BMJ Open Effects of smartphone-based chatbot intervention to increase influenza and **COVID-19** vaccine uptake among South Asian ethnic minorities in Hong Kong: Tree and waitlist— Carmen Wing Han Chan □, STRENGTHS AND LIMITATIONS OF THIS STUDY ⇒ The content of educational text messages within a simple chatbot was underpinned by the 5C model to understand antecedents of vaccination behaviours. ⇒ To enhance rigour, this study incorporates cluster sampling, single-blinding and randomisation. ⇒ Due to the nature of the intervention, blinding of participants and the interventionist will be impractical. INTRODUCTION Influenza is a common cause of morbidity and mortality worldwide. It can cause serious diseases in high-risk groups and even healthy minutes. protocol for a randomised waitlistcontrolled trial

Cho Lee Wong (0), Winnie Kwok Wei So, Carmen Wing Han Chan (0), Kai Chow Choi, Huiyuan Li

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The Nethersole School of Nursing, The Chinese University of Hong Kong, Faculty of Medicine, Hong Kong, Hong

Correspondence to

Dr Huivuan Li: huiyuanli@cuhk.edu.hk

ABSTRACT

Introduction Protecting non-native ethnic minority groups against cocirculation of influenza and COVID-19 is crucial, and vaccination could be a viable option. Smartphonebased chatbots offer promising opportunities for improving vaccine knowledge and addressing barriers encountered by ethnic minorities. This trial aims to evaluate the effects of smartphone-based chatbot intervention on influenza and COVID-19 vaccine uptake, intention to receive vaccination and vaccine hesitancy among South Asian ethnic minorities in Hong Kong.

Method and analysis An assessor-blinded, clusterrandomised, waitlist-controlled trial will be conducted. This study consists of two phases. In phase I, a smartphonebased chatbot intervention will be developed, including designing a simple chatbot called 'Ali' to deliver prewritten educational text messages and vaccination reminders as well as respond to users' questions, and on-demand option for communication with research assistants. An expert panel will be invited to review the designed chatbot, and pilot testing will be performed. In phase II, a total of 612 South Asians will be recruited from each of the six participating non-governmental community centres or ethnic minority associations. They will be randomly allocated to intervention (n=306) or waitlist control group (n=306). The intervention group will receive inapp notifications related to the education text messages and vaccination reminders via the smartphone-based chatbot twice a week for two weeks. The waitlist control group will receive usual care only. Evaluation will include vaccination uptake, intention to receive vaccination and vaccine hesitancy. Assessments will take place at baseline (T0), immediately postintervention (T1) and 3-month postintervention (T2).

Ethics and dissemination This study has been approved by the Joint Chinese University of Hong Kong-New Territories East Cluster Clinical Research Ethics Committee (CREC Ref. No.: 2021.688). The findings will be disseminated in peer-reviewed journals and through local or interventional conference presentations.

Trial registration number ChiCTR2200061503.

diseases in high-risk groups and even healthy **3** people. In Hong Kong, the influenzaassociated hospital admission rate during the peak season was 0.92 admissions per 10000 ≥ population and resulted in 169 adults being admitted to the intensive care unit in 2020.² Meanwhile, the recent COVID-19 pandemic 💆 has had an unrivalled impact on the global healthcare system. Hong Kong is no exception. As of 27 July 2023, 1 226 467 COVID-19 cases have been recorded, and 9287 patients have died from the disease.

Influenza and COVID-19 share many common features, and the fifth wave of 2 COVID-19 has been coincided, at least in & part, with the circulation of seasonal influenza in the next few years. The cocirculating influenza and COVID-19 viruses likely intensify the burden on hospitalisation and intensive care unit admission.³ This highlights the importance of optimising measures to manage both respiratory infections simultaneously and effectively.³

Vaccination is one of the effective ways to prevent the unnecessary spread of vaccine-preventable diseases and promote herd immunity. Despite these benefits, the influenza vaccination rates in most countries are still less than 50%⁴ of the expected coverage. A more worrisome problem is the even lower vaccine uptake among ethnic minorities.⁵ A cohort study including a database of 12 million people in England observed low vaccine coverage in people from South Asian backgrounds. A recent study corresponded to these findings revealing that the COVID-19 vaccination rate among ethnic minorities (20.5%) was much lower than that of the general population (42.5%).

