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COVER-ME: developing and evaluating community-based interventions to promote vaccine uptake for COVID-19 and influenza in East London minority ethnicity (ME) and underserved individuals - protocol for a pilot randomised controlled trial

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ABSTRACT

Introduction Under-vaccination among underserved groups remains low due to existing disparities. This is particularly the case with postpandemic COVID-19 vaccinations and other vaccine-preventable diseases, including measles, mumps, rubella or influenza. Therefore, we aim to (1) determine the feasibility and practicality of implementing a patient engagement tool (PET) and gain vital insights to plan a subsequent definitive randomised controlled trial (RCT) to evaluate the effectiveness of this tool for increasing uptake of COVID-19 and influenza vaccinations and (2) define the appropriate level of support needed for healthcare providers at site-level to ensure successful implementation of the PET and to identify supporting activities needed to implement interventions for COVID-19 and influenza vaccinations.

Methods and analysis This is a randomised controlled feasibility study evaluating a co-designed PET, involving randomisation at individual and cluster levels. For individual randomisation, patients will be individually randomised 1:1 to receive the intervention (PET) or routine care; whereas for cluster randomisation, six GP (General Practitioner) practices will be randomised 1:1 and divided into two tranches at two separate time points. Both groups will receive training and software activation. Data will be analysed using statistical software R (V.4.0 or greater) or STATA (V.17 or greater). Baseline characteristics will be summarised and presented in groups based on an intention-to-treat basis with categorical data, including demographics, socioeconomic variables, comorbidities and vaccination status.

Ethics and dissemination Ethical approval was granted by the Westminster Ethics Committee (ref: 316860). Our dissemination strategy targets three audiences: (1) policy makers, public and health service managers, and clinicians responsible for delivering vaccines and infection prevention services; (2) patients and public from underserved population groups and (3) academics.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The sample size may be affected by opt-in consent, as patients declining to take part could reduce the sample size, which could affect the power calculation.
⇒ The methods used will assist in the co-design of a patient engagement tool, which may mitigate low vaccine coverage among underserved and minoritised communities in East London and similar groups across the UK.
⇒ The study materials have been adapted to collect data and useful findings that may be transferrable and will guide current national vaccination efforts to address under-vaccination overall and in specific population groups.

Trial registration number ClinicalTrials.gov (NCT05866237).

BACKGROUND

Vaccinations can prevent up to 1.5 million deaths per year;[1] however, there are considerable disparities in uptake among some groups. These include migrants or socioeconomically deprived individuals. Under-vaccination among these populations remains a problem in deprived regions of the UK, where there are barriers to implementing routine immunisation and vaccinations.[2] For example, during the COVID-19 vaccination roll-out, vaccine uptake was considerably lower among black and South Asian communities in comparison with the white British population and was also lower among lower socioeconomic

groups compared with the general population in the UK. Specifically, vaccine uptake has been low among black, Bangladeshi and Pakistani communities, who form a large proportion of the East London population.[2] Under-vaccination is also common for other vaccine-preventable diseases such as measles, mumps, rubella or influenza.[1]

For such illnesses, including COVID-19, under-vaccinated population groups have a higher risk of infection and disease, and their under-vaccination can result in a higher burden of morbidity and mortality. For influenza, measles and polio, the picture is similar. This means that while the COVID-19 pandemic has ended and rates are decreasing, our research is transferable and will guide current national vaccination efforts to address under-vaccination overall and in specific population groups.

To explore vaccination uptake among marginalised groups, we conducted a qualitative study involving semi-structured interviews, focus group discussions and workshops with different community members and healthcare professionals within East London. This enabled us to collate social and cultural concepts, perceptions, experiences and views on COVID-19 and other vaccines across individuals of migrant and/or minority ethnicity (ME) backgrounds. A systematic review was conducted to gain better insight into how different underserved populations vary in vaccination uptake behaviours, and to what extent and how certain determinants influence vaccination uptake in such groups. Factors identified as being associated with a low uptake of vaccines included mistrust in vaccine development, information (too much and/or too little), health and religious beliefs, travel abroad and frontline work situations, where working in the healthcare services or the public sector vaccine uptake was mandatory. Both these studies are currently unpublished but have been drafted and finalised by the authors to be published soon.

