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STUDY PROTOCOL

ADDICTION SSA

Effectiveness of a self-determination theory-based smoking cessation intervention plus instant messaging via mobile application for smokers with cancer: Protocol for a pragmatic randomized controlled trial

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Abstract

Background and aims: Despite evidence that patients living with cancer who continue to smoke after diagnosis are at higher risk for all-cause mortality and reduced treatment efficacy, many cancer patients continue to smoke. This protocol is for a study to test the effectiveness of a self-determination theory-based intervention (quit immediately or progressively) plus instant messaging (WhatsApp or WeChat) to help smokers with cancer to quit smoking.

Design: This will be a multi-centre, two-arm (1:1), single-blind, pragmatic, individually randomized controlled trial.

Setting: Taking part will be specialist outpatient clinics in five major hospitals in different location-based clusters in Hong Kong.

Participants: The sample will include 1448 Chinese smokers living with cancer attending medical follow-ups at outpatient clinics.

Interventions: The intervention group will receive brief advice (approximately 5–8 minutes) from research nurses in the outpatient clinics and then be invited to choose their own quit schedules (immediate or progressive). During the first 6-month follow-up period they will receive instant messaging with smoking cessation advice once per week for the first 3 months, and thereafter approximately once per month. They will also receive four videos, and those opting to quit progressively will receive a smoking reduction leaflet. The control group will also receive brief advice but be advised to quit immediately, and instant messaging with general health advice during the first 6-month follow-up period using the same schedule as the intervention group. Participants in both groups will receive smoking cessation leaflets.

Measurements: The primary outcome is biochemically validated smoking abstinence at 6 months, as confirmed by saliva cotinine level and carbon monoxide level in expired air.

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Secondary outcomes include biochemically validated smoking abstinence at 12 months, self-reported 7-day point prevalence of smoking abstinence at 6 and 12 months, self-reported ≥ 50% reduction of cigarette consumption at 6 and 12 months and quality of life at 6 and 12 months. All time-points for outcomes measures are set after randomization.

Comments: The results could inform research, policymaking and health-care professionals regarding smoking cessation for patients living with cancer, and therefore have important implications for clinical practice and health enhancement.

KEYWORDS
Cancer, instant messaging, quality of life, self-determination theory, smoking cessation, specialist outpatient clinics

INTRODUCTION

Despite evidence that smoking has detrimental effects on almost every organ in the body and is associated with many types of cancer [1, 2], many patients living with cancer continue to smoke [3]. Cancer is the leading cause of death in Hong Kong and claimed 14 805 lives in 2020, which accounted for approximately one-third of all deaths in the local population [3]. In total, 34 179 new cancer cases were diagnosed in Hong Kong in 2020: an incidence of approximately 220 cases per 100 000 population [3]. The thematic household survey conducted by the Census and Statistics Department in 2021 indicated that there were approximately 581 500 daily conventional cigarette smokers (83.1% male), which accounted for 9.5% of people aged ≥ 15 years [4]. Furthermore, smoking prevalence varied by age, sex and economic activity [4].

Evidence shows that patients living with cancer who continue to smoke after diagnosis are at high risk for all-cause mortality, reduced treatment efficacy and survival duration, cancer recurrence and second primary cancers [5, 6]. Conversely, quitting smoking after being diagnosed with cancer may reduce the risk for disease progression [6, 7], ameliorate adverse effects of treatment and improve patients' prognosis and quality of life [5]. Recent evidence suggests that smoking cessation at any age slows the accumulation of further damage and promotes replenishment of the bronchial epithelium with cells undamaged by tobacco exposure [8]. Given the potential health hazards of continued smoking and the health benefits of smoking cessation, it is essential that health-care professionals help this vulnerable group to quit smoking. However, quitting smoking can be difficult, especially for patients with cancer who have smoked for a long time. It is often difficult for these patients to overcome their craving for cigarettes during the process of quitting smoking, and they are prone to relapse after quitting smoking for a short time [9, 10]. A national health and nutrition survey [11] and a cross-sectional study [12] of smokers with cancer in the United States showed that approximately one-third to one-half of patients living with cancer in the United States smoke after receiving a cancer diagnosis. One study in Hong Kong [13] suggested that approximately 14% of patients living with cancer continue to smoke after receiving a cancer diagnosis.

