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Effectiveness of WhatsApp online group discussion for smoking relapse prevention: protocol for a pragmatic randomized controlled trial

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ABSTRACT

Background and aims Sustained psychosocial support via online social groups may help former tobacco users maintain abstinence. This study aims to examine the effectiveness of participating in a WhatsApp social group for long-term smoking cessation. **Design** Two-arm, open-labelled, pragmatic, individually randomized controlled trial. **Setting** All participants are service users of smoking cessation clinics, and all interventions are delivered via mobile phones. **Participants** Participants included 1008 adult quitters who self-report no tobacco use in the past 3–30 days. **Interventions** The intervention group (n = 504) will join a WhatsApp social group to receive standardized and theory-based reminders of smoking relapse prevention and participate in discussion with other WhatsApp group members using their own mobile phones. All social groups will be led by counselors or specialist nurse practitioners. The control group (n = 504) will receive similar reminders via short messages to their own mobile phones but will not interact with other participants. The intervention duration for both groups is 8 weeks. Both groups will receive a booklet at baseline about how to prevent smoking relapse. **Measurements** The primary outcome is biochemically validated tobacco abstinence at 12 months after consent. **Comments** The findings will provide evidence concerning the utility of operating online social group discussion for prevention of smoking relapse and sustaining long-term abstinence.

Keywords Group discussion, intervention, randomized controlled trial, relapse prevention, smoking cessation, WhatsApp.

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INTRODUCTION

"Offer help to quit tobacco use" is an effective tobacco control measure recommended by the World Health Organization to reduce smoking prevalence [1]. In quitters who received cessation services and achieved short-term abstinence, approximately half of them would relapse within 6 months [2]. Effective smoking cessation medication can achieve a continuous quit rate from 13–22.5% at 1-year follow-up [3], but many quitters still cannot sustain long-term abstinence. Therefore, most quitters need adequate support and treatment to prevent smoking relapse. Randomized controlled trials (RCTs) assessing the effectiveness of relapse prevention interventions for tobacco abstainers are still scarce. Our team attempted to explore and assess the effectiveness of a new group-based intervention for relapse prevention in a previous RCT [4].

Risk factors for smoking relapse in recent quitters can be affective (e.g. anxiety and depressed mood), physiological (e.g. strong nicotine dependence and withdrawal symptoms), cognitive (e.g. low self-efficacy and knowledge), behavioral (e.g., smoking slips), and social (e.g. lack of social network and social support) [5]. To cope with these barriers, behavioral interventions are typically used to identify coping strategies for high-risk situations, increase self-efficacy, improve skills and knowledge, and confront "failure" and "mistakes" perceptions about smoking lapses [5]. These interventions can be delivered via peer sharing,

where peers share their experience of quitting smoking and using cessation aids. Peer sharing is much more convincing than expert advice; moreover, it can increase engagement [6] and facilitate mutual support [7]. However, a recent systematic review showed that traditional face-to-face group discussion, counseling sessions and follow-up phone calls may not be effective for relapse prevention [8]. The underlying reasons could be that group sessions can only engage participants for a limited number of counselling sessions, and therefore are unlikely to deliver immediate advice and support when quitters need coping strategies during exposure to smoking cues in a real-world environment [9, 10]. Moreover, face-to-face counselling sessions, which are often led by trained counsellors, cannot attract many smokers and incur high manpower cost [11]. Therefore, the reach and benefits of traditional group-based smoking cessation treatment is limited due to its ineffectiveness.

Behavioral and social support via information technology for smoking relapse prevention is now more acceptable, affordable, and accessible than it has been in previous years. Online discussion platforms for promoting physical activity [12, 13], a healthy diet [14], and reducing alcohol use [15, 16] have been tested with RCTs. Several retrospective studies on the discussion content of the online social groups for smoking cessation have shown that this online chat-based intervention possibly increases motivation or quitting [6, 17–20], but no large RCTs have been conducted. These interventions not only reach many smokers in the community but also increase interaction and mutual support among smokers [21]. Online platforms and use of mobile devices have the potential to enhance immediate assistance when participants experience cravings and other withdrawal symptoms in their out-of-clinic environment [22]. However, smartphone apps usually have low participant engagement, poor adherence of cessation treatment guidelines, and lack of tailored feedback to participants [23]. Instead, existing communication tools and forms of social media (e.g. WhatsApp and Facebook) already have high popularity. Interventions using these communication tools promise to achieve higher uptake than those requiring installation of smartphone apps because users do not need to learn and adapt to new tools for interventions. They can also freely send feedback and receive reminders on their own mobile phones without having time and location limitations.