In Hong Kong, the government has launched a seasonal influenza programme and a territory-wide COVID-19 vaccination programme to provide eligible Hong Kong residents with free/subsided seasonal influenza vaccination and free COVID-19 vaccine. However, the overall uptake of influenza vaccine and the acceptance rate of COVID-19 vaccine among the local population was only 29.1% and 37.2%, respectively. Although there is a lack of publicly available vaccination rates among South Asians (from India, Nepal and Pakistan), one of the largest (14%)¹⁰ and one of the fastest growing ethnic minority groups in Hong Kong, international data, 89 have already provided some insights into the significant risks of their low uptake rates of both vaccines.

Vaccine hesitancy, characterised by ambivalence or refusal to vaccinate, has been identified by the WHO as one of the top 10 global health threats in 2019. 11 Vaccine hesitancy is a complex and multifaceted construct that exists on a continuum, which encompasses a range of beliefs, attitudes and behaviours towards vaccination that can vary significantly between individuals and across different vaccine types. 11 On the basis of the Health Belief Model and Theory of Planned Behaviour, as well as the work of the WHO advisory group, researchers have posited the 5C model to understand antecedents of vaccination behaviours. 5C includes confidence (trust in vaccine effectiveness, safety and necessity and the system that provides it), complacency (perceived low risk of diseases), constraints (structural and psychological barriers), calculation (extensive information searching) and collective responsibility (willingness to protect others). 12 Ethnicity intersects with low literacy levels and language barriers accentuating the vaccination disparities.¹³ For South Asians in Hong Kong, vaccine hesitancy towards COVID-19 and influenza vaccines may exhibit dynamic variance. While initial COVID-19 vaccine hesitancy may be high due to safety and trust concerns, acceptance increased as the vaccines proved effective. In contrast, influenza vaccine acceptance is relatively more stable and higher, as the community is familiar with its safety and perceived necessity, though individual factors like access and past experiences still impact acceptance levels. 13 Nevertheless, people who are hesitant can still be convinced of vaccination uptake with the provision of accurate information.¹⁴ Thus, effective interventions aimed at promoting knowledge and awareness of vaccines

and removing barriers are critical to the success of vaccination programmes.

A review of interventions to promote vaccination among ethnic minorities recommended multicomponent strategies. In Jamon various strategies, patient-focused interventions with education initiatives adjunct with vaccination reminders were the most effective. In Oroviding educational information, as one of the effective strategies, has widely been used to increase knowledge and awareness of vaccination and reduce vaccine hesitancy. In particular, the use of smartphones to deliver educational text messages seems to be an effective approach. In particular, the use of smartphones to deliver educational text messages seems to be an effective approach in educational text messages to remind patients to make vaccination reminder function can be integrated into educational text messages to remind patients to make vaccination reminders can help increase influenza vaccine uptake and advance health literacy related to immunisations.

However, the effectiveness of this educational-only text message approach is subjected to a decline in users' participation and engagement over time due to a lack of interactivity. In addition, a previous study has shown that the leaks of interactive options may have the least beneficial effect on increasing vaccination coverage, as those who have not been vaccinated early may require an alternative approach to the information delivery to make vaccination decisions. Chalbot, which can be built as part of smartphone-based interventions, may help improve interactivity and users' engagement. Successing (ie, the ability and users' dissatisfaction. Successing (ie, the ability of understand and interpret human language repr

the needs of ethnic minorities, thereby improving the saliency and trustworthiness of the information delivered. 18'24 Third, the smartphone application platform can provide users with on-demand options for communicating with the human backend, so as to address specific questions from ethnic minorities that the chatbot is unable to answer. The live support component in the chatbots is also intended to build trust and rapport with participants, improving their engagement and adherence to the programmes and providing valuable feedback to inform future refinements to the chatbot's function.

