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Effects of smartphone-based chatbot intervention to increase influenza and COVID-19 vaccine uptake amongst South Asians: protocol for a randomised waitlist-controlled trial

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Conflict of Interest Statement

No conflict of interest has been declared by all the authors.

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Abstract

Introduction

Protecting non-native ethnic minority group against co-circulation of influenza and COVID-19 is crucial, and vaccination could be a viable option. Smartphone-based 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 amongst South Asian ethnic minorities in Hong Kong.

Method and analysis

An assessor-blinded, cluster-randomised, waitlist-controlled trial will be conducted. This study consists of two phases. In Phase I, a smartphone-based chatbot intervention will be developed, including designing a simple chatbot called 'Ali' to deliver prewritten educational text message 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 be recruited from each of the 6 participating non-governmental community centers or ethnic minorities associations. They will be randomly allocated to intervention (n = 306) or waitlist control group (n = 306). The intervention group will receive the in-app notification related to the education text messages and vaccination reminders via the smartphone-based chatbot twice a week within four 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 post-intervention (T1), and three months post-intervention (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

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local or interventional conference presentations.

Trial registration number

ChiCTR2200061503.

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Strengths and limitations of this study

- This is the first study to develop a smartphone-based chatbot intervention and evaluate vaccination uptake of both influenza and COVID-19 for South Asians in Hong Kong.

- The content of educational text message 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.

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Introduction

Influenza is a common cause of morbidity and mortality worldwide. It can cause serious diseases in high-risk groups and even healthy people.[1] In Hong Kong, the influenza-associated hospital admission rate during the peak season was 0.92 admissions per 10,000 population and resulted in 169 adult to be 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 9,287 patients have died from the disease.

Influenza and COVID-19 share many common features, and the fifth wave of COVID-19 has been coincided, at least in part, with the circulation of seasonal influenza in the next few years. The co-circulating 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% of the expected coverage. A more worrisome problem is the even lower vaccine uptake amongst ethnic minorities.[4] A cohort study including a database of 12 million people in England observed low vaccine coverage in people from South Asian backgrounds.[5] A recent study corresponded these findings revealing that the COVID-19 vaccination rate amongst ethnic minorities (20.5%) was much lower than that of the general population (42.5%).[6]

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 amongst the local population was only 29.1%[7] and 37.2%,[8] respectively. Although there is a lack of publicly available vaccination rates amongst South Asians (from India, Nepal and Pakistan), one of the largest (14%) and one of the fastest growing ethnic minority groups in Hong Kong, international data 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 World Health Organization (WHO) as one of the top ten global health threats in 2019.[9] 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 (willing to protect others).[10] Ethnicity intersects with low literacy level and language barriers accentuating the vaccination disparities.[11] Nevertheless, people who are hesitant can still be convinced of vaccination uptake with the provision of accurate information.[12] 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 amongst ethnic minorities recommended multi-component strategies.[13–15] Amongst various strategies, patient-focused interventions with education initiatives adjunct with vaccination reminders were the most effective.[13,14]

Providing educational information has widely been used to increase knowledge and awareness of vaccination. A systematic review of 13 studies showed that it increased vaccine uptake by more than 25%.[13] In particular, the use of smartphones to deliver educational text messages seems to be an effective approach.[16] The vaccination reminder function can be integrated into educational text messages to remind patients to make vaccination appointments. Two randomised controlled trials (RCT) targeting ethnic minorities and a review showed that educational text messages adjunct with vaccination reminders can help increase influenza vaccine uptake and advance health literacy related to immunisations.[17–19]

However, the effectiveness of this educational-only text message approach is subject to the decline of users' participation and engagement over time due to lack of interactivity. In addition, a previous study has shown that the lack of interactive options may have the least beneficial effect on increasing vaccination coverage, as those who

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have not been vaccinated early may require alternative approach of the information delivery to make vaccination decisions.[19] Chatbot, which can be built as part of smartphone-based interventions, may help improve interactivity and users' engagement.[20]

Chatbot is computer program designed to imitate human-like communications with user. It covers a board range from simple to smart. Smart chatbots use machine learning (a type of artificial intelligence) and natural language processing to learn information from data without explicitly programming. Apple's Siri and Amazon's Alexa are examples. However, smart chatbots do not have complete human language capabilities, which can lead to misunderstandings and users' dissatisfaction.[20] By contrast, simple chatbots are rule-based which rely on pre-written keywords and programmed scripts which allows providers to disseminate accurate educational information and reminders to users that simulate interactivity experienced by real-life conversation.[22]

The unique features of smartphone-based chatbots make it a promising tool for addressing barriers encountered by ethnic minorities. Firstly, its technical capabilities allow audio and text-to-speech output in multiple languages to facilitate comprehension, which is ideal for ethnic minorities with low literacy levels. Secondly, the programmed scripts allow tailored information to meet the needs of ethnic minorities, thereby improving the saliency and trustworthiness of the information delivered.[16,21] Thirdly, smartphone application platform can provide users with on-demand options for communicating with human backend so as to address specific questions from ethnic minorities that the chatbot is unable to answer.

A review of six studies indicated that chatbots have been widely used to disseminate health information and knowledge about COVID-19.[22] 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.[23] 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

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mental health issues; and promote physical health of lay people, which achieved a moderate amount of evidence in supporting its acceptability and usability with messages sent twice a week.[21] Another meta-analysis that included 19 clinical and nonclinical 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.[20,21] Most importantly, no smartphone-based chatbot on 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 amongst 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, waitlist-controlled trial is to evaluate the effects of smartphone-based chatbot intervention on influenza and COVID-19 vaccine uptake amongst 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 upon completion of the smartphone-based 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; and

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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 (ChiCTR2200061503).

This study has two phases:

Phase I: Development and validation of smartphone-based 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 in the smartphone application; and (2) on-demand option for users to communicate with trained research assistants.

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 GPS of the clinics registered under the vaccination

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scheme and steps to book a vaccination appointment (target constraints and calculation).

'Ali' will send in-app prewritten educational text messages and vaccination reminders to users twice a week (for a total of four weeks) 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.