In Hong Kong, WhatsApp is at top social media platform for messaging services, encompassing approximately 82% of Hong Kong internet users in 2019 [24]. Our previous pilot RCT in Hong Kong showed that a relapse prevention intervention with a 2-month online group discussion via WhatsApp increased self-reported tobacco abstinence (WhatsApp: 64% versus control: 39% OR and 95% CI = 2.86, 1.22–6.67) and validated tobacco abstinence (WhatsApp: 26.0% versus control: 15.0%, OR and 95% CI 2.04, 0.74–5.65) at 6-month follow-up, but the 95% CI was wide due to small sample size [4]. The process evaluation showed that the WhatsApp groups had enhanced both emotional and informational support relevant to relapse prevention among the participants [25]. Approximately 50% of the participants' posts addressed the components for helping recent quitters prevent relapse recommended in the US Clinical Practice Guideline [26]. Some participants were satisfied about the informational reminders about maintaining abstinence and learning about the quitting experience [25]. Except this trial, we found no other published studies that have tested the effectiveness of a similar intervention.

The results of the pilot RCT suggested a few improvements for further examination and implementation. First, many participants had been abstinent for 2 months at baseline, and hence reported few cravings at study initiation. Given that most relapses occur within the first few weeks of abstinence [27], this can be improved by recruiting quitters who have recently abstained from smoking and starting the WhatsApp groups as soon as possible. Second, the intervention content and dosage through social media need to be revised to increase participation. In our pilot RCT, only 6 of the 16 participants in the WhatsApp groups, who reported a relapse at 2 months, shared their relapse experience in the group [25]. The small number of reports of relapse posed barriers for early intervention. Due to limited number of eligible participants, some groups had only two to five participants, which led to inactive discussion. Approximately 25% of the participants only read the posts in the group, but did not post anything. These findings highlighted the importance of skillful and theory-driven group moderation, and inclusion of more updated and interesting content to increase the participation level.

Given our experience of the pilot RCT, this study aims to examine the effectiveness and cost-effectiveness of WhatsApp group discussion among a group of recent quitters for smoking relapse prevention. In addition, the present RCT will document discussion topics, social support and satisfaction in the WhatsApp groups for process evaluation.

METHODS

Study design

This is a two-arm open-labelled pragmatic RCT (allocation ratio 1:1), by comparing the 12-month tobacco abstinence between the tobacco abstainers who are individually randomized to participate in the WhatsApp group discussion (intervention group) and those receiving text messages (control group) (Fig. 1). The intervention content for both trial arms will be similar and delivered via participants' own mobile phones. Only the intervention platform

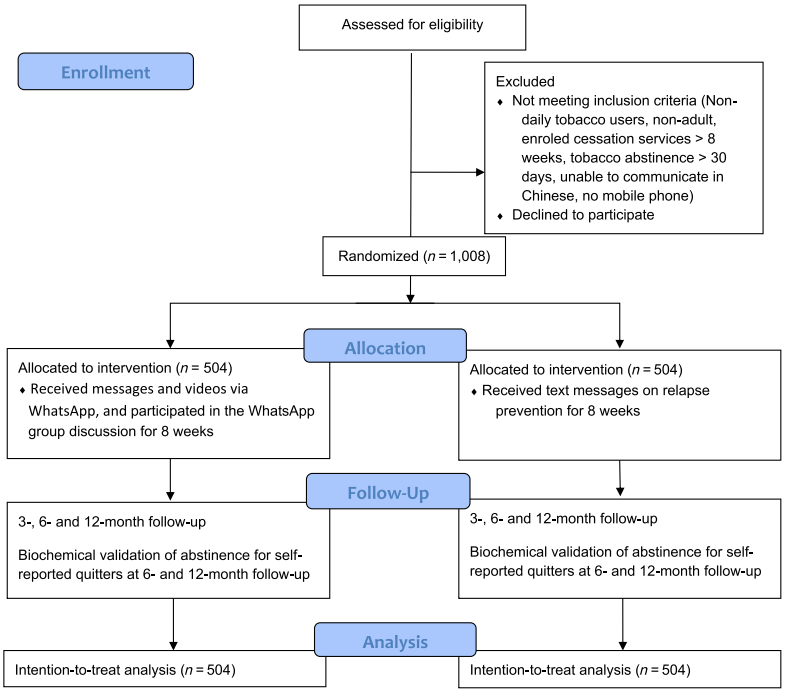

Figure 1 Flow diagram. [Colour figure can be viewed at wileyonlinelibrary.com]