The qualitative study and systematic review informed the co-design of a feasible patient engagement tool (PET), which is a digital platform available via a mobile phone consisting of educational components such as informative text messages regarding the benefits of vaccine uptake, as well as reminders adapted to the needs and preferences of the target group to promote vaccination uptake.

For our detailed co-design, we worked collaboratively with Appt Health,[3] a service used by healthcare commissioners and GP practices to engage their patients and increase the uptake of preventive healthcare through integrating with GP patient records to deliver enhanced patient communication and booking workflows so that preventive healthcare is delivered to everyone. There are no competing interests.

We will then carry out a small pilot randomised controlled trial (RCT) on the PET that has been developed for COVID-19 and influenza vaccination uptake for underserved at-risk populations, including migrants and individuals with ME backgrounds in East London. A Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist is available in online supplemental appendix 1. The success of the trial is to be demonstrated through various outcomes, one of which is feasibility. Other outcomes include acceptability to patients and healthcare workers, measures of effect to aid the design and sample size calculations of a larger trial in the future.

Therefore, through this pilot trial, we aim to determine the feasibility and practicality of implementing the PET and gain vital insights to plan a subsequent definitive RCT to evaluate the effectiveness of this tool for increasing the uptake of COVID-19 and influenza vaccinations. We will also estimate COVID-19 and/or influenza vaccination uptake and the effect of the intervention, as well as measure vaccine uptake variation by population group and other parameters, which help us design the definitive RCT. In addition, we also aim to define the appropriate level of support needed for healthcare providers at the site level to ensure successful implementation of the PET and to identify supporting activities required to implement interventions for COVID-19 and influenza vaccinations.

METHODS AND ANALYSIS

Overall design

This is a randomised controlled pilot study evaluating and assessing the feasibility of a co-designed PET. The PET was co-designed in the qualitative work packages with members of the community as well as healthcare professionals (ethical approval: REF QMERC22.266) that precedes this pilot trial. This study will involve individual and cluster level randomisation, as described below. The trial start date is 1 January 2024, and it is expected to finish on 30 January 2025.

Individual randomisation

Randomisation will take place at the Appt Health level on behalf of each practice provider. People will be individually randomised 1:1 to receive the intervention (PET) or routine care. Appt Health is a nominated and appointed provider for the NHS and has data processing agreements in place with the East London GP practices. Appt Health, therefore, acts on behalf of patient-facing providers, and this process has been used for numerous other health promotion activities, allowing clinicians to identify patients using our predefined criteria in this study.

Individual randomisation will be stratified by GP, using a random block allocation list implemented into the software used for the study.

Cluster randomisation

Six GP practices will be randomised 1:1 and divided into two tranches at two separate time points. This will include three GPs being randomised first, and then later the other three practices. The start dates will be at least 1 month apart. This will enable additional comparison at the cluster (practice level). The first group of GPs will receive training and software activation, and patients will

be randomised to intervention or routine care workflows during the first study period. For the second group of GPs, this will occur in the second period after randomisation, 1 month later.

During the first period, data will be used in all six GP practices for a cluster comparison analysis. The individual-randomisation comparison will use data from all GPs, with the second group contributing data from the second period only. This individual-randomised and cluster-randomised design will enable us to assess the feasibility of a study with both (or either) individual-randomised and cluster-randomised comparisons.

Surveys

Individuals' views on acceptability and user-friendliness will be determined through a questionnaire, which will be available through a link that will be sent out via a text message. The questionnaire will also be available in paper format and in local languages.

A healthcare provider questionnaire will also be distributed to evaluate the feasibility and acceptability of the PET among healthcare providers online supplemental file 3. These will be distributed by the research team in paper format, and completed by staff at each GP surgery.

