appointments with service providers during onsite recruitment and text messaging referral (TMR) that used mobile text messaging to promote the use of smoking cessation services. The two modified approaches resulted significantly higher self-reported abstinence at 6 months than AWARD model-guided advice (17.7% and 17.1%, vs. 12.0%; both $P < 0.050$) [10]. Active referral approaches were effective, but adherence was suboptimal as less than 27% used the smoking cessation service with the 6-month period after receiving active referrals (25.1% in OSR, 26.8% in CBR, 8.1% in TMR).

Financial incentives are external motivators and may increase intervention adherence and service attendance [11, 12]. Financial incentives by converging the costs of smoking cessation treatment increased service enrolment [13], medications use, the use of behavioral support [12], and service providers would offer them effective treatments to increase abstinence [12]. Our previous trial revealed that time mismatch and low interest is the main barriers of not using the smoking cessation service [9]. Despite smoking cessation services in Hong Kong are mostly free or at minimal charges, proactive models that offer referral assistance with a small financial incentive may increase smoker's motivation to overcome perceived barriers. However, incentive-based trials to increase both service use and abstinence showed mixed findings. Our previous community-based trial suggested that offering a cash incentive (HK$500 ≈ US$64) for successful quitting increased quit attempt, but it did not increase service use and abstinence [14]. A recent clinical trial (n = 173) in Hong Kong found offering service fee reimbursement (HK$50 ≈ US$6.4) increased service booking but not the service use and abstinence [15]. Different from previous trials, we are more interested in offering financial incentives when proactively promoting smoking cessation services to smokers in the community.

In this trial, we aim to investigate whether a small financial incentive (HK$300 ≈ US$38) combined with an active referral (CBR model) and brief (e.g. AWARD) model-guided advice in the community would increase biochemically validated abstinence at 6 months. We anticipate that the financial incentive would enhance their motivation of using the service.

## Methods

*Study design*

This is a two-arm, accessor-blinded, pragmatic, cluster randomized controlled trial nested within the 9th "Quit to Win" (QTW) Smoke-free Community Campaign. The QTW campaign [9, 10, 14, 16-19] is a community-based smoking cessation contest organized by the Hong Kong Council on Smoking and Health annually. Figure 1 shows the CONSORT flow diagram.

(Insert Figure 1 here)

*Recruitment and participants*

Similar to previous QTW campaign [9, 10, 14, 16-19], recruitment activities (n = 68) are organized in the community (e.g., shopping malls and public areas) of all 18 Hong Kong districts. Using the "foot-in-the-door" approach [20], trained smoking cessation advisors proactively approach smokers, explain the QTW contest, and invite for participation. Smokers are informed that the intervention involve a baseline assessment on their exhaled carbon monoxide level, brief questions on past smoking behaviors (baseline questionnaire) and further phone interviews (follow-up questionnaires at 1, 2, 3 and 6 months). Eligible participants are Hong Kong resident aged ≥ 18 years, currently smoking ≥ 1 cigarette per day during the past 3 months with exhaled carbon monoxide level ≥ 4 part per million (ppm), able to communicate in Cantonese or read Chinese, and motivated to quit or reduce smoking. Exclusion criteria are either having physical or cognitive difficulties in communication or currently participating in other smoking cessation programs.

*Randomization and blinding*

Randomization occurs at the community level. Participants within the same recruitment session are cluster-randomized in a 1:1 ratio to intervention or control groups. The randomization sequence (random permuted blocks of 2, 4 and 6) is generated using a web-based system (www.sealedenvelope.com). One investigator who is not involved in participant enrolment implements the allocation sequence and notifies the recruitment staff one day prior to the recruitment session. Because of the nature of the intervention, recruitment staff delivering the interventions cannot be blinded to the participant allocation and participants are not informed about the treatment in the other group. Outcome assessors and statistical analysts are blinded from the group allocation.

*Sample size*

Our previous trial showed the biochemically validated abstinence at 6 month was about 9.0% in the CBR group and 5% in the control group [9]. Full financial coverage on the costs of smoking cessation treatment had an effect size of 1.77 on abstinence when compared to no incentive in the healthcare setting [12]. We conservatively estimate an effect size of 1.27 for a small financial incentive to use smoking cessation services combining with the CBR in a community-based trial. Validated abstinence at 6 months is therefore expected to be 11.43% in the intervention group and 5% in the control group. Using G*Power software to achieve the 95% confidence level (alpha = 0.05) and 80% power (1-beta = 0.80), the required sample size is 286

per group. Assuming an intra-cluster correlation coefficient as 0.015 [17] with an average cluster size of 18 and a retention rate of 70% at the 6-month follow-up, the overall sample size of the study should be 1026 for the 2 groups (286 x 2 groups x 1.255 design effect / 70% retention rate).

*Treatment integrity*

Smoking cessation advisors (n = 99) are university students or volunteers of non-governmental organizations with experience on health promotion. They attend a full-day workshop (6-hour) before participant recruitment. The contents of the workshop include (1) overview of QTW contest, intervention contents (e.g., AWARD model-guided advice, active referral, and financial incentives), and recruitment demonstration (e.g., foot-in-the-door approach, test on exhaled carbon monoxide); (2) knowledge on smoking harms and quitting benefits (3) smoking cessation methods and counseling techniques; and (4) sharing from successful quitters. We conduct a pre- and post-test to assess advisors' knowledge, attitudes and practice on smoking cessation.

An experienced research staff provide supervision and assistance at each recruitment session. To ensure the accurate delivery of the intervention, all advisors are instructed to follow a standardized recruitment script and fill an adherence checklist outlining each of the intervention components. Eligible smokers who decline to participant are asked to provide a reason for refusing.

*Interventions*

*AWARD model-guided advice*

Well-trained smoking cessation advisors deliver AWARD model-guided advice to both intervention and control groups at onsite. AWARD advice lasts 3-5 minutes and includes 5 steps: *A*sk about the smoking history, (2) *W*arn smokers about the harms of smoking (using the test result of exhaled carbon monoxide level), (3) *A*dvise to quit or reduce smoking as soon as possible, (4) *R*efer to existing cessation services, and (5) *D*o it again if fails to quit. Participants also receive a 12-page generic self-help booklet used in our previous trials [9, 10, 14, 16-19]**.** The contents of the self-help booklet include smoking harms, benefits and methods of quitting, relapse prevention and existing smoking cessation services.

*Call-back referral (CBR) to smoking cessation services*

Participants in the intervention group receive intensified interventions on *Refer* and *Do it again*, which is more tailored and personalized than that of the control group.

At baseline, smoking cessation advisors assist participants to choose preferred services with a 3-fold pocket-sized referral card. A referral card outlines the existing five major smoking cessation services in Hong Kong, together with available therapies, working time and locations of branches (Appendix 1). For participants agreed to be referred, research staff email participants' name and telephone numbers to the chosen service providers within 1 week (*Refer*). The providers call back participants within 1-2 weeks and arrange an appointment for phone counseling or smoking cessation clinic visit afterwards. Research staff monitor the use

of smoking cessation services at each follow-up (1, 2, 3 and 6 months), encourage and assist participants to book or re-book the services if they fail to quit (*Do it again*).

*Incentives for promoting smoking cessation service use*

Participants in the intervention group are informed to receive a small financial incentive for using any of the smoking cessation services within 3 months. The incentive is a HK$300 (~ US$38) coupon to a widespread local supermarket. Participants who agree to book the smoking cessation services sign two copies of referral forms stating that they are willing to use the selected services (Appendix 2). Participants keep one copy for information and reminding; research staff retain one copy for recording. The conditions for the incentive also outline in the referral form. The incentive has no restrictions on the types of smoking cessation treatments use, which include pharmacotherapy (e.g., nicotine replacement therapy), behavioral support (e.g., face to face/ phone counselling, group therapy) or a combination thereof. Post-payment financial incentives are distributed to participants in the intervention group who self-reported of using the smoking cessation service at 1-, 2-, and 3-month follow-ups. The mailing procedure is standardized. The incentive is sent by a registered mail with an accompanying cover letter explaining the purpose of the incentive.

*Procedures*

Participants are assessed at baseline, 1, 2, 3 and 6 months after treatment initiation (Table 1). The baseline questionnaire measures participants' smoking behavior (e.g., daily cigarette consumption, the age of starting smoking, the time of having the first cigarette upon waking up in the morning, attempts to quit or reduce, methods used in past quitting attempts), intention to quit, and perceived self-efficacy of quitting (importance, difficulties and confidence) and sociodemographic characteristics. Participants are informed that they may withdraw from the study at any time without giving a reason. Participants are followed up at 1, 2, 3 and 6 months by trained smoking cessation counsellors with a maximum of 7 telephone calls at different times. Qualitative evaluations on a subsample of participants receiving the intervention will be done after the end of the study.

(Insert Table 1 here)

*Outcomes*

The primary outcome is bio-verified abstinence at 6 months after treatment initiation confirmed by exhaled carbon monoxide result of < 4 ppm and salivary cotinine level of < 10 ng/mL [21, 22]. Exhaled carbon monoxide samples are collected by research staff with a piCO™ Smokerlyzer® (Bedfont Scientific Ltd) and saliva cotinine samples are measured by a NicAlert® test strip (Nymos Pharmaceutical Corporation). Secondary outcomes are bio-verified abstinence at 3 months (end of treatment); self-reported 7-day point-prevalence abstinence; smoking reduction, defined by at least 50% reduction in daily cigarette consumption compared with that at baseline; and cumulative use of smoking cessation service, defined by using at least one treatment session (e.g., face to face/ phone counseling, nicotine replacement therapy, acupuncture) at 1, 2, 3 and 6 months.

*Statistical analyses*

Data will be analyzed according to intention-to-treat (ITT) principles. Chi-squared tests and *t* tests will be used to compare baseline characteristics of participants to assess balance between the two groups. The intervention effect on primary and secondary outcomes will be analyzed by using logistic regression with and without adjustment for imbalanced baseline characteristics. Generalized Estimating Equation (GEE) models will be used to adjust the potential clustering effect of recruitment sessions. The analysis of variance method will be used to calculate intra-cluster correlation for abstinence outcomes. Sensitivity to missing data will be examined using multiple imputation by chained equations assuming the data will be missing at random [23].

We will also examine the association between the intervention adherence (e.g., used the smoking cessation services, received the financial incentive) with the primary outcome. Intervention effect by subgroups will be assessed respectively, including age group, gender, education level, household income, previous quit attempt, cigarette dependence and intention to quit. We will combine the results of our previous trials [9, 10] for comparing different levels of active referral on the primary outcome. Statistical analyses will be conducted using Stata v15.1 (Stata Corp, Texas, USA).

Individual semi-structured interviews will be conducted for process evaluation. We will conduct up to 20 interviews (or until data saturation is reached) with participants in the intervention group after 6-month follow-up. Participants will be sampled purposively based on sociodemographic characteristics, smoking status and intervention adherence. All interviews will be audio-recorded and transcribed verbatim. The transcripts will be analyzed following the principles of thematic analysis [24].

**Ethics and dissemination**

The trial is conducted and reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement for clinical trials reporting, and has been registered at ClinialTrials.gov (registration number: NCT03565796). Ethical approval has been granted by the Institutional Review Board of the University of Hong Kong/ Hospital Authority Hong Kong West Cluster (IRB reference number: UW 18–318). Authorship will be determined in accordance with the International Committee of Medical Journal Editors (ICMJE) guidelines. Findings will be published in peer-reviewed journals and presented at local, national and international conferences to publicize and explain the research to key audiences.

**Discussion**

To the best of our knowledge, this is the first trial using active referral plus financial incentives as a model to increase abstinence in the community setting. If the intervention is found to be effective, this would be valuable for decision-makers to prioritize financial support to encourage the use of smoking cessation services, which would increase smoking abstinence ultimately.