<u>On-demand option</u>

On top of 'Ali', there will be an on-demand option for project participants to communicate with well-trained research assistants of this project when needed. 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 reminder 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 research assistants) so that the content can be narrated in spoken languages commonly used by South Asians (English, Hindi and Nepali) to facilitate understanding and comprehension.[15,22] The smartphone-based chatbot is open to the public for free download. It will also include a 'members only' feature to facilitate on-demand communication between project participants and research assistant of the same ethnicity. Registration is required, 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 system.

Validation and pilot study of the smartphone-based chatbot

A panel of experts (consisting of IT expert, 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 layout and design of smartphone application and chatbot, are linguistically and culturally relevant to South Asians.

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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 smartphone-based chatbot before it is officially launched.

Phase II: Implementation of the chatbot-based intervention

Participants

Trained research assistants will approach potential subjects whilst they are participating in various activities organised by the six participating non-governmental community centres or ethnic minorities associations, which provide support programme 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 three years; (4) able to communicate with English, Hindi, Nepali or Hindi and read English, Urdu and Nepali; and (5) have a 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 (e.g. 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 vaccine uptake rate. A recent local study found a low uptake rate of influenza vaccine (29%) in a general population in Hong Kong.[7] The vaccine uptake rate amongst ethnic minority can be less

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than half as compared with the general population.[6] We anticipate that our smartphone-based chatbot intervention can increase the uptake rate in ethnic minority to the level of general population. By using the power analysis software GPower 3.1, it is estimated that a sample size of 121 participants per each of the intervention and control groups will be required to achieve 80% power at 5% level of significance (2-sided) to detect at least a 15% difference in the uptake rate (30% in intervention group vs 15% in control group) between the two groups. To allow for up to 20% attrition rate, totally 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 6 participating non-governmental community centers or ethnic minorities 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 (smartphone-based 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 a research assistant blinded to the group allocation.

Waitlist control group

Participants in the control group will receive usual care provided by the ethnic minority associations or centers. They will be offered with the smartphone-based

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 whilst emphasise 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 the in-app notification to participants related to the educational text messages and remind them to receive vaccination twice a week (total of 4 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 research assistants 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 research assistants (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 of various

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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 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 the influenza and COVID-19 vaccine when available on an 11-point Likert scale (0 = definitely no; 10 = definitely yes).[24]

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.[25] 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 of the corresponding antecedents. This scale has been used in a local study to assess vaccine hesitancy.[26] It will be translated to Urdu and Nepali by our research team.

Socio-demographic characteristics

The age, ethnic group, monthly household income, years of formal education, marital status, employment status, number of years' residence in Hong Kong, history of Covid-19 and health insurance status of participants will be collected. Cues to action

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to vaccination (e.g. knowing where to go for vaccination) will also be collected.

Data collection procedures

The instruments (except for the socio-demographic questionnaire) will be administered by the RA blinded to group allocation at three points: baseline (T0, i.e. upon entry to the study before randomisation and intervention during the face-to-face meeting at enrolment); telephone interview post-intervention (T1, i.e. upon completion of the intervention); and 3 months post-intervention (T2, i.e. telephone interview at 3 months after completion of the intervention). The data collection plan is shown in Table 1.

The 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 questionnaire. All participants will receive a $200 coupon after completion of the baseline assessment and two post-intervention 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 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.

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Data analysis

Data will be summarised and presented using appropriate descriptive statistics. Normality of continuous variables will be assessed using skewness and kurtosis statistics and normal probability plot. Suitable transformations will be made on skewed variables before subjecting to inferential analysis, if needed. Homogeneity of participants' characteristics between the two groups will be assessed by independent t, chi-square, or Fisher's exact tests, as appropriate.

The effectiveness of the intervention will be assessed by comparing the uptake rate between the two groups, and by comparing the between-group differences in the changes in vaccination intention and vaccine hesitancy 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 inter-correlation within the same cluster and intra-correlated repeated measure data in a cluster RCT with a small number of clusters. The GEE analysis will be performed with the procedure GLIMMIX, implemented in the SAS (SAS Institute, Cary, NC, release 9.4). All statistical tests involved will be two-sided with 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 and return it to the research assistants. 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

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disseminated in peer-reviewed journals and through local or interventional conference presentations.

Discussion

Influenza and COVID-19 vaccination uptake can vary among different demographic groups, including non-active ethnic minorities, due to various factors such as access to healthcare, language barriers, cultural beliefs, and trust in the healthcare system. It's 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 amongst 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' would 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 non-governmental community centres or ethnic minorities associations, the intervention implementation will provide a good opportunity for healthcare providers and cultural influencers in Hong Kong to engaging ethnic minority populations effectively. This will also benefit the South Asian receive timely and effectively medical services from the local health

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authorities, thus realising health equity and service generalisation.

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Contributors CLW and HL contributed to the conception and design of the trial. 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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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details**.**

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Table 1. SPIRIT schedule of the trial.

	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation		Close-out	
TIMEPOINT**	$-t_0$	0			t_1	t_2
ENROLMENT:						
Eligibility screen	▓					
Informed consent	▓					
Demographics and clinical characteristics	▓					
Random allocation		▓				
INTERVENTIONS:						
[Smartphone-based chatbot intervention]			←——————→			
[Waitlist control]			←——————→			
ASSESSMENTS:						
Vaccination uptake					▓	▓
Intention to receive vaccination					▓	▓
5C scale for Vaccine hesitancy					▓	▓
Socio-demographic characteristics	▓					

T0: baseline; T1: immediately post-intervention; T2: three months post-intervention.