A qualitative study from Scotland that identified barriers to quitting smoking among smokers with cancer found that people continued to smoke after their diagnosis because of the stress of diagnosis, desire to maintain personal control and lack of understanding of the links between smoking, cancer and health [14]. Another qualitative study conducted at a large United Kingdom head-and-neck cancer centre reported that some patients with cancer had difficulty quitting smoking when they felt lonely or bored [15]. That study highlighted the lack of evidence from effective interventions and well-designed studies for smoking cessation in patients with cancer, which was consistent with the findings from a systematic review of 23 studies [16] on smoking cessation interventions for smokers diagnosed with cancer conducted between 2015 and 2020 representing United States, Canada, England, Lebanon and Australia.

A randomized controlled trial (RCT) was conducted between 2012 and 2016 to examine the effectiveness of a brief risk communication-based intervention to help 528 Hong Kong Chinese patients living with cancer quit smoking (intervention group: n = 268, control group: n = 260) [17]. However, the results showed no statistically significant differences in the self-reported 7-day point prevalence of smoking abstinence between the intervention and control groups at 6 months [15.7 versus 16.5%; odds ratio (OR) = 0.94, 95% confidence interval (CI) = 0.59–1.50) and 12 months (14.9 versus 20.4%; OR = 0.69, 95% CI = 0.44–1.08). However, the biochemically validated quit rate was higher in the intervention group than in the control group (5.2 versus 3.8% at 6 months; 5.6 versus 4.6% at 12 months), although significance was not reached [17]. These results suggested that the risk communication-based smoking cessation intervention was ineffective in helping patients living with cancer to quit smoking. That RCT [17] had several limitations. First, the response rate was low; of 1425 eligible smokers identified, only 528 (37.1%) participated in the study. Secondly, the retention rates were low; only 58.2 and 57.3% for the intervention and control groups, respectively, were included in the 12-month follow-up. Thirdly, the biochemical validation participation rate was low (27.6%), and many participants were hesitant about returning for validation. That study reported that 72.9% of participants had no intention of quitting smoking at the time of recruitment [17]. Furthermore, many patients living with cancer who continued to smoke were chronic smokers with a long smoking history (42.0 ± 13.2 years on average) and found it extremely difficult to overcome withdrawal symptoms or cigarette cravings [18]. However, some patients living with cancer

who were reluctant to quit were willing to reduce the number of cigarettes smoked per day [17].

Another RCT examined the effectiveness of a brief self-determination intervention for smoking cessation among Hong Kong Chinese people attending accident and emergency departments between 2015 and 2017 [18]. Participants in the intervention group (n = 787) could choose to quit smoking immediately or progressively, and those in the control group (n = 784) received a leaflet on smoking cessation. The intervention group had significantly higher self-reported and biochemically validated 7-day point prevalence of smoking abstinence rates at 6 months [6.7% (53/787) versus 2.8% (22/784), $P < 0.001$] and 12 months [7.0% (55/787) versus 3.7% (29/784), $P < 0.001$] than the control group, as confirmed by saliva cotinine level and carbon monoxide level in exhaled air [18]. Those findings suggested that giving the option of immediate or gradual cessation was effective in motivating smokers to quit. However, it remains unclear whether this approach constitutes an effective strategy to promote smoking cessation in patients living with cancer.