This trial is innovative for 3 main reasons. First, as one of the sequential interventions on active referral, our trial combining an active referral with financial incentives has important

implications on research and practice. We intensify CBR model by offering incentives to service use, which is easy to implement into practice. Compared to OSR and TMR models, CBR plus incentives shifts the burden of onsite referral and uses money (instead of low-intensity text messaging) to motive service use. Our findings on the effectiveness of different models of active referral provide insight for the development of the high-quality adaptive trials [25] on smoking cessation. Second, despite a handful of trials used incentives to reward successful cessation [26], we provide financial incentives to increase service use. Strategies to increase the adherence of smoking cessation treatment are important but understudied [27]. Our findings will provide the evidence of incentives to increase motivation of service use. Third, the incentive amount of our trial (~US$38) is much smaller than that of financial-based trials (ranges from US$45 to US$1185) included in a recent meta-analysis [26], while the findings showed the amount of financial incentive had no impact on cessation outcomes. Incentives in a larger amount probably cannot be sustained in real-world practice. Small incentive may be adequate for behavioral change if using an effective approach to deliver the potential health benefits [28].

There are also a number of strengths to this trial. We use proactive approach to recruit smokers from a broader, community-based population, who are not in the clinical setting and are mostly undetermined to quit. The brief intervention mode for promoting smoking cessation is flexible, feasible and low in cost. And we use biochemically verified abstinence (i.e., exhaled carbon monoxide and salivary cotinine tests) as the primary outcome to increase scientific rigor and decrease misreporting [29].

This trial also has several potential limitations. First, we cannot evaluate the relative contribution of each intervention component (brief advice, active referral, financial incentives) in the current trial. We are more interested in the combined effect of the multicomponent trial which targets several barriers with maintaining abstinence. Second, we are unable to assess the long-term effect of the intervention (e.g., 12 months) because of the budget constraint. Nevertheless, 4 consecutive follow-ups (1, 2, 3 and 6 months) allow us to keep track of the cessation outcomes, service use and changes in cessation-related factors in the short term (≤ 6 months). Third, as women's smoking prevalence rates are relatively low in Hong Kong [8], we expect a higher proportion of male participants compared to female participants. This may limit the generalizability of our findings to other settings where female smoking is more prevailing (e.g., western countries). Fourth, our findings may be less generalizable to other countries lacking accessible and affordable smoking cessation services.

**Trial status**

This is protocol version 2. Recruitment started on June 2018 and is ongoing. All recruitment, follow-up and data collection will be expected to be completed in June 2020.

**Acknowledgements**

The authors would like to thank the participants, helpers from the universities and non-governmental organizations and research assistants who involved in this study.

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**Contributions**: MPW, XW and THL participated in study concept and design. MPW, XW and CYL participated in conducting the study. XW drafted the manuscript. MPW, HCL, YTC, CYL, CSK, WYL and SCC provided critical comments. All authors have read and approved the final manuscript.

**Funding**: This study is funded by the Hong Kong Council on Smoking and Health. The funders have no role in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript.

**Disclaimer:** The funding source do not have any role in the study design, data collection, analysis and interpretation, writing of the report or the decision to submit the paper for publication.

**Competing interests:** None declared.

**Ethics approval:** The study has been approved by the research ethics committee of the University of Hong Kong and the Hong Kong West Cluster of the Hospital Authority (IRB reference no.: UW18–318).

**Patient consent for publication:** Not required.

**Provenance and peer review:** Not commissioned; externally peer reviewed.

**Data availability statement:** Data are available on reasonable request.

**Supplementary information**

Appendix 1 Referral card

Appendix 2 Referral form

Figure 1. CONSORT flow diagram

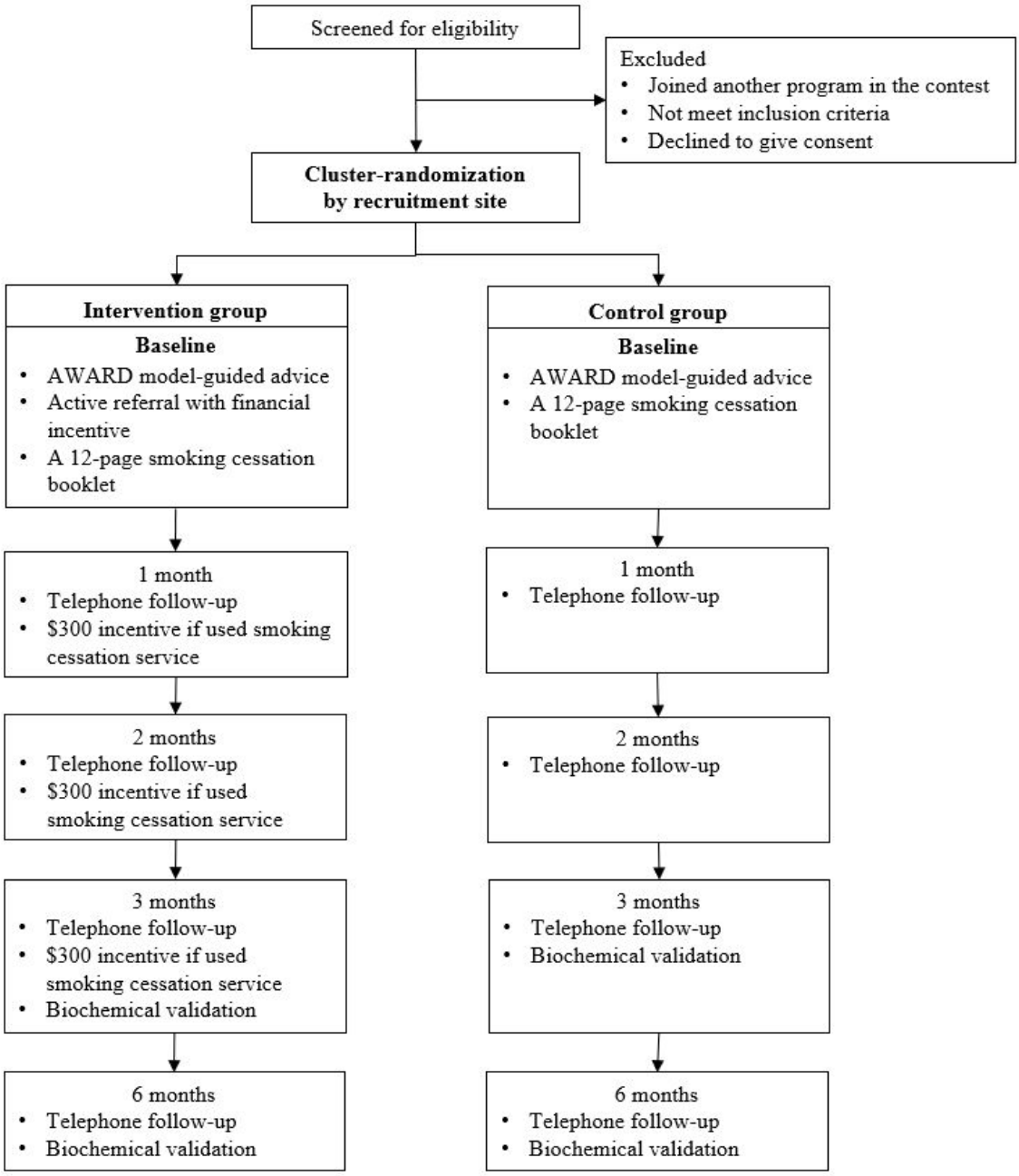

Table 1. Schedule of baseline and follow-up assessments

| Assessments | Time-point | | | | |
|---|---|---|---|---|---|
| | Baseline | 1 Month | 2 Months | 3 Months | 6 Months |
| Informed consent | × | | | | |
| Eligibility screen | × | | | | |
| Randomization | × | | | | |
| Intervention/control initiation | × | | | | |
| Sociodemographic characteristics [a] | × | | | | |
| Smoking behavior | × | × | × | × | × |
| Quit attempts | × | × | × | × | × |
| Use of smoking cessation services | × | × | × | × | × |
| Self-efficacy of quitting | × | | | × | × |
| Biochemically validated abstinence | | | | × | × |
| Qualitative evaluation | | | | | × |

[a] Sociodemographic characteristics include age, sex, education level, number of children, occupation, marital status, and household income.

Appendix 1 Referral card

Appendix 2 Referral form

Referral consent form - QTW2018 (Last Update: 30/05/2018, version 1)

香港吸煙與健康委員會
HONG KONG COUNCIL ON SMOKING AND HEALTH

## 第九屆「戒煙大贏家」無煙社區計劃
## 戒煙承諾書（舉辦機構存檔）

香港大學
護理學院
公共衞生學院

☑ 我，_____（姓名），承諾於 2018 年___月___日起，決心戒煙，並同意獲轉介至下列戒煙服務以作跟進。

- ☐ 1. 東華三院綜合戒煙服務中心
- ☐ 2. 博愛醫院中醫針灸戒煙服務
- ☐ 3. 衞生署戒煙輔導服務
- ☐ 4. 醫院管理局戒煙輔導服務
- ☐ 5. 香港大學青少年戒煙熱線

**三個月內**參與最少一次戒煙輔導，核實後可獲超市現金券$300。

參加者聲明：

- 本人明白資料將由香港大學護理學院及公共衞生學院轉交至上述之戒煙熱線作跟進之用。
- 本人明白於三個月內參與最少一次由上述機構提供的戒煙輔導後可獲得三百元超市現金券。
- 本人明白香港大學將在本人簽署承諾書後的六個月內跟進本人之戒煙情況。
- 本人確保承諾書上之資料皆屬真實及正確。

姓名：_____年齡：_____歲　　一氧化碳讀數：_____ppm

性別：☐男　☐女　　聯絡電話：_____

簽名：_____　　日期：_____

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香港吸煙與健康委員會
HONG KONG COUNCIL ON SMOKING AND HEALTH

## 第九屆「戒煙大贏家」無煙社區計劃
## 戒煙承諾書（參加者保存）

香港大學
護理學院
公共衞生學院

☑ 我承諾於 2018 年___月___日起，決心戒煙，並同意獲轉介至下列戒煙服務以作跟進。

- ☐ 1. 東華三院綜合戒煙服務中心
- ☐ 2. 博愛醫院中醫針灸戒煙服務
- ☐ 3. 衞生署戒煙輔導服務
- ☐ 4. 醫院管理局戒煙輔導服務
- ☐ 5. 香港大學青少年戒煙熱線

**三個月內**參與最少一次戒煙輔導，核實後可獲超市現金券$300。

參加者聲明：

- 本人明白資料將由香港大學護理學院及公共衞生學院轉交至上述之戒煙熱線作跟進之用。
- 本人明白於三個月內參與最少一次由上述機構提供的戒煙輔導後可獲得三百元超市現金券。
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- 本人確保承諾書上之資料皆屬真實及正確。