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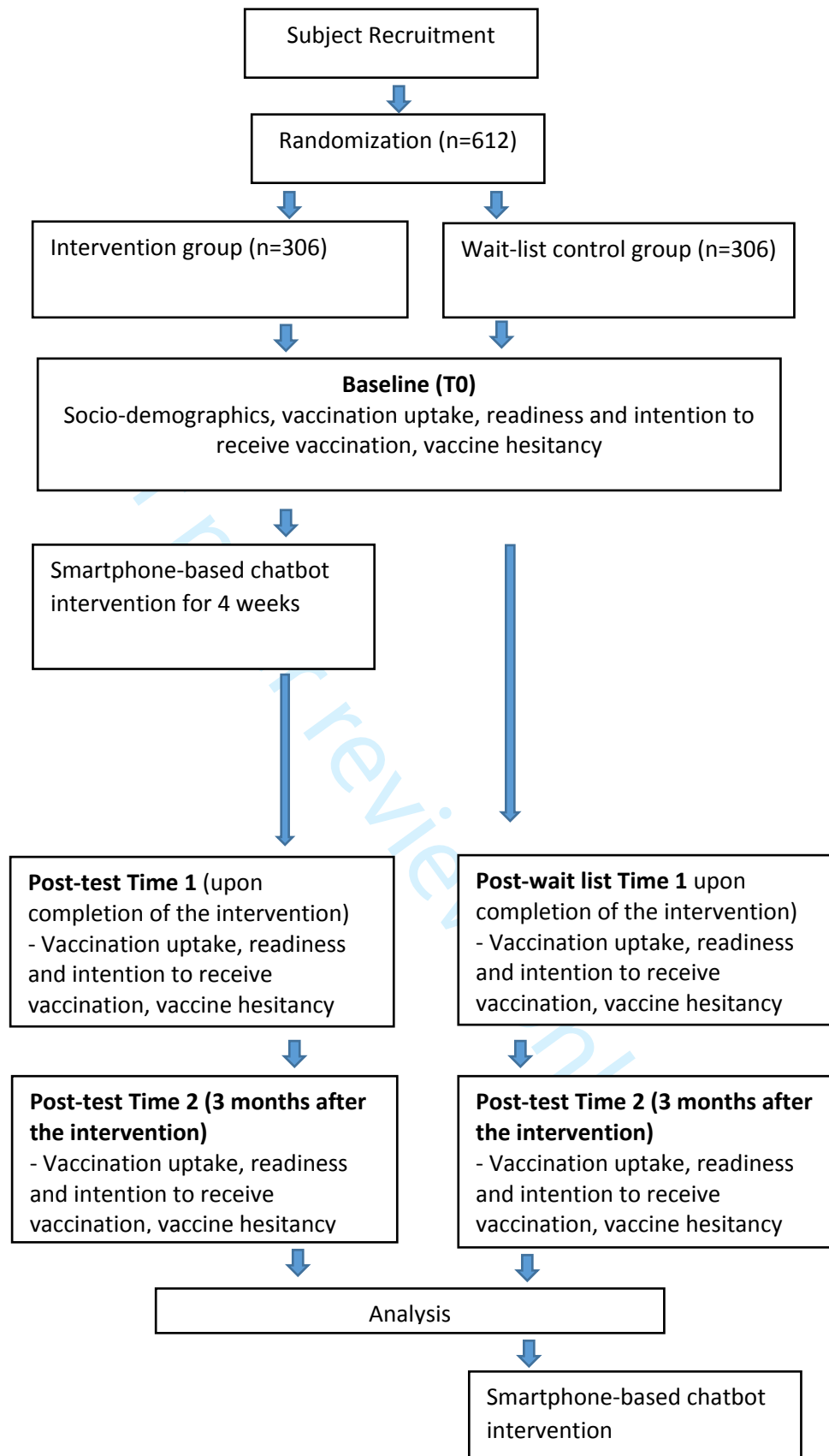43
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Figure 1. The flow diagram of intervention and data collection points

BMJ Open

Effects of smartphone-based chatbot intervention to increase influenza and COVID-19 vaccine uptake amongst South Asian ethnic minorities in Hong Kong: protocol for a randomised waitlist-controlled trial

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1 **Effects of smartphone-based chatbot intervention to increase influenza and**

2 **COVID-19 vaccine uptake amongst South Asian ethnic minorities in Hong Kong:**

3 **protocol for a randomised waitlist-controlled trial**

4

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59   **Abstract**

60   **Introduction**

61   Protecting non-native ethnic minority groups against co-circulation of influenza and

62   COVID-19 is crucial, and vaccination could be a viable option. Smartphone-based

63   chatbots offer promising opportunities for improving vaccine knowledge and

64   addressing barriers encountered by ethnic minorities. This trial aims to evaluate the

65   effects of smartphone-based chatbot intervention on influenza and COVID-19 vaccine

66   uptake, intention to receive vaccination and vaccine hesitancy amongst South Asian

67   ethnic minorities in Hong Kong.

68   **Method and analysis**

69   An assessor-blinded, cluster-randomised, waitlist-controlled trial will be conducted.

70   This study consists of two phases. In Phase I, a smartphone-based chatbot intervention

71   will be developed, including designing a simple chatbot called 'Ali' to deliver

72   prewritten educational text messages and vaccination reminders as well as respond to

73   users' questions, and on-demand option for communication with research assistants

74   (RAs). An expert panel will be invited to review the designed chatbot, and pilot testing

75   will be performed. In phase II, a total of 612 South Asians will be recruited from each

76   of the 6 participating non-governmental community centres or ethnic minority

77   associations. They will be randomly allocated to intervention (n = 306) or waitlist

78   control group (n = 306). The intervention group will receive in-app notifications related

79   to the education text messages and vaccination reminders via the smartphone-based

80   chatbot twice a week for four weeks. The waitlist control group will receive usual care

81   only. Evaluation will include vaccination uptake, intention to receive vaccination and

82   vaccine hesitancy. Assessments will take place at baseline (T0), immediately post-

83   intervention (T1), and three months post-intervention (T2).

84   **Ethics and dissemination**

85   This study has been approved by the Joint Chinese University of Hong Kong-New

86   Territories East Cluster Clinical Research Ethics Committee (CREC Ref. No.:

87   2021.688). The findings will be disseminated in peer-reviewed journals and through

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88 local or interventional conference presentations.

89 **Trial registration number**

90 ChiCTR2200061503.

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117 **Strengths and limitations of this study**

118 • The content of educational text messages within a simple chatbot was underpinned

119   by the 5C model to understand antecedents of vaccination behaviours.

120 • To enhance rigour, this study incorporates cluster sampling, single-blinding, and

121   randomisation.

122 • Due to the nature of the intervention, blinding of participants and the

123   interventionist will be impractical.

124

125 **Introduction**

126   Influenza is a common cause of morbidity and mortality worldwide. It can cause

127 serious diseases in high-risk groups and even healthy people.[1] In Hong Kong, the

128 influenza-associated hospital admission rate during the peak season was 0.92

129 admissions per 10,000 population and resulted in 169 adults being admitted to the

130 intensive care unit in 2020.[2] Meanwhile, the recent COVID-19 pandemic has had an

131 unrivalled impact on the global healthcare system. Hong Kong is no exception. As of

132 27 July 2023, 1,226,467 COVID-19 cases have been recorded, and 9,287 patients have

133 died from the disease.

