



BMJ Open Novel intervention to promote COVID-19 protective behaviours among Black and South Asian communities in the UK: protocol for a mixed-methods pilot evaluation

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ABSTRACT

Introduction Culturally appropriate interventions to promote COVID-19 health protective measures among Black and South Asian communities in the UK are needed. We aim to carry out a preliminary evaluation of an intervention to reduce risk of COVID-19 comprising a short film and electronic leaflet.

Methods and analysis This mixed methods study comprises (1) a focus group to understand how people from the relevant communities interpret and understand the intervention's messages, (2) a before-and-after questionnaire study examining the extent to which the intervention changes intentions and confidence to carry out COVID-19 protective behaviours and (3) a further qualitative study exploring the views of Black and South Asian people of the intervention and the experiences of health professionals offering the intervention. Participants will be recruited through general practices. Data collection will be carried out in the community.

Ethics and dissemination The study received Health Research Authority approval in June 2021 (Research Ethics Committee Reference 21/L0/0452). All participants provided informed consent. As well as publishing the findings in peer-reviewed journals, we will disseminate the findings through the UK Health Security Agency, NHS England and the Office for Health Improvement and Disparities and ensure culturally appropriate messaging for participants and other members of the target groups.

INTRODUCTION

In the UK, the COVID-19 pandemic has inflicted a disproportionate burden of illness and death who define themselves as belonging to the Black and South Asian communities.^{1–4} It is widely accepted in the public health community that health promotion interventions should be adapted for the target population.⁵ Therefore, culturally appropriate interventions to promote COVID-19 health protective behaviours among people

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study is a preliminary pragmatic evaluation of a novel intervention designed rapidly to address an urgent public health problem—lower uptake of COVID-19 health protective behaviours, including testing and vaccination, among people in the Black and South Asian communities.
- ⇒ The study will use a number of novel approaches to public health research, including using automated text messaging from general practices to recruit participants rapidly, which will allow us to reach a large number of people belonging to the target population, and using mobile telephone number as an identifier to link preintervention and postintervention data, rather than personal data, to minimise risk of disclosure.
- ⇒ The quantitative measures will not be formally validated because of time constraints.
- ⇒ Reliable denominator data are not available for the target group, so we will not be able to judge what proportion of the target population we reach.
- ⇒ The intervention is only available in English and, therefore, data collection will be carried out only in English, which means that our results will not be generalisable to those who are not confident and competent communicating in English.

from ethnically diverse communities are needed.^{6–9} Black and South Asian communities have been shown to be less likely to engage in COVID-19 testing and vaccination programmes than White communities.^{10–14} The evidence of effectiveness of interventions to promote vaccine uptake in adults does not currently provide clear guidance in this context.¹⁵

A culturally appropriate intervention aiming to promote health protective

behaviours has been coproduced with people from Black and South Asian (Indian, Bangladeshi and Pakistani) communities (report about development in preparation), based on qualitative research carried out in 2020.¹⁶ The intervention development was based on our team's previous work to promote uptake of viral hepatitis testing.⁸ We developed the film script and other content in collaboration with a wide range of Black church and community organisations, the Muslim Council of Britain, the British Sikh Association and Hindu organisations, among others as well as a number of primary care professionals and a professional film maker.

The intervention has two variations, one for people who define themselves as from the Black community and one for people who define themselves as from the South Asian community. The justification for this was the shared cultural identity within these groups and the different cultural experience between these two groups; however, we do recognise that this is a simplification: within these groups, there is a wide range of subgroup identities and lived experiences, and intersectionality with other characteristics.^{17 18}

Each intervention variation comprises a 3.5 min YouTube film and an electronic leaflet (e-leaflet) that can be viewed on a mobile device or computer.¹⁹ Available in English only, the intervention promotes COVID-specific health protective behaviours including handwashing, wearing masks, social distancing, room ventilation, testing and vaccination, in a culturally appropriate manner. It is intended to be widely distributed through general practices, national health bodies and social media.

The aims of the study are to (1) understand how people from the Black and South Asian communities understand and interpret COVID-19 health messages in the intervention, (2) evaluate its effect on intentions to carry out COVID-19 protective behaviours and (3) capture health professionals' experiences of offering the intervention.

METHODS AND ANALYSIS

This is a mixed methods study with three workstreams. Workstream 1 is a qualitative focus group study aiming to understand whether people from Black and South Asian communities interpret and understand the intervention's messages as intended. Workstream 2 is a before-and-after questionnaire study examining the extent to which the intervention changes intentions and confidence to carry out COVID-19 protective behaviours. Workstream 3 is a qualitative interview study with participants in workstream 2, exploring their views of COVID-19 protective behaviours, and health professionals involved in implementation, to understand their experiences of offering it.