一氧化碳讀數：_____ppm

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SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

| Section/item | Item No | Description | Page Number on which item is reported |
|---|---|---|---|
| **Administrative information** | | | |
| Title | 1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | 1 |
| Trial registration | 2a | Trial identifier and registry name. If not yet registered, name of intended registry | 2 |
| | 2b | All items from the World Health Organization Trial Registration Data Set | NA |
| Protocol version | 3 | Date and version identifier | 8 |
| Funding | 4 | Sources and types of financial, material, and other support | 11 |
| Roles and responsibilities | 5a | Names, affiliations, and roles of protocol contributors | 2, 11 |
| | 5b | Name and contact information for the trial sponsor | 11 |
| | 5c | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities | 11 |
| | 5d | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) | NA |

| | | | |
|---|---|---|---|
| **Introduction** | | | |
| Background and rationale | 6a | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention | 3 |
| | 6b | Explanation for choice of comparators | NA |
| Objectives | 7 | Specific objectives or hypotheses | 3 |
| Trial design | 8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) | 4 |
| **Methods: Participants, interventions, and outcomes** | | | |
| Study setting | 9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained | 4 |
| Eligibility criteria | 10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) | 4 |
| Interventions | 11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | 5-6 |
| | 11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) | NA |
| | 11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) | 5-6 |

| | | | |
|---|---|---|---|
| | 11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | NA |
| Outcomes | 12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended | 6-7 |
| Participant timeline | 13 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) | 6, 13 |
| Sample size | 14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations | 4-5 |
| Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size | 4-6 |
| **Methods: Assignment of interventions (for controlled trials)** | | | |
| Allocation: | | | |
| Sequence generation | 16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | 4 |

| | | | |
|---|---|---|---|
| Allocation concealment mechanism | 16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned | 4 |
| Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | 4 |
| Blinding (masking) | 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | 4 |
| | 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | 4 |
| **Methods: Data collection, management, and analysis** | | | |
| Data collection methods | 18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol | 6-7 |
| | 18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols | 6 |
| Data management | 19 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol | 7 |

| | | | |
|---|---|---|---|
| Statistical methods | 20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol | 7 |
| | 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | 7 |
| | 20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) | 7 |
| **Methods: Monitoring** | | | |
| Data monitoring | 21a | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed | 4, 11 |
| | 21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial | NA |
| Harms | 22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct | NA |
| Auditing | 23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | NA |
| **Ethics and dissemination** | | | |
| Research ethics approval | 24 | Plans for seeking research ethics committee/institutional review board (REC/IRB) approval | 7 |

| | | | |
|---|---|---|---|
| Protocol amendments | 25 | Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) | NA |
| Consent or assent | 26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | 11 |
| | 26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | 6, Appendix 2 |
| Confidentiality | 27 | How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial | 4 |
| Declaration of interests | 28 | Financial and other competing interests for principal investigators for the overall trial and each study site | 11 |
| Access to data | 29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | Any data required to support the protocol can be supplied on request. |
| Ancillary and post-trial care | 30 | Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation | Active referral of smoking cessation service will continue to be available post trial.<br>There is no anticipated harm and compensation for trial participation. |
| Dissemination policy | 31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions | 7 |

| | | | |
|---|---|---|---|
| | 31b | Authorship eligibility guidelines and any intended use of professional writers | 11 |
| | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | The datasets analysed during the current study are available from the corresponding author on reasonable request. |
| **Appendices** | | | |
| Informed consent materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates | |
| Biological specimens | 33 | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable | NA |

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

# Effects of active referral combined with a small financial incentive on smoking cessation: study protocol for a cluster-randomized controlled trial



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| Journal: | *BMJ Open* |
| Manuscript ID | bmjopen-2020-038351.R1 |
| Article Type: | Protocol |
| Date Submitted by the Author: | 17-Jun-2020 |
| Complete List of Authors: | Weng, Xue; University of Hong Kong, School of Nursing<br>Wang, Man Ping; University of Hong Kong, School of Nursing<br>LI, Ho Cheung William; University of Hong Kong<br>Cheung, Yee Tak Derek; University of Hong Kong, School of Nursing<br>Lau, Ching Yin; University of Hong Kong, School of Nursing<br>Kwong, Antonio Cho Shing ; Hong Kong Council on Smoking and Health<br>Lai, Vienna; Hong Kong Council on Smoking and Health<br>Chan, Sophia; University of Hong Kong, School of Nursing<br>Lam, Tai Hing; University of Hong Kong, School of Public Health |
| Primary Subject Heading: | Smoking and tobacco |
| Secondary Subject Heading: | Health services research, Public health |
| Keywords: | Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PUBLIC HEALTH, Clinical trials < THERAPEUTICS, PREVENTIVE MEDICINE |
| | |

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# Effects of active referral combined with a small financial incentive on smoking cessation: study protocol for a cluster-randomized controlled trial

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**Word count:** 2893 (main text only)

## Abstract

### Introduction

Evidence-based smoking cessation treatments are effective but underutilized, accentuating the need for novel approaches to increase use. This trial investigates the effects of active referral combined with a financial incentive to use smoking cessation services on smoking abstinence among community smokers.

### Methods and analysis

This ongoing study is a two-arm, assessor-blinded, pragmatic, cluster randomized controlled trial with follow-ups at 1, 2, 3 and 6 months after randomization. We aim to enroll 1026 daily smokers from 70 community sites (clusters) in Hong Kong. All participants receive AWARD (Ask, Warn, Advise, Refer, Do-it-again) guided advice and a self-help booklet at baseline. Additionally, participants in the intervention group receive an offer of referral to smoking cessation services at baseline and a small financial incentive (HK$300 ≈ US$38) contingent upon using any of such services within 3 months. The primary outcomes are bio-verified abstinence [exhaled carbon monoxide < 4 parts per million (ppm), and salivary cotinine < 10 ng/mL] at 3 and 6 months. Secondary outcomes include self-reported 7-day point prevalence of abstinence, smoking reduction rate, and the use of smoking cessation services at 3 and 6 months. An intention-to-treat approach and logistic regression will be used in primary analyses.

### Ethics and dissemination

This protocol has been approved by the Institutional Review Board of the University of Hong Kong/Hospital Authority Hong Kong West Cluster (IRB reference number: UW 18–318). The results of this trial will be submitted for publication in peer-reviewed journals, and the key findings will be presented at national and international conferences.

### Trial registration

ClinicalTrials.gov, NCT03565796.


### Strengths and limitations of this study

- This trial examines the effectiveness of active referral combined with a financial incentive to increase the use of smoking cessation services in promoting abstinence in the community.
- A proactive approach is used to recruit smokers from a broader, community-based population, who are mostly undetermined to quit in the short term.
- Using biochemically verified abstinence as the primary outcome increases scientific rigor and decreases misreporting.
- The findings of this trial may be less generalizable to other countries lacking accessible and affordable smoking cessation services.

## Introduction

Smoking cessation counselling and medications are cost-effective in reducing tobacco-related morbidity and mortality [1-3]. Effective smoking cessation treatments are readily available, yet service utilization is low, as 70% of the world's population does not have access to cessation services [4]. Publicly funded services for smoking cessation are widely available in Hong Kong [5-7]; however, very few daily smokers (2.7%) use existing treatments that are proven to be effective [8].

To increase the use of smoking cessation services, we designed sequential trials of active referral approaches that proactively connect community smokers with smoking cessation service providers, yielding promising results. Call-back referral (CBR), which assists smokers to book their preferred service provider by calling them back to arrange an appointment for smoking cessation treatment, showed a significantly higher bio-verified abstinence at 6 months than did a control condition in which participants received advice according to the AWARD (Ask, Warn, Advise, Refer, Do-it-again) model [9.0% vs. 5.0%; odds ratio (OR) = 1.85, 95% confidence interval (CI) = 1.06-3.23, $P$ = 0.04] [9]. We sequentially proposed two active referral approaches with different intensities: onsite referral (OSR), which assists smokers to book appointments with preferred service providers during onsite recruitment, and text messaging referral (TMR), which uses mobile text messaging to promote the use of smoking cessation services. The two modified approaches showed significantly higher bio-verified abstinence at 6 months than AWARD-guided advice (7.6% and 7.8%, vs. 3.9%; OR for OSR vs. control = 2.02, 95% CI = 1.07-3.81; OR for TMR vs. control = 2.07, 95% CI = 1.10-3.92; both $P < 0.050$) [10]. Active referral approaches were effective but adherence was suboptimal, as less than 27% of participants used the smoking cessation service within the 6-month period after receiving active referrals (25.1% in OSR, 26.8% in CBR, and 8.1% in TMR).

Financial incentives are external motivators and may increase intervention adherence and service attendance [11, 12]. Financial incentives increased service enrolment [13] and use of tobacco dependence treatment (medications, nicotine replacement therapies, and counselling) [14-17], and service providers have offered them effective treatments to increase abstinence [12]. Our previous trial revealed that time constraints and low interest are the main barriers to use smoking cessation services [9]. Although smoking cessation services in Hong Kong are mostly free or charge minimal fees, proactive models that offer referral assistance with a small financial incentive may increase smokers' motivation to overcome perceived barriers. However, incentive-based trials to increase both service use and abstinence have shown mixed findings. Our previous community-based trial suggested that offering a cash incentive (HK$500 ≈ US$64) for successful quitting increased quit attempts but did not increase service use or abstinence [18]. Recent trials have shown that referral assistance (e.g., proactive calls, patient navigation) combined with a financial incentive increased treatment engagement and abstinence among smokers of low socioeconomic status (SES) [14, 19, 20]. Based on previous trials, it seems more effective to offer a financial incentive to increase the use of smoking cessation services among population-based, community-recruited smokers.

In this trial, we aim to investigate whether a small financial incentive (HK$300 ≈ US$38)

combined with active referral (CBR model) and brief (e.g. AWARD-guided) advice in the community will increase bio-verified abstinence at 6 months. We anticipate that the financial incentive will enhance smokers' motivation to use the services.

## Methods and analysis

*Study design*

This is a two-arm, assessor-blinded, pragmatic, cluster randomized controlled trial nested within the 9th "Quit to Win" (QTW) Smoke-Free Community Campaign. The QTW campaign [9, 10, 18, 21-24] is a community-based smoking cessation contest organized annually by the Hong Kong Council on Smoking and Health. Figure 1 shows the Consolidated Standards of Reporting Trials (CONSORT) flow diagram.

(Insert Figure 1 here)

*Recruitment and participants*

Similar to the previous QTW campaign [9, 10, 18, 21-24], recruitment activities are conducted in community sites (n = 70) (e.g., shopping malls and public areas) of all 18 Hong Kong districts. Using the "foot-in-the-door" approach [25], trained smoking cessation advisors proactively approach smokers at smoking hotspots in the vicinity of recruitment booths, explain the QTW contest, and invite smokers to participate. Smokers are informed that the intervention involves a baseline assessment of their exhaled carbon monoxide level, brief questions on past smoking behaviors (baseline questionnaire), and further telephone interviews (follow-up questionnaires at 1, 2, 3, and 6 months) (Appendix 1). Eligible participants are Hong Kong residents aged ≥ 18 years, currently smoking ≥ 1 cigarette per day during the past 3 months, with an exhaled carbon monoxide level ≥ 4 ppm, able to communicate in Cantonese or read Chinese, and motivated to quit or reduce smoking. Exclusion criteria are either having physical or cognitive difficulties in communication or currently participating in other smoking cessation programs.

*Randomization and blinding*

Randomization occurs at the community level. Participants within the same recruitment session are cluster-randomized in a 1:1 ratio to the intervention or control group. The randomization sequence (random permuted blocks of 2, 4, and 6) is generated using a web-based system (www.sealedenvelope.com). One investigator who is not involved in participant enrolment implements the allocation sequence and notifies the recruitment staff 1 day prior to the recruitment session. Because of the nature of the intervention, the recruitment staff delivering the interventions cannot be blinded to participant allocation, but participants are not informed about the treatment in the other group. Outcome assessors and statistical analysts are blinded to the group allocation.

*Sample size*

Our previous trial showed that bio-verified abstinence at 6 months was about 9.0% in the CBR group and 5% in the control group [9]. Full financial coverage of the costs of smoking cessation treatment had an effect size of 1.77 on abstinence when compared with no incentive in a

healthcare setting [12]. We conservatively estimate an effect size of 1.27 for a small financial incentive to use smoking cessation services combined with CBR in a community-based trial. Validated abstinence at 6 months is therefore expected to be 11.43% in the intervention group and 5% in the control group. Using G*Power software, in order to achieve a 95% confidence level (alpha = 0.05) and 80% power (1-beta = 0.80), the required sample size was calculated to be 286 per group. Assuming an intra-cluster correlation coefficient of 0.015 [22] with an average cluster size of 18 and a retention rate of 70% at 6-month follow-up [9, 26], the overall sample size of the study should be 1026 for the 2 groups (286 × 2 groups × 1.255 design effect / 70% retention rate).

