

PACCMan

Persistent **A**uditory **C**onsequences of **COVID-19**
A **Man**chester research study

You are being invited to take part in a research study on COVID-19 and hearing. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

Who is carrying out this research study?

Professor Kevin Munro, Professor Chris Plack, and Dr Hannah Guest (University of Manchester hearing researchers) and Dr Nazia Chaudhury and Dr Seema Brij (respiratory consultants).

What is the purpose of the study?

Many illnesses can affect hearing, and this may include COVID-19. We're offering state-of-the-art hearing assessments to people who've recently recovered from COVID-19 or other illnesses, and we'll compare the results to see if COVID-19 has any special effects on hearing.

Am I suitable to take part?

To take part, you must...

- Be aged **18-70**
- Have been **hospitalised** in 2020-21, either for COVID-19 or another illness

Unfortunately, the following people can't take part:

- People who have been hospitalised **more than twice** in 2020-21
- People who cannot **safely climb** the small steps into our hearing-testing van (we apologise to wheelchair users, who will not be able to take part)
- People who have long-term **profound hearing loss** (little or no hearing)
- People who have had COVID-19 but were **not hospitalised** for it

What will I be asked to do if I take part?

We'll visit you in our custom-built hearing-testing van, or you can come to us on the University campus if that is more suitable. First, we'll talk about what the session will involve. Then we'll check your ears to make sure we can complete the study safely. We might also take a picture of the inside of your ear canal. If we find a build-up of ear wax, we will either ask a trained colleague to remove the wax (with your consent), or we might decide it is not safe to complete some of the tests.

Then you'll experience a range of cutting-edge hearing tests. You'll wear headphones or have an earphone inserted, and during one of the tests, you'll also have sticky sensors on your scalp.

Some of the tests involve actively listening, but most are automatic (so you can relax in a recliner while a hi-tech earphone does all the work). The tests are varied, and quite interesting! You'll hear beeps, clicks, buzzes, and speech, and the equipment will test your ear drum, inner ear, and even your brain's response to sound. We will also ask you some questions about your hearing and general health, and may ask for details of previous hearing tests if you have had one.

Afterwards, with your consent, staff at the hospital where you were treated will share information from your hospital records (e.g. symptoms and medications) with the research team, to help us understand how your illness and treatment might have affected your hearing.

When and where will it happen?

We'll visit you once, at whatever location is easiest for you (probably parked outside your home). We'll arrange this for a time that suits your schedule, and stay for no more than 2.5 hours. You can also come to us on the University campus if that is more appropriate.

Will I be compensated for taking part?

We'll give you £10 per hour, to say 'thank you' for helping out with the study.

What are the risks if I take part?

We will be looking in your ears and playing sounds through various earphones, so we must be careful not to hurt your ears or play you any excessively loud sounds. We have thorough training to make sure of this. We must help you move in and out of the van safely, to minimise any risk of harm to you (from tripping, slipping, other vehicles, and so on.) One of the tests involves applying sticky sensors, and we'll need to exfoliate small patches of skin first, so we must make sure that this doesn't irritate your skin. Finally, we must make sure we minimise COVID-19 risk; information on this is given towards the end of this document. Occasionally we may offer ear wax removal to allow you to take part. This can risk irritation of the ear canal. If you are offered wax removal we will fully discuss the risks specific to you and get your express consent to go ahead.

Who has reviewed this research study?

The study has been reviewed by the NHS London Central Research Ethics Committee.

Who is funding the study?

The Royal National Institute for Deaf People, The Eleanor Peel Trust, and the UofM COVID-19 Research Appeal Fund.

What happens if I don't want to take part or change my mind?

It is up to you to decide whether or not to take part. If you would like to, then get in touch with **Iain Jackson** using the contact details at the end of this information sheet. If you do decide to take part you will be given this information sheet to keep and will be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the project once it has been anonymised as we will not be able to identify your specific data. This does not affect your data protection rights. If you decide not to take part you do not need to do anything further.

Data protection and confidentiality

What information will you collect about me? In order to participate in this research project we will need to collect information that could identify you, called "personal identifiable information". Specifically we will need to collect: (a) your name, (b) your contact details, (c) health and demographic data from your medical records, (d) your postal sector.

Under what legal basis are you collecting this information? We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is "a public interest task" and "a process necessary for research purposes".

What are my rights in relation to the information you will collect about me? You have a number of rights under data protection law regarding your personal information. For example you can

request a copy of the information we hold about you. If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our Privacy Notice for Research (<http://documents.manchester.ac.uk/display.aspx?DocID=37095>).

