Participant Information Sheet

Study title: COVER-ME: ***COVER-ME:*** *Covid-19 vaccination coverage among underserved populations: Developing and Evaluating community-based interventions in East London minority ethnicity (ME) backgrounds; underserved migrants; persons with low income.*

Version number and date: Version 4, 03.09.2023

Researcher's name: Dominik Zenner

IRAS number: 316860

Invitation paragraph

This study seeks to understand low uptake of vaccination, specifically COVID-19 among persons from minority ethnic, migration background or those who have low-income. A total of 2400 patients will be recruited across 6 GP practices. If you are interested to participate, please see details below regarding further information about the study.

What is the purpose of the study?

The main aim of this research study is to design, develop and then pilot-test an effective, acceptable and feasible patient-engagement tool (PET) for vaccination uptake including for COVID-19 for persons from migrant and/or ethnic minority backgrounds or those who have low-income in East London.

Why have I been invited to take part?

The reason for you being chosen to participate within this study is because you are from the population of interest, including those who have not been vaccinated, who have had their initial dose but refused the second or booster dose. We are interested specifically in the reasons why you may be vaccinated or not and the impact of the engagement tool to help increase uptake of vaccines.

Do I have to take part?

No. You DO NOT have to participate if you do not wish to. If you decide that this is not for you it will not affect your involvement or access to any healthcare services. If you do decide to participate, an automated text message will be sent by your GP practice to confirm you are happy to receive text messages regarding vaccinations. If so, you will be redirected to a link providing information on how we will use your data. All data will be anonymised. However, if you are unhappy to participate, a text

message will be sent containing another link, which will give an option to opt out, no longer receive text messages or use any of your data.

What will happen to me if I take part?

If you agree to participate in this study after reading this information sheet the following will occur:

Randomisation:

All individuals will be selected from across six GP practices from Tower Hamlets and Newham. You will be randomly allocated (1:1) to either receive the PET within the intervention group and routine care; or routine care alone within the control group during the study. This will help make comparisons and determine the efficacy of the PET to improve vaccine uptake. Individual randomisation will be stratified by GP, using a random block allocation list implemented into a software used for the study. Participants will be followed up until study completion at 9 months, but this a electronic process which does not need to involve direct contact.

We are also interested in a clustered comparison between GP. Therefore, there will be a clustered randomisation of GPs after they have been recruited to the study, 1:1 into two groups of size (n=3 vs. n=3). This will enable a comparison of the intervention to a control group at a practice level. The first group of GPs will receive training, activation of the software, and patients will be randomised to the different intervention workflows. The second group of GPs will not receive training, software or randomise patients individually.

Receive Text Messages

You will receive text messages sent out by the PET along with your routine care, containing useful material and content regarding vaccines.

Completion of Surveys

Your views on the tool will be determined through completing a survey questionnaire about the acceptability, user friendliness addressed. The questionnaire will be available online and in paper format; if required, it will be available in your local languages. Your consent will be sought prior to completing the surveys, and ensuring you understand how your data will be used and kept safe. You will be asked to complete surveys 3 times (at 3, 6 and 9 months). The completion of surveys will be mandatory, as the survey data will help evaluate and determine the feasibility and effectiveness of the PET.

Follow-up

Vaccine uptake will be monitored during the course of the study at different time points (at 3, 6 and 9 months) to determine whether the PET has made a difference or not.

If you are unhappy to participate you will be given the choice to withdraw. You can do this by writing to your GP practice stating that you do not wish to have your data shared and would like to withdraw from all study proceedings.

Expenses and payments?

There will be no expenditure to take part in this study; therefore, no expenses or payments will be reimbursed.

What are the possible disadvantages and risks of taking part?

It is unlikely that there will be any disadvantages of participating within the study and there will be no risk to the physical health. However, if you became distressed by the content of the survey questionnaire, the researcher can signpost to your local healthcare provider or to easily accessible services, such as mental health charity services across various sites in UK providing counselling for psychological support. Psychological support can also be sought through helplines such as 'Samaritans' (https://www.smaritans.org) or 'Saneline' (SANEline services - SANE) which offer confidential emotional support via telephone, email, letter and face to face for people in distress.