A review of six studies indicated that chatbots have been used to disseminate health information and knowledge about COVID-19.²³ For instance, the WHO has developed a chatbot with several languages to provide information on a wide range of topics for users to ask and find answers related to COVID-19.²⁵ Likewise, the German government developed a 'flight COVID messenger bot'; in India, a smartphone application with parallel connection of a chatbot has been developed to enhance awareness of COVID-19.

A systematic review showed that smartphone-based chatbots have been developed to address adolescents' questions about sex, drugs and alcohol interactively; address mental health issues and promote the physical health of lay people, which achieved a moderate amount of evidence in supporting its acceptability and usability with messages sent twice a week. 24 Another meta-analysis that included 19 clinical and non-clinical RCTs reported the effectiveness of chatbots in improving health-related outcomes (such as pain management and weight loss). However, most studies aimed at evaluating chatbot interventions were quasi-experimental in design and lacked clear outcome measures.^{22 24} Most importantly, no smartphone-based chatbot for promoting influenza and COVID-19 vaccine uptake has been developed and investigated to date.

In summary, smartphone-based chatbots offer promising opportunities for improving vaccine knowledge and addressing barriers encountered by ethnic minorities. To generate rigorous evidence, we propose a randomised waitlist-controlled trial to evaluate the effect of a smartphone-based chatbot intervention on the uptake of influenza and COVID-19 vaccines among South Asian ethnic minorities in Hong Kong. This innovative approach will likely provide practical significance in addressing needs and reducing barriers, thereby increasing the vaccination rate of South Asians. The ultimate impact of this project is to reduce the burden of influenza and COVID-19 by decreasing vaccination disparities.

Aim and hypothesis

The primary aim of this cluster-randomised, waitlistcontrolled trial is to evaluate the effects of smartphonebased chatbot intervention on influenza and COVID-19 vaccine uptake among South Asian ethnic minorities in Hong Kong. The secondary aim is to assess the effects of such an intervention on the intention of influenza

and COVID-19 vaccination as well as improve vaccine hesitancy.

Compared with the waitlist control group, South Asians in the intervention group are expected to exhibit the following outcomes on completion of the smartphonebased chatbot intervention:

- 1. Higher rate of influenza and COVID-19 vaccination uptake as evidenced by vaccination records.
- 2. Higher rate in expressing intention to receive influenza and COVID-19 vaccines as measured by two questions on the intention to receive vaccination.
- 3. Higher levels of confidence and collective responsibility and lower levels of complacency, constraints and calculation as measured by the 5C scale that measures vaccine hesitancy.

METHODS AND ANALYSIS Design

A cluster-randomised, waitlist-controlled trial will be conducted. Figure 1 shows the study procedure. The protocol has been registered on the Chinese Clinical Trial Registry.

This study has two phases:

Phase I: development and validation of smartphonebased chatbot intervention.

Phase II: implementation and evaluation of the effects of the intervention.

IMPLEMENTATION

Phase I: development of smartphone-based chatbot

The smartphone-based chatbot intervention consists of two components: (1) a simple chatbot that is built into the smartphone application; and (2) on-demand option for users to communicate with trained research assistants (RAs).

A simple chatbot

A simple chatbot called 'Ali' (a commonly used name in South Asians) will be designed to deliver prewritten educational text messages and vaccination reminders as well as respond to users' questions in the smartphone application platform.

The content of educational text messages is developed based on the 5C model in the following topics: (1) influenza and COVID-19 incidence, mortality, risks, signs and symptoms and preventive measures (target complacency); (2) available options for vaccines, effectiveness, safety, necessity and benefits of vaccination (target confidence and collective responsibility); (3) myths and misconceptions of vaccines (target constraints); (4) vaccination programme offered by the department of health, as well as the contact number, address and global positioning system (GPS) of the clinics registered under the vaccination scheme and steps to book a vaccination appointment (target constraints and calculation).