(WhatsApp versus text messaging service) and the communication mode (one-way versus interactive) will be different between the two groups. To assess the effect due to treatment modality through the WhatsApp social group, we will analyze the frequency and topics of the posts in each social group and by each participant. The trial design was highly pragmatic based on the PRECIS-2 criteria [28] to examine the effect of our intervention delivered under a real-life setting (Data S1).

Ethics

The study has obtained ethical approval from the University of Hong Kong, the Hong Kong West Cluster of Hospital Authority (HKU/HA HKW) Institutional Review Board (UW 18–018).

Participants

Patients who are receiving smoking cessation service (including pharmacotherapy and/or behavioral interventions) in the ten smoking cessation clinics in Hong Kong will be invited by their healthcare professionals to go through a screening process. These clinics are under Hospital Authority (n = 3), or are non-governmental organizations that are funded by the government (n = 7). Patients with the following inclusion criteria will be invited to participate in the RCT: (i) daily tobacco user before service intake; (ii) aged 18 years or older; (iii) enrolling in a full course of smoking cessation treatment for no more than 8 weeks; (iv) not using tobacco products (including traditional cigarettes and heat-not-burn tobacco products) for 3 to 30 days; (v) able to communicate in Cantonese/Mandarin and read Chinese; and (vi) own a smartphone with local network connection. We will target quitters who are experiencing cravings and withdrawal symptoms when starting abstinence, so we will exclude those who will have maintained abstinence for more than 30 days. Nearly 90% of the Hong Kong residents speak Chinese, so we choose it as the language in the WhatsApp groups. Exclusion criteria include (i) not using WhatsApp as a communication tool and showing no interest in using WhatsApp; (ii) having an unstable physical or psychological conditions as advised by doctors or the counsellor in charge; and (iii) having become pregnant in the past 2 months. A small souvenir worthy of HK$20 (US$2.6) will be given to all participants at baseline. Participants will receive a HK$50 (US$6.4) shopping voucher for completing one follow-up survey and HK$100 (US$12.8) for completing one biochemical validation.

Recruitment

During a usual smoking cessation counseling session, the clinic counsellor or onsite trial recruitment staff will briefly introduce the importance of relapse prevention and our phone-based relapse prevention intervention. If the patient agrees to join, the recruitment staff will then assess their eligibility. Patients who meet all the eligibility criteria will (i) be informed about the RCT, that they will be randomized to either the intervention or control group, and will participate in all follow-up assessments; (ii) be asked to sign the

consent form; (iii) fill in a baseline questionnaire; and (iv) receive a leaflet, a self-help booklet and a souvenir. Our research staff will collect the information of all the consenting participants from the recruitment staff, and then proceed to randomization and inform the participants of their group allocation via telephone.

We realize that participants may intend to stop smoking, but have yet to stop by the time of recruitment. If participants meet all eligibility criteria in the first screening except the tobacco abstinence for 3 to 30 days, the recruitment staff will invite them to set a quit day and complete the above recruitment procedures, but not to be randomized at that time. Our research staff will contact these participants 3 days after the quit date, and re-assess the eligibility of the RCT. If these participants reported that they have abstained from tobacco use in past 3 days at the follow-up, they will be randomized and receive the respective intervention. On the other hand, if participants have not quit smoking for 3 days, our research staff will ask them to set a quit date again and ask for their consent to be recontacted for another telephone screening after the new quit date. Patients who do not want to be recontacted will not be included in either the RCT or the final analysis.

Intervention

Our WhatsApp group moderator will form a new WhatsApp group of ~7–14 participants (who have met all eligibility criteria) every 1 or 2 weeks. Each WhatsApp group will allow group discussion for 8 weeks. The participants will receive three text messages or videos each week from the moderator. All content was prepared by the principal investigator and the experienced counselors of the smoking cessation clinics, who moderated WhatsApp groups in our previous RCT. All messages will address the five common problems leading to smoking relapse delineated in "Treatments for the Recent Quitter" of the US Clinical Practice Guidelines on Treating Tobacco Use and Dependence [26], including (i) lack of support for cessation; (ii) negative mood or depression; (iii) strong prolonged withdrawal symptoms; (iv) weight gain; and (v) smoking lapses. The messages can be found in Data S2.

