

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 3, 02/08//2022

**Researcher’s name**

Dominik Zenner

**Queen Mary Ethics of Research Committee reference number:**

[**QMERC22.266**]

**Invitation paragraph**

This study seeks to understand low uptake of vaccination, specifically COVID among persons from minority ethnic, migration background or those who have low-income. 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 experiences and perceptions among your population group, including reasons why you may be vaccinated or not and the impact of engagement tool to help increase uptake of vaccines.

**Do I have to take part?**

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, a consent form will be provided for you to sign. However, prior to signing the consent form it is still acceptable to withdraw from the study whenever you may wish to.

**What will happen to me if I take part?**

If you agree to participate in this study after reading this information sheet and having time to ask questions you will have, the following will occur:

*Prior to interviews and Focus group discussions (FGDs)*

1. Discuss with the researcher a location that is convenient to you (for example your local community centre).
2. Discuss translations needs and agree a plan. All study instruments and interviews will be translated in the preferred language of the participants
3. Sign consent form and clarify with the researcher any issues you may have.

*During the interviews and FGDs*

1. You are then invited to participate in a face-to-face, semi-structured interview and/or Focus group discussions. Ideally, we would like for you to take part in both the interview and FGD, but it is also acceptable if you choose to do one or the other.
2. A researcher will take notes and record the interview (with your permission in order to understand on your experiences related to the vaccinations. This may relate to many factors, including personal or cultural views or barriers to care.

If you are participating in the FGDs you will be made aware of who the other focus group attendees may be, to ensure you are still comfortable to take part. If you are unhappy to participate you will be given the choice to withdraw.

*After the Interviews and FGDs*

1. Interviews and FGDs will help form an understanding of a social and cultural acceptability of a patient engagement tool (PET). Therefore, you may be invited to the second part of the study which will be designing and developing a PET with educational components adapted to your needs and preferences to promote vaccination uptake.
2. The purpose of the PET will develop to help educate and inform individuals about the benefits of COVID-19 vaccination through culturally adapted educational support, including content, design, mode and timing of delivery of messages. This will help generate knowledge about what people think including their fears and doubts, which can help us to find acceptable ways to encourage the highest uptake possible in these communities. This may result in different approaches for information materials, appointment types and places, or use of technology or other suggestions which we have not considered.

**Expenses and payments?**

We will refund your travel and transport expenses to show appreciation of your time to participate.

**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 interviews or discussions, 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’ or ‘Saneline’ 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/interviews or feel uncomfortable, the interview can be stopped and postponed to another date and time. You are free to withdraw and exit the FGD/interview 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. Your input will be highly appreciated and the result of the study could inform appropriate PETs that are tailored to ME 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; Professor Karina Kielmann, e: kkielmann@itg.be; Dr Felicity Morrow, e: f.morrow@qmul.ac.uk m: 07470387449) who will do their 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 Research Ethics Facilitators by email: research-ethics@qmul.ac.uk. When contacting the Research ethics Facilitators please provide details of the study title, description of the study and QMREC reference number (where possible), the researcher(s) involved, and details of the complaint you wish to make.

**Will my taking part in the study be kept confidential?**

Yes, your confidentiality will be respected at all times during and after the study. Patient details will be anonymous, and responses will also be anonymous no identifiers such as names will be asked for. Data from interviews and FGDs will be kept secure computer system. It will be ensured that all quotes used from the interviews within future publications will be unidentifiable to any individuals and only be accessible to members within the research team. 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.

**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 interview if they wish to, you will also be given the opportunity to have your data fully withdrawn. However, we kindly request a time frame of two weeks following an interview session for deletion of interview data.

It is important that you understand that if you decide to withdraw in focus group discussions you can only withdraw before or during the focus group.

Contact details of all researchers are provided below

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

Dr Felicity Morrow, e: f.morrow@qmul.ac.uk m: 07470387449

**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 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.

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

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

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