134   Influenza and COVID-19 share many common features, and the fifth wave of

135 COVID-19 has been coincided, at least in part, with the circulation of seasonal

136 influenza in the next few years. The co-circulating influenza and COVID-19 viruses

137 likely intensify the burden on hospitalisation and intensive care unit admission.[3] This

138 highlights the importance of optimising measures to manage both respiratory infections

139 simultaneously and effectively.[3]

140   Vaccination is one of the effective ways to prevent the unnecessary spread of

141 vaccine-preventable diseases and promote herd immunity. Despite these benefits, the

142 influenza vaccination rates in most countries are still less than 50%[4] of the expected

143 coverage. A more worrisome problem is the even lower vaccine uptake amongst ethnic

144 minorities.[5] A cohort study including a database of 12 million people in England

145 observed low vaccine coverage in people from South Asian backgrounds.[6] A recent

146 study corresponded to these findings revealing that the COVID-19 vaccination rate

147 amongst ethnic minorities (20.5%) was much lower than that of the general population

148 (42.5%).[7]

149   In Hong Kong, the government has launched a seasonal influenza programme and

150 a territory-wide COVID-19 vaccination programme to provide eligible Hong Kong

151 residents with free/subsided seasonal influenza vaccination and free COVID-19 vaccine.

152 However, the overall uptake of influenza vaccine and the acceptance rate of COVID-

153 19 vaccine amongst the local population was only 29.1%[8] and 37.2%,[9] respectively.

154 Although there is a lack of publicly available vaccination rates amongst South Asians

155 (from India, Nepal and Pakistan), one of the largest (14%)[10] and one of the fastest

156 growing ethnic minority groups in Hong Kong, international data[8,9] have already

6

157 provided some insights into the significant risks of their low uptake rates of both

158 vaccines.

159 Vaccine hesitancy, characterised by ambivalence or refusal to vaccinate, has been

160 identified by the World Health Organization (WHO) as one of the top ten global health

161 threats in 2019.[11] Vaccine hesitancy is a complex and multifaceted construct that exists

162 on a continuum, which encompasses a range of beliefs, attitudes, and behaviours

163 towards vaccination that can vary significantly between individuals and across different

164 vaccine types.[11] On the basis of the Health Belief Model and Theory of Planned

165 Behaviour, as well as the work of the WHO advisory group, researchers have posited

166 the 5C model to understand antecedents of vaccination behaviours. 5C includes

167 confidence (trust in vaccine effectiveness, safety and necessity and the system that

168 provides it), complacency (perceived low risk of diseases), constraints (structural and

169 psychological barriers), calculation (extensive information searching) and collective

170 responsibility (willingness to protect others).[12] Ethnicity intersects with low literacy

171 levels and language barriers accentuating the vaccination disparities.[13] For South

172 Asians in Hong Kong, vaccine hesitancy toward COVID-19 and flu vaccines may

173 exhibit dynamic variance. While initial COVID-19 vaccine hesitancy may be high due

174 to safety and trust concerns, acceptance increased as the vaccines proved effective. In

175 contrast, flu vaccine acceptance is relatively more stable and higher, as the community

176 is familiar with its safety and perceived necessity, though individual factors like access

177 and past experiences still impact acceptance levels.[13] Nevertheless, people who are

178 hesitant can still be convinced of vaccination uptake with the provision of accurate

179 information.[14] Thus, effective interventions aimed at promoting knowledge and

180 awareness of vaccines and removing barriers are critical to the success of vaccination

181 programmes.

182 A review of interventions to promote vaccination amongst ethnic minorities

183 recommended multi-component strategies.[15-17] Amongst various strategies, patient-

184 focused interventions with education initiatives adjunct with vaccination reminders

185 were the most effective.[15,16]

186 Providing educational information, as one of the effective strategies, has widely

187 been used to increase knowledge and awareness of vaccination and reduce vaccine

188 hesitancy.[15,18] A systematic review of 13 studies showed that it increased vaccine

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189 uptake by more than 25%.[15] In particular, the use of smartphones to deliver educational

190 text messages seems to be an effective approach.[18] The vaccination reminder function

191 can be integrated into educational text messages to remind patients to make vaccination

192 appointments. Two randomised controlled trials (RCT) targeting ethnic minorities and

193 a review showed that educational text messages adjunct with vaccination reminders can

194 help increase influenza vaccine uptake and advance health literacy related to

195 immunisations.[19-21]

196 However, the effectiveness of this educational-only text message approach is

197 subject to a decline in users' participation and engagement over time due to a lack of

198 interactivity. In addition, a previous study has shown that the lack of interactive options

199 may have the least beneficial effect on increasing vaccination coverage, as those who

200 have not been vaccinated early may require an alternative approach to the information

201 delivery to make vaccination decisions.[21] Chatbot, which can be built as part of

202 smartphone-based interventions, may help improve interactivity and users'

203 engagement.[22]

204 Chatbot is a computer programme designed to imitate human-like communications

205 with users.[22] It covers a broad range from simple (simple rule-based systems) to smart

206 (utilises artificial intelligence (AI) and machine learning techniques). Smart chatbots

207 use machine learning (i.e. training algorithms to identify patterns in data) and natural

208 language processing (i.e. the ability to understand and interpret human language input)

209 to learn information from data without explicit programming.[22] Apple's Siri and

210 Amazon's Alexa are examples. However, smart chatbots do not have complete human

211 language capabilities, which can lead to misunderstandings and users' dissatisfaction.[22]

212 By contrast, simple chatbots are rule-based and rely on pre-written keywords and

213 programmed scripts which allow providers to disseminate accurate educational

214 information and reminders to users that simulate interactivity experienced by real-life

215 conversation.[23]

216 The unique features of smartphone-based chatbots make it a promising tool for

217 addressing barriers encountered by ethnic minorities. Firstly, its technical capabilities

218 allow audio and text-to-speech output in multiple languages to facilitate comprehension,

219 which is ideal for ethnic minorities with low literacy levels. Secondly, the programmed

220 scripts allow tailored information to meet the needs of ethnic minorities, thereby

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

228　　A review of six studies indicated that chatbots have been used to disseminate
229　health information and knowledge about COVID-19.[23] For instance, the WHO has
230　developed a chatbot with several languages to provide information on a wide range of
231　topics for users to ask and find answers related to COVID-19.[25] Likewise, the German
232　government developed a 'flight COVID messenger bot'; in India, a smartphone
233　application with parallel connection of a chatbot has been developed to enhance
234　awareness of COVID-19.