*Treatment integrity*

Smoking cessation advisors are recruited through university mass emails and advertising posters. They include university students (with an hourly rate of HK$66 ≈ US$8.5) and volunteers of non-governmental organizations. All smoking cessation advisors are required to attend a full-day workshop (6 hours) before participant recruitment. The contents of the workshop include: 1) overview of QTW contest, intervention contents (e.g., AWARD-guided advice, active referral, and financial incentives), and recruitment demonstration (e.g., foot-in-the-door approach, test on exhaled carbon monoxide); 2) knowledge of smoking harms and quitting benefits; 3) smoking cessation methods and counseling techniques; and 4) sharing of successful quitters. We conduct a pre- and post-test to assess advisors' knowledge, attitudes and practice regarding smoking cessation.

An experienced research staff provides supervision and assistance at each recruitment session. To ensure the accurate delivery of the intervention, all advisors are instructed to follow a standardized recruitment script and complete an adherence checklist outlining each of the intervention components. Eligible smokers who decline to participate are asked to provide a reason for refusing.

*Interventions*

*AWARD-guided advice*

Well-trained smoking cessation advisors deliver advice based on the AWARD model to both intervention and control groups on site. AWARD-guided advice lasts 3-5 minutes and includes five steps: 1)*A*sk about the smoking history, 2) *W*arn smokers about the harms of smoking (using the result of exhaled carbon monoxide level), 3) *A*dvise to quit or reduce smoking as soon as possible, 4) *R*efer to existing cessation services, and 5) *D*o it again if quitting fails. Participants also receive a 12-page generic self-help booklet used in our previous trials [9, 10, 18, 21-24]**.** The contents of the self-help booklet include smoking harms, benefits and methods of quitting, relapse prevention and existing smoking cessation services.

*Call-back referral (CBR) to smoking cessation services*

Participants in the intervention group receive intensified interventions based on *Refer* and *Do it again*, which is a more tailored and personalized approach than that of the control group.

At baseline, smoking cessation advisors assist participants to choose their preferred services using a three-fold pocket-sized referral card, which outlines the five major smoking cessation services in Hong Kong, together with available therapies, opening hours and branch locations (Appendix 2). For participants who agree to be referred, research staff email participants' name and telephone number to the chosen service providers within 1 week (*Refer*). The providers call back participants within 1-2 weeks and arrange an appointment for telephone counseling or a smoking cessation clinic visit. Research staff monitor the use of smoking cessation services at each follow-up (1, 2, 3, and 6 months), and encourage and assist participants to book or re-book the services if they fail to quit (*Do it again*).

*Incentives for promoting smoking cessation service use*

Participants in the intervention group are informed that they will receive a small financial incentive for using any of the smoking cessation services within 3 months. The incentive is a HK$300 (≈ US$38) coupon for a popular local supermarket. Participants who agree to book the smoking cessation services sign two copies of the referral form stating that they are willing to use the selected services (Appendix 3). Participants keep one copy as information/reminder; research staff retain one copy for the records. The conditions for receiving the incentive are also outlined in the referral form. The incentive has no restrictions on the type of smoking cessation treatments used, which include pharmacotherapy (e.g., nicotine replacement therapy), behavioral support (e.g., face-to-face/ phone counselling, group therapy), or a combination thereof. Post-payment financial incentives are distributed to participants in the intervention group who self-report using the smoking cessation service at 1-, 2-, and 3-month follow-ups. The mailing procedure is standardized. The incentive is sent by registered mail with an accompanying cover letter explaining the purpose of the incentive.

*Procedures*

Participants are assessed at baseline, 1, 2, 3, and 6 months after treatment initiation (Table 1). The baseline questionnaire measures participants' smoking behavior (e.g., daily cigarette consumption, age of starting smoking, time of first cigarette upon waking up in the morning, attempts to quit or reduce, methods used in past quit attempts), intention to quit, perceived self-efficacy regarding quitting (importance, difficulties and confidence), and sociodemographic characteristics. Participants are informed that they may withdraw from the study at any time without giving a reason. Participants are followed up at 1, 2, 3, and 6 months by trained smoking cessation counsellors with a maximum of 7 telephone calls at different times. Participants who self-report abstinence for more than 7 days at 3 and 6 months are invited for a biochemical validation. Exhaled carbon monoxide samples are collected by research staff with a piCO™ Smokerlyzer® (Bedfont Scientific Ltd), and saliva cotinine samples are measured using a NicAlert® test strip (Nymos Pharmaceutical Corporation). To increase participation, participants receive a cash incentive of HK$500 (≈ US$64) for passing the biochemical validation.

(Insert Table 1 here)

*Outcomes*

The primary outcomes are bio-verified abstinence at 3 months (end of treatment) and 6 months after treatment initiation confirmed by an exhaled carbon monoxide level< 4 ppm and salivary cotinine level < 10 ng/mL [27, 28].

Secondary outcomes include the following:

1. Self-reported 7-day point-prevalence abstinence;
2. Smoking reduction, defined by at least 50% reduction in daily cigarette consumption compared with that at baseline;
3. Cumulative use of smoking cessation services, defined by using at least one treatment session (e.g., face-to-face/ phone counseling, nicotine replacement therapy, acupuncture).

*Statistical analyses*

Data will be analyzed according to intention-to-treat (ITT) principles. Chi-squared and *t* tests will be used to compare baseline the characteristics of participants to assess balance between the two groups. The intervention effect on primary and secondary outcomes will be analyzed using logistic regression with and without adjustment for imbalanced baseline characteristics. Generalized estimating equation (GEE) models will be used to adjust for the potential clustering effect of recruitment sessions. Analysis of variance method will be used to calculate intra-cluster correlation for abstinence outcomes. Sensitivity to missing data will be examined using multiple imputation by chained equations assuming the data will be missing at random [29].

We will also examine the association between intervention adherence (e.g., received referral, used smoking cessation services, received financial incentive) and the primary outcome within the participants in the intervention group. The intervention effect by subgroups will be assessed respectively, including age group, sex, education level, household income, previous quit attempts, cigarette dependence, and intention to quit. Statistical analyses will be conducted using Stata v15.1 (Stata Corp, Texas, USA).

*Post-trial qualitative evaluation*

Qualitative evaluations using a subsample of participants receiving the intervention will be conducted after the end of the study. The semi-structured interview aims to explore participants' experience of the intervention and adherence to it, and obtain study feedback. The sample size for the qualitative evaluation will be determined by data saturation. Participants will be sampled purposively based on sociodemographic characteristics, smoking status and intervention adherence. We anticipate that up to 20 participants will be included subject to data saturation. All interviews will be audio-recorded and transcribed verbatim. The transcripts will be organized using a thematic framework [30] based on topics specified in the interview guide and emerging themes identified through a process of familiarization with the transcripts.

*Patient and public involvement*

Neither patients or the public are directly involved in the study design or conduct of the study. Study results will be disseminated to the general public.

**Ethics and dissemination**

The trial is conducted and reported in accordance with the CONSORT statement for clinical trials reporting, and has been registered at ClinialTrials.gov (registration number: NCT03565796). Ethical approval has been granted by the Institutional Review Board of the University of Hong Kong/ Hospital Authority Hong Kong West Cluster (IRB reference number: UW 18–318). Authorship will be determined in accordance with the International Committee of Medical Journal Editors (ICMJE) guidelines. Findings will be published in peer-reviewed journals and presented at local, national, and international conferences to publicize and explain the research to key audiences.

**Discussion**

This trial uses active referral plus a financial incentive as a model to increase smoking cessation attendance and abstinence in the community. If the intervention is found to be effective, this will be valuable for decision-makers to prioritize financial support to encourage the use of smoking cessation services, which will ultimately increase smoking abstinence.

This trial is innovative for three main reasons. First, as one of the sequential interventions using active referral, our trial combining an active referral with a financial incentive has important implications for research and practice. We intensified the CBR model by incentivizing service use, which is easy to implement in practice. Compared to OSR and TMR models, CBR plus incentive shifts the burden of onsite referral and uses money (instead of low-intensity text messaging) to motivate service use. Our findings regarding the effectiveness of different models of active referral provide insight for the development of high-quality adaptive trials [31] on smoking cessation. Second, a handful of trials used incentives to reward successful cessation [32]; however, we provide financial incentives to increase service use. Strategies to increase adherence to smoking cessation treatment are important but understudied [33]. Our findings will provide evidence regarding the use of incentives to increase the motivation to use services. Third, the incentive amount in our trial (≈ US$38) is much smaller than that in the incentive-based trials (ranging from US$45 to US$1185) included in a recent meta-analysis [32], which showed that the incentive size had no impact on cessation outcomes. Large incentives probably cannot be sustained in real-world practice. Small incentives may be adequate for behavioral change if using an effective approach to deliver the potential health benefits [34].

This trial has a number of strengths. We use a proactive approach to recruit smokers from a broader, community-based population, who are not in clinical settings and are mostly undetermined to quit in the short term. The brief intervention mode for promoting smoking cessation is flexible, feasible, and low cost. Moreover, we use bio-verified abstinence (i.e., exhaled carbon monoxide and salivary cotinine tests) as the primary outcome to increase scientific rigor and decrease misreporting [35].

This trial also has several potential limitations. First, the trial is pragmatic and cannot completely disentangle the effect of each intervention component (brief advice, active referral, financial incentive). However, we are more interested in the combined effect of the multicomponent trial, which targets several barriers for maintaining abstinence. Future research comparing the effect of different levels of active referral (e.g., CBR plus incentive vs. CBR

only) on abstinence is warranted. Second, we are unable to assess the long-term effects of the intervention (e.g., 12 months) because of budget constraints. Nevertheless, four consecutive follow-ups (at 1, 2, 3, and 6 months) allow us to keep track of cessation outcomes, service use, and changes in cessation-related factors in the short term (≤ 6 months). Third, as women's smoking prevalence rates are relatively low in Hong Kong [36], we expect a higher proportion of male participants relative to female participants. This may limit the generalizability of our findings to other settings where female smoking is more prevailing (e.g., Western countries). Fourth, our findings may be less generalizable to other countries lacking accessible and affordable smoking cessation services.

**Trial status**

This is protocol version 2. Recruitment started on June 2018 and is ongoing. All recruitment, follow-up and data collection will be expected to be completed in June 2020.

**Acknowledgements**

The authors would like to thank the participants, helpers from the universities and non-governmental organizations and research assistants who involved in this study.

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**Contributions**: MPW, XW and THL participated in study concept and design. MPW, XW and CYL participated in conducting the study. XW drafted the manuscript. MPW, HCL, YTC, CYL, CSK, WYL and SCC provided critical comments. All authors have read and approved the final manuscript.

**Funding**: This study is funded by the Hong Kong Council on Smoking and Health. The funders have no role in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript.

**Disclaimer:** The funding source do not have any role in the study design, data collection, analysis and interpretation, writing of the report or the decision to submit the paper for publication.

**Competing interests:** None declared.

**Ethics approval:** The study has been approved by the research ethics committee of the University of Hong Kong and the Hong Kong West Cluster of the Hospital Authority (IRB reference no.: UW18–318).

**Patient consent for publication:** Not required.

**Provenance and peer review:** Not commissioned; externally peer reviewed.

**Data availability statement:** Data are available on reasonable request.

**Supplementary information**

Appendix 1 Participant's consent form

Appendix 2 Referral card

Appendix 3 Referral form

Figure 1. CONSORT flow diagram

Table 1. Schedule of baseline and follow-up assessments

| Assessments | Time-point | | | | |
|---|---|---|---|---|---|
| | Baseline | 1 Month | 2 Months | 3 Months | 6 Months |
| Informed consent | × | | | | |
| Eligibility screen | × | | | | |
| Randomization | × | | | | |
| Intervention/control initiation | × | | | | |
| Sociodemographic characteristics [a] | × | | | | |
| Smoking behavior | × | × | × | × | × |
| Quit attempts | × | × | × | × | × |
| Use of smoking cessation services | × | × | × | × | × |
| Self-efficacy of quitting | × | | | × | × |
| Biochemically validated abstinence | | | | × | × |
| Qualitative evaluation | | | | | × |

[a] Sociodemographic characteristics include age, sex, education level, number of children, occupation, marital status, and household income.