Group moderators are either registered nurses or counsellors who have graduated from psychology programs or related disciplines. They have received additional training on smoking cessation knowledge and moderating skills to motivate participants to share their experiences in the WhatsApp group. The moderating skills are based on Positive Psychology theories using four principles [29]: (i) using active listening skills to understand the thoughts and feelings behind individual's sharing; (ii) showing sincere, immediate, specific, and concrete appreciation and gratitude toward their sharing; (iii) mindful awareness of the group dynamics and giving strategic reactions; and (iv) enhancement of self-efficacy, sense of control, and satisfaction among the individuals. Each moderator will be responsible for posting the standardized messages in the WhatsApp group and facilitating discussion among the group members. The moderators will have a log book to document what and when the standardized messages are sent in each group. All group conversations will be archived for compliance checks. If any participant shares their lapse or relapse experience in the group, the moderator will engage other participants to provide insights and support, or, if that individual agrees, actively refer him/her to existing cessation services. All moderating principles and guidelines are found in Data S3.

The control group will only receive three mobile phone text messages each week for 8 weeks. The content of these messages is similar to those received by the intervention group in the WhatsApp groups (Data S4), but no video clips and pictures can be sent. Participants in this group will not be enabled to interact with each other throughout the study. Our intervention will not interrupt the cessation services that are being received by all participants in the cessation clinics.

Adverse events

No health-related adverse events are expected. As WhatsApp group participants will use their own mobile phone for the intervention, their telephone number will be known to other group participants. Several measures will be enforced to protect the privacy and internet safety of the participants joining the WhatsApp groups. First, male and female participants in the WhatsApp group will be separated into different WhatsApp groups to reduce the possibility of misconduct or harassment. Second, participants will be informed that all the WhatsApp posts can only be read by the group members and the moderator. Third, they will be informed that their telephone numbers will appear in their group. We will design specific regulations regarding the use of WhatsApp groups for all participants before the group discussion starts. Moderators will encourage all participants in the WhatsApp groups to share and post messages in the group and to avoid one-to-one individual communication via any channels within the study period. The moderator will also monitor the group conversation and report any events involving the misuse of contact information to the lead investigator.

Randomization, blinding, and allocation concealment

Participants were randomly assigned on an individual level to the two trial groups. All recruitment staff and participants will be concealed to the group allocation at recruitment. The principal investigator will generate a list of random numbers to create a list of random group

allocation (either intervention or control; allocation ratio 1:1), using the rand function of Excel. Our research staff will perform the randomization procedure, by assigning consenting participants who meet all eligibility criteria to the two groups using the list.

Because the intervention for all trial groups is behavioral, participants and group moderators will not be blinded to the intervention. Recruitment staff, assessors of the follow-up outcomes, and the research analysts will not be involved in intervention delivery, hence they will be blinded to the group allocation (i.e. single-blinded).

Baseline data collection

Baseline assessment included socio-demographic and smoking characteristics, daily cigarette consumption, Fagastrom Test of Nicotine Dependence [30], ever use and past 30-day use of electronic cigarettes and/or heat tobacco products, frequency of smoking urges in the past week [31], intensity of smoking urges in the past 24 hours, the Minnesota Nicotine Withdrawal Scale (MNWS) [32], the 12-item Smoking Self-Efficacy Questionnaire (SEQ-12) [33], and the Breathlessness, Cough and Sputum Scale [34] (Table 1).

Outcomes

The primary outcome is prevalence of carbon monoxide (CO) (<4 ppm) and saliva cotinine (<10 ng/mL) validated tobacco abstinence at 12-month follow-up, which have been confirmed as a stringent criterion for abstinence verification for tobacco abstainers who use nicotine replacement therapy [35]. At 6- and 12-month follow-up, only participants who self-report abstinence in past 7 days will be invited for the above validations. Secondary outcomes include prevalence of biochemically validated abstinence at the 6-month follow-up, self-reported tobacco abstinence of 7 days, continuous abstinence, and the relapse rate [36], which is defined as the proportion of quitters who smoke at least five cigarettes in 3 consecutive days, at 3-, 6-, and 12-month follow-up. Ancillary outcomes include time to relapse, number of posts made by participants in WhatsApp groups, change in frequency and intensity of smoking urges, change in the Minnesota Nicotine Withdrawal Scale (MNWS) [32], and the change in EuroQoL 5-dimension 5-level (EQ-5D-5 L) health utility scores from baseline to follow-ups [37]. For cost-effectiveness analysis, the outcomes are the incremental cost-effectiveness ratio (ICER) in terms of cost per an additional tobacco abstinence gained for intervention compared to the control group, and the ICER in terms of cost per life-years gain or quality-adjusted life-years gained for the intervention group versus the control group.