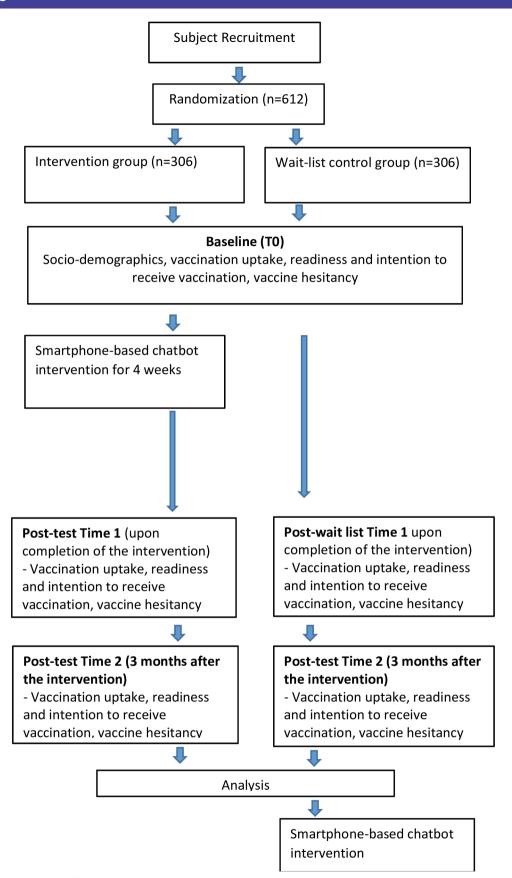


Figure 1 The flow diagram of intervention and data collection points.

'Ali' will send in-app prewritten educational text messages and vaccination reminders to users twice a week (for a total of fourweeks) related to the four developed topics. Each message with 'Ali' will follow the same basic structure. The users will receive a notification with a basic greeting from 'Ali' (Hello! Its' me, your buddy bot!). 'Ali' will then continue the conversation by asking questions related to each topic and proposing answers for it. This helps positively influence users' intention to continue the intervention, enhance users' knowledge and motivate them to receive the vaccinations.

On-demand option

On top of 'Ali', there will be an on-demand option for project participants to communicate with well-trained RAs of this project when needed. The research team will extensively train the RAs on the content and functionality of the chatbots as well as best practices for providing personalised and helpful support to participants. The RAs will have access to a preapproved content library that they can reference when responding to participant questions and concerns, which will help ensure consistency and accuracy in their replies. In addition, the RAs will be required to document the types of questions and issues raised by participants during the live support sessions. This documentation will be for systematic analysis by the research team to identify common themes and areas for improvement in the chatbot's content and functionality. This option serves as a backup in case users cannot find answers related to their inquiries from 'Ali'.

The educational modules, text messages and vaccination reminders are prepared in English, Urdu and Nepali (written languages commonly used by South Asians). Most importantly, users can choose the voice narration option (recorded by RAs), so that the content can be narrated in spoken languages commonly used by South Asians (English, Hindi and Nepali) to facilitate understanding and comprehension. 17 23 The smartphone-based chatbot is open to the public for free download. It will also include a 'members only' feature, designed as a private communication channel, to facilitate on-demand communication between project participants and RA of the same ethnicity. Within the 'members only' functionality, participants will have access to a variety of communication tools and collaboration features, including private one-on-one messaging, group messaging, sharing-relevant materials securely, a community forum for broader discussions and an integrated notification system for upcoming vaccine injection and other updates relevant to vaccination. Registration is required to become a member, and a password will be provided to the participants. The Android platform is chosen for its widespread popularity and availability on various devices and operating systems.

Validation and pilot study of the smartphone-based chatbot

A panel of experts (consisting of IT experts, healthcare professionals, educators and South Asian community leaders) will be invited to review whether the contents of educational modules, text messages and reminders, as well as the layout and design of smartphone applications and chatbot, are linguistically and culturally relevant to South Asians.

In addition, nine South Asians (three Indians, three Pakistanis and three Nepalese) will be invited to pilot test the smartphone-based chatbot intervention and provide comments and feedback. Their comments and suggestions will be incorporated to optimise the smartphonebased chatbot before it is officially launched.

Phase II: implementation and effects' evaluation of the chatbot-based intervention

Participants

Trained RAs will approach potential subjects while they are participating in various activities organised by the six participating non-governmental community centres or ethnic minority associations, which provide support programmes and services for ethnic minorities in different regions in Hong Kong. After the introductory presentation, South Asians who are interested in participating in the study will be screened for eligibility.