Selection criteria and recruitment

Inclusion criteria are listed below. We will operationalise eligibility for study participation based on age, gender, ethnicity and postcode and whether they are able to receive text messages based on coding in the practice patient information system (Egton Medical Information Systems (EMIS), which provides the patient's full name and address).

The care team will not need to approach or identify patients or access patient data. Appt Health will assist with identifying patients, as they only have access to those who did not opt out either for data sharing or receiving texts. Our initial text will introduce an additional opt-out for our study. A text message (short messaging service) flow has been attached as online supplemental material to demonstrate the consent process.

Only individuals who consented to receive routine care messages from their GP surgery are enrolled, and they will receive a message with an option to decline study participation.

Inclusion criteria

- Patient registered at the study site (GP practice).
- Adult (aged 18 years or older) at the time of randomisation.
- Eligible for COVID-19 vaccination and/or influenza vaccine (ie, not received either a first, second or booster vaccination).

AND

From an underserved population group, defined as:

1. Non-white ethnicity.

OR

2. Non-white and white ethnicity residing in a postcode in the bottom 20% of the index of multiple deprivation.

OR

3. Those receiving low income based on the postcode of residence.

The English indices of deprivation (2019) will be used to allow us to access data on postcodes to determine areas of deprivation and low income from 2019 to 2024 in East London.

Exclusion criteria

- Individuals unable or unwilling to consent (including those who do not consent to text messaging and those who opt out from taking part in research studies).

Gaining patient consent

Eligible participants will have consented to receive routine care messages from their GP surgery and have the option to decline participation. EMIS codes will be used to determine eligibility for study participation based on age, gender, ethnicity and postcode.

Participants will receive a message containing opt-out consent. The process of consent has been split up into three parts as below:

1. Consent to receive messages from the PET—those with an EMIS code have consented to receive messages from the GP and PET.
2. Consent to use data (anonymously)—participants will be sent a text message to opt out if they refuse to have data shared.
3. Consent for survey—a message for opt-in consent will be sent. The first part of the survey covers consent and data-sharing procedures to which participants will agree or disagree.

Regarding data sharing, all data will be completely anonymised for analysis (including stripping PID (patient identifiable data), such as NHS (National Health Service) number, address, names, DOB (Date of Birth), etc).

Appt Health has a Data Processing Agreement in place with every practice they work with, which covers the legal basis for contacting patients. This data sharing is a routine entity, which has been used for multiple health promotion and preventative care projects and is fully compliant with GDPR (General Data Protection Regulation) and GCP (Good Clinical Practice).

Outcome measures

Primary outcome

The primary outcome is to increase vaccination uptake through using and engaging with the PET in patients individually randomised from the six GP practices. This will be measured as the number (per cent) of relevant Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) codes in eligible patients. Uptake will be measured from the time that the eligible group in each practice is identified (and randomised) until 6 months follow-up (>180 days since randomisation).

Secondary outcome

1. Vaccination uptake in patients after 3 and 9 months of follow-up (>90 and >270 days). This will be measured as the number (per cent) of relevant SNOMED codes in eligible patients identified during the period.
2. Mean vaccination rate after 3, 6 and 9 months of follow-up. This will be measured as the number of patients vaccinated divided by the follow-up time. Time is defined as the period from randomisation until the earliest of vaccination, leaving the GP, withdrawal of consent for use of data or death.
3. Acceptability of the intervention
   To patients:
   1. The proportion of patients randomised to the intervention who engage with the PET and/or linked patient resources, as determined by user statistics logged on the software.
      1. The SMS messaging tool (number of SMS sent).
      2. Number (per cent) of patients who view the linked patient awareness resources.
      3. Usage of the patient work list tool, which consists of specific targets, for example, vaccine status and patient lists from the specified GPs included in the study.
   2. Patients' responses to the questionnaire about acceptability and user-friendliness.
      To staff:
      1. Number and proportion of eligible patients randomised to the intervention processed using the patient work list tool.
      2. Healthcare providers' responses to the questionnaire to evaluate the feasibility and acceptability of the PET among healthcare workers.
      3. The feasibility of study-related work processes using process observations.
4. Feasibility of the intervention and randomisation:
   1. The number and proportion of eligible patients randomised.
   2. Support required for healthcare providers at the site level for implementation (using process observations to understand and analyse the environment and workflows).
   3. Clinical capacity: number of slots available for vaccination bookings for each GP practice and each day, by appointment time.
5. Feasibility of the study design for a subsequent trial:
   1. Number and proportion of patients with all inclusion/exclusion data available on the electronic health records.
   2. Number and proportion of patients eligible for the intervention.
   3. Number and proportion of patients randomised who are sent information via text messages from the intervention (letter/SMS).
   4. Number and proportion of patients eligible by vaccination status (none, first, second, with booster or without booster).
   5. Number and proportion of patients who opt out of their data being used or withdraw from the study.
   6. Number and proportion of patients who consent to further questionnaires.
   7. Number and proportion of patients who are booked for a vaccination appointment.
   8. Number and proportion of patients who are categorised as a 'failed encounter' (not booked for an appointment or no more action taken).