All participants will be contacted via telephone for a follow-up by an allocation-blinded interviewer at 3-, 6-, and 12-month intervals after giving consent. Participants will be offered a HK$50 (US$6.4) shopping voucher upon completing one follow-up assessment. Only the participants who report abstinence in the past 7 days will be invited to measure their exhaled CO with a PiCO Smokerlyzer (Bedfont Scientific, Kent, UK) and saliva cotinine with NicAlert strips (Nymox Pharmaceutical, St. Laurent, QC, Canada), near their residence or workplace, as preferred by the quitters. To increase participation, the participants

Table 1 Schedule of enrollment and follow-up assessments.

	Time point				
	Baseline	*First 2 months*	*3 months*	*6 months*	*12 months*
Referred by SC counsellors	x				
Informed consent	x				
Eligibility screening	x				
Randomization	x				
Intervention		x			
Socio-demographic characteristics[a]	x				
Smoking-related characteristics[b]	x				
Frequency and intensity of smoking urge	x		x	x	x
Minnesota Nicotine Withdrawal Scale	x		x	x	x
Smoking Self-Efficacy Questionnaire	x		x	x	x
Breathlessness, Cough and Sputum Scale	x		x	x	x
EuroQoL 5-dimension 5-level	x		x	x	x
Self-reported smoking status			x	x	x
Validated smoking status				x	x

[a]Socio-demographic characteristics include sex, age, marital status, living with child at home, occupation, education level, monthly income, place of birth, and type of housing. [b]Smoking-related characteristics include daily cigarette consumption, Fagastrom Test of Nicotine Dependence (6-item), reasons to quit smoking, quit attempt history, ever or current use of electronic cigarettes.

will be given HK$100 (US$12.8) as a compensation for the cost of their time in the biochemical validation.

Sample size

Our pilot RCT showed that the OR of the CO validated quit rates between the intervention and control group was 2.04 (95% CI = 0.74–5.65) (intervention: 26.0%, control: 15.0%) [4]. Because our proposed RCT will recruit participants who have recently quit and the control group will receive text messages (there was no intervention for the control group in the pilot RCT), we have conservatively estimated that the OR will be 1.70 (23.0% versus 15.0%). To detect a significant difference of quit rate by using a two-tailed z-test between the two groups with a power of 90% (to reduce type II error) and 5% significant level (type I error), we will need 1008 participants in total (504 participants per group).

Withdrawal of participants

Participants in both groups can withdraw from participation any time without giving a reason. These participants will still be contacted for follow-up. According to the intention-to-treat principle, all participants who fulfill the eligibility criteria and consent to the RCT participation will be included in the final analysis.

Pre-registered hypothesis

We hypothesized that the intervention group would have a higher prevalence of biochemically validated abstinence at the 12-month follow-up than the control group (https://clinicaltrials.gov/ct2/show/NCT03760224?term=NCT03760224&draw=2&rank=1).

Data analysis

Main analysis

Using intention-to-treat analysis, participants who are lost to follow-up or drop out will be treated as smokers with no changes in daily cigarette consumption. The OR, risk difference, and 95% CI will be used to compare the primary and secondary outcomes between the two trial groups. Number needed to treat (NNT), which shows the number of treated participants needed to have one additional quitter at 12-month, will be computed by taking the reciprocal of the risk difference between the two trial groups. Assuming the missing outcomes are dependent on observed data (missing at random), an analysis using the multiple imputation (MI) procedure to impute the missing data will be conducted as sensitivity analysis. On the assumption that there will be no heterogeneity of intervention effect across clinics, the primary analysis will be conducted using logistic regression with and without adjustment for baseline characteristics. The assumption of homogeneity will first be checked by testing the clinic by intervention interaction with clinic as a fixed effect in the logistic model. If there is evidence of heterogeneity (i.e. P value <0.1), an analysis by generalized linear mixed (GLM) model with clinic as a random effect will be used to summarize the intervention effect on the primary outcome. Number of posts received and posted by each participant will be documented, and then included in the final GLM model to assess their association with the cessation outcome. All data analysis will be done using IBM SPSS version 25.0.