Inclusion criteria

Patients who are (1) South Asians (from Pakistan, India or Nepal); (2) aged 18 or older; (3) unvaccinated for influenza or COVID-19 in the past 3 years; (4) able to communicate with English, Hindi, Nepali or Hindi and read English, Urdu and Nepali and (5) have an Android smartphone.

Exclusion criteria

Patients who have (1) participated in any intervention related to influenza and COVID-19 in the past year; (2) known vaccine contraindications (eg, a history of severe hypersensitivity to any vaccine component or previous dose of influenza vaccine).

Sample size

The sample size is estimated on the basis of the outcome of the vaccine uptake rate. A recent local study found a low uptake rate of influenza vaccine (29%) in the general population in Hong Kong.8 The vaccine uptake rate among ethnic minorities can be less than half as compared with the general population. We anticipate that our smartphone-based chatbot intervention can increase the uptake rate in ethnic minorities to the level of the general population. By using the power analysis software GPower V.3.1, it is estimated that a sample size of 121 participants ${f @}$ per each of the intervention and control groups will be required to achieve 80% power at a 5% level of significance (two sided) to detect at least a 15% difference in the uptake rate (30% in the intervention group vs 15% in the control group) between the two groups. To allow for up to a 20% attrition rate, a total of 304 participants, with 152 per group will be needed. Furthermore, to account for the clustering design by allowing for an intracluster correlation coefficient up to 0.01 in our proposed trial, at least 102 participants will be recruited from each of the

six participating non-governmental community centres or ethnic minority associations.

Randomisation and blinding

Six centres and associations agreed to participate in this study. Each centre or association will be randomly assigned to one of the two arms: an intervention group (n=3) that will receive immediate treatment (smartphonebased chatbot intervention) or a waitlist control group (n=3) that will receive delayed treatment (the same intervention but provided after the intervention group has completed the immediate treatment). Participants from each centre/association will be randomly assigned in a 1:1 ratio to either the control group or the intervention group to avoid 'contamination' across participants. The computer-generated randomisation scheme will be conducted by a statistician to maintain concealment. The group identifiers for each centre/association will then be placed in serially numbered sealed opaque envelopes. The patient's group allocation will be assigned according to the sequence of enrolment in the study and the group identifier contained in the corresponding numbered envelopes. Assessments of vaccination uptake and other secondary outcomes will be performed by an RA blinded to the group allocation.

Waitlist control group

Participants in the control group will receive usual care provided by the ethnic minority associations or centres. They will be offered with the smartphone-based chatbot intervention after their counterparts have completed the intervention.

Intervention group

Participants in the intervention group will receive the smartphone-based chatbot intervention developed in phase I. The details of the intervention have been detailed in a previous section. Two well-trained RAs (Nepali RA2 and Pakistani RA3) will first demonstrate to participants the smartphone-based chatbot as an easy-to-use and supporting application for vaccination while emphasising that they are chatting with an automated system but not a person. They will invite participants to access the smartphone application via the QR code printed on the card. Each participant will be linked to the personalised code printed on this card. This connection between the participants and their designated RA will enable 'Ali' to recognise the participants, so that it can link back to its assigned RA to answer inquiries as needed. The intervention will last for 4 weeks. The smartphone-based chatbot will send in-app notifications to participants related to the educational text messages and remind them to receive vaccination twice a week (a total of four weeks). In addition, it will answer questions raised by participants at any time. In case participants cannot find an answer from 'Ali', the on-demand options can help link the participant with well-trained RAs of this project to answer their questions.

Fidelity of the intervention

Strategies will be used to monitor the intervention fidelity. Standardisation in the delivery of the intervention will be implemented through the use of written protocol. The RAs (RA2 and RA3) who implement the interventions are required to strictly follow the protocol. They will also receive 3-day training by the principal investigator. The training aims to equip RAs with knowledge and competence. A package of training materials will be prepared in accordance with the latest vaccination guidelines. The training contains four modules that are the same as those in the smartphone application. In addition, the training will focus on the following strategies (1) initiate discussions about vaccination, (2) clarify misconceptions about vaccination, (3) strategies to overcome possible vaccination barriers and (4) access to various vaccination resources. Throughout the project, the principal investigator will supervise and closely monitor the on-demand responses that the RAs provide to participants' inquiries to assess their competence. The principal investigator will also meet with RAs monthly and provide feedback.