Sample size

In each GP practice, with a size of 10 000 patients, we estimate that at least 40% meet the eligibility criteria based on their ethnicity or deprivation quintile. If 90% of these are already vaccinated, then at least 400 patients will be eligible for randomisation at each GP; therefore, a total of 2400 eligible patients from six GP practices will be randomised 1:1. If 10% of these patients would get vaccinated over 6 months without intervention, then our study would have approximately 90% power to show a 40% increase in vaccination rate (from 10% to 14.4%) when testing between the two groups using a z-test at the 5% level. While we expect the loss to follow-up to be small, we will report the number of participants who withdraw from the study after randomisation.

Analysis

All analysis will be undertaken using the statistical software R (V.4.0 or greater) or STATA (V.17 or greater). We will summarise baseline characteristics, including demographics, socioeconomic variables, comorbidities and vaccination status.

Characteristics will be presented in groups based on an intention-to-treat (ITT) basis with categorical data as number and percentage and continuous data as mean/SD or median/IQR.

In the primary analysis, we will present the uptake of COVID-19 and influenza vaccinations in each arm on an ITT basis. We will assess the individual-level randomised component. This analysis will include all patients who are eligible for the intervention and who were randomised to receive one of the two workflows on an individual basis (standard of care or the PET). All patients from the first group of GPs (n=3) in both study periods and only patients from the second group (n=3) who are eligible in the second period (ie, any eligible patient from the first period in the second group of GPs who was vaccinated in the first period would not be part of the analysis sample) will be included. The uptake (from the time of randomisation) will be estimated overall. An uptake of 95% CIs will be obtained based on binomial assumption, as well as from a mixed-effects model that allows for hierarchical (random effects) variation by GP and booster groups. Logistic regression with the adjustment described below will be used to estimate the marginal OR of the PET compared with the standard of care, and a profile-likelihood ratio CI for the OR will be reported. Adjustment of prior COVID-19 and influenza vaccination status,

GP practice, age and sex will be used for the logistic regression model.

Secondary endpoints will be reported as point estimates with 95% CIs as appropriate. Summary statistics for each outcome by arm will be presented on an ITT basis. Categorical data will be shown with numbers and percentages. Continuous data will be shown as median and IQR or mean and SD if following approximal normal distribution.

Analysis of the primary and secondary endpoints and potential heterogeneity in uptake by prespecified subgroups will be undertaken. This includes GP practice, deprivation, age group, sex and ethnicity.

We will explore the cluster-randomised component of this study. This analysis of uptake will take clustering in the design into account by using generalised linear models with normal random intercepts, and the model will also be used to obtain an estimate of the intraclass correlation coefficient. CIs will be based on methods that are most suitable when the number of clusters is not large. We will also explore whether a per-protocol analysis would be possible by determining the feasibility of defining compliance/contamination from individual randomised allocation using process data.