Text mining of the WhatsApp group conversation

All discussion content will be archived and anonymized to remove identifying personal information. Due to the large number of messages from the WhatsApp groups, we will use automatic, computational text mining and visualization of the dataset for the content analysis. First, using a lexicon of keywords derived from our qualitative analysis of the pilot RCT, we will develop a heatmap visualization to illustrate the prevalence of the discussion topics [38]. Second, we will apply topic modelling to investigate emerging themes in our WhatsApp dataset, using the Mallet [39] implementation of the Latent Dirichlet Allocation topic modelling algorithm [40]. Topic modelling algorithms take a text dataset (in this case, the WhatsApp dataset) as input, and output a set of topics (and their associated keywords) in addition to estimates of the proportion of each topic [41].

Cost-effectiveness analysis

Within and lifetime cost-effectiveness analyses will be populated based on the healthcare provider perspective. Within trial cost-effectiveness of the WhatsApp intervention versus the control group will be evaluated using the total cost of delivering the intervention, the number of tobacco abstinence and total quality adjusted life- years (QALYs) over the study period. EQ-5D-5 L utility data at baseline and follow-ups from trial will estimate QALYs in two groups using the area under the curve technique. Lifetime cost-effectiveness will be performed via Markov modelling that will simulate the annual health status progression of subjects in either the intervention or control group. Both the successful and unsuccessful quitters after the trial will be subject to the annual transition probability from a status of no diseases to lung cancer, cardiovascular diseases, and other diseases, and then mortality. Discounting will only be applied to total costs and QALY calculation under the lifetime horizon. Sensitivity analyses will be conducted where each parameter will be set at plausible lower and upper bounds based on 95% CI of estimates in the above data analysis.

The incremental cost-effectiveness ratio (ICER) in terms of cost per an additional tobacco abstinence gained,

life-years gained, or QALYs gained for the intervention group in comparison to the control group will be reported. The WhatsApp intervention will be considered as cost-effective if its ICER is less than three times the per capita gross domestic product in Hong Kong recommended by WHO or the potential ICER threshold in Hong Kong. The cost-effectiveness model will be built using Microsoft Excel or Treeage Pro software.

Current status

Recruitment started on 1 October 2018. The treatment will be expected to complete on 30 April 2020. All outreach activities, follow-up and data collection will be expected to be completed in April 2021.

DISCUSSION

Three caveats should be considered when the findings are interpreted. First, this pragmatic RCT will not guarantee "full" intervention compliance in all participants. For instance, WhatsApp group participants have the right to leave the group during the intervention period. Participants are encouraged to discuss in the WhatsApp group, but moderators will not interfere with their participation level in the WhatsApp group discussion. Hence, they can choose to either respond to others' posts or remain silent throughout the intervention period. As a result, the RCT will show the effectiveness of delivering such communication platform for smoking cessation, but we expect there will be a variety of participation level in the WhatsApp discussion. Nevertheless, all WhatsApp group conversation will be archived for further content analysis and compliance analysis. The actual impact of participating in the WhatsApp group can be investigated by filtering out participants with low participation.

Second, we will only recruit tobacco abstainers who have used a smoking cessation service in this RCT, therefore the findings will not be generalized for unassisted tobacco abstainers. Future trials that customize the intervention for smokers recruited outside of clinical settings are warranted.

To sum up, WhatsApp is capable of enhancing social support and health communication among recent quitters and smoking cessation counselors. The findings from this RCT will provide evidence to support the utility of operating online social group discussion for prevention of smoking relapse and sustaining long-term abstinence.

Clinical trial registration

ClinicalTrials.gov Identifier: NCT03760224.

Declaration of interests

T.H.L. was/is the principal investigator of two family well-being projects, and M.P.W. is the co-investigator of one of the two projects funded by Hong Kong Jockey Club Charities Trust.

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Supporting Information

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

Data S1. PRECIS-2 scores for trial domains.

Data S2. Structure and schedule of the WhatsApp messages and videos.

Data S3. Guideline for WhatsApp group moderation.

Data S4. Structure and schedule of the text messages for the control group.