In 2014, a pilot pragmatic RCT was conducted with 136 patients in hospitals in Hong Kong that showed the use of instant messaging via WhatsApp was effective in enhancing treatment compliance and preventing smoking relapse [19]. The World Health Organization defines medical and public health practice supported by mobile devices as mobile health, which represents a new strategy for promoting health [20, 21]. An advantage of using WhatsApp or WeChat is that these applications can offer quick, real-time interactions, thereby delivering continuous professional advice and personalized support to participants to help them to quit smoking and overcome withdrawal symptoms or cravings [22]. WhatsApp or WeChat is very commonly used in Hong Kong and China and is widely used as a digital-based intervention to promote smoking cessation [23]. Importantly, instant messaging is more flexible, efficient and time-saving than face-to-face meetings. Another RCT involving 1023 expectant fathers in China between 2017 and 2018 also demonstrated the efficacy of delivering short videos with health advice messages via WeChat to promote smoking cessation [23]. An advantage of using a video format to deliver instant health advice messages to smokers is the use of sound and images, which can elicit emotions, improve comprehension of abstract concepts and improve retention of new information through auditory, visual and verbal stimulation [23]. Moreover, the delivered content can be viewed by participants at their convenience and own pace. The literature suggests that video imagery can help the brain to create initial impressions, which supplemented with detailed and in-depth verbal descriptions, have sustainable effects on smokers' intention to quit smoking [24]. In addition, improvements in information technology have facilitated the inexpensive production of videos and the necessary equipment is now available at low cost.

The RCTs [18, 19, 23] described above demonstrated the feasibility and acceptability of using self-determination theory-based smoking cessation intervention and instant messaging via mobile application for smokers. However, it remains uncertain whether an integrated self-determination theory-based intervention combined with instant messaging via mobile application can have synergistic effects in promoting smoking cessation for patients living with cancer. Findings from these previous studies supported the use of this innovative strategy to develop a study protocol to provide rigorous empirical scrutiny of the efficacy of this approach in helping Chinese smokers with cancer to quit smoking. Our hypothesis is that participants who receive the intervention described in the study protocol will show a significantly higher biochemically validated quit rate, self-reported 7-day point prevalence of smoking abstinence and reduction in daily cigarette consumption of at least 50%, and better quality of life at 6 and 12 months than those who receive only brief advice to quit immediately.

METHODS

Study design

We will conduct a single-blinded, multi-centre, RCT with a two-group pre-test and repeated post-test between-subjects design following the Consolidated Standards of Reporting Trials (CONSORT) 2010 guideline (see Figure 1 for the flow-chart).

