Chat-based instant messaging support combined with brief smoking cessation interventions for Chinese community smokers in Hong Kong: Rationale and study protocol for a pragmatic, cluster-randomized controlled trial

Author information

Tzu Tsun Luk[1], William Ho Cheung Li[1], Derek Yee Tak Cheung[1], Sze Wing Wong[1], Antonio Cho Shing Kwong[2], Vienna Wai Yin Lai[2], Sophia Siu-chee Chan[1], Tai Hing Lam[3], Man Ping Wang[1]*

[1]School of Nursing, The University of Hong Kong, Hong Kong

[2]Hong Kong Council on Smoking and Health, Hong Kong

[3]School of Public Health, The University of Hong Kong, Hong Kong

***Corresponding Author:**

Man Ping Wang, PhD
School of Nursing
The University of Hong Kong
4/F, William M.W. Mong Block
21 Sassoon Road, Pokfulam
Hong Kong, China
Phone: +852-3917-6636
Email: mpwang@hku.hk

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ABSTRACT

Background: Novel approaches to engage community smokers in smoking cessation are needed as smokers typically lack motivation to quit or use evidence-based tobacco dependence treatment. Mobile instant messaging apps (e.g., WhatsApp, Facebook Messenger) are widely used but under-studied as a mobile health modality for delivering smoking cessation support. This paper presents the rationale and study design of a trial which aims to evaluate the effectiveness of a chat-based intervention using mobile instant messaging combined with brief interventions for community smokers.

Methods: This is a two-arm, parallel, accessor-blinded, pragmatic cluster-randomized controlled trial on an estimated 1172 daily cigarette smokers aged ≥18 years proactively recruited from 68 community sites (cluster) throughout Hong Kong. Subjects in intervention group received three months of chat-based, instant messaging support guided by acceptance and commitment therapy and other behavioural change techniques, integrated with brief advice and active referral to a smoking cessation service using the AWARD (Ask, Warn, Advise, Refer, Do-it-again) intervention model. Control group received brief advice to quit plus a self-help booklet at baseline. Outcomes were assessed at 1-, 2-, 3- and 6-month after baseline. The primary outcome is abstinence validated by exhaled carbon monoxide (<4 ppm) and salivary cotinine (<10 ng/mL) at 6-month after baseline. Primary analyses will be based on intention-to-treat.

Comments: This is the first trial examining the effectiveness of a chat-based cessation support programme combined with brief interventions in promoting abstinence. The intervention model can be adapted for other behavioural change treatments and more advanced digital smoking cessation intervention.

Keywords: mHealth; digital health; chat intervention; instant messaging; tobacco dependence treatment; WhatsApp

1. Introduction

Over half (68.4%) of the world's population does not have access to proper tobacco dependence treatment, and few smokers in the community actively seek help to quit [1]. Proactive recruitment can engage disadvantaged or unmotivated smokers in tobacco dependence treatment [2]. Trials on proactive conventional cessation interventions such as brief advice, counselling and nicotine replacement therapy have been found effective in promoting abstinence amongst smokers in clinical and community settings [3-6].

Widespread use of mobile communication devices provides a low-cost and scalable means to deliver smoking cessation support. Systematic reviews have found cessation support delivered through SMS (short-message services) text messaging to be modestly effective (odds ratios ranging from 1.38-1.83) in increasing abstinence among smokers in different settings [7, 8]. Among these interventions, some allowed two-way communication whereby the smokers could text keywords to acquire on-demand support from the automatic response system. Smokers' perceived psychosocial support (e.g., a feeling of being cared) were found mediating the effect of such text messages on quitting [9, 10].

Mobile instant messaging apps (e.g., WhatsApp and Facebook Messenger) have rapidly supplanted SMS as the most commonly used mobile messaging tool. We found that health information exposure from instant messaging was associated with healthier behaviours, including less smoking [11]. Our pilot trial in recent quitters have found WhatsApp social group chatting to be effective in preventing smoking relapse [12], supporting the feasibility of using mobile instant messaging for smoking cessation in this population. Comparing to text messaging, instant messaging may facilitate more intensive, real-time interaction between the treatment providers and smokers, potentially improving their perception of psychosocial support, and may be a more conducive mobile health (mHealth) modality for delivering personalised smoking cessation support [13].