All data will be collected in English, due to time constraints, which will not allow for translation and interpreters. We will recognise this as a limitation of the study.

Recruitment of participating general practices will start in July 2021 and data collection will be carried out between 1 September 2021 and 31 January 2022.

Workstream 1: focus groups

Participants and recruitment

The participants will be people aged 18+ who identify as being from Black or South Asian communities and registered with participating general practices, which will be recruited through the National Institute of Health and Care Research Local Clinical Research Networks. For this workstream, potential participants will be approached by healthcare professionals during consultations. The practice will send a participant information sheet (online supplemental file 1) and consent form (online supplemental file 2) to those who show interest in participating. The information sent by the practice will ask them to contact the researchers directly if they are willing to participate. We will attempt to gain some heterogeneity in the sample by purposive sampling by age group and gender. Participants will be offered a £25 voucher for taking part in this part of the study.

Data collection

We will carry out two virtual focus groups, each of 5–7 people, one with people from the Black community and one with people from the South Asian community. Before the focus groups, we will ask participants to provide informed verbal consent. At this point, all participants will be informed that communication between participants must be respectful and that if their comments are perceived to be disrespectful, they will be moved to a breakout room with a research assistant.

Each focus group will be hosted by an experienced qualitative researcher and two research assistants, who will ensure that all participants have the opportunity to express their views. One research assistant will be responsible for managing the technology and the other for monitoring group dynamics, intervening where necessary to manage any issues that may arise, for example, conflict, rudeness or some participants not being heard. Participants in each focus group will watch the film and then the qualitative researcher will prompt discussion using a Topic Guide (online supplemental file 3). We will assess comprehension and emotional responses by:

- ▶ Checking if respondents are interpreting key messages in the way they are intended.
- ▶ Determining whether any elements are difficult to understand or offensive.
- ▶ Checking whether they found the messages persuasive.

The focus groups will be video recorded, with consent. If participants do not agree to be recorded, they will be excluded from the focus group (they may be offered an interview within workstream 3). The researcher will ask the participants to provide information on age group, gender and more detail of ethnic group.

Data management and analysis

The recordings will be transcribed verbatim. Recordings and transcriptions from the focus groups will have personal information replaced by an identification number and will be stored on the University of Surrey

server. The data will be analysed using Framework Analysis.²⁰ We will initially develop an analytical coding framework based on previous knowledge of the topic and initial impressions from the data, which will be refined iteratively after rereading each transcript, adding new codes if needed. This will lead to the identification, definition and interpretation of themes. Subsequently, the new framework will be reapplied to the coded data to refine the interpretation further. Two members of the research team will review and compare codes and theme findings to ensure congruence.

Workstream 2: before-and-after questionnaire study

Participants and recruitment

The participants will be people aged 18+ who identify as being from Black or South Asian communities and registered with participating general practices. Participants will be invited to take part by their general practices either during primary care consultations or by text message:

From primary care consultations

During consultations for mild illness or chronic disease management, primary care health professionals at the participating practices (recruited through the National Institute for Health Research Clinical Research Network) will approach people who are shown on their primary care record as identifying as from the Black or South Asian community and aged 18+ to take part in the study. The health professional will provide potential participants with the information sheet (online supplemental file 4), which explains the study and advises that the questionnaire will only take a few minutes to complete. They will arrange for a text to be sent to the potential participant by the secure AccuRx system (<https://www.accurx.com/>), which complies with national standards and legislation in relation to data security and is used in many general practices for one-way text correspondence. The wording of the text will be:

Dear [Name], Thank you for discussing the research study about preventing COVID-19 among people from Black and Asian groups with us when you came to the practice. I attach further information about the study. If you are interested in taking part, here is a link to a form where you can confirm that you agree to do so [link]. From (name of practice)

The link will lead the potential participant to the online consent form (online supplemental file 5) on an electronic survey platform (Qualtrics Software V.October 2021, Qualtrics 2020, Provo, Utah. <https://www.qualtrics.com>).

By text message

Participating general practices (recruited through the National Institute for Health Research Local Clinical Research Networks) will identify people on their registered patient lists who are recorded as identifying as from Black or South Asian communities and aged 18+. The

practices will approach potential participants through the AccuRx system, a novel approach. The wording of the text will be:

Dear [Name],[Name of practice] is taking part in a study to test a film and leaflet about preventing COVID-19 among people from Black and Asian groups. We are doing this with a research team based at the Royal Surrey Foundation Trust. We would like to invite you to take part. Here is a link to some further information about what the study involves. From [name of practice]

The link will direct the potential participant to the participant information sheet (online supplemental file 4, as for recruitment via primary care consultations) and subsequently to the consent form (online supplemental file 5, as for recruitment via primary care consultations) both provided on the electronic survey platform. [Figure 1](#) illustrates the recruitment process.