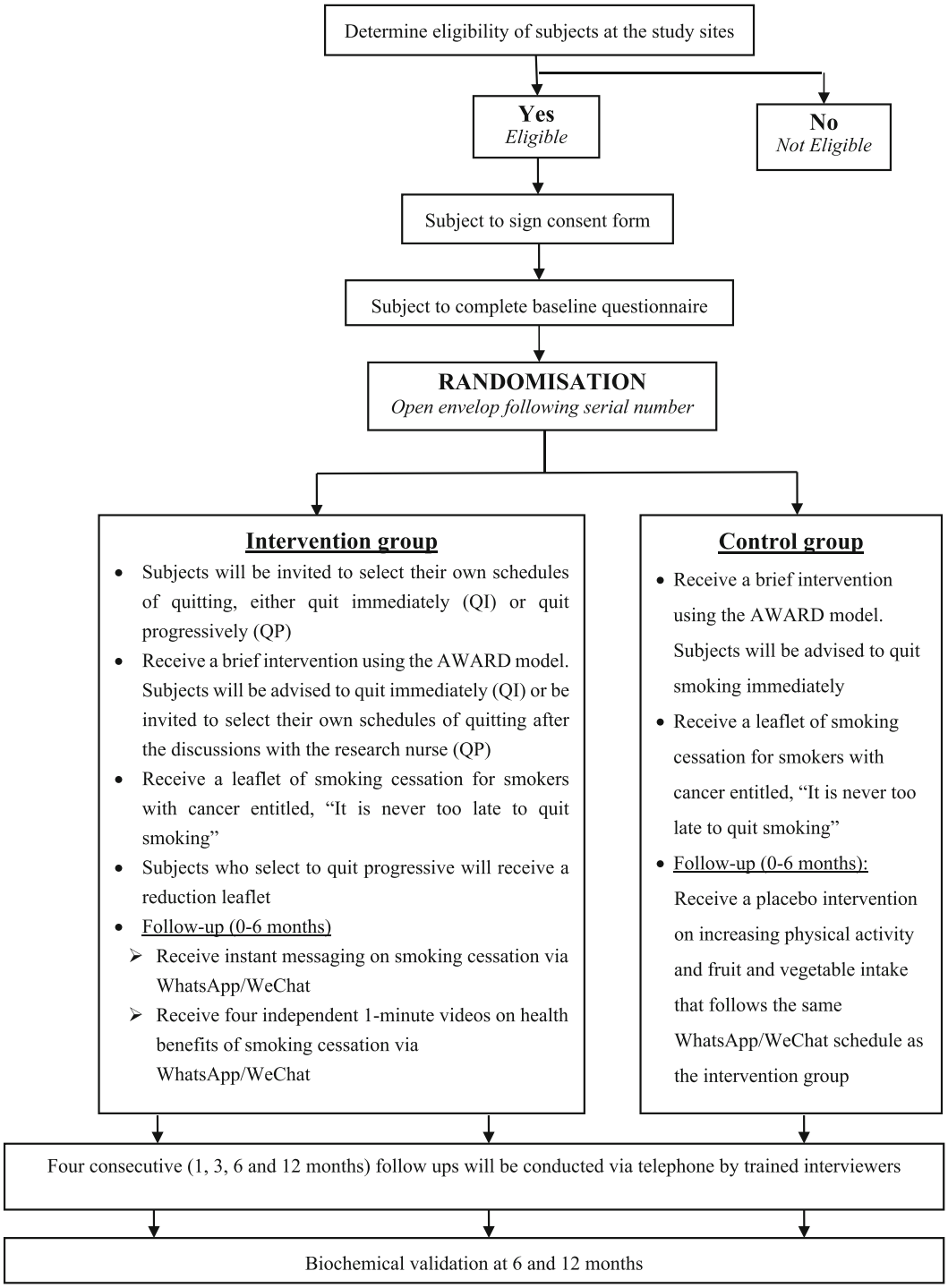
Ethics

This study obtained ethical approval from the Hong Kong New Territories East Cluster Clinical Research Ethics Committee (2022.447-T), the Hong Kong West Cluster Institutional Review Board (UW 22-740) and the Central Institutional Review Board (CIRB-2022-050-5).

Participants

Chinese smokers with cancer attending medical follow-ups at specialist outpatient clinics of five major hospitals in different Hong Kong clusters will be invited to participate in the study. The inclusion criteria are patients: (a) that smoked weekly in the last 6 months; (b) with a diagnosis of any cancer for at least 6 months and at all cancer stages (I, II, III, or IV); (c) aged ≥ 18 years, (d) able to communicate in Cantonese/mandarin and read Chinese; and (e) who own a smartphone and are able to use instant messaging (e.g. WhatsApp or WeChat). The exclusion criteria are: (a) individuals with unstable medical conditions, poor cognitive state or mental illness (e.g. anxiety disorders, schizophrenia and delusional disorder) as informed by the doctor or nurse in charge and noted on their medical records; (b) those participating in other smoking cessation programs; and (c) those who do not own a smartphone or are unable to receive WhatsApp/WeChat messages.

Almost all patients admitted to public hospitals under the Hospital Authority of Hong Kong are Chinese. Our training for research nurses



AWARD: (a) Ask about smoking history, (b) Warn about the high risk, 'one in two smokers will be killed by smoking,' (c) Advise to quit now, (d) Refer smokers to a smoking cessation clinic, and (e) Do it again: repeat the intervention

FIGURE 1 The design of this trial is in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement.

and assistants, including all training materials, has therefore been prepared in Chinese. To recruit a homogenous group of smokers, we decided to exclude non-Chinese smokers from our trial. However, we will provide these smokers with an English language self-help smoking cessation booklet and a quit hotline at outpatient clinics.

The Thematic Household Survey Report [4] showed that 92.9% of Hong Kong residents used a smartphone in 2017. Furthermore, a pilot RCT involving 60 smokers in Hong Kong from 2019 to 2020 found that more than 90% of participants owned a smartphone and could use an instant messaging application (e.g. WhatsApp/WeChat)

to communicate [25]. Smokers who do not own a smartphone or are unable to receive WhatsApp/WeChat messages and those with mental illness will receive a smoking cessation leaflet and brief advice on smoking cessation, but will be excluded from the study. However, with their consent and permission, they will be referred to a smoking cessation clinic or a smoking cessation hotline.