Like many other developed Western countries, engaging community smokers in smoking cessation has remained a challenge in Hong Kong, where daily cigarette smoking prevalence is

decreasing (10.0% in 2017) [14]. Further decline is increasingly difficult due to hardening of smokers after implementation of stringent tobacco control policies [15]. Only 31.2% of daily cigarette smokers ever made a quit attempt and only 2.4% of current smokers ever utilized smoking cessation services [14], which are free and effective in Hong Kong (52-week quit rate ranging from 18.4%-35.9%) [16-19]. We developed and have continuously evaluated and refined a brief intervention model "AWARD" (Ask, Warn, Advise, Refer, Do-it-again) for promoting quitting and use of smoking cessation services in community smokers [20-22]. Capitalizing on the extensive smartphone penetration (88.6%) in Hong Kong [14], we developed a chat-based cessation intervention delivered through a mobile instant messaging application (WhatsApp), integrated with brief advice and active referral to smoking cessation services using the AWARD framework. This study protocol presents the design of a pragmatic cluster-randomized controlled trial which aims to examine the effect of the combined intervention on SC outcomes in proactively recruited community smokers in Hong Kong.

2. Material and methods

2.1. Study design

This study is a two-arm, parallel, accessor-blinded, pragmatic cluster-randomized controlled trial. The trial is nested within the "Quit to Win (QTW)" Smoke-free Community Campaign 2017, The QTW campaign is an annual smoking cessation contest organized by the Hong Kong Council on Smoking and Health to encourage community smokers to quit through incentives [20-24]. The conduct of the study is guided by the CONSORT extension for cluster trial. Figure 1 shows the trial flowchart. The research protocol has been registered with ClinicalTrials.gov (NCT03182790). Ethical approval was granted by the Institutional Review Board of the University of Hong Kong/ Hospital Authority Hong Kong West Cluster (UW 17-246).

(Please insert Figure 1 here)

2.2. Participants and settings

Similar to our previous QTW trials, participants recruitment lasted from June to September of the year. Sixty-eight community sites (e.g., shopping malls and housing estates) were selected from

all 18 districts in Hong Kong for participant enrolment. Trained smoking cessation ambassadors comprising of college/ university students and volunteers from non-governmental organizations proactively approached smokers near the recruitment sites using a "foot-in-the-door" approach [25]. The ambassadors first initiated conversations with the smokers by asking about their smoking behaviors, assessed their exhaled carbon monoxide level, and invited them to join the QTW contest to quit or reduce smoking. Smokers interested in participating in the contest were then screened for their eligibility. Inclusion criteria include: (1) being a Hong Kong resident aged ≥18 years; (2) having smoked ≥1 cigarette(s) per day in the past 3 months, verified by an exhaled carbon monoxide level of ≥4 ppm; (3) be motivated to quit or reduce smoking, signified by joining the QTW contest; (4) and able to use an instant messaging application installed on a cell phone. Individual who cannot communicate in Cantonese or read Chinese, or currently participating in other smoking cessation programs will be excluded. Our previous QTW study showed that the participants recruited by this method were largely similar to the local daily cigarette smoking population in terms of age, sex and daily cigarette consumption (Cohen effect sizes<0.03) [26].

2.3. Intervention

Both the intervention and control groups received brief smoking cessation advice at baseline. The smoking cessation ambassadors asked the smokers about their smoking behaviors (Ask), warn about the harms of continue smoking using the test result of their exhaled carbon monoxide level (Warn), and then advised them to quit or reduce smoking as soon as possible (Advise).

The AWARD model was used to integrate the additional treatment (Active referral to smoking cessation services [Refer] and Chat-based instant messaging support [Do-it-again]; see below) delivered to the intervention group.

2.3.1. Active referral to smoking cessation services

Using a 3-fold pocket-sized information card, which contains highlights of treatment modalities and contacts of each smoking cessation services in Hong Kong (Appendix), the ambassadors introduced the smoking cessation services in Hong Kong to the smokers and encouraged

them to select a service at baseline. Details of these services have been reported elsewhere [16-19, 27]. Telephone contacts of the participants agreed to be referred were sent to the service providers for arrangement of further treatments.