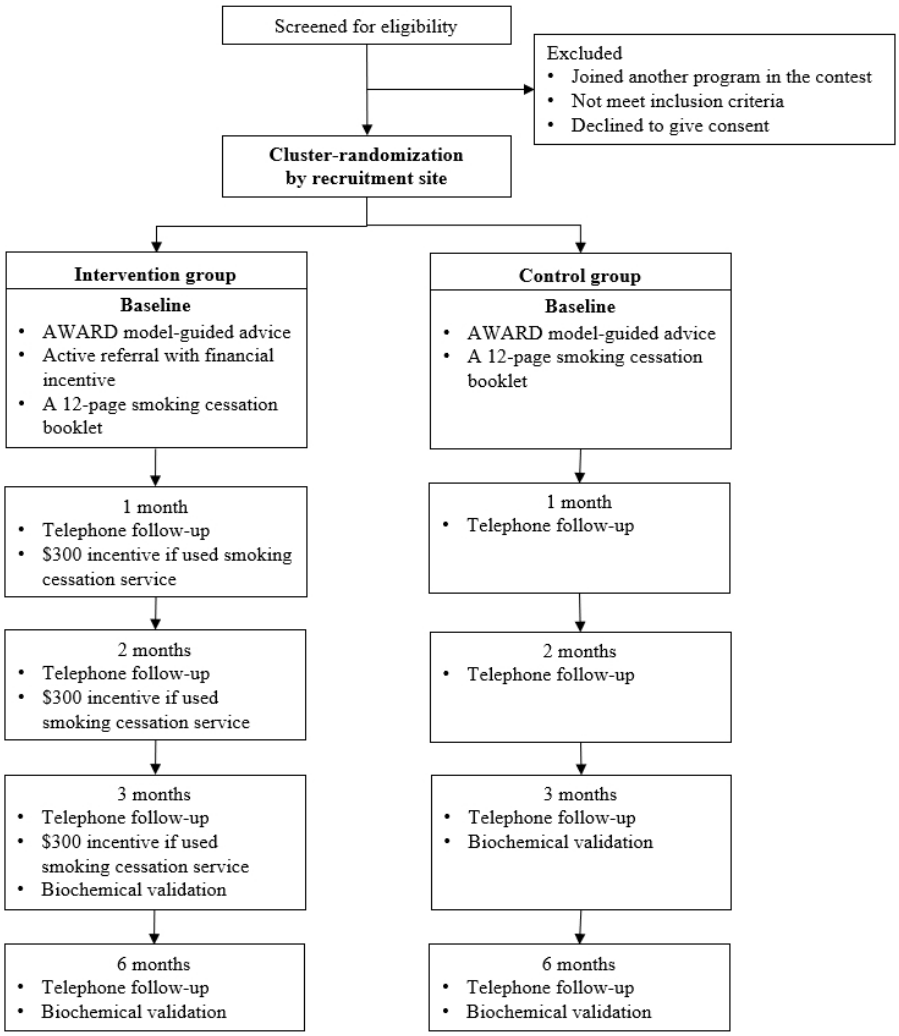


Figure1. CONSORT flow diagram

Appendix 1 Participant's consent form



香港吸煙與健康委員會
HONG KONG COUNCIL ON SMOKING AND HEALTH

香港大學
護理學院
公共衞生學院

## 第九屆「戒煙大贏家」無煙社區計劃

## 參加者自願參加同意書

香港大學護理學院及公共衞生學院受香港吸煙與健康委員會委託，現正進行一項為吸煙者提供即場輔導跟進及獎勵戒煙的「戒煙大贏家」比賽和隨機對照研究。如果你願意參與這項比賽和研究，請你填寫一份關於吸煙情況的問卷。我們會即場測量你的一氧化碳水平及提供戒煙輔導，整個輔導過程大約需時 5 分鐘。我們亦會提供有關戒煙的資料，包括介紹一些戒煙方法及吸煙的害處等。

如果你同意參與這項研究，你將會被以 1:1 比例隨機分配到兩種戒煙輔導組之中的任一組。你會於第一、第二、第三及第六個月，接收到共 4 次電話跟進訪問和計劃的資訊，每次電話跟進過程大約需時 8 分鐘。若你成功完成所有跟進活動，則可以獲得現金獎港幣$100。此外，如你於第三及六個月跟進訪問時已經戒煙 7 天或以上，我們將邀請你進行一氧化碳及可的寧水平測量，以核實成功戒煙。核實測量內容：用一氧化碳測定儀量度你呼氣中的一氧化碳水平及使用可的寧測試紙測量你吐出的口水中的可的寧水平。

這項研究絕對安全，不會令你產生不安。根據香港法律《個人資料(私隱)條例》(第 486 章)，所有收集的資料會絕對保密，例如在本項研究中或與本項研究有關的個人資料的收集、保管、保留、管理、控制、使用(分析或比較)、在香港內外轉讓、不披露、消除和/或任何方式處理。此研究經已由香港大學及醫管局港島西醫院聯網研究倫理委員會審閱及批准。你可以選擇是否參與這項研究及有權隨時退出而不影響我們提供之服務。香港大學護理學院及公共衞生學院保留任何爭議的最終決定權。如果你希望知道你本人的測試結果或對整項研究結果或有任何疑問，請聯絡我們的研究團隊：

計劃總監：王文炳博士 → 電話 3917-6636
計劃統籌：翁…雪博士 → 電話 3917-6304 → 劉正彥先生 → 電話 3917-6951

| (請在適當方格填上√): | | 是 | 否 |
|---|---|---|---|
| 1. | 本人已閱畢及明白上述資料，及有機會對這項研究提出查詢。 | | |
| 2. | 本人**自願**參與是項研究，並知道有權隨時退出，不用作出任何解釋。這將不會影響本人所接受的服務或權益。 | | |
| 3. | 本人明白所有個人資料會完全保密，只有授權主要研究者及其研究團隊和香港大學及醫管局港島西醫院聯網研究倫理委員會獲得，並只會用於研究用途。 | | |
| 4. | 我**同意**參與這項研究，並同意研究員日後聯絡我，以便跟進。 | | |

| | | |
|---|---|---|
| 被訪者姓名（請用正楷） | 簽署 | 日期 |
| 研究員姓名（請用正楷） | 簽署 | 日期 |
| 王文炳博士 | | |
| 計劃總監姓名（請用正楷） | 簽署 | 日期 |

Appendix 2 Referral card


Appendix 3 Referral form

Referral consent form - QTW2018 (Last Update: 30/05/2018, version 1)

香港吸煙與健康委員會
HONG KONG COUNCIL ON SMOKING AND HEALTH

香港大學
護理學院
公共衞生學院

## 第九屆「戒煙大贏家」無煙社區計劃
## 戒煙承諾書（舉辦機構存檔）

☑ 我，_____（姓名），承諾於 2018 年___月___日起，決心戒煙，並同意獲轉介至下列戒煙服務以作跟進。

- ☐ 1. 東華三院綜合戒煙服務中心
- ☐ 2. 博愛醫院中醫針灸戒煙服務
- ☐ 3. 衞生署戒煙輔導服務
- ☐ 4. 醫院管理局戒煙輔導服務
- ☐ 5. 香港大學青少年戒煙熱線

**三個月內**參與最少一次戒煙輔導，核實後可獲超市現金券$300。

參加者聲明：

- 本人明白資料將由香港大學護理學院及公共衞生學院轉交至上述之戒煙熱線作跟進之用。
- 本人明白於三個月內參與最少一次由上述機構提供的戒煙輔導後可獲得三百元超市現金券。
- 本人明白香港大學將在本人簽署承諾書後的六個月內跟進本人之戒煙情況。
- 本人確保承諾書上之資料皆屬真實及正確。

姓名：_____年齡：_____歲　　一氧化碳讀數：_____ppm

性別：☐男 ☐女　　聯絡電話：_____

簽名：_____　　日期：_____

收集個人資料聲明：

- 根據香港法律《個人資料(私隱)條例》(第 486 章)，所有收集的資料會絕對保密，例如在本項研究中或與本項研究有關的個人資料的收集、保管、保留、管理、控制、使用(分析或比較)、在香港內外轉讓、不披露、消除和/或任何方式處理。
- 參加者有權要求查詢及更正由香港吸煙與健康委員會持有之個人資料。有關要求，可以書面郵寄至「香港灣仔皇后大道東 183 號合和中心 44 樓 4402-03 室」，向香港吸煙與健康委員會提出。

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香港吸煙與健康委員會
HONG KONG COUNCIL ON SMOKING AND HEALTH

香港大學
護理學院
公共衞生學院

## 第九屆「戒煙大贏家」無煙社區計劃
## 戒煙承諾書（參加者保存）

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- ☐ 2. 博愛醫院中醫針灸戒煙服務
- ☐ 3. 衞生署戒煙輔導服務
- ☐ 4. 醫院管理局戒煙輔導服務
- ☐ 5. 香港大學青少年戒煙熱線

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參加者聲明：

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- 本人確保承諾書上之資料皆屬真實及正確。

一氧化碳讀數：_____ppm

收集個人資料聲明：

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- 參加者有權要求查詢及更正由香港吸煙與健康委員會持有之個人資料。有關要求，可以書面郵寄至「香港灣仔皇后大道東 183 號合和中心 44 樓 4402-03 室」，向香港吸煙與健康委員會提出。

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

| Section/item | Item No | Description | Page Number on which item is reported |
|---|---|---|---|
| **Administrative information** | | | |
| Title | 1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | 1 |
| Trial registration | 2a | Trial identifier and registry name. If not yet registered, name of intended registry | 2 |
| | 2b | All items from the World Health Organization Trial Registration Data Set | NA |
| Protocol version | 3 | Date and version identifier | 9 |
| Funding | 4 | Sources and types of financial, material, and other support | 12 |
| Roles and responsibilities | 5a | Names, affiliations, and roles of protocol contributors | 1, 12 |
| | 5b | Name and contact information for the trial sponsor | 12 |
| | 5c | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities | 12 |
| | 5d | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) | NA |

| | | | |
|---|---|---|---|
| **Introduction** | | | |
| Background and rationale | 6a | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention | 3 |
| | 6b | Explanation for choice of comparators | NA |
| Objectives | 7 | Specific objectives or hypotheses | 3-4 |
| Trial design | 8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) | 4 |
| **Methods: Participants, interventions, and outcomes** | | | |
| Study setting | 9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained | 4 |
| Eligibility criteria | 10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) | 4 |
| Interventions | 11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | 5-6 |
| | 11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) | NA |
| | 11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) | 5-6 |

| | | | |
|---|---|---|---|
| | 11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | NA |
| Outcomes | 12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended | 6-7 |
| Participant timeline | 13 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) | 6, 14 |
| Sample size | 14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations | 4-5 |
| Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size | 4-6 |
| **Methods: Assignment of interventions (for controlled trials)** | | | |
| Allocation: | | | |
| Sequence generation | 16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | 4 |

| | | | |
|---|---|---|---|
| Allocation concealment mechanism | 16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned | 4 |
| Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | 4 |
| Blinding (masking) | 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | 4 |
| | 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | 4 |
| **Methods: Data collection, management, and analysis** | | | |
| Data collection methods | 18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol | 6-7 |
| | 18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols | 6 |
| Data management | 19 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol | 7 |

| | | | |
|---|---|---|---|
| Statistical methods | 20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol | 7 |
| | 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | 7 |
| | 20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) | 7 |
| **Methods: Monitoring** | | | |
| Data monitoring | 21a | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed | 4, 12 |
| | 21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial | NA |
| Harms | 22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct | NA |
| Auditing | 23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | NA |
| **Ethics and dissemination** | | | |
| Research ethics approval | 24 | Plans for seeking research ethics committee/institutional review board (REC/IRB) approval | 7 |

| | | | |
|---|---|---|---|
| Protocol amendments | 25 | Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) | NA |
| Consent or assent | 26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | 4, Appendix 3 |
| | 26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | 6, Appendix 2 |
| Confidentiality | 27 | How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial | 4 |
| Declaration of interests | 28 | Financial and other competing interests for principal investigators for the overall trial and each study site | 12 |
| Access to data | 29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | Any data required to support the protocol can be supplied on request. |
| Ancillary and post-trial care | 30 | Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation | Active referral of smoking cessation service will continue to be available post trial.<br>There is no anticipated harm and compensation for trial participation. |
| Dissemination policy | 31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions | 7 |