Recruitment

Potential participants will be assessed for eligibility and receive an explanation about the purpose, design, procedures and potential benefits and risks of the study. Informed written consent will then be sought. All participants will be assured that their participation will be voluntary, no prejudice will be attached to refusal and that the information they provide will be kept confidential.

Intervention

Theoretical framework

The intervention is guided by the self-determination theory [26], which is shown in Supporting information, Data S1.

Intervention group

In outpatient clinics, participants will first receive a brief intervention using the Ask, Warn, Advise, Refer and Do-it-again (AWARD) model. Previous clinical trials of smoking cessation involving smokers (n = 1571) attending emergency departments between 2015 and 2017 and smokers (n = 1226) in the community in 2015 provided evidence of the effectiveness of brief interventions using the AWARD model [18, 27]. The brief intervention in this study will comprise the five AWARD steps: (1) ask about smoking history; (2) warn about the high morbidity and mortality risks associated with smoking; (3) advise to quit: participants will be allowed to select their own quit schedules after discussing their situation with the research nurse (quit immediately [QI] or quit progressively [QP] with the ultimate goal of complete cessation); (4) refer smokers to a smoking cessation clinic or a smoking cessation hotline; and (5) do it again: repeat the intervention and encourage smokers who fail to quit or that relapse to try again during each telephone follow-up. The whole intervention will last approximately 5–8 minutes. This brief intervention will be cost-effective and feasible for routine use in clinical practice by health-care professionals after minimal training [28]. Scripts for the QI and QP interventions are shown in Supporting information, Data S2; this content emphasizes the health benefits of quitting.

Participants who opt to quit progressively will receive a smoking reduction leaflet (Supporting information, Data S3), which contains reduction strategies and a suggested plan to reduce smoking. These participants will also be given the option to consider a tailored quit schedule after their discussion with the research nurse. The research nurse will motivate participants to reduce cigarette consumption and then quit at their own pace, but the whole process should not exceed 6 months.

At the end of the face-to-face session, participants will be informed that the research nurse will help them to adhere to their schedules over the next 6 months by sending WhatsApp/WeChat messages. Each participant will receive a specially designed leaflet (Supporting information, Data S4) for smokers with cancer entitled: 'It is never too late to quit smoking'. The content will highlight smoking risks, the benefits of quitting and myths about quitting smoking. The advisory messages given to participants will be standardized with reference to the specially designed leaflet.

Follow-up booster intervention (0–6 months)

During the first 3 months of the study, the research nurse will deliver WhatsApp/WeChat messages at least once per week. Scripts for these follow-ups are shown in Supporting information, Data S5. In addition, participants will receive four independent 1-minute videos (one video in weeks 1, 5, 9 and 13) via WhatsApp/WeChat. The video content will focus upon the health benefits of smoking cessation after a cancer diagnosis. Between the 3- and 6-month follow-up assessments, infrequent messages (approximately one WhatsApp/WeChat message per month) will be sent by the research nurse to follow participants' progress, respond to their questions and maintain contact.

Control group

In outpatient clinics, participants will receive a brief intervention using the AWARD model. However, all participants will be advised to quit immediately. Control group participants will receive the same leaflet for smokers with cancer as the intervention group participants.

Follow-up

Participants in the control group will receive a low-level intervention that follows the same WhatsApp/WeChat schedule as the intervention group, but the messages will contain only general health advice, such as performing more physical activity and eating more fruit and vegetables. The control group will not receive any videos.

Training and quality assurance

Detailed training and quality assurance of intervention implementation are reported in the Supporting information section, Data S6.

TABLE 1 Schedule of enrolment and follow-up assessments.