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

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

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253 by decreasing vaccination disparities.

Aim and hypothesis

255 The primary aim of this cluster-randomised, waitlist-controlled trial is to evaluate
256 the effects of smartphone-based chatbot intervention on influenza and COVID-19
257 vaccine uptake amongst South Asian ethnic minorities in Hong Kong. The secondary
258 aim is to assess the effects of such an intervention on the intention of influenza and
259 COVID-19 vaccination, as well as improve vaccine hesitancy.

260 Compared with the waitlist control group, South Asians in the intervention group
261 are expected to exhibit the following outcomes upon completion of the smartphone-
262 based chatbot intervention:

263 1. Higher rate of influenza and COVID-19 vaccination uptake as evidenced by
264 vaccination records;

265 2. Higher rate in expressing intention to receive influenza and COVID-19 vaccines
266 as measured by two questions on the intention to receive vaccination; and

267 3. Higher levels of confidence and collective responsibility and lower levels of
268 complacency, constraints and calculation as measured by the 5C scale that
269 measures vaccine hesitancy.

270

Methods and analysis

Design

273 A cluster-randomised, waitlist-controlled trial will be conducted. Figure 1 shows
274 the study procedure. The protocol has been registered on the Chinese Clinical Trial
275 Registry (ChiCTR2200061503).

276 This study has two phases:

277 **Phase I**: Development and validation of smartphone-based chatbot intervention.

278 **Phase II**: Implementation and evaluation of the effects of the intervention.

279

Implementation

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281 **Phase I: Development of smartphone-based chatbot**

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

285 A simple chatbot

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

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

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

304 On-demand option

305   On top of 'Ali', there will be an on-demand option for project participants to
306 communicate with well-trained RAs of this project when needed. The research team
307 will extensively train the RAs on the content and functionality of the chatbots, as well
308 as best practices for providing personalised and helpful support to participants. The
309 RAs will have access to a pre-approved content library that they can reference when
310 responding to participant questions and concerns, which will help ensure consistency
311 and accuracy in their replies. In addition, the RAs will be required to document the

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312 types of questions and issues raised by participants during the live support sessions.

313 This documentation will be for systematic analysis by the research team to identify

314 common themes and areas for improvement in the chatbot's content and functionality.

315 This option serves as a backup in case users cannot find answers related to their

316 inquiries from 'Ali'.

317   The educational modules, text messages and vaccination reminders are prepared

318 in English, Urdu and Nepali (written languages commonly used by South Asians). Most

319 importantly, users can choose the voice narration option (recorded by RAs) so that the

320 content can be narrated in spoken languages commonly used by South Asians (English,

321 Hindi and Nepali) to facilitate understanding and comprehension.[17,23] The smartphone-

322 based chatbot is open to the public for free download. It will also include a 'members

323 only' feature, designed as a private communication channel, to facilitate on-demand

324 communication between project participants and ~~research assistant~~ RA of the same

325 ethnicity. Within the 'members only' functionality, participants will have access to a

326 variety of communication tools and collaboration features, including private one-on-

327 one messaging, group messaging, sharing relevant materials securely, a community

328 forum for broader discussions, and an integrated notification system for upcoming

329 vaccine injection and other updates relevant to vaccination. Registration is required to

330 become a member, and a password will be provided to the participants. The Android

331 platform is chosen for its widespread popularity and availability on various devices and

332 operating systems.

333 *Validation and pilot study of the smartphone-based chatbot*

334   A panel of experts (consisting of IT experts, healthcare professionals, educators,

335 and South Asian community leaders) will be invited to review whether the contents of

336 educational modules, text messages and reminders, as well as the layout and design of

337 smartphone applications and chatbot, are linguistically and culturally relevant to South

338 Asians.

339   In addition, nine South Asians (three Indians, three Pakistanis and three Nepalese)

340 will be invited to pilot test the smartphone-based chatbot intervention and provide

341 comments and feedback. Their comments and suggestions will be incorporated to

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342   optimise the smartphone-based chatbot before it is officially launched.

343

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

Participants

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

352

Inclusion criteria

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

Exclusion criteria

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

Sample size

364   The sample size is estimated on the basis of the outcome of the vaccine uptake
365   rate. A recent local study found a low uptake rate of influenza vaccine (29%) in the
366   general population in Hong Kong.[8] The vaccine uptake rate amongst ethnic minorities
367   can be less than half as compared with the general population.[7] We anticipate that our
368   smartphone-based chatbot intervention can increase the uptake rate in ethnic minorities
369   to the level of the general population. By using the power analysis software GPower

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370 3.1, it is estimated that a sample size of 121 participants per each of the intervention

371 and control groups will be required to achieve 80% power at a 5% level of significance

372 (2-sided) to detect at least a 15% difference in the uptake rate (30% in the intervention

373 group vs 15% in the control group) between the two groups. To allow for up to a 20%

374 attrition rate, a total of 304 participants, with 152 per group will be needed. Furthermore,

375 to account for the clustering design by allowing for an intracluster correlation

376 coefficient up to 0.01 in our proposed trial, at least 102 participants will be recruited

377 from each of the 6 participating non-governmental community centres or ethnic

378 minority associations.

379

380 **Randomisation and blinding**

381   Six centres and associations agreed to participate in this study. Each centre or

382 association will be randomly assigned to one of the two arms: an intervention group (n

383 = 3) that will receive immediate treatment (smartphone-based chatbot intervention) or

384 a waitlist control group (n = 3) that will receive delayed treatment (the same

385 intervention but provided after the intervention group has completed the immediate

386 treatment). Participants from each centre/association will be randomly assigned in a 1:1

387 ratio to either the control group or the intervention group to avoid 'contamination'

388 across participants. The computer-generated randomisation scheme will be conducted

389 by a statistician to maintain concealment. The group identifiers for each

390 centre/association will then be placed in serially numbered sealed opaque envelopes.