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|---|---|---|---|
| | 31b | Authorship eligibility guidelines and any intended use of professional writers | 12 |
| | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | The datasets analysed during the current study are available from the corresponding author on reasonable request. |
| **Appendices** | | | |
| Informed consent materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates | Appendix 3 |
| Biological specimens | 33 | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable | NA |

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

# Effects of active referral combined with a small financial incentive on smoking cessation: study protocol for a cluster-randomized controlled trial



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|---|---|
| Journal: | *BMJ Open* |
| Manuscript ID | bmjopen-2020-038351.R2 |
| Article Type: | Protocol |
| Date Submitted by the Author: | 26-Sep-2020 |
| Complete List of Authors: | Weng, Xue; University of Hong Kong, School of Nursing<br>Wang, Man Ping; University of Hong Kong, School of Nursing<br>LI, Ho Cheung William; University of Hong Kong<br>Cheung, Yee Tak Derek; University of Hong Kong, School of Nursing<br>Lau, Ching Yin; University of Hong Kong, School of Nursing<br>Kwong, Antonio Cho Shing ; Hong Kong Council on Smoking and Health<br>Lai, Vienna; Hong Kong Council on Smoking and Health<br>Chan, Sophia; University of Hong Kong, School of Nursing<br>Lam, Tai Hing; University of Hong Kong, School of Public Health |
| Primary Subject Heading: | Smoking and tobacco |
| Secondary Subject Heading: | Health services research, Public health |
| Keywords: | PUBLIC HEALTH, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Clinical trials < THERAPEUTICS |
| | |

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# Effects of active referral combined with a small financial incentive on smoking cessation: study protocol for a cluster-randomized controlled trial

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**Word count:** 2889 (main text only)

## Abstract

### Introduction

Evidence-based smoking cessation treatments are effective but underutilized, accentuating the need for novel approaches to increase use. This trial investigates the effects of active referral combined with a financial incentive to use smoking cessation services on smoking abstinence among community smokers.

### Methods and analysis

This ongoing study is a two-arm, assessor-blinded, pragmatic, cluster randomized controlled trial with follow-ups at 1, 2, 3 and 6 months after randomization. We aim to enroll 1026 daily smokers from 70 community sites (clusters) in Hong Kong. All participants receive AWARD (Ask, Warn, Advise, Refer, Do-it-again) guided advice and a self-help booklet at baseline. Additionally, participants in the intervention group receive an offer of referral to smoking cessation services at baseline and a small financial incentive (HK$300 ≈ US$38) contingent upon using any of such services within 3 months. The primary outcomes are bio-verified abstinence [exhaled carbon monoxide < 4 parts per million (ppm), and salivary cotinine < 10 ng/mL] at 3 and 6 months. Secondary outcomes include self-reported 7-day point prevalence of abstinence, smoking reduction rate, quit attempts, and the use of smoking cessation services at 3 and 6 months. An intention-to-treat approach and regression models will be used in primary analyses.

### Ethics and dissemination

This protocol has been approved by the Institutional Review Board of the University of Hong Kong/Hospital Authority Hong Kong West Cluster (IRB reference number: UW 18–318). The results of this trial will be submitted for publication in peer-reviewed journals, and the key findings will be presented at national and international conferences.

### Trial registration

ClinicalTrials.gov, NCT03565796.


### Strengths and limitations of this study

- This trial examines the effectiveness of active referral combined with a financial incentive to increase the use of smoking cessation services in promoting abstinence in the community.
- A proactive approach is used to recruit smokers from a broader, community-based population, who are mostly undetermined to quit in the short term.
- Using biochemically verified abstinence as the primary outcome increases scientific rigor and decreases misreporting.
- The findings of this trial may be less generalizable to other countries lacking accessible and affordable smoking cessation services.

## Introduction

Smoking cessation counselling and medications are cost-effective in reducing tobacco-related morbidity and mortality [1-3]. Effective smoking cessation treatments are readily available, yet service utilization is low, as 70% of the world's population does not have access to cessation services [4]. Publicly funded services for smoking cessation are widely available in Hong Kong [5-7]; however, very few daily smokers (2.7%) use existing treatments that are proven to be effective [8].

To increase the use of smoking cessation services, we designed sequential trials of active referral approaches that proactively connect community smokers with smoking cessation service providers, yielding promising results. Call-back referral (CBR), which assists smokers to book their preferred service provider by calling them back to arrange an appointment for smoking cessation treatment, showed a significantly higher bio-verified abstinence at 6 months than did a control condition in which participants received advice according to the AWARD (Ask, Warn, Advise, Refer, Do-it-again) model [9.0% vs. 5.0%; odds ratio (OR) = 1.85, 95% confidence interval (CI) = 1.06-3.23, $P$ = 0.04] [9]. We sequentially proposed two active referral approaches with different intensities: onsite referral (OSR), which assists smokers to book appointments with preferred service providers during onsite recruitment, and text messaging referral (TMR), which uses mobile text messaging to promote the use of smoking cessation services. The two modified approaches showed significantly higher bio-verified abstinence at 6 months than AWARD-guided advice (7.6% and 7.8%, vs. 3.9%; OR for OSR vs. control = 2.02, 95% CI = 1.07-3.81; OR for TMR vs. control = 2.07, 95% CI = 1.10-3.92; both $P < 0.050$) [10]. Active referral approaches were effective but adherence was suboptimal, as less than 27% of participants used the smoking cessation service within the 6-month period after receiving active referrals (25.1% in OSR, 26.8% in CBR, and 8.1% in TMR).

Financial incentives are external motivators and may increase intervention adherence and service attendance [11, 12]. Financial incentives increased service enrolment [13] and use of tobacco dependence treatment (medications, nicotine replacement therapies, and counselling) [14-17], and service providers have offered them effective treatments to increase abstinence [12]. Our previous trial revealed that time constraints and low interest are the main barriers to use smoking cessation services [9]. Although smoking cessation services in Hong Kong are mostly free or charge minimal fees, proactive models that offer referral assistance with a small financial incentive may increase smokers' motivation to overcome perceived barriers. However, incentive-based trials to increase both service use and abstinence have shown mixed findings. Our previous community-based trial suggested that offering a cash incentive (HK$500 ≈ US$64) for successful quitting increased quit attempts but did not increase service use or abstinence [18]. Recent trials have shown that referral assistance (e.g., proactive calls, patient navigation) combined with a financial incentive increased treatment engagement and abstinence among smokers of low socioeconomic status (SES) [14, 19, 20]. Based on previous trials, it seems more effective to offer a financial incentive to increase the use of smoking cessation services among population-based, community-recruited smokers.

In this trial, we aim to investigate whether a small financial incentive (HK$300 ≈ US$38)

combined with active referral (CBR model) and brief (e.g. AWARD-guided) advice in the community will increase bio-verified abstinence at 6 months. We anticipate that the financial incentive will enhance smokers' motivation to use the services.

## Methods and analysis

*Study design*

This is a two-arm, assessor-blinded, pragmatic, cluster randomized controlled trial nested within the 9th "Quit to Win" (QTW) Smoke-Free Community Campaign. The QTW campaign [9, 10, 18, 21-24] is a community-based smoking cessation contest organized annually by the Hong Kong Council on Smoking and Health. Figure 1 shows the Consolidated Standards of Reporting Trials (CONSORT) flow diagram.

(Insert Figure 1 here)

*Recruitment and participants*

Similar to the previous QTW campaign [9, 10, 18, 21-24], recruitment activities are conducted in community sites (n = 70) (e.g., shopping malls and public areas) of all 18 Hong Kong districts. Using the "foot-in-the-door" approach [25], trained smoking cessation advisors proactively approach smokers at smoking hotspots in the vicinity of recruitment booths, explain the QTW contest, and invite smokers to participate. Smokers are informed that the intervention involves a baseline assessment of their exhaled carbon monoxide level, brief questions on past smoking behaviors (baseline questionnaire), and further telephone interviews (follow-up questionnaires at 1, 2, 3, and 6 months) (Appendix 1). Eligible participants are Hong Kong residents aged ≥ 18 years, currently smoking ≥ 1 cigarette per day during the past 3 months, with an exhaled carbon monoxide level ≥ 4 ppm, able to communicate in Cantonese or read Chinese, and motivated to quit or reduce smoking. Exclusion criteria are either having physical or cognitive difficulties in communication or currently participating in other smoking cessation programs.

*Randomization and blinding*

Randomization occurs at the community level. Participants within the same recruitment session are cluster-randomized in a 1:1 ratio to the intervention or control group. The randomization sequence (random permuted blocks of 2, 4, and 6) is generated using a web-based system (www.sealedenvelope.com). One investigator who is not involved in participant enrolment implements the allocation sequence and notifies the recruitment staff 1 day prior to the recruitment session. Because of the nature of the intervention, the recruitment staff delivering the interventions cannot be blinded to participant allocation, but participants are not informed about the treatment in the other group. Outcome assessors and statistical analysts are blinded to the group allocation.

*Sample size*

Our previous trial showed that bio-verified abstinence at 6 months was about 9.0% in the CBR group and 5% in the control group [9]. Full financial coverage of the costs of smoking cessation treatment had an effect size of 1.77 on abstinence when compared with no incentive in a healthcare setting [12]. We conservatively estimate an effect size of 1.25 for a small financial

incentive to use smoking cessation services combined with CBR in a community-based trial. Validated abstinence at 6 months is therefore expected to be 11.0% in the intervention group and 5% in the control group. Using G*Power software, in order to achieve a 95% confidence level (alpha = 0.05) and 80% power (1-beta = 0.80), the required sample size was calculated to be 286 per group. Assuming an intra-cluster correlation coefficient of 0.015 [22] with an average cluster size of 17 and a retention rate of 70% at 6-month follow-up [9, 26], the overall sample size of the study should be 1134 for the 2 groups (320 × 2 groups × 1.24 design effect / 70% retention rate).

*Treatment integrity*

Smoking cessation advisors are recruited through university mass emails and advertising posters. They include university students (with an hourly rate of HK$66 ≈ US$8.5) and volunteers of non-governmental organizations. All smoking cessation advisors are required to attend a full-day workshop (6 hours) before participant recruitment. The contents of the workshop include: 1) overview of QTW contest, intervention contents (e.g., AWARD-guided advice, active referral, and financial incentives), and recruitment demonstration (e.g., foot-in-the-door approach, test on exhaled carbon monoxide); 2) knowledge of smoking harms and quitting benefits; 3) smoking cessation methods and counseling techniques; and 4) sharing sessions of ex-smokers. We conduct a pre- and post-test to assess advisors' knowledge, attitudes and practice regarding smoking cessation.

An experienced research staff provides supervision and assistance at each recruitment session. To ensure the accurate delivery of the intervention, all advisors are instructed to follow a standardized recruitment script and complete an adherence checklist outlining each of the intervention components. Eligible smokers who decline to participate are asked to provide a reason for refusing. Information on the number of approached smokers is gathered and smokers' declining reasons are recorded verbatim by smoking cessation advisors.

*Interventions*

*AWARD-guided advice*

Well-trained smoking cessation advisors deliver advice based on the AWARD model to both intervention and control groups on site. AWARD-guided advice lasts 3-5 minutes and includes five steps: 1)*A*sk about the smoking history, 2) *W*arn smokers about the harms of smoking (using the result of exhaled carbon monoxide level), 3) *A*dvise to quit or reduce smoking as soon as possible, 4) *R*efer to existing cessation services, and 5) *D*o it again if smokers fail to quit. Participants also receive a 12-page generic self-help booklet used in our previous trials [9, 10, 18, 21-24]**.** The contents of the self-help booklet include smoking harms, benefits and methods of quitting, relapse prevention and existing smoking cessation services.