	Time-point				
	Baseline	**1-month**	**3-month**	**6-month**	**12-month**
Recruitment in specialist outpatient clinics	X				
Informed consent	X				
Eligibility screening	X				
Randomization	X				
Intervention	X				
Follow-up booster intervention delivered via WhatsApp/WeChat (for the first 6 months)		X	X	X	
Structured questionnaire: • Socio-demographic and clinical characteristics[a] • Smoking-related characteristics[b]	X				
Carbon monoxide level in the participants' exhaled air at baseline	X				
EuroQoL 5-Dimension 5-level	X			X	X
Self-reported smoking status	X	X	X	X	X
Validated smoking status: • Saliva cotinine level • Carbon monoxide level in expired air				X	X
Process evaluation[c]					X

[a]Socio-demographic characteristic include sex, age, marital status, educational level, employment status, and monthly household income.
[b]Smoking-related characteristics include daily cigarette consumption, nicotine dependence by the Heaviness of Smoking index, quit attempt history and ever or current use of electronic cigarette.
[c]Process evaluation will be conducted after the 12-month follow-up.

Baseline variables

Participants' demographic and clinical characteristics, including smoking history, medical diagnosis and medical history, will be obtained at baseline. Furthermore, we will measure participants' health-related quality of life using the EuroQoL 5-Dimension 5-level (EQ-5D-5L), and check the carbon monoxide level in participants' exhaled air. The schedule of enrolment and follow-up assessments is shown in Table 1.

Randomization and allocation concealment

After obtaining consent and collecting baseline data, the research nurse will input the collected data into a web-based trial entry form linked to a computerized database, and randomization will then be performed by an independent statistician. Randomly permuted block sizes of four, eight and 12 will be used to ensure a similar number of participants in the intervention and control groups. The group sequence list will be password protected, stored on a computer and only accessible to the staff responsible for group allocation who have no other involvement in the study. Each participant in each stratum will be sequentially assigned to their group based on the corresponding group identifier in the randomized grouping list. The group allocation will be concealed from the outcome assessors. The baseline assessment and intervention delivery for each participant will be implemented in a single room or cubicle to ensure privacy and prevent the possibility of interaction between the two participant groups.

We note that we changed from envelope to electronic randomization after receiving comments from a reviewer. However, we have not changed the randomization process, which is still based on computer-generated random numbers to generate random group allocation sequence for each subject recruitment site (hospital). The random group allocation sequences will be saved in password-protected computer to enhance the allocation concealment.

Data processing and analysis

A structured questionnaire has been developed by adapting existing international and locally validated instruments. The information gathered at baseline will include smoking and quitting history, stage of readiness to quit, use of existing smoking cessation services and demographic information (e.g. age, gender and marital status). We consider people who use e-cigarettes or vape to be smokers, and this information will be measured at baseline and recorded in the questionnaire. Some demographic and clinical information will be obtained from participants' medical records.

The EQ-5D-5L will be used to measure participants' health-related quality of life at baseline, 6 and 12 months [29]. The psychometric properties of the Chinese version of the EQ-5D-5L have been tested, and showed that this tool is a valid, reliable and sensitive measure of health-related quality of life [30]. A Chinese-specific EQ-5D-

5L value set will enable the estimation of health utility scores applicable to the Chinese population and quality-adjusted life-years for cost-effectiveness analysis (CEA) [30].

Process evaluation will be conducted with participants after the 12-month follow-up. Process evaluation can help to identify the strengths and limitations of a new care delivery model from participants' perspectives. Moreover, process evaluation can help to identify the most important elements of the intervention and improve future implementation of the intervention. Importantly, this evaluation provides information about optimizing the quality and efficacy of a newly developed model of care. Based on their smoking status, 40 participants from the intervention group (20 quitters and 20 non-quitters) will be interviewed and a final sample determined using data saturation. A one-to-one audiotaped semi-structured in-depth interview (face-to-face) will be conducted with each participant. The semi-structured interview guide (Supporting information, Data S7) was developed by the research team, which includes a professor with extensive experience and knowledge of conducting smoking-related research and another professor with considerable experience in qualitative research. An incentive in the form of a HK$200 (US$26.0) coupon will be offered to participants to thank them for their participation in the interviews.

Outcomes

The primary outcome measure is (i) biochemically validated smoking abstinence at the 6-month follow-up. Only individuals who self-reported smoking abstinence within the past 7 days will be invited to participate in the above validation. The biochemically validated 7-day point prevalence of abstinence will be confirmed by parallel testing of a saliva cotinine level of < 30 ng/ml and carbon monoxide level in exhaled air of < 4 parts per million (p.p.m.) to provide good agreement with self-reported smoking status. All time-points for outcomes measures will be set after randomization.