Will my participation in the study be confidential and my personal identifiable information be protected? In accordance with data protection law, the University of Manchester is Data Controller for this project. That means we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:

Your identifiable information (name and contact details) will be stored securely and separately from your other data (demographics, health and treatment information, and hearing measurements). Your data will be marked with an ID number, not your name. The key linking your ID number to your identity will be accessible only by the research team, and will be discarded at the close of the study. Your name and contact details will also be discarded, unless you choose for us to keep them to let you know the results of the study. Your consent form (including your name and signature) will be retained for 2 years, separately from the remainder of your data, in a locked filing cabinet.

Individuals from The University of Manchester, NHS Trust, or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data, but all individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

At the end of the project we will deposit a fully anonymised dataset in an open data repository where it will be permanently stored. Researchers at other institutions and others can access the anonymised data directly from the repository and use it for further research or to check our analysis and results.

Will the outcomes of the research be published?

The outcomes will be reported at scientific conferences and in peer-reviewed journals. (You won't be identified in these.) And if you like, we'll contact you to let you know the results of the study.

What if I want to make a complaint?

If you have a complaint that you wish to direct to members of the research team, please contact **Iain Jackson** (iain.jackson@manchester.ac.uk, 07785401460). If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact the Research Ethics Manager, Research Office, Christie Building, University of Manchester, Oxford Road, M13 9PL, by emailing research.complaints@manchester.ac.uk or by phoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the university and we will guide you through the process of exercising your rights. You also have a right to direct complaints relating to your personal identifiable information to the Information Commissioner's Office (ico.org.uk/make-a-complaint) or phone 0303 123 1113).

How does COVID-19 affect how this research is conducted?

Given the COVID-19 pandemic, we have designed this study to adhere to the latest government advice on social distancing, and taken all reasonable precautions to limit the spread of the virus. You should carefully consider all of the information provided below before deciding if you still want to take part. If you have any additional queries about any of the information provided, please speak with **Iain Jackson**, using the contact details at the end of this information sheet.

What COVID-19 risks should I consider when deciding whether to take part?

You will be visited by two researchers and will enter our hearing-testing van to provide hearing measurements. During some parts of the session, maintaining social distancing will not be possible. At some times, a researcher will be 1-2 metres away from you, when asking you questions or giving you information. At other times, a researcher will be close to you, in order to look in your ears, fit you with an earphone, or place sticky sensors on your scalp.

What steps will be taken to keep me safe when I take part?

The hearing-assessment van/test room will be cleaned thoroughly before our visit to you, to minimise the risk that COVID-19 virus will be present on the equipment and surfaces you could come into contact with. The researchers will practice careful hand hygiene throughout the session. When filling in questionnaires, you will use a clean, disposable pen. The equipment that comes into direct contact with your ears and scalp is disposable and is discarded between patients. When social distancing cannot be maintained (i.e., a researcher is less than 2 metres from you), the researcher will wear a fluid-resistant surgical mask. Disposable gloves and aprons are available should you wish the researcher to use them, but they are not recommended as standard procedure for low risk contact.

Is there any additional COVID-19 information that I need to know?

If government advice (on how to prevent the spread of COVID-19) changes, we may need to change how we conduct this research. If this happens, and any of the information in this sheet becomes out-of-date, we will detail the changes in an additional information sheet. You will be given a copy of this written information to keep, and we will explain it in detail before you sign a consent form and go ahead with the study. It is also possible that changing government guidance could lead to cancellation or postponement of our visit to you. If so, we would try to give you as much notice as possible, and to reschedule for a time convenient to you.

What if I'm entitled to compensation?

In the unlikely event that something does go wrong and you are harmed during the research, you may have grounds for a legal action for compensation against the University of Manchester but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

What do I do now?

Contact **Iain Jackson** or **Anisa Visram** with any questions or to take part. You can do this by phone or email. (Iain is the best person to contact first, because Anisa is often driving the van! If you phone when we're **both** busy doing hearing tests, you'll get our voicemail, but we'll get back to you.)



Iain Jackson

Manchester Centre for Audiology and Deafness
Ellen Wilkinson Building
University of Manchester
Oxford Road
Manchester M13 9PL

Email: iain.jackson@manchester.ac.uk

Phone: 07785 401 460



Anisa Visram

Manchester Centre for Audiology and Deafness
Ellen Wilkinson Building
University of Manchester
Oxford Road
Manchester M13 9PL

Email: anisa.visram@manchester.ac.uk

Phone: 07543 228 856

This project has been approved by The NHS London Central Research Ethics Committee