Sample size

Because this is a novel intervention in a novel context, and it is crucial to roll out the intervention as soon as possible, during the pandemic, we have not had time to generate sufficient data in advance of this study to inform what the size of effect on the primary outcome might be, nor indeed which outcome would be most appropriate as the primary outcome. We, therefore, will aim to maximise the sample size, recruiting as many participants as possible, within the time constraints, so as to maximise the chances of high precision around our estimates of the proportion who changed their confidence in the vaccination programme's benefit and the proportion who changed their intention to be vaccinated. We will also be able to generate potential effect size of a meaningful primary outcome for a future study, for example, the proportions intending to be vaccinated before and after the intervention.

We will recruit at least seven large practices (with a total population approximately 40000 registered patients) targeting those with a relatively high proportion of people from the Black or South Asian communities. We do not know which practices will respond to our invitation and we recognise that recording of ethnicity in general practice records is highly incomplete,²¹ so it is not possible to know how many people are eligible in each general practices in advance of data collection. We think it is reasonable to aim to recruit 600–800 participants who have not yet been vaccinated providing data. However, we recognise that response rates are likely to be lower in this study of healthy people who may be less interested in the topic than in studies recruiting people with a specific health condition.^{22–24}

Data collection instruments and collection

Once the participant consents, he or she will be linked automatically to the Pre-Intervention Questionnaire on the electronic survey platform (online supplemental file