Survey analyses

Surveys will be analysed typically using descriptive and inferential statistics. Descriptive statistics will be used to scrutinise sociodemographic data, collated during data collection. Independent-sample t-test and one-way analysis of variance will analyse and examine the independent patient outcomes, HCP (Health Care Practitioner) satisfaction levels, engagement with the PET and vaccine behaviour change across the multiple variables (eg, age, gender, comorbidities, ethnicity, postcode).

Missing data

Most of the data will be complete by design, and data capture will be maximised where feasible. If the level of missing data is likely to affect reported point estimates and estimates of effect size, then multiple imputation will be used for analyses when appropriate, as well as complete-case analysis.

Assessment and management of risk

Although this research is unlikely to inflict any risk or harm, the participant may not want to share or disclose their vaccination status. It is stressed to only share information a participant feels comfortable sharing. However, if participants feel distressed or do not wish to respond to certain questions asked during surveys, they may take a break and return when they are ready. The research team can signpost them to their local healthcare provider or to easily accessible services, such as mental health charity services across various sites in the UK providing counselling for psychological support. Participants would be directed to access additional support from their care provider for referral to other agencies if issues are raised.

All participants are eligible to withdraw at any point during the study if they wish to, without affecting ongoing healthcare. They will also be given the opportunity to have their data fully withdrawn.

Annual safety reporting

The chief investigator (CI) DZ will send an Annual Progress Report to the REC (Research Ethics Committee) and the sponsor using the Health Research Authority (HRA) template on the anniversary of the REC's 'favourable opinion'.

Data management

Electronic case report forms will be used. Routine data and vaccination status will be extracted from the patient's electronic record. This database will be stored in a secure folder using a bespoke database from CASTOR. Access will be limited to data administrators and investigators. A full audit trail will be generated for amendments to the database.

Record retention and archiving

All records are the responsibility of the CI and must be kept in secure conditions. When the trial is complete, it is a requirement of the Research Governance Framework and Trust Policy that the records be kept for a further 25 years. For trials involving Barts Health Trust patients, undertaken by Trust staff and sponsored by Barts Health Trust or QMUL (Queen Mary University London), the approved repository for long-term storage of local records is the Trust Modern Records Centre (Barts Health NHS Trust, London, UK).

Monitoring and auditing

On-site monitoring will be performed as per the study monitoring plan. Monitoring will include source data verification to ensure data integrity as well as compliance with the protocol and GCP. The sponsor or delegate retains the right to audit any study, study site or central facility. Any part of the study may be audited by the funders, where applicable.

Trial committees

The day-to-day management of the study will be carried out by a Study Management Group (SMG), supported by a Patient and Public Involvement (PPI) advisory group and a data monitoring committee. The SMG with overall responsibility for the study will be chaired by the main applicant (DZ), and membership will include co-applicants, key collaborators and a PPI representative. The SMG will meet fortnightly, hold responsibility for the overall management and ensure that all project deliverables and stages are completed within time and budget. We will identify a PPI advisory group through collaborations. The SMG will also liaise regularly with key external stakeholders, including Public Health England (vaccination and inclusion departments), local health authorities, GP networks and local authorities, as well as with groups

who research related topics to exchange information on national and regional vaccination efforts.

Patient and public involvement

Our team is well connected to local health services and community organisations with excellent links to NHS England and Public Health England. For the proposed research, we will closely follow National Institute for Health and Care Research (previously INVOLVE) guidance to ensure the research is done 'with' rather than 'to' local communities. To coordinate this, we have already reached out to local community organisations and will establish a PPI advisory group that will directly report to the SMG. We will make use of our existing networks to establish the PPI advisory group, which will help coordinate PPI involvement at all stages of the study.