391 The patient's group allocation will be assigned according to the sequence of enrolment

392 in the study and the group identifier contained in the corresponding numbered

393 envelopes. Assessments of vaccination uptake and other secondary outcomes will be

394 performed by a RA blinded to the group allocation.

395

396 **Waitlist control group**

397   Participants in the control group will receive usual care provided by the ethnic

398 minority associations or centers. They will be offered with the smartphone-based

399 chatbot intervention after their counterparts have completed the intervention.

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Intervention group

401

402   Participants in the intervention group will receive the smartphone-based chatbot

403 intervention developed in Phase I. The details of the intervention have been detailed in

404 a previous section. Two well-trained RAs (Nepali RA2 and Pakistani RA3) will first

405 demonstrate to participants the smartphone-based chatbot as an easy-to-use and

406 supporting application for vaccination whilst emphasising that they are chatting with

407 an automated system but not a person. They will invite participants to access the

408 smartphone application via the QR code printed on the card. Each participant will be

409 linked to the personalised code printed on this card. This connection between the

410 participants and their designated RA will enable 'Ali' to recognise the participants so

411 that it can link back to its assigned RA to answer inquiries as needed. The intervention

412 will last for 4 weeks. The smartphone-based chatbot will send in-app notifications to

413 participants related to the educational text messages and remind them to receive

414 vaccination twice a week (a total of 4 weeks). In addition, it will answer questions raised

415 by participants at any time. In case participants cannot find an answer from 'Ali', the

416 on-demand options can help link the participant with well-trained RAs of this project

417 to answer their questions.

418

Fidelity of the intervention

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420   Strategies will be used to monitor the intervention fidelity. Standardisation in the

421 delivery of the intervention will be implemented through the use of written protocol.

422 The RAs (RA2 and RA3) who implement the interventions are required to strictly

423 follow the protocol. They will also receive 3-day training by the principal investigator.

424 The training aims to equip RAs with knowledge and competence. A package of training

425 materials will be prepared in accordance with the latest vaccination guidelines. The

426 training contains four modules that are the same as those in the smartphone application.

427 In addition, the training will focus on the following strategies (1) initiate discussions

428 about vaccination, (2) clarify misconceptions about vaccination, (3) strategies to

429 overcome possible vaccination barriers and (4) access of various vaccination resources.

430 Throughout the project, the principal investigator will supervise and closely monitor

431 the on-demand responses that the RAs provide to participants' inquiries to assess their

432 competence. The principal investigator will also meet with RAs monthly and provide

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433   feedback.

434

Outcome measurements

Primary outcome: Vaccination uptake

437   Participants will be assessed whether they have received influenza and COVID-
438   19 vaccination separately as evidenced by their vaccination records.

Secondary outcomes:

Intention to receive vaccination

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

Vaccine hesitancy

446   Vaccine hesitancy will be measured by the 5C Scale. It is a 15-item tool developed
447   from a '5C model' of five psychological antecedents to vaccination.[27] The five
448   antecedents comprise confidence, complacency, constraints, calculation and collective
449   responsibility. It will be assessed by three rating items on a 7-point scale (1 = strongly
450   disagree; 7 = strongly agree). Mean scores of items under each domain will be
451   computed, with a high score indicating a high level of agreement with the corresponding
452   antecedents. This scale has been used in a local study to assess vaccine hesitancy.[28] It
453   will be translated into Urdu and Nepali by our research team.

Socio-demographic characteristics

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

459

Data collection procedures

461   With consent, the baseline characteristics of the participants, including the socio-

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462 demographic characteristics and research outcomes, will be evaluated at baseline (T0,

463 i.e. upon entry to the study before randomisation and intervention during the face-to-

464 face meeting at enrolment). The instruments will also be administered by the RA

465 blinded to group allocation at the other two points: post-intervention (T1, i.e. telephone

466 interview upon completion of the intervention); and 3 months post-intervention (T2,

467 i.e. telephone interview at 3 months after completion of the intervention). The data

468 collection plan is shown in Table 1.

469 The self-reported questionnaires are available in English, Nepali and Urdu.

470 Content validity will be assessed by the expert panel. The blinded RA will contact the

471 participants in both groups to complete the paper version of the questionnaire. All

472 participants will receive a $200 coupon after completion of the baseline assessment and

473 two post-intervention questionnaires.

474

475 **Data management**

476 Information collected about the subjects will be kept strictly confidential, with

477 only the research team able to access the encrypted data file. All hard copies of

478 documents will be kept in a locked cabinet and will be destroyed within six years of the

479 study's completion. The electronic data will be stored in a hard disk protected with

480 passwords kept for ten years.

481

482 **Patient and public involvement**

483 Participants were involved in the development of the intervention. Before the start

484 of the full-scale study, participants were first invited to participate in the main sessions

485 of the study to ensure clarity and comprehension. After the intervention delivery,

486 participants in the intervention group will be evaluated to explore their experiences on

487 the intervention's usefulness and acceptability.

488

489 **Data analysis**

490 Data will be summarised and presented using appropriate descriptive statistics.

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491 The normality of continuous variables will be assessed using skewness and kurtosis
492 statistics and a normal probability plot. Suitable transformations will be made on
493 skewed variables before subjecting them to inferential analysis if needed. The
494 homogeneity of participants' characteristics between the two groups will be assessed
495 by independent t, chi-square, or Fisher's exact tests, as appropriate.

496 The effectiveness of the intervention will be assessed by comparing the uptake rate
497 of COVID-19 and flu vaccines separately between the two groups, and by comparing
498 the between-group differences in the changes in vaccination intention and vaccine
499 hesitancy on COVID-19 and flu vaccines separately at T1 and T2 with respect to T0.
500 The intention-to-treat principle will be adopted in the outcome evaluation between the
501 two groups. The generalised estimating equations (GEE) approach, in conjunction with
502 a small sample correction for sandwich variance estimate, will be used to compare the
503 outcomes between the two groups. This approach can be used to account for the inter-
504 correlation within the same cluster and intra-correlated repeated measure data in a
505 cluster RCT with a small number of clusters. The GEE model will also handle the
506 randomly missing data with correlated data, which can provide valid parameter
507 estimates and standard errors while accounting for the missing data mechanism and the
508 flexibility to model various correlation structures. The GEE analysis will be performed
509 with the procedure GLIMMIX, implemented in the SAS (SAS Institute, Cary, NC,
510 release 9.4). All statistical tests involved will be two-sided with the level of significance
511 set at 0.05.

