Participant Information Sheet

Final v1.1

03.09.2021

IRAS Project ID: 303339

Title of Study Barriers and facilitators of flu, pneumonia and SARS-CoV-2 vaccination in adults with inflammatory conditions treated with immune-suppressing drugs (OPINION study)

Name of Chief Investigator Professor Abhishek, Professor of Rheumatology

Local Researcher(s) Dr Amy Fuller, Research Fellow

We would like to invite you to take part in a research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. Ask us if anything is not clear by contacting the study team on 0115 823 1756.

What is the purpose of the study?

People with inflammatory conditions treated with medicines that dampen the body's immune system are not able to fight off infection as well as others. They are at risk of getting unwell if they catch flu, pneumonia or Covid-19. As a result, vaccination against these infections are recommended for them. However, many people with inflammatory conditions treated with medicines that dampen the immune-system get vaccinated while others do not.

We would like to invite you to take part in a study which aims to better understand why some people get vaccinated while others do not. We would like to invite you to take part in this research study regardless of whether you have had all, some, or none of the vaccinations against pneumonia, flu and Covid-19.

In this study, we will seek to better understand your understanding of these infections; your understanding and views on vaccinations; and the reasons for choosing or not choosing to be vaccinated against these infections.

The findings of this study will be used to inform the content of patient education leaflets. We will share our findings with doctors and nurses to help them understand what stops people from being vaccinated so that these may be addressed during GP and hospital appointments.

Why have I been invited?

You are being invited to take part because you have an inflammatory condition such as rheumatoid arthritis, gut inflammation, psoriasis etc. and are treated with medicines that dampen the immune system. We are inviting up to 24 participants to take part in the interview.

Do I have to take part?

It is up to you to decide whether or not to take part. If you are invited to take part in an interview, and decide to participate, you will be asked to sign a consent form. (See section below: "What will happen to me if I take part?")

You will be free to withdraw at any time and without giving a reason. This would not affect your legal rights. Your medical treatment and care will not be affected, whatever your decision about this research.

What will happen to me if I take part?

If you are interested in taking part, please complete the reply slip and return it to us in the enclosed free-post envelope. It should take no more than 5 minutes to complete and asks about you, your medical condition(s), and which vaccines you have had. This will help us select a wide range of people to talk to.

Not everyone that returns a reply slip will be invited to participate in the interview study. This is because we would like to capture the views of people with different conditions, from different ethnicities, age-groups and genders. If we have already interviewed sufficient people similar to you, unfortunately, we will not be able to interview you. We will write to you to inform you of this should this occur.

The answers you provide in the reply slip will be kept securely and anonymously, regardless of whether you are chosen to participate in an interview. We will use these answers to report the characteristics of those interviewed and not interviewed in our study reports.

If eligible to be interviewed, you will be contacted by telephone inviting you to take part in the research interview, and arrange a suitable date and time. The interview will either be face-to-face in Academic Rheumatology at the City Hospital Nottingham *[delete option if COVID restrictions in place]*, by telephone or video-call, depending upon your preference.

If you agree to participate, and prefer to do the interview over a telephone call or via video conference, the person calling you will go through the information sheet with you and answer any questions you have. A separate phone call can be arranged for this if you prefer. We will also send you a consent form by email to complete before the interview.

If you select to do the interview face-to-face we will ask you to complete the consent form when you come to interview instead *[delete option if COVID restrictions in place]*. One of our team will go through the information sheet with you and answer any questions you have before you given consent for the interview. We will also send a reminder text message in the week before this date.

The interview may last up to one hour. With your consent, the interview will be digitally audio-recorded and hand-written notes may be taken. The voice recordings will be typed-up. Where an external typing service is used a confidentiality agreement will be in place. Interview text will be anonymised by removing any identifiable information and analysed by the researcher. Anonymous direct quotes from the interview may be used in the resulting publication(s). We will remove all identifiable information from any quotes and it will not be possible to identify you from these.

Expenses and payments

Participants will not be paid to take part in the study, but travel expenses will be reimbursed if they travel for a face-to-face interview.

What are the possible disadvantages and risks of taking part?

It will take time out of your day, but we do not foresee any disadvantages to taking part in the study. Every effort will be made to minimise inconvenience and to ensure your comfort in the interview process. Many people value the opportunity to talk about their experiences, but it will be possible to take a break or stop at any point during the interview. If during the interview you tell us something that needs to be brought to your GP's attention, we will advise you to contact your GP to discuss this.

What are the possible benefits of taking part?

There are no direct benefits for you from taking part in the study. The information from this study will help us better understand why some people with inflammatory conditions on immune-suppressing medications do not get vaccinated. This information will help doctors and nurses address these factors.

What happens when the research study stops?

Once we have recruited a sufficient number of participants for the study, the research team will analyse the information gathered. The findings will be used to shape messaging about vaccinations to patients with inflammatory conditions treated with immune-suppressing medication. The study findings will be published in medical journals. A summary of the study findings will be shared with everyone that takes part in the interview study unless they do not wish to receive it.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers' contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting Nottingham University Hospitals Patient and Liaison Service.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Nottingham but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence. With your permission we will inform your GP of your participation in the study.

If you join the study, we will use information collected from you during the course of the research. This information will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database at the University of Nottingham. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate.

You can find out more about how we use your information and to read our privacy notice at:
https://www.nottingham.ac.uk/utilities/privacy.aspx

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Your contact information will be kept by the University of Nottingham for up to 12 months after the end of the study so that we are able to contact you about the findings of the study (unless you advise us that you do not wish to be contacted). All other research data will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those

involved to maintain your confidentiality, only members of the research team given permission by the data custodian will have access to your personal data.

In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.

Although what you say to us is confidential, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons. For instance, the Lead Safeguarding Officer at the University of Nottingham, University of Nottingham security office, police, and social services may need to be informed for Safeguarding, Prevent, criminal and social issues respectively. Should anything of relevance to your clinical care be revealed during the study, we may recommend that you seek advice from your GP.

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

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw we will no longer collect any information about you or from you but we will keep the information about you that we have already obtained as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses.

Who is organising and funding the research?

This research is being organised by the department of Academic Rheumatology, University of Nottingham and Nottingham NIHR BRC. It is funded by the National Institute of Health Research.

Who has reviewed the study?

All research in healthcare is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Brighton and Sussex Research Ethics Committee.

Further information and contact details:

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