2.3.2. Chat-based instant messaging support

Participants received three months of individual, chat-based cessation support delivered through a mobile instant messaging application (WhatsApp). The design and content of the intervention was informed by five formative focus group interviews with 21 local community smokers [13]. The intervention allowed a trained smoking cessation counsellor has real-time (synchronous), one-to-one interaction with a participant and provide personalized behavioural support according to his or her needs (see below). The intensity of the conversation between the participant and counsellor was completely variable and depends on the participant. While the participant could send a message anytime, the counsellors could only response during day time on working days due to resource constraint. The messages from the counsellor were tailored according to the participant' characteristics (e.g. age, sex and smoking pattern). The language style (spoken vs written language) was also adjusted according to the participant's preference.

The chat-based intervention followed the counselling model of acceptance and commitment therapy (ACT) [28]. ACT for smoking cessation aims to strengthen the smokers' motivation to quit based on their values (commitment) and help them to overcome the negative experiences associated with craving using mindfulness skills (acceptance). Guided by previous trials of ACT for smoking cessation [29, 30], we developed a guideline on delivery of ACT for use in this study (Table 1). The counsellor helped the participants to identify values that could act as motivators for them to quit. For participants who had expressed difficulty to deal with craving, the counsellors attempted to increase their psychological capacity to overcome their urge to smoke using ACT metaphors and simple experiential exercises.

(Please insert Table 1 here)

As an extension of the AWARD model ("Do-it-again") at baseline, the chat-based intervention also applied other behavioural change techniques (BCTs) that promote adjuvant activities to aid cessation [31]. Specifically, for participants who were not ready to be referred to smoking cessation services at baseline, the counsellor provided information about the smoking cessation services (BCT code: A5), advised them to utilize the services (A1), actively referred them to the service providers (A3), and followed-up their experience of using the services (A4). Subject to the needs indicated by the participants through instant messaging, the counsellor also applied BCTs that maximize their self-regulatory capacity or skills (e.g., setting a quit date [BS9]) and other supportive BCTs such as assessing their withdrawal symptoms (RI4) and answering questions related to smoking cessation raised by the participants (RC2).

To initiate and facilitate interaction between the counsellors and participants, 16 regular messages were sent to the participants with a tapering schedule (from twice weekly in the first month to once a week in the third month). These messages covered generic information about the benefits of quitting, methods to avoid/ manage craving or withdrawal symptoms, and encouragement to quit and use smoking cessation services. A reminder to participate in the telephone follow-up were also be sent at 1-, 2-, 3- and 6-month, making up a total of 20 messages.

2.3.3. Control

Participants in the control group only received brief advice to quit at baseline (Ask, Warn, Advise) without offers of referral to a smoking cessation services and chat-based cessation support. They received 4 SMS messages delivered at 1-, 2-, 3- and 6-month as reminders for participating in telephone follow-up surveys. Both groups also received a generic 12-page self-help booklet [32], which has been routinely distributed in previous QTW contests (Appendix) [20-24].

2.3.4. Intervention fidelity

All smoking cessation ambassadors were required to attend a half-day training workshop and completed a pre- and post-test of their knowledge, attitudes and practice prior to subject recruitment. The workshop covered an overview of the research project and the knowledge and skills to

approaching smokers in the community and delivering baseline brief interventions (AWARD advice and active referral). A research staff was available on-site at each recruitment session to provide supervision and assistance as needed. The counsellors who delivered chat-based cessation support comprised of research staff who had at least one year of experience in smoking cessation research, supervised by a registered nurse specialized in smoking cessation counselling and a master's level psychotherapist (with training in ACT) who provided immediate support in handling difficult cases. All instant messaging conversations were recorded and monitored for quality control. The counsellors also met at least weekly to discuss the case loads.