Secondary outcomes are (ii) biochemically validated smoking abstinence at 12-month follow-up, (iii) self-reported 7-day point prevalence of smoking abstinence at 6 and 12 months, (iv) self-reported reduction of ≥ 50% cigarette consumption at 6 and 12 months and (v) quality of life at 6 and 12 months. To increase the participation rate, biochemical validation will be conducted at the participants' homes. Moreover, we will offer participants who complete all biochemical validations a HK$100 (∼US$23) coupon. Participants will be considered non-reducers if they reduced their exhaled carbon monoxide level by < 1 p.p.m. compared with baseline. For participants using nicotine replacement therapy, biochemical validation will be conducted 7 days after the completion of therapy.

Sample size

G*Power will be used to estimate the sample size, based on two previous RCTs conducted in Hong Kong for smokers with cancer (2012–15; n = 528) [16] and smokers attending emergency departments (2015–17; n = 1571) [18]. We predict that the proposed intervention will result in at least a 4% difference (7 versus 3%) in biochemically validated abstinence between the two groups at 6 months. The research team reached consensus that such changes constitute a minimally important difference (i.e. are clinically significant) and therefore warrant a change in patient management. To detect a significant difference between the intervention and control group quit rates with a power of 90% and a significance level of 5%, at least 507 participants are needed per group. Referring to our previous intervention studies [18, 19, 22] we allow a potential retention rate of 70% at the 12-month follow-up, and 1448 participants (724 per group) will be recruited to maintain the statistical power in a complete case sensitivity analysis. To boost retention rate, we will offer a HK$300 (US $ ∼ 39.0) coupon to each eligible individual who participates in the study and completes four consecutive telephone follow-ups (at 1, 3, 6 and 12 months). Primary and secondary outcomes will be assessed at 6 and 12 months, whereas the follow-up calls at 1 and 3 months will simply be to follow-up on participants' quit or reduction progress, answer their questions and maintain contact.

Data analysis

Appropriate descriptive statistics will be used to summarize participants' baseline characteristics and outcome data throughout the study time-points. The primary outcome is biochemically validated smoking abstinence at 6-month follow-up. A generalized estimating equation (GEE) analysis will be conducted to compare the incidence rate of biochemically validated smoking abstinence at the 6-month follow-up between the intervention and control groups, with adjustment for the potential clustering effect from participants recruited from different hospitals. An additional adjusted analysis will be conducted by further controlling for all participant characteristics which are identified as prognostic of outcome (P < 0.1). GEE analyses will also be conducted to compare the secondary outcomes with adjustment for the clustering effect and with/without controlling for potential prognostic factors. The intention-to-treat principle will be adopted in the primary analyses for all the primary and secondary outcomes by imputing missing follow-up outcome data with their baseline values (i.e. assuming failure for the primary outcome and no change after the intervention for the secondary outcomes) under the assumption of data missing not at random. This assumption is plausible, in the sense that missing data because of dropouts or non-responses are more likely among those who are failed to smoking abstinence.

Sensitivity analyses for the primary and secondary outcomes will also be conducted under the assumptions of (1) data are missing completely at random (MCAR) and (2) data are missing at random (MAR) to evaluate the robustness of the primary analysis results. Complete case analyses will be conducted for the primary and secondary outcomes, the results of which are anticipated to be unbiased under the condition of MCAR. The Little's MCAR test will be used to justify the plausibility of the assumption. Furthermore, if the

assumption of MCAR is not supported, the sensitivity analyses will be conducted based on multiple imputations under the assumption of MAR. Subgroup analysis will be conducted to explore any interaction effects.

Our health economist (a Co-A) will conduct a CEA (Supporting information, Data S8) using standard methods [31].

The process evaluation data analysis will begin immediately after each individual interview in accordance with the thematic analysis framework introduced by Braun & Clarke [32], using NVivo version 12 (QSR International Pty Ltd, 2018), which is shown in Supporting information, Data S8.

Current status

Recruitment began on 1 July 2023. The treatment is expected to be completed on 31 December 2024. All outreach activities, follow-up and data collection are expected to be completed in December 2025.