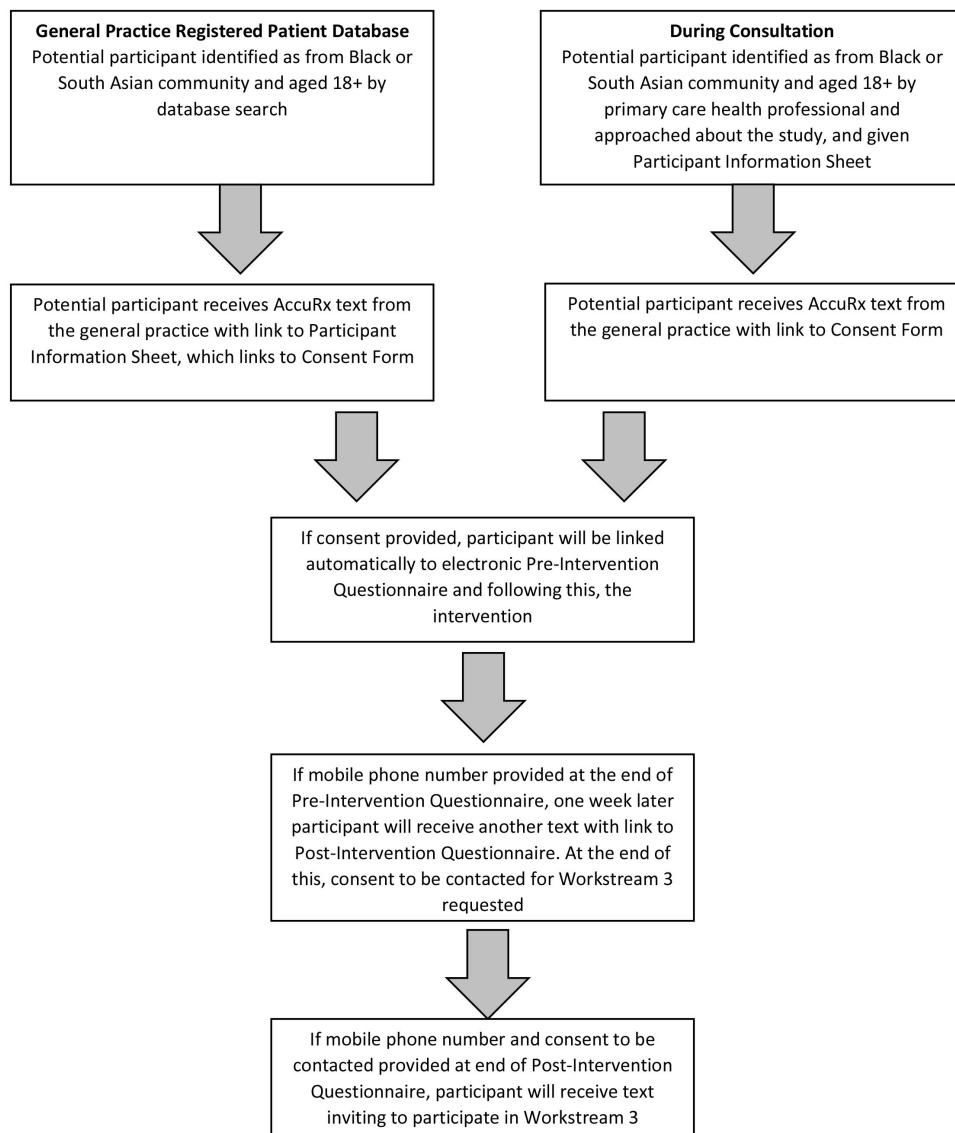


Figure 1 Workstreams 2 and 3 recruitment flowchart.

6). At the end of the Pre-Intervention Questionnaire, the participant will receive a link to the 3.5 min YouTube film and e-leaflet. Also, at the end of the Pre-Intervention Questionnaire, the participant will be given the option to provide their mobile phone number, so that the research team may send them a questionnaire by text a week later. If the participant provides their mobile phone number, the research team will send the participant a text with a link to the electronic Post-intervention Questionnaire (online supplemental file 7) 1 week later. The wording of the text will be:

Dear [Name], Thank you for completing the questionnaire about preventing COVID-19 among people from Black and Asian communities last week. If you follow this link you will find a further short questionnaire about COVID-19 prevention and what you thought about the film and the e-leaflet [link]. From Professor Ala and the research team.

The Pre and Post-Intervention Questionnaires will be developed rapidly for the purposes of this study responsive to an urgent public health need and will not be validated formally. Questionnaire development will be based first on qualitative evidence from our previous study¹⁶ and second on the idea of measuring vaccine hesitancy, not simply refusal, because refusal is an extreme manifestation of hesitancy.²⁵ We are also interested in vaccine confidence, which can be conceptualised as the inverse of hesitancy.²⁶ Common reasons for vaccine hesitancy have been conceptualised as ‘confidence, complacency and convenience’;²⁷ so we will devise questions around these three concepts, adding in extra questions in relation to concerns about safety and efficacy in the vaccine because these are prominent themes in previous research.²⁸

Data management and analysis

The research team will upload the data sets onto the secure University server, at which time the electronic

survey platform data sets will be destroyed. Responses to Pre and Post-Intervention Questionnaires will be linked using mobile phone number as the unique identifier. The participants will then be assigned a non-identifiable identification number and mobile phone numbers will be stripped from the data set.

We will identify the number of people completing Pre and Post-intervention Questionnaires. We will calculate response rates for both questionnaires based on the number of people the practice patient lists identified as being from the Black or South Asian communities. We recognise that we may receive more than one response from a single individual because we are using two methods of recruitment. To address this, for the Pre and Post-intervention Questionnaires separately, we will examine whether there are duplicate mobile phone numbers, where these have been provided. Otherwise, we will not be able to identify duplicates because we will have no identifiable data. We will recognise this as a limitation of the study.

We will calculate the proportions of participants who give each response to each questionnaire and report these as percentages. We will calculate the proportion who are vaccine hesitant (reporting refusing vaccination, not intending to take it up or not sure about taking up vaccination if it was offered to them). Using data from participants who complete both questionnaires, we will calculate the proportions who changed their confidence in the vaccination programme's benefit, who changed their reported COVID-19 protective behaviours and changed their vaccine hesitancy.

Workstream 3: qualitative interview study

Participants and recruitment

People who took part in workstream 2

We will identify participants from those who agree that the research team may contact them by text at the end of the Post-Intervention Questionnaire in workstream 2 (see [figure 1](#)). We will select people from this group aiming to recruit 20 people (10=Black ethnicity; 10=South Asian ethnicity). They will be purposively sampled according to whether they indicate they have changed their intention to be vaccinated against COVID-19 or not after watching the YouTube film (see [table 1](#)). The rationale for including those who do and do not change their intention is to explore the role the film played, if any, in changing their mind. In addition, we will explore their experience of the process by which they are provided with the link to the film and whether this could be changed or improved. We

will stratify by age group and gender if we have sufficient response to recruitment to workstream 3.

After initial agreement by mobile phone, potential participants will be sent a copy of the participant information sheet (online supplemental file 8). Participants will be offered a £25 voucher for taking part in this part of the study. They will be given at least 48 hours after which time the researcher will make contact again to find out whether they are willing to participate.