2.4. Outcomes

The primary outcome is biochemically validated abstinence at 6-month after randomization [33], defined by an exhaled carbon monoxide level of <4 ppm measured by a Smokerlyzer® [34] and salivary cotinine level of < 10 ng/mL using a NicAlert test strip [35]. Main secondary outcome is biochemically validated abstinence at 3-month (end of treatment). Other secondary outcomes include self-reported past 7 days abstinence, smoking reduction by at least 50% of baseline consumption, number of quit attempts (abstinence for ≥ 24 hours) and smoking cessation service use at 3- and 6-month. Participants in both study arms received a small cash incentive of HK$500 (≈ US$64) for passing the validation at 3- and 6-month (total HKD1,000 ≈ US$128) to increase participation rate, which have been found to have no effect on abstinence in our population [23].

Table 2 shows the schedule of data collection. At baseline, smokers completed a questionnaire on their smoking behaviour (daily cigarette consumption, time to first cigarette upon waking up in the morning, age of weekly smoking initiation, history of previous quit/ reduction attempt, readiness to quit, perceived self-efficacy on quitting (measured on a 10-point scale), and sociodemographic characteristics. Nicotine dependence was assessed by the Heaviness of Smoking Index (HSI). Telephone follow-up surveys were conducted at 1-, 2-, 3- and 6-month after initiation of intervention (i.e., baseline). To encourage participation, an incentive of HK$100 (≈ US$12.8) was given to participants for completing the follow-ups. Participants were considered lost to follow-up

after 7 telephone calls at different time and day of the week but were not removed from the contact list for the next follow-up.

(Please insert Table 2 here)

For process evaluation of the intervention, information on the type of smoking cessation service accessed and treatment received, and perceived usefulness of each component of the intervention were collected at each telephone follow-up. Data on changes in perceived self-efficacy to quit were also assessed at 3- and 6-month.

2.5. Sample size

Our previous trial which has equivalent study design and control condition showed that the intention-to-treat biochemically validated abstinence at 6-month was 5.1% [22]. The estimated effect size is based on the relative risk for biochemically validated abstinence at 6 months (=1.83) reported in a meta-analysis of mHealth intervention for smoking cessation [7]. With a power of 80% and 2-sided 5% level of significance, 586 participants per group will be needed to detect a significant between-group difference in the primary outcome calculated by PS Power and Sample Size version 3.1.2.. Despite the potential diminished return in power due to cluster randomization, our previous QTW trial showed that the intra-cluster correlation coefficient for biochemically-validated abstinence at 6-month was negligible (< 0.001) [21]. Thus, the total number of participants needed is 1172 (=586×2 group).

2.6. Randomization and blinding

Recruitment sessions (n=68) were randomized in a 1:1 ratio to intervention group and control group with random permuted block size of 2, 4 and 6 to ensure same number of sessions in both study arms. The randomization sequence is generated by a non-investigator using Microsoft Office Excel. Participants within the same recruitment session receive the same intervention to prevent contamination. The group allocation is concealed to the ambassadors until the beginning of each recruitment session. Blinding of participants and study personnel is not possible for behavioural

intervention, but the participants are not informed about the treatment in the other group. Outcomes assessors and statistical analysts are blinded to the group allocation.

2.7. Data analyses

2.7.1. Primary analyses

All statistical analyses will be conducted in Stata/MP version 15.1. The primary analysis will examine the intervention effect on biochemically validated abstinence at 6-month by intention-to-treat. Non-respondents at follow-up will be assumed to have no change in smoking behaviours from baseline [33]. Generalized estimating equation (GEE) model with an exchangeable correlation structure will be used to account for the clustering effect [36]. Intra-cluster correlation coefficient for the primary outcome will be calculated using analysis of variance.

As a sensitivity test, multivariable analyses will be used to account for potential imbalance of baseline characteristic. Sensitivity to attrition/ missing data in biochemically validated abstinence at 6-month will be examined using multiple imputation by fully conditional specification under the assumption that the data will be missing at random. Complete case analyses which exclude participants lost to follow-up will also be conducted. The intervention effect on the secondary outcomes will be similarly examined.

2.7.2. Secondary analyses

We will conduct subgroup analyses by baseline characteristics, including age group, gender, readiness to quit to in 30 days, previous quit attempt and level of nicotine dependence assessed by HSI. Although the trial is not powered to examine interaction, multiplicative interaction terms of baseline characteristics × group allocation will be included in GEE models to calculate p value for interaction.