Outcome measurements

Primary outcome: vaccination uptake

Participants will be assessed whether they have received influenza and COVID-19 vaccination separately as evidenced by their vaccination records.

Secondary outcomes

Intention to receive vaccination

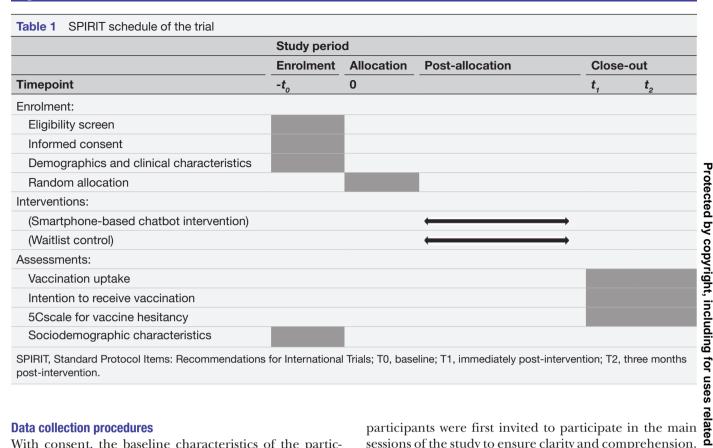
The intention to receive influenza and COVID-19 vaccines will be measured by two items asking participants how likely they will take influenza and COVID-19 vaccine separately when available on an 11-point Likert scale (0=definitely no; 10=definitely yes).²⁶

Vaccine hesitancy

Vaccine hesitancy will be measured by the 5C Scale. It is a 15-item tool developed from a '5C model' of five psychological antecedents to vaccination. The five antecedents comprise confidence, complacency, constraints, calculation and collective responsibility. It will be assessed by three rating items on a 7-point scale (1=strongly disagree; 7=strongly agree). Mean scores of items under each domain will be computed, with a high score indicating a high level of agreement with the corresponding antecedents. This scale has been used in a local study to assess vaccine hesitancy. It will be translated into Urdu and Nepali by our research team.

Sociodemographic characteristics

The age, ethnic group, monthly household income, years of formal education, marital status, employment status, number of years of residence in Hong Kong, history of COVID-19 and health insurance status of participants will be collected. Cues to action to vaccination (eg, knowing where to go for vaccination) will also be collected.



Data collection procedures

With consent, the baseline characteristics of the participants, including the sociodemographic characteristics and research outcomes, will be evaluated at baseline (T0, that is, on entry to the study before randomisation and intervention during the face-to-face meeting at enrolment). The instruments will also be administered by the RA blinded to group allocation at the other two points: postintervention (T1, that is, telephone interview on completion of the intervention) and 3 months postintervention (T2, that is, telephone interview at three months after completion of the intervention). The data collection plan is shown in table 1.

The self-reported questionnaires are available in English, Nepali and Urdu. Content validity will be assessed by the expert panel. The blinded RA will contact the participants in both groups to complete the paper version of the questionnaire. All participants will receive a HK\$200 coupon after completion of the baseline assessment and two postintervention questionnaires.

Data management

Information collected about the subjects will be kept strictly confidential, with only the research team able to access the encrypted data file. All hard copies of documents will be kept in a locked cabinet and will be destroyed within six years of the study's completion. The electronic data will be stored in a hard disk protected with passwords kept for ten years.

Patient and public involvement

Participants were involved in the development of the intervention. Before the start of the full-scale study,

participants were first invited to participate in the main sessions of the study to ensure clarity and comprehension. After the intervention delivery, participants in the intervention group will be evaluated to explore their experiences on the intervention's usefulness and acceptability.

Data analysis

Data will be summarised and presented using appropriate descriptive statistics. The normality of continuous variables will be assessed using skewness and kurtosis statistics and a normal probability plot. Suitable transformations will be made on skewed variables before subjecting them to inferential analysis if needed. The homogeneity of participants' characteristics between the two groups will be assessed by independent t, χ^2 or Fisher's exact tests, as appropriate.