512

513 **Ethics and dissemination**

514 Ethical approval has been sought from the Joint Chinese University of Hong Kong-
515 New Territories East Cluster Clinical Research Ethics Committee with reference
516 number: 2021.688. The study complies with the Declaration of Helsinki. Eligible
517 participants will be briefed on the study details, its aims and objectives, and their rights
518 to withdraw at any time. They will be given an assurance as to anonymity and
519 confidentiality. An information sheet with details of the study and an informed consent
520 form will be provided, and they will be available in English, Nepali and Urdu. Potential
521 participants interested in the study will be asked to sign the consent form

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522 (Supplementary Material 1) and return it to the RAs. It will be emphasised that their

523 participation is voluntary and that they can leave the study at any time without giving a

524 reason. The findings will be disseminated in peer-reviewed journals and through local

525 or international conference presentations.

526

527 **Discussion**

528   Influenza and COVID-19 vaccination uptake can vary among different

529 demographic groups, including non-active ethnic minorities, due to various factors such

530 as access to healthcare, language barriers, cultural beliefs, and trust in the healthcare

531 system. It's important for public health authorities to address any disparities in

532 vaccination rates and ensure equitable access to vaccines for all communities, including

533 ethnic minorities, to achieve widespread vaccination coverage and protect the entire

534 population. This novel study is the first to develop and evaluate the effectiveness of the

535 smartphone-based chatbot intervention in improving vaccination uptake, intention to

536 receive vaccination and vaccine hesitancy amongst South Asian ethnic minorities in

537 Hong Kong. This innovative approach will likely provide practical significance in

538 addressing needs and reducing barriers, thereby increasing the vaccination rate of South

539 Asians. The ultimate impact of this project is to reduce the burden of influenza and

540 COVID-19 by decreasing vaccination disparities. It is anticipated that the chatbot 'Ali'

541 will become a friendly using application in the community. The chatbot can be

542 culturally sensitive and respectful of the diverse backgrounds and beliefs of ethnic

543 minority communities, especially people with South Asian backgrounds. The language,

544 tone, and content are tailored to address cultural nuances and can avoid any potential

545 misunderstandings or misinterpretations. The chatbot is also multilingual or provides

546 language options for South Asians to accommodate their different language preferences.

547 In addition, this study will be conducted collaborated with six non-governmental

548 community centres or ethnic minority associations; the intervention implementation

549 will provide a good opportunity for healthcare providers and cultural influencers in

550   Hong Kong to engage ethnic minority populations effectively. This will also benefit the

551   South Asian receive timely and effective medical services from the local health

552   authorities, thus realising health equity and service generalisation.

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564 **Patient and public involvement** Patients and/or the public were involved in the design,

565 or conduct, or reporting, or dissemination plans of this research. Refer to the Methods

566 section for further details**.**

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570 **ORCID ID**

571 Huiyuan Li https://orcid.org/0000-0002-0207-691X

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692 **Table 1. SPIRIT schedule of the trial.**

	STUDY PERIOD				
	Enrolment	Allocation	Post-allocation	Close-out	
TIMEPOINT**	$-t_0$	0		t_1	t_2
ENROLMENT:					
Eligibility screen					
Informed consent					
Demographics and clinical characteristics					
Random allocation					
INTERVENTIONS:					
[Smartphone-based chatbot intervention]			←——————→		
[Waitlist control]			←——————→		
ASSESSMENTS:					
Vaccination uptake					
Intention to receive vaccination					
5C scale for Vaccine hesitancy					
Socio-demographic characteristics					

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694   T0: baseline; T1: immediately post-intervention; T2: three months post-intervention.

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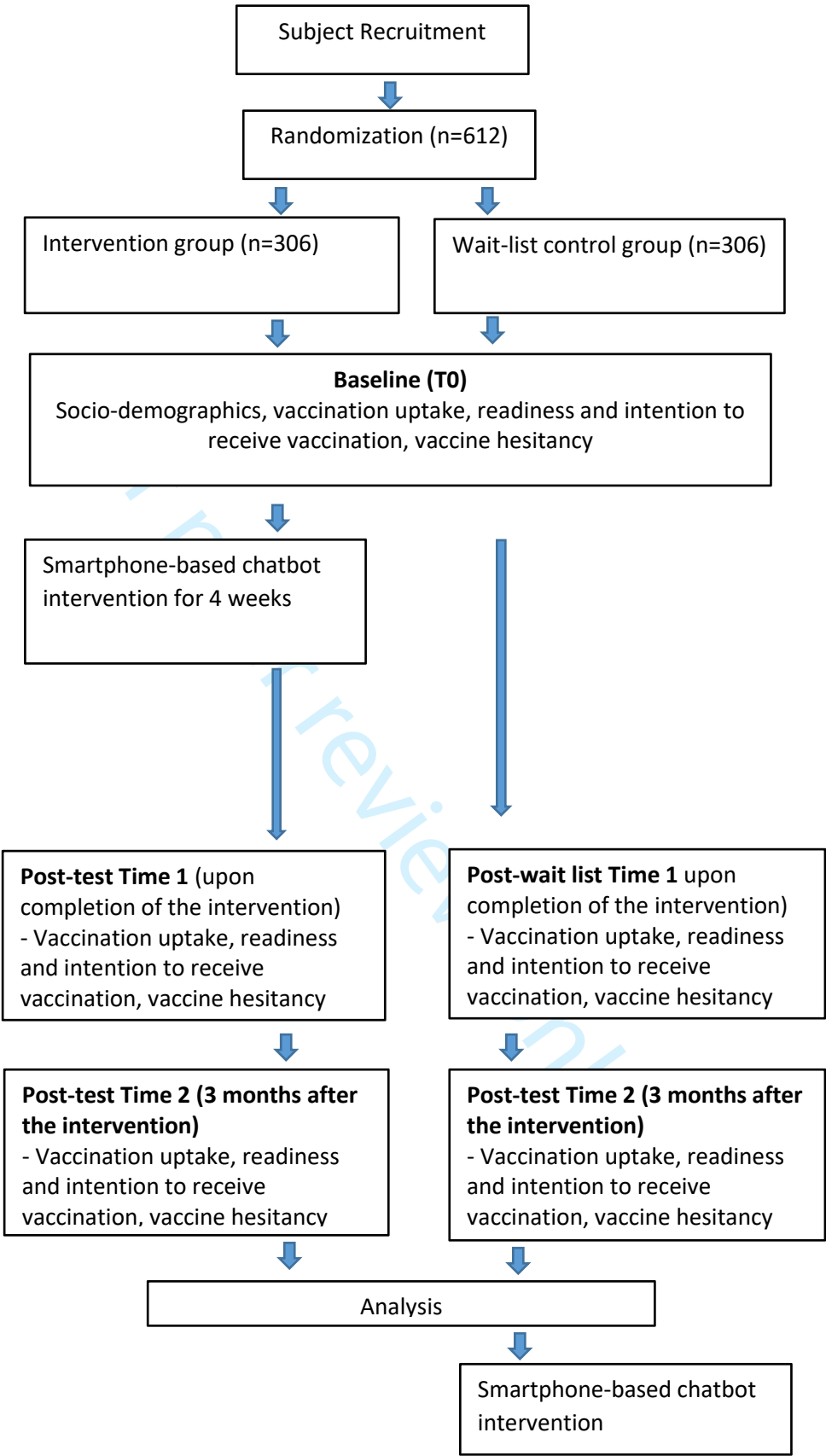44
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Figure 1. The flow diagram of intervention and data collection points