To evaluate the utility of instant messaging support for smoking cessation, we will examine the baseline smoking behaviour (e.g. history of previous quit/ reduction attempt, readiness to quit) and socio-demographic correlates of participants engagement in instant messaging conversation with

counsellors. Content analysis of the instant messaging dialogues between the participants and counsellor will also be conducted. The content of conversations will be independently coded by 2 researchers using the typology of BCTs [31].

3. Discussion

The trial described in this study protocol has several distinctive features. First, unlike most previous smoking cessation trials, which enrol smokers in the clinical settings or through passive means in the community (e.g., advertisement), we used proactive recruitment approach to reach smokers in the community, who typically have minimal interest in quitting. Second, we trained and used student helpers rather than research or healthcare staff for participant recruitment and delivery of baseline interventions, which may be more cost-effective and sustainable [21]. Third, to our knowledge, this will be the first trial examining the effectiveness of using chat-based intervention on smoking cessation through mobile instant messaging. The intervention model, if found effective in promoting smoking cessation, can be adapted for treating other modifiable behaviours such as alcohol use disorder and physical inactivity. The trial may also act as a feasibility or prototypical study exploring the potential of more scalable and technologically advanced digital intervention such as Chat bots [37], which can provide more sustainable, interactive and synchronous personalized cessation support to smokers.

Unlike previous text-messaging trials that utilized a computer-based automatic SMS system to deliver the messages, our instant messaging intervention involves a smoking cessation councillor to interact with the participants in real-time and provide individualized smoking cessation supports according to the needs of the participants. Through person-to-person interaction, the chat-based intervention may also strengthen the perception of psychosocial support, an underutilized mechanism to promote smoking cessation [38]. The cost of sending SMS message might limit interactive messaging use [39]. Instant messaging apps allow free exchange of text, emojis, voice messages and multimedia files through internet. The widespread use of instant messaging apps worldwide may be more scalable and market-ready than other smartphone applications for mHealth smoking cessation intervention.

This trial has some potential limitations. First, due to the lower daily cigarette smoking rate in women (2.7%) than men (18.1%) in Hong Kong [14], subjects enrolled in this study will likely consist of a greater proportion of male participants, which have been observed in our earlier trials conducted within the QTW contests [20-24]. The findings may thus be less applicable to other populations (e.g., Caucasian), where female smokers are more common. Second, the trial uses a pragmatic design wherein minimal restrictive criteria on subject recruitment is imposed and participants' utilization of smoking cessation services and chat-based cessation support might be expectedly lower than more selective sample. Such approach provides real-world evidence on the effectiveness of the intervention to inform clinical practice but may underestimate its beneficial effect [40]. Third, the trial does not address any long-term outcome (e.g. 12 months) due to limited resources. Finally, the trial is nested in a QTW contest with a small cash incentive to encourage quit attempt. Nevertheless, small cash incentive was not found effective no effect on abstinence in our previous QTW trial [23].

Declaration of interests

None.

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Appendix A: Supplementary materials