*Call-back referral (CBR) to smoking cessation services*

Participants in the intervention group receive intensified interventions based on *Refer* and *Do it again*, which is a more tailored and personalized approach than that of the control group.

At baseline, smoking cessation advisors assist participants to choose their preferred services

using a three-fold pocket-sized referral card, which outlines the five major smoking cessation services in Hong Kong, together with available therapies, opening hours and branch locations (Appendix 2). For participants who agree to be referred, research staff email participants' name and telephone number to the chosen service providers within 1 week (*Refer*). The providers call back participants within 1-2 weeks and arrange an appointment for telephone counseling or a smoking cessation clinic visit. Research staff monitor the use of smoking cessation services at each follow-up (1, 2, 3, and 6 months), and encourage and assist participants to book or re-book the services if they fail to quit (*Do it again*).

*Incentives for promoting smoking cessation service use*

Participants in the intervention group are informed that they will receive a small financial incentive for using any of the smoking cessation services within 3 months. The incentive is a HK$300 (≈ US$38) coupon for a popular local supermarket. Participants who agree to book the smoking cessation services sign two copies of the referral form stating that they are willing to use the selected services (Appendix 3). Participants keep one copy as information/reminder; research staff retain one copy for the records. The conditions for receiving the incentive are also outlined in the referral form. The incentive has no restrictions on the type of smoking cessation treatments used, which include pharmacotherapy (e.g., nicotine replacement therapy), behavioral support (e.g., face-to-face/ phone counselling, group therapy), or a combination thereof. Post-payment financial incentives are distributed to participants in the intervention group who self-report using the smoking cessation service at 1-, 2-, and 3-month follow-ups. The mailing procedure is standardized. The incentive is sent by registered mail with an accompanying cover letter explaining the purpose of the incentive.

*Procedures*

Participants are assessed at baseline, 1, 2, 3, and 6 months after treatment initiation (Table 1). The baseline questionnaire measures participants' smoking behavior (e.g., daily cigarette consumption, age of starting smoking, time of first cigarette upon waking up in the morning, attempts to quit or reduce, methods used in past quit attempts), intention to quit, perceived self-efficacy regarding quitting (importance, difficulties and confidence), and sociodemographic characteristics. Participants are informed that they may withdraw from the study at any time without giving a reason. Participants are followed up at 1, 2, 3, and 6 months by trained smoking cessation counsellors with a maximum of 7 telephone calls at different times. Participants who self-report abstinence for more than 7 days at 3 and 6 months are invited for a biochemical validation. Exhaled carbon monoxide samples are collected by research staff with a piCO™ Smokerlyzer® (Bedfont Scientific Ltd), and saliva cotinine samples are measured using a NicAlert® test strip (Nymos Pharmaceutical Corporation). To increase participation, participants receive a cash incentive of HK$500 (≈ US$64) for passing the biochemical validation at 3 and 6 months.

(Insert Table 1 here)

*Outcomes*

The primary outcomes are bio-verified abstinence at 3 months (end of treatment) and 6 months

after treatment initiation confirmed by an exhaled carbon monoxide level< 4 ppm and salivary cotinine level < 10 ng/mL [27, 28].

Secondary outcomes include the following:

1. Self-reported 7-day point-prevalence abstinence;
2. Smoking reduction, defined by at least 50% reduction in daily cigarette consumption compared with that at baseline;
3. Quit attempts;
4. Cumulative use of smoking cessation services, defined by using at least one treatment session (e.g., face-to-face/ phone counseling, nicotine replacement therapy, acupuncture).

*Statistical analyses*

Data will be analyzed according to intention-to-treat (ITT) principles. Chi-squared and *t* tests will be used to compare baseline the characteristics of participants to assess balance between the two groups. The intervention effect on primary and secondary outcomes will be analyzed using regression models with and without adjustment for imbalanced baseline characteristics. Generalized estimating equation (GEE) models will be used to adjust for the potential clustering effect of recruitment sessions. Analysis of variance method will be used to calculate intra-cluster correlation for abstinence outcomes. Sensitivity to missing data will be examined using multiple imputation by chained equations assuming the data will be missing at random [29].

We will also examine the association between intervention adherence (e.g., received referral, used smoking cessation services, received financial incentive) and the primary outcome within the participants in the intervention group. The intervention effect by subgroups will be assessed respectively, including age group, sex, education level, household income, previous quit attempts, cigarette dependence, and intention to quit. Statistical analyses will be conducted using Stata v15.1 (Stata Corp, Texas, USA).

*Post-trial qualitative evaluation*

Qualitative evaluations using a subsample of participants receiving the intervention will be conducted after the end of the study. The semi-structured interview aims to explore participants' experience of the intervention and adherence to it, and obtain study feedback. The sample size for the qualitative evaluation will be determined by data saturation. Participants will be sampled purposively based on sociodemographic characteristics, smoking status and intervention adherence. We anticipate that up to 20 participants will be included subject to data saturation. All interviews will be audio-recorded and transcribed verbatim. The transcripts will be organized using a thematic framework [30] based on topics specified in the interview guide and emerging themes identified through a process of familiarization with the transcripts.

*Patient and public involvement*

Neither patients or the public are directly involved in the study design or conduct of the study. Study results will be disseminated to the general public.

**Ethics and dissemination**

The trial is conducted and reported in accordance with the CONSORT statement for clinical trials reporting, and has been registered at ClinialTrials.gov (registration number: NCT03565796). Ethical approval has been granted by the Institutional Review Board of the University of Hong Kong/ Hospital Authority Hong Kong West Cluster (IRB reference number: UW 18–318). Authorship will be determined in accordance with the International Committee of Medical Journal Editors (ICMJE) guidelines. Findings will be published in peer-reviewed journals and presented at local, national, and international conferences to publicize and explain the research to key audiences.

**Discussion**

This trial uses active referral plus a financial incentive as a model to increase smoking cessation attendance and abstinence in the community. If the intervention is found to be effective, this will be valuable for decision-makers to prioritize financial support to encourage the use of smoking cessation services, which will ultimately increase smoking abstinence.

This trial is innovative for three main reasons. First, as one of the sequential interventions using active referral, our trial combining an active referral with a financial incentive has important implications for research and practice. We intensified the CBR model by incentivizing service use, which is easy to implement in practice. Compared to OSR and TMR models, CBR plus incentive shifts the burden of onsite referral and uses money (instead of low-intensity text messaging) to motivate service use. Our findings regarding the effectiveness of different models of active referral provide insight for the development of high-quality adaptive trials [31] on smoking cessation. Second, a handful of trials used incentives to reward successful cessation [32]; however, we provide financial incentives to increase service use. Strategies to increase adherence to smoking cessation treatment are important but understudied [33]. Our findings will provide evidence regarding the use of incentives to increase the motivation to use services. Third, the incentive amount in our trial (≈ US$38) is much smaller than that in the incentive-based trials (ranging from US$45 to US$1185) included in a recent meta-analysis [32], which showed that the incentive size had no impact on cessation outcomes. Large incentives probably cannot be sustained in real-world practice. Small incentives may be adequate for behavioral change if using an effective approach to deliver the potential health benefits [34].

This trial has a number of strengths. We use a proactive approach to recruit smokers from a broader, community-based population, who are not in clinical settings and are mostly undetermined to quit in the short term. The brief intervention mode for promoting smoking cessation is flexible, feasible, and low cost. Moreover, we use bio-verified abstinence (i.e., exhaled carbon monoxide and salivary cotinine tests) as the primary outcome to increase scientific rigor and decrease misreporting [35].

This trial also has several potential limitations. First, the trial is pragmatic and cannot completely disentangle the effect of each intervention component (brief advice, active referral, financial incentive). However, we are more interested in the combined effect of the multicomponent trial, which targets several barriers for maintaining abstinence. Future research comparing the effect of different levels of active referral (e.g., CBR plus incentive vs. CBR

only) on abstinence is warranted. Second, we are unable to assess the long-term effects of the intervention (e.g., 12 months) because of budget constraints. Nevertheless, four consecutive follow-ups (at 1, 2, 3, and 6 months) allow us to keep track of cessation outcomes, service use, and changes in cessation-related factors in the short term (≤ 6 months). Third, the evidence on the use of smoking cessation services is based on self-reporting. This is done for practical reasons as the records of service utilization cannot be directly obtained by the research team. Fourth, as women's smoking prevalence rates are relatively low in Hong Kong [36], we expect a higher proportion of male participants relative to female participants. This may limit the generalizability of our findings to other settings where female smoking is more prevailing (e.g., Western countries). Fifth, our findings may be less generalizable to other countries lacking accessible and affordable smoking cessation services.

**Current status**

Recruitment started on June 2018. All recruitment, follow-up, and data collection are expected to be completed in June 2020.

**Acknowledgements**

The authors would like to thank the participants, helpers from the universities and non-governmental organizations and research assistants who involved in this study.

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**Contributions**: MPW, XW and THL participated in study concept and design. MPW, XW and CYL participated in conducting the study. XW drafted the manuscript. MPW, HCL, YTC, CYL, CSK, WYL and SCC provided critical comments. All authors have read and approved the final manuscript.

**Funding**: This study is funded by the Hong Kong Council on Smoking and Health (reference no.: N/A). The funders have no role in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript.

**Disclaimer:** The funding source do not have any role in the study design, data collection, analysis and interpretation, writing of the report or the decision to submit the paper for publication.

**Competing interests:** None declared.

**Ethics approval:** The study has been approved by the research ethics committee of the University of Hong Kong and the Hong Kong West Cluster of the Hospital Authority (IRB reference no.: UW18–318).

**Patient consent for publication:** Not required.

**Provenance and peer review:** Not commissioned; externally peer reviewed.

**Data availability statement:** Data are available on reasonable request.

**Supplementary information**

Appendix 1 Participant's consent form

Appendix 2 Referral card

Appendix 3 Referral form

Figure 1. CONSORT flow diagram

Table 1. Schedule of baseline and follow-up assessments

| Assessments | Time-point | | | | |
|---|---|---|---|---|---|
| | Baseline | 1 Month | 2 Months | 3 Months | 6 Months |
| Informed consent | × | | | | |
| Eligibility screen | × | | | | |
| Randomization | × | | | | |
| Intervention/control initiation | × | | | | |
| Sociodemographic characteristics [a] | × | | | | |
| Smoking behavior | × | × | × | × | × |
| Quit attempts | × | × | × | × | × |
| Use of smoking cessation services | × | × | × | × | × |
| Self-efficacy of quitting | × | | | × | × |
| Biochemically validated abstinence | | | | × | × |
| Qualitative evaluation | | | | | × |

[a] Sociodemographic characteristics include age, sex, education level, number of children, occupation, marital status, and household income.