The effectiveness of the intervention will be assessed by comparing the uptake rate of COVID-19 and influenza vaccines separately between the two groups, and by comparing the between-group differences in the changes in vaccination intention and vaccine hesitancy on COVID-19 and influenza vaccines separately at T1 and T2 with respect to T0. The intention-to-treat principle will be adopted in the outcome evaluation between the two groups. The generalised estimating equations (GEE) approach, in conjunction with a small sample correction for sandwich variance estimate, will be used to compare the outcomes between the two groups. This approach can be used to account for the intercorrelation within the same cluster and intracorrelated repeated measure data in a cluster RCT with a small number of clusters. The GEE model will also handle the randomly missing data

with correlated data, which can provide valid parameter estimates and SEs while accounting for the missing data mechanism and the flexibility to model various correlation structures. The GEE analysis will be performed with the procedure GLIMMIX, implemented in the SAS (SAS Institute, Cary, North Carolina, release V.9.4). All statistical tests involved will be two sided with the level of significance set at 0.05.

ETHICS AND DISSEMINATION

Ethical approval has been sought from the Joint Chinese University of Hong Kong-New Territories East Cluster Clinical Research Ethics Committee with reference number: 2021.688. The study complies with the Declaration of Helsinki. Eligible participants will be briefed on the study details, its aims and objectives and their rights to withdraw at any time. They will be given an assurance as to anonymity and confidentiality. An information sheet with details of the study and an informed consent form will be provided, and they will be available in English, Nepali and Urdu. Potential participants interested in the study will be asked to sign the consent form (online supplemental material 1) and return it to the RAs. It will be emphasised that their participation is voluntary and that they can leave the study at any time without giving a reason. The findings will be disseminated in peer-reviewed journals and through local or international conference presentations.

DISCUSSION

Influenza and COVID-19 vaccination uptake can vary among different demographic groups, including nonactive ethnic minorities, due to various factors such as access to healthcare, language barriers, cultural beliefs and trust in the healthcare system. It is important for public health authorities to address any disparities in vaccination rates and ensure equitable access to vaccines for all communities, including ethnic minorities, to achieve widespread vaccination coverage and protect the entire population. This novel study is the first to develop and evaluate the effectiveness of the smartphone-based chatbot intervention in improving vaccination uptake, intention to receive vaccination and vaccine hesitancy among South Asian ethnic minorities in Hong Kong. This innovative approach will likely provide practical significance in addressing needs and reducing barriers, thereby increasing the vaccination rate of South Asians. The ultimate impact of this project is to reduce the burden of influenza and COVID-19 by decreasing vaccination disparities. It is anticipated that the chatbot 'Ali' will become a friendly using application in the community. The chatbot can be culturally sensitive and respectful of the diverse backgrounds and beliefs of ethnic minority communities, especially people with South Asian

backgrounds. The language, tone and content are tailored to address cultural nuances and can avoid any potential misunderstandings or misinterpretations. The chatbot is also multilingual or provides language options for South Asians to accommodate their different language preferences. In addition, this study will be conducted collaborated with six nongovernmental community centres or ethnic minority associations; the intervention implementation will provide a good opportunity for healthcare providers and cultural influencers in Hong Kong to engage ethnic minority populations effectively. This will also benefit the South Asian receive timely and effective medical services from the local health authorities, thus realising health equity and service generalisation.

Contributors CLW and HL contributed to the conception and design of the trial and acted as the guarantors. CWHC, WKWS and HL provided expert advice and commented on the intervention contents. KCC is responsible for sample size calculation and statistical analyses. CLW, WKWS, CWHC and HL wrote the manuscript, and all authors read and approved the manuscript.

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Patient consent for publication Consent obtained directly from patients.

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ORCID iDs

Cho Lee Wong http://orcid.org/0000-0001-6640-1323
Carmen Wing Han Chan http://orcid.org/0000-0003-0696-2369
Huiyuan Li http://orcid.org/0000-0002-0207-691X

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