Health professionals

We will interview 10 health professionals from the participating general practices, the aim being to explore the process of inviting people to receive the intervention, for example, practical difficulties with identifying and asking patients to take part, negative or positive feedback from participants, reasons for not inviting potential participants. Potential participants will be sent a copy of the participant information sheet (online supplemental file 8). They will be given a minimum of 48 hours before the researcher makes contact again to ascertain their decision regarding participation.

Data collection instruments and collection

People who took part in workstream 2

Prior to the interview, the researcher will ask participants to provide video-recorded informed consent (online supplemental file 9). Interviews will be conducted by an experienced qualitative researcher virtually and will last 15–30 min. The interview will be guided by a topic guide (online supplemental file 10) and, with permission, video recorded.

Health professionals

Prior to the interview, the researcher will ask participants to provide audio-recorded informed consent (online supplemental file 9). Interviews will be conducted by an experienced qualitative researcher via telephone. The interviews will last 15–30 min and will be guided by a topic guide (online supplemental file 11).

Data management and analysis

Recordings will be transcribed verbatim. Recordings and transcriptions will be stored on the University of Surrey secure server. Data will be analysed thematically using Framework Analysis as described for workstream 1.²⁰ Data from patient and professional interviews will be compared to determine whether there are themes that are common to both groups.

Patient and public involvement

We have consulted widely to develop this protocol with Black church and community organisations, Muslim Council of Britain, British Sikh Association, Hindu, Buddhist and Christian organisations, among others. We have established a national steering committee with representatives of these organisations to ensure that their perspectives are considered as being of equal merit to the 'expert' opinion. Representatives of the community

Table 1 Workstream 3 purposive sampling frame

	Black	South Asian	Total
Intend to be vaccinated (or been vaccinated)	5	5	10
Do not intend to be vaccinated	5	5	10
Total	10	10	20



organisations and the national steering group were sent drafts of the protocol for comment during the few weeks of development. We collected their opinions through written comments and telephone conversations, as there was insufficient time to convene meetings.

ETHICS AND DISSEMINATION

Ethics approval and participant consent

The study received Health Research Authority approval in June 2021 (Research Ethics Committee Reference 21/LO/0452).

All participants who are not participating in their role as health professional will be first approached by a health professional, who will provide an information sheet requesting consent to be contacted by the research team. Consent will be recorded using an audio or videorecording or on the electronic survey platform.

Participants may withdraw their consent from the study at any stage. If a participant states that they no longer wish to take part or contribute to the study, they will be withdrawn. Data collected up to the point of withdrawal will be included in the study analysis, unless the participant wishes us to destroy the data. If a participant decides to withdraw from the study, their healthcare or legal rights will not be affected in any way.

Data security and confidentiality

No data will be shared outside of the direct care team at any point until after the potential participant's consent. Individual identifiable data will only be accessible by the researchers after consent. Once the data are collected (with consent), these will be uploaded to the University of Surrey server in files that are encrypted, password-protected and accessible only to named members of the research team. The University server is maintained in accordance with the Government Cyber Security Essentials guidelines. Any personal data will be kept separate to the recordings and transcripts, also in an encrypted and password-protected file on the University of Surrey server. All data will be destroyed after 3 years.

The electronic survey platform used provides a high level of data security complying with the common law duty of confidentiality and General Data Protection Regulation. None of the electronic survey instruments will collect identifiable data, except mobile phone number, if the participant provides this. The research team will not have access to name, email, date of birth, address, IP address, location or any other identifiable data. The research team will only use mobile phone number for the purposes set out in this protocol. When building the electronic questionnaire, we will disable location or IP address data collection. The questionnaires will ask some sensitive data on ethnicity, religion and place of birth and whether or not they have had COVID-19 vaccination, but these data cannot be linked to the identity of the person in the data set.

Only tested external companies that have been previously used by the University will be sought for transcription and will be required to sign a confidentiality agreement. Files will be labelled with study identification number.

The study will not generate any paper data and there are, therefore, no risks to confidentiality based on storage of these. Dissemination reports will include no identifiable data about participants. Individual-level data will be destroyed after 3 years.

Dissemination

We are mindful of the need to disseminate information rapidly and accurately collected in a timely manner to support the behavioural change needed to control the pandemic. The research team will ensure seamless communication and engagement with policymakers, including NHS England and Public Health England and its successors. We will feedback to the participants via the steering groups and national policymakers. We will provide a summary of the findings written in plain English for all participants participating in the study if they request this. We plan to publish and disseminate our findings via peer-reviewed general medical, public health, infectious diseases and healthcare journals and relevant scientific and policy conferences.

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