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Information sheet for participants (Phase II)

Title of the study

Effects of smartphone-based chatbot intervention to increase influenza and COVID-19 vaccine uptake among South Asians: a wait-list randomized controlled trial

Purpose of the study

The purpose of the study is to evaluate the effects of smartphone-based chatbot intervention on influenza and COVID-19 vaccine uptake amongst South Asians (from Pakistan, India, or Nepal) in Hong Kong.

Procedure

We are going to recruit 612 South Asians to join the study. Six community centers or ethnic minorities associations have agreed to participate the project will be randomly selected as 3 intervention groups and 3 control groups for the study. Potential subjects will be approached by the research assistant (RA) whilst they are participating in various activities organised by these six centers or associations. After the introductory presentation, South Asians who are interested in participating in the study will be screened for eligibility.

Eligible participants are:

(1) South Asians (from Pakistan, India or Nepal);

(2) aged 18 or older;

(3) unvaccinated for influenza or COVID-19 in the past year;

(4) able to communicate with English, Hindi, Nepali or Hindi and read English, Urdu and Nepali; and

(5) have a smartphone.

For those who (1) are South Asians from Bangladesh and Sri Lanka; (2) participated in any intervention related to influenza and COVID-19 in the past year; (3) have known vaccine contraindications (e.g. a history of severe hypersensitivity to any vaccine component or previous dose of influenza vaccine) will be excluded from the study.

If you are willing to participate in the study, you will be given this information sheet to keep and asked to sign an informed consent form.

Intervention group

A smartphone-based chatbot intervention is developed and introduced to the South Asians to

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increase the influenza and COVID-19 vaccination uptake. It consists of two components: (1) a simple chatbot that is built in the smartphone application; and (2) on-demand option for users to communicate with trained research assistants. A simple chatbot called 'Ali' will be designed to deliver prewritten educational text messages and vaccination reminders as well as respond to users' questions in the smartphone application platform. Two well-trained RAs will first demonstrate to participants how to use the smartphone-based chatbot and access application via the QR code. Each participant will be linked to the personalised code and connected between the participants and their designated RA that enable 'Ali' to recognise the participants. The intervention will last for 4 weeks. The smartphone-based chatbot will send the in-app notification to participants related to the educational text messages and remind them to receive vaccination twice a week (total of 4 weeks). In case participants cannot find an answer from 'Ali', the on-demand options can help link the participant with well-trained research assistants of this project to answer their questions.

Control group
Subjects in the control group will be offered with the smartphone-based chatbot intervention after their counterparts have completed the intervention.

In order to evaluate the intervention study, you will be asked to complete the questionnaire at the study enrollment (T0), upon completion of the intervention (T1) and 3 months after the intervention (T2).
The questionnaire consists of socio-demographics, vaccination uptake, readiness and intention to receive vaccination, vaccine hesitancy.

If you decide to take part, you are still free to withdraw at any time and without giving a reason.

Risks and benefits
There is no potential risk for the participants. All participants will receive HK$200 for completing the questionnaires.

Confidentiality of participants
All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you will be anonymized using a unique number identification so that you cannot be recognized from it. 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 kept for ten years.

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Ethical review

The study has been reviewed by the Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee.

Inquiry

The study is organized by the Nethersole School of Nursing, The Chinese University of Hong Kong. If you have any questions about this study, please feel free to contact the following personnel:

Dr Jojo Wong
Assistant Professor
The Nethersole School of Nursing
Faculty of Medicine
The Chinese University of Hong Kong
Phone Number   (852) 3943 8166
E-mail   jojowong@cuhk.edu.hk

Thank you for taking part in this study

Remarks: The Urdu or Nepali version of this information sheet will be available upon request.

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PARTICIPANT CONSENT FORM (Phase II)

Code Number:

Title of Project:
Effects of smartphone-based chatbot intervention to increase influenza and COVID-19 vaccine uptake among South Asians: a wait-list randomized controlled trial

Organizer and funding body:
The study is organized by the Nethersole School of Nursing, The Chinese University of Hong Kong.

Principal investigator's name and contact number:
Dr Jojo Wong   Phone Number: (852) 3943 8166

If I have any questions regarding the subject rights, I may contact the Joint CUHK-NTEC Clinical Research Ethics Committee at 3505 3935 for clarification.

Please initial the appropriate boxes

1. I confirm that I have read and understood the information sheet dated __/__/__ for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, legal rights being affected. ☐

3. I understand that all information collected during the course of the research will be kept strictly confidential and my identity will be anonymized. ☐

4. I understand that sections of any of my research record may be looked at by responsible individuals from regulatory authorities (including NTEC-CUHK Cluster REC/IRB) where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐

5. I understand that I will receive HK$200 upon completing the study. ☐

6. I agree to be contacted via the mobile number: _____ for future studies. ☐

Remarks: The Urdu or Nepali version of this consent form will be available upon request.

Name of participant	*Date*	*Signature*

Researcher	*Date*	*Signature*

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