We will work closely with patients and local community groups at all stages of the project, particularly with representatives of key vulnerable groups in East London. The PPI advisory group will advise us on the development of the study protocol, the approach to participants and developing the ethics application and supporting material such as information sheets and posters. It will also be advising us on the conduct of interviews and focus groups, which will include guidance on the content of questions for the interview guide. Individuals from our PPI group will be asked to 'walk through' the study before recruitment starts to highlight potential questions that participants may have. PPI involvement will be central to any input into further development of the study and will be involved at every step. We are also planning to support training members of local underserved communities as community researchers in collaboration with Social Action for Health to particularly support the qualitative component that has already taken place (ethical approval: REF QMERC22.266). We are also keen to develop local research capacity in the community, which we hope will stay as a legacy of this project.

ETHICS AND DISSEMINATION

Ethical approval was granted by the Westminster Ethics Committee, National Research Ethics Service and HRA (REC reference: 23/LO/0587; application ref: 316860).

A meeting will be held after the end of the trial to allow discussion of the main results among the collaborators prior to publication. The success of the trial depends entirely on the wholehearted collaboration of many patients, carers and healthcare professionals. For this reason, chief credit for the main results will be given not to the committees or central organisers but to all those who have collaborated in the trial. A writing committee will be convened to produce publications on behalf of the Trial Steering Committee and the SMG. They will not be permitted to publish data obtained from participants in the trial that use study outcome measures without discussion with the CI and/or the Trial Steering Committee. Only anonymised data will be used for dissemination of research findings.

Our dissemination strategy targets three audiences: (1) policymakers, public and health service managers and clinicians responsible for delivering vaccines and infection prevention services; (2) patients and the public from underserved population groups and (3) academics.

DISCUSSION

This protocol outlines the processes in the co-design, development and piloting of an effective, acceptable and feasible PET for COVID-19 and influenza vaccination uptake for underserved at-risk populations in East London.

Vaccination uptake is a complex and multifaceted process. Our preceding qualitative research showed that reasons for poor uptake range from concerns about the vaccine itself (eg, adverse effects) to practical and logistical health access barrier issues to issues around the availability and presentation of information. Multiple interacting factors influencing vaccine uptake have also been observed in a recent systematic review of vaccination uptake among migrants.[2] Findings have demonstrated that people from marginalised or minoritised groups may be more inclined to trust familiar and accessible sources, including their GP, rather than more distant parts of the health system, like the Department of Health and Social Care. Therefore, there is a clear need to ensure greater engagement of local primary care providers and suitable interventions to promote vaccination uptake.

Based on previous research[3 4] and lessons from our own qualitative data, we co-designed a patient engagement intervention to address low vaccine uptake in underserved population groups. This pilot RCT is designed to assess the feasibility and effectiveness of a PET in an underserved population group. It is a preparatory study for a larger RCT and explores multiple issues around feasibility, acceptability and statistical uncertainty. We expect that our initial findings will inform a larger RCT to explore under-vaccination at a much larger scale among other populations across the UK.

Our study has some limitations, including the small sample size, which may also be affected by opt-in consent, as patients declining to take part could reduce the sample size, which could affect the power calculation. A smaller sample may also not allow us to explore certain variables or conduct subgroup analyses. In addition, the cluster design may have limitations in exploring the individual effects and feasibility of the PET. However, we will explore this further during individual and cluster randomisations, and we will analyse individual data in individual randomisation.

Our study is the first step to testing a co-designed patient engagement tool, which may mitigate low vaccine coverage among underserved and minoritised communities in East London and similar groups across the UK.

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Contributors DZ is responsible for the overall content as guarantor. TC conceptualised the study aims, study design, inclusion and exclusion criteria and data curation. Senior support was provided by DZ, who is also the CI of this study. PT will be supporting the study by coordinating tasks and processes involved in the recruitment of GP practices and patients for randomisation. HZT and AB are the statisticians who will be assisting in the analyses of results. HS is the founder of Appt Health and has assisted in the co-design of the PET. HS is also responsible for the randomisation of patients. TC wrote all drafts of the manuscript with input from DZ. All coauthors listed verified the analysis, commented on the manuscript and approved it for submission.

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Competing interests HS is the CEO of the Appt Health platform used in the study, as well as a CO-I.

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

Patient consent for publication Not applicable.

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