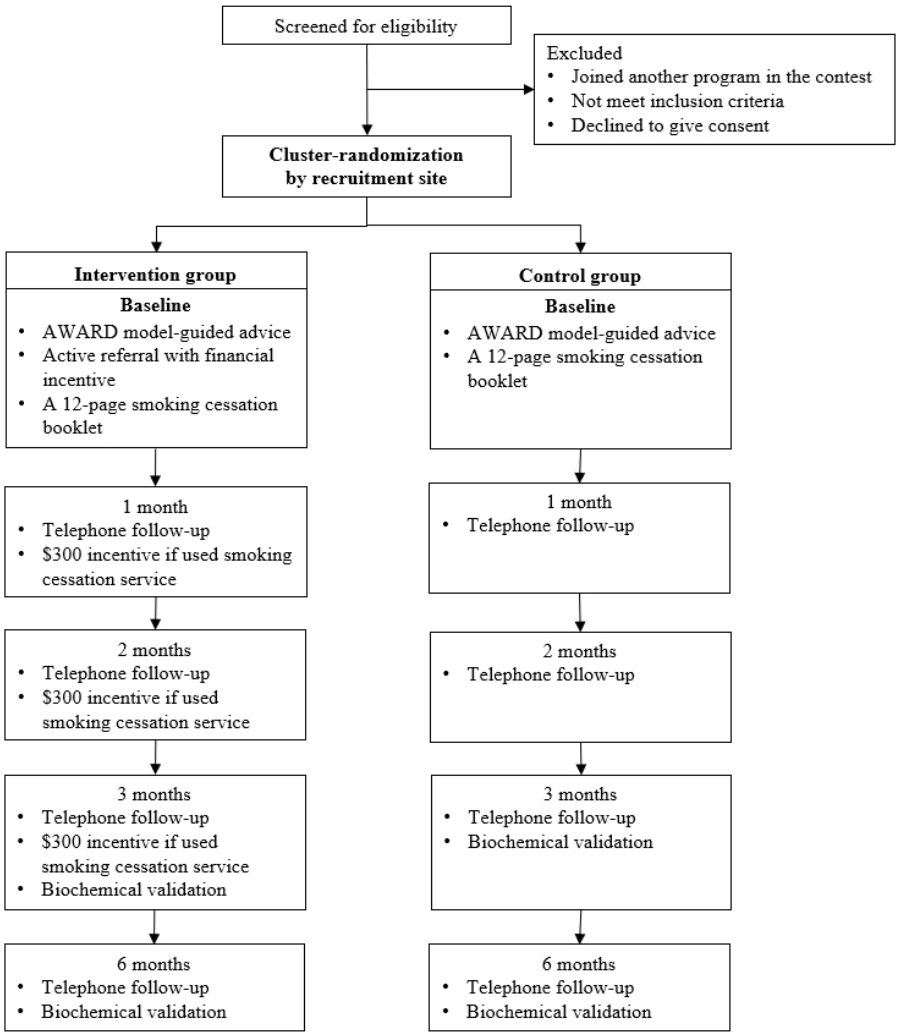


Figure1. CONSORT flow diagram

Appendix 1 Participant's consent form



香港吸煙與健康委員會
HONG KONG COUNCIL ON SMOKING AND HEALTH

香港大學
護理學院
公共衞生學院

## 第九屆「戒煙大贏家」無煙社區計劃

## 參加者自願參加同意書

香港大學護理學院及公共衞生學院受香港吸煙與健康委員會委託，現正進行一項為吸煙者提供即場輔導跟進及獎勵戒煙的「戒煙大贏家」比賽和隨機對照研究。如果你願意參與這項比賽和研究，請你填寫一份關於吸煙情況的問卷。我們會即場測量你的一氧化碳水平及提供戒煙輔導，整個輔導過程大約需時 5 分鐘。我們亦會提供有關戒煙的資料，包括介紹一些戒煙方法及吸煙的害處等。

如果你同意參與這項研究，你將會被以 1:1 比例隨機分配到兩種戒煙輔導組之中的任一組。你會於第一、第二、第三及第六個月，接收到共 4 次電話跟進訪問和計劃的資訊，每次電話跟進過程大約需時 8 分鐘。若你成功完成所有跟進活動，則可以獲得現金獎港幣$100。此外，如你於第三及六個月跟進訪問時已經戒煙 7 天或以上，我們將邀請你進行一氧化碳及可的寧水平測量，以核實成功戒煙。核實測量內容：用一氧化碳測定儀量度你呼氣中的一氧化碳水平及使用可的寧測試紙測量你吐出的口水中的可的寧水平。

這項研究絕對安全，不會令你產生不安。根據香港法律《個人資料(私隱)條例》(第 486 章)，所有收集的資料會絕對保密，例如在本項研究中或與本項研究有關的個人資料的收集、保管、保留、管理、控制、使用(分析或比較)、在香港內外轉讓、不披露、消除和/或任何方式處理。此研究經已由香港大學及醫管局港島西醫院聯網研究倫理委員會審閱及批准。你可以選擇是否參與這項研究及有權隨時退出而不影響我們提供之服務。香港大學護理學院及公共衞生學院保留任何爭議的最終決定權。如果你希望知道你本人的測試結果或對整項研究結果或有任何疑問，請聯絡我們的研究團隊：

計劃總監：王文炳博士 → 電話 3917-6636
計劃統籌：翁…雪博士 → 電話 3917-6304 → 劉正彥先生 → 電話 3917-6951

| (請在適當方格填上√): | | 是 | 否 |
|---|---|---|---|
| 1. | 本人已閱畢及明白上述資料，及有機會對這項研究提出查詢。 | | |
| 2. | 本人**自願**參與是項研究，並知道有權隨時退出，不用作出任何解釋。這將不會影響本人所接受的服務或權益。 | | |
| 3. | 本人明白所有個人資料會完全保密，只有授權主要研究者及其研究團隊和香港大學及醫管局港島西醫院聯網研究倫理委員會獲得，並只會用於研究用途。 | | |
| 4. | 我**同意**參與這項研究，並同意研究員日後聯絡我，以便跟進。 | | |

| | | |
|---|---|---|
| 被訪者姓名（請用正楷） | 簽署 | 日期 |
| 研究員姓名（請用正楷） | 簽署 | 日期 |
| 王文炳博士 | | |
| 計劃總監姓名（請用正楷） | 簽署 | 日期 |

Appendix 2 Referral card


Appendix 3 Referral form

Referral consent form - QTW2018 (Last Update: 30/05/2018, version 1)

香港吸煙與健康委員會
HONG KONG COUNCIL ON SMOKING AND HEALTH

香港大學
護理學院
公共衞生學院

## 第九屆「戒煙大贏家」無煙社區計劃
## 戒煙承諾書（舉辦機構存檔）

☑ 我，_____（姓名），承諾於 2018 年___月___日起，決心戒煙，並同意獲轉介至下列戒煙服務以作跟進。

- ☐ 1. 東華三院綜合戒煙服務中心
- ☐ 2. 博愛醫院中醫針灸戒煙服務
- ☐ 3. 衞生署戒煙輔導服務
- ☐ 4. 醫院管理局戒煙輔導服務
- ☐ 5. 香港大學青少年戒煙熱線

**三個月內**參與最少一次戒煙輔導，核實後可獲超市現金券$300。

參加者聲明：

- 本人明白資料將由香港大學護理學院及公共衞生學院轉交至上述之戒煙熱線作跟進之用。
- 本人明白於三個月內參與最少一次由上述機構提供的戒煙輔導後可獲得三百元超市現金券。
- 本人明白香港大學將在本人簽署承諾書後的六個月內跟進本人之戒煙情況。
- 本人確保承諾書上之資料皆屬真實及正確。

姓名：_____年齡：_____歲　　一氧化碳讀數：_____ppm

性別：☐男 ☐女　　聯絡電話：_____

簽名：_____　　日期：_____

收集個人資料聲明：

- 根據香港法律《個人資料(私隱)條例》(第 486 章)，所有收集的資料會絕對保密，例如在本項研究中或與本項研究有關的個人資料的收集、保管、保留、管理、控制、使用(分析或比較)、在香港內外轉讓、不披露、消除和/或任何方式處理。
- 參加者有權要求查詢及更正由香港吸煙與健康委員會持有之個人資料。有關要求，可以書面郵寄至「香港灣仔皇后大道東 183 號合和中心 44 樓 4402-03 室」，向香港吸煙與健康委員會提出。

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香港吸煙與健康委員會
HONG KONG COUNCIL ON SMOKING AND HEALTH

香港大學
護理學院
公共衞生學院

## 第九屆「戒煙大贏家」無煙社區計劃
## 戒煙承諾書（參加者保存）

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- ☐ 2. 博愛醫院中醫針灸戒煙服務
- ☐ 3. 衞生署戒煙輔導服務
- ☐ 4. 醫院管理局戒煙輔導服務
- ☐ 5. 香港大學青少年戒煙熱線

**三個月內**參與最少一次戒煙輔導，核實後可獲超市現金券$300。

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- 本人明白於三個月內參與最少一次由上述機構提供的戒煙輔導後可獲得三百元超市現金券。
- 本人明白香港大學將在本人簽署承諾書後的六個月內跟進本人之戒煙情況。
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一氧化碳讀數：_____ppm

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- 參加者有權要求查詢及更正由香港吸煙與健康委員會持有之個人資料。有關要求，可以書面郵寄至「香港灣仔皇后大道東 183 號合和中心 44 樓 4402-03 室」，向香港吸煙與健康委員會提出。

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

| Section/item | Item No | Description | Page Number on which item is reported |
|---|---|---|---|
| **Administrative information** | | | |
| Title | 1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | 1 |
| Trial registration | 2a | Trial identifier and registry name. If not yet registered, name of intended registry | 2 |
| | 2b | All items from the World Health Organization Trial Registration Data Set | NA |
| Protocol version | 3 | Date and version identifier | 9 |
| Funding | 4 | Sources and types of financial, material, and other support | 12 |
| Roles and responsibilities | 5a | Names, affiliations, and roles of protocol contributors | 1, 12 |
| | 5b | Name and contact information for the trial sponsor | 12 |
| | 5c | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities | 12 |
| | 5d | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) | NA |

| | | | |
|---|---|---|---|
| **Introduction** | | | |
| Background and rationale | 6a | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention | 3 |
| | 6b | Explanation for choice of comparators | NA |
| Objectives | 7 | Specific objectives or hypotheses | 3-4 |
| Trial design | 8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) | 4 |
| **Methods: Participants, interventions, and outcomes** | | | |
| Study setting | 9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained | 4 |
| Eligibility criteria | 10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) | 4 |
| Interventions | 11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | 5-6 |
| | 11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) | NA |
| | 11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) | 5-6 |

| | | | |
|---|---|---|---|
| | 11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | NA |
| Outcomes | 12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended | 6-7 |
| Participant timeline | 13 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) | 6, 14 |
| Sample size | 14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations | 4-5 |
| Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size | 4-6 |
| **Methods: Assignment of interventions (for controlled trials)** | | | |
| Allocation: | | | |
| Sequence generation | 16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | 4 |

| | | | |
|---|---|---|---|
| Allocation concealment mechanism | 16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned | 4 |
| Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | 4 |
| Blinding (masking) | 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | 4 |
| | 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | 4 |
| **Methods: Data collection, management, and analysis** | | | |
| Data collection methods | 18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol | 6-7 |
| | 18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols | 6 |
| Data management | 19 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol | 7 |

| | | | |
|---|---|---|---|
| Statistical methods | 20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol | 7 |
| | 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | 7 |
| | 20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) | 7 |
| **Methods: Monitoring** | | | |
| Data monitoring | 21a | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed | 4, 12 |
| | 21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial | NA |
| Harms | 22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct | NA |
| Auditing | 23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | NA |
| **Ethics and dissemination** | | | |
| Research ethics approval | 24 | Plans for seeking research ethics committee/institutional review board (REC/IRB) approval | 7 |

| | | | |
|---|---|---|---|
| Protocol amendments | 25 | Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) | NA |
| Consent or assent | 26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | 4,<br>Appendix 1 Participant's consent form<br>Appendix 3 Referral form |
| | 26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | 6, Appendix 2 Referral card |
| Confidentiality | 27 | How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial | 4 |
| Declaration of interests | 28 | Financial and other competing interests for principal investigators for the overall trial and each study site | 12 |
| Access to data | 29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | Any data required to support the protocol can be supplied on request. |
| Ancillary and post-trial care | 30 | Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation | Active referral of smoking cessation service will continue to be available post trial.<br>There is no anticipated harm and compensation for trial participation. |
| Dissemination policy | 31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions | 7 |

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| | 31b | Authorship eligibility guidelines and any intended use of professional writers | 12 |
| | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | The datasets analysed during the current study are available from the corresponding author on reasonable request. |
| **Appendices** | | | |
| Informed consent materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates | Appendix 1 Participant's consent form |
| Biological specimens | 33 | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable | NA |

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.