If you do not wish to respond to certain questions asked during survey or feel uncomfortable, you may take a break and return when you are ready. You are free to withdraw and exit from the survey at any time. Confidentiality of information will be respected at all times.

What are the possible benefits of taking part?

There are no personal benefits from participating; however, this study intervention aims to increase uptake of vaccines that are already recommended through national guidance. The main benefit to patients and the community is protection from adverse health issues due to COVID-19 or flu. Your input will be highly appreciated and the result of the study could inform appropriate PETs that are tailored to Minority Ethnic patient preferences.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the main researcher (Dr Tahreem Chaudhry, e: t.chaudhry@qmul.ac.uk, m: 07464280087; who will do her best to answer your questions. If you remain unhappy and wish to complain formally you can do this by contacting the Chief Investigator (Dr Dominik Zenner, e: d.zenner@qmul.ac.uk , m: 07981624455); Yvonne Carter Building, White Chapel Campus, Queen Mary University London, 58 Turner street, E1 2AB.

If you have a complaint which you feel cannot be discussed with the researchers then you should contact the Patient Advice and Liaison (PALS service details to be added locally for each site)

Will my taking part in the study be kept confidential?

Yes, your confidentiality will be respected at all times during and after the study. You will be asked to consent in the case of data sharing to allow secondary analysis by a member of the original research team. Patient details will be anonymous, and survey responses will also be anonymous no identifiers such as names will be asked for. However, any concerning information disclosed that is illegal, or suggests risk to yourself or others, the researcher is duty bound to report it to the appropriate authorities.

How will we use information about you?

We will need to use information from you and your medical records for this study for this research project. Accessible data will include demographic data including age, sex, gender, ethnicity, deprivation, or co-morbidities needed for this study. We will keep all your data safe and

secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from [**X**]
- by asking one of the research team
- by sending an email to [data-protection@qmul.ac.uk], or
- by ringing us on [**phone number**].

Under what legal basis are you collecting this information?

Queen Mary University of London processes personal data for research purposes in accordance with the lawful basis of 'public task'

Please read Queen Mary's privacy notice for research participants containing important information about your personal data and your rights in respect. If you have any questions regarding to data protection, please contact Queen Mary's Data Protection Office, Queen's Building, Mile End Road, London. E1 4NS or data-protection@qmul.ac.uk or 020 78882 7596

What will happen if I don't carry on with the study?

All participants are eligible to withdraw at any point during the study if they wish to, without affecting your on-going healthcare. You will also be given the opportunity to have your data fully withdrawn. Participants may opt out of having their data used for research by writing to the practice. We will record the number who do so, but no further data about them will be recorded or used.

Contact details of all researchers are provided below

What will happen to the results of the research study?

The data will only be used for non-commercial, scholarly research and teaching, and stored for up to 25 years after the project is finished. Findings of the study will also be published in national and international journals in the hope to make better changes to healthcare practice, supporting practitioners looking after individuals with similar experiences. Your details will not be shared and

will remain confidential. A summary of the research findings will be available and disseminated to you.

Who is organising or sponsoring the research?

The sponsor of the study is Queen Mary, University of London, the contact details are provided below; and the study is being organised by the chief investigator Dr Dominik Zenner, and the wider research team from within Queen Mary University of London

Further information and contact details:

If any further concerns, please do not hesitate to contact the researcher or chief investigator Dominik Zenner.

Sponsor: Tumi Kaminskas (Research Governance and Performance Manager) e: t.kaminskas@qmul.ac.uk t: 020 7882 7207

Dr Tahreem Chaudhry, e: t.chaudhry@qmul.ac.uk, m: 07464280087

Dr Dominik Zenner, e: d.zenner@qmul.ac.uk , m: 07981624455