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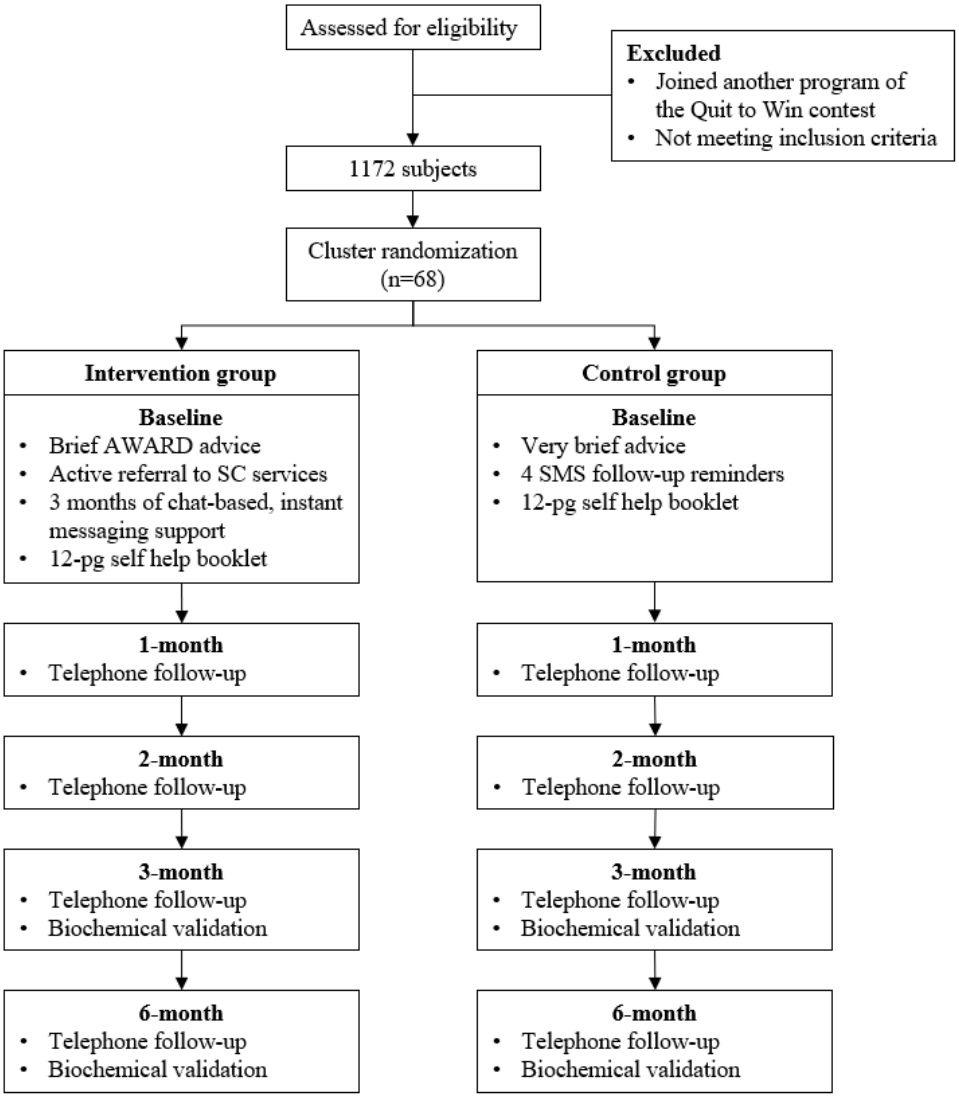

Figure 1. Study flowchart. AWARD=Ask, Warn, Advise, Refer, Do-it-again. SC=Smoking cessation. SMS=Short message services.

Table 1 Guideline on delivery of Acceptance and Commitment Therapy

Commitment	**Acceptance**
1. Invite and help the participants to think about and share things that they consider important and meaningful (values, e.g. family health). 2. Connect their values to SC (e.g. "SC can protect your family [value] from tobacco smoke exposure"). 3. Reinforce their value by providing further information (e.g. "SC can also promote family harmony and happiness") and encouraging them to act upon their values (e.g. setting a quit date/ selecting a SC service for further treatment). 4. Remind their values from time to time in subsequent conversation to maintain their commitment to quit.	1. Help the participants to identify their internal experiences like thoughts or feelings (e.g. stress) associated with their desire to smoke a cigarette/ craving. 2. Provide rationale for accepting these thought/ feeling using metaphors (e.g. tug-of-war metaphor), by which participants will learn to dissociate these aversive internal experiences with their urge to smoke a cigarette. 3. Encourage the participants to experience those thoughts/ feelings without acting on them. 4. Provide exercises (e.g. breathing) to help participants to expand their awareness of the presence of difficult thought/ feelings as well as what is present in the environment at the present moment

Table 2 Schedule of data collection

	Baseline	1-month	2-month	3-month	6-month
Socio-demographics	×				
Smoking behaviour	×	×	×	×	×
Quit attempt	×	×	×	×	×
Use of SC service use	×	×	×	×	×
Process evaluation		×	×	×	×
Perceived self-efficacy to quit	×			×	×
Biochemically validated abstinence				×	×