DISCUSSION

Many patients living with cancer who continue to smoke are chronic smokers and find it difficult to quit, despite being aware of the health hazards associated with smoking. These smokers are also unlikely to be affected by current tobacco control interventions or policies. We anticipate that the new strategies used in the study described in this protocol study will facilitate recruitment and increase the retention rate among Chinese smokers, intervention compliance and biochemical validation participation rates among smokers with cancer. In particular, if this new inexpensive intervention achieves a high level of smoking abstinence, it could offer a cost-effective and sustainable approach for improving the physical wellbeing and health-related quality of life of patients living with cancer who smoke, and could save more lives. The results could inform future research, policymaking and health-care professionals regarding smoking cessation for patients living with cancer, and therefore have important implications for clinical practice and health enhancement.

Our aim is to describe the protocol for a pragmatic trial to implement the intervention in real-world settings and evaluate its effectiveness, emphasizing practicality rather than theory and ideology. An important advantage of pragmatic trials is that research results can be more easily generalized to clinical practice. However, the Pragmatic Explanatory Continuum Indicator Summary 2 (PRECIS-2) tool suggests that this trial can only be considered fairly pragmatic, as we will offer small financial incentives to participants who complete follow-ups and biochemical validations, which is not the usual practice in a real-world setting [33]. The incentive may potentially increase smokers' acceptance of and compliance with smoking cessation treatments. However, the incentive will be given to both groups of participants, meaning that any effects on treatment will balance each other out.

Positive findings from this study may promote the development of new clinical practice guidelines and evidence-based smoking cessation services. Importantly, the findings could be used to create a new smoking cessation service model that uses a flexible, low-cost, proactive and personalized approach to help smokers with cancer quit smoking. Attendance at outpatient clinics represents an excellent opportunity to implement smoking cessation interventions. The average waiting-time for medical consultation is generally longer than 30 minutes. This period provides health-care professionals with an excellent opportunity to advise smokers with cancer to quit and inform patients about available smoking cessation programs (potential facilitators). However, many health-care professionals hesitate to initiate smoking cessation interventions in their work-places because of the busy clinical environment and lack of training, experience and confidence in helping patients to quit smoking (potential barriers). To overcome these potential barriers, in the study we describe in this protocol we are assessing the impact of health-care professionals working in specialist outpatient clinics providing brief interventions to motivate smokers to quit, and actively referring patients to existing cessation services for continuous personalized support via instant messaging [34].

If successful, this study is likely to have a substantial long-term impact on the health-care industry, particularly on smokers with cancer. It will contribute to reducing health-care expenditure and the economic burden on society by reducing the risks of morbidity and mortality. Importantly, it will help to improve the physical wellbeing and health-related quality of life of smokers with cancer and protect the public, especially vulnerable groups such as women and children, from exposure to second-hand smoke. This will ultimately save more lives, protect the environment and boost sustainable development.

AUTHOR CONTRIBUTIONS

William Ho Cheung Li: Conceptualization (lead); funding acquisition (lead); writing—original draft (lead). **David Chi Leung Lam:** Conceptualization (supporting); funding acquisition (supporting); writing—review and editing (equal). **Kit Man Sin:** Conceptualization (supporting); funding acquisition (supporting); writing—review and editing (equal). **Eliza Lai Yi Wong:** Conceptualization (supporting); funding acquisition (supporting); writing—review and editing (equal). **Carlos King Ho Wong:** Conceptualization (supporting); funding acquisition (supporting); methodology (supporting); writing—review and editing (equal). **Herbert Ho Fung Loong:** Conceptualization (supporting); funding acquisition (supporting); writing—review and editing (equal). **Kai Yeung Cheung:** Conceptualization (supporting); funding acquisition (supporting); writing—review and editing (equal). **Wei Xia:** Conceptualization (supporting); funding acquisition (supporting); writing—review and editing (equal). **Peige Song:** Conceptualization (supporting); funding acquisition (supporting); writing—review and editing (equal). **Joyce Oi Kwan Chung:** Conceptualization (supporting); funding acquisition (supporting); writing—review and editing (equal).

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DECLARATION OF INTERESTS

None.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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