Understanding personal shielding experiences: The voices of people living with arthritis and musculoskeletal disease

Participant Information Sheet (PIS) – Focus groups

You are being invited to take part in a research study which aims to understand the experiences of people living with arthritis and musculoskeletal conditions, including rare auto-immune rheumatic diseases, who 'shielded' during the COVID-19 pandemic. 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 for you. Please take time to read the following information carefully before deciding whether or not 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. If you would like, one of our team can go through the information sheet with you and answer any questions you have. Thank you for taking the time to read this. We understand you may need some time to think about your decision before deciding whether to take part.

About the research

➢ Who will conduct the research?

We are a team of researchers and patient research partners based at the Centre for Epidemiology Versus Arthritis, University of Manchester. The study is led by Dr Charlotte Sharp, NIHR Clinical Lecturer, and patient partners, Joyce Fox and Lynn Laidlaw.

➢ What is the purpose of the research?

People identified at high risk of severe illness from COVID-19 were labelled as being "clinically extremely vulnerable", and advised to 'shield'. Shielding included being advised to minimise contact with other people, including those within their own households, and only to leave home for medical appointments. People living with arthritis and musculoskeletal disease were amongst those identified as clinically extremely vulnerable and advised to shield.

There has been some research using questionnaires and surveys into people's shielding experiences, which has identified that people's experience of the shielding identification process varied. So far, little research has involved talking to people. We want explore people's experiences of the identification shielding process and their experiences of shielding, by talking to them about their experiences. We hope that this will increase our understanding of the experiences of those who shielded and to generate recommendations to help improve the process if people are advised to shield again in the future.

We are recruiting up to 12 people with arthritis and musculoskeletal disease to take part in focus groups. Focus group participants would take part in a single focus group, alongside up to five other participants. You have been asked to take part because you shielded due to your arthritis or musculoskeletal condition.

➢ Will the outcomes of the research be published?

Our findings will be published in a final report, which will be shared with all participants. We will also publish in academic journals and present at conferences. Any quotations from focus groups used in any publications will be anonymised.

➢ Who has reviewed the research project?

The project has been reviewed by The University of Manchester Research Ethics Committee, number 2021-11544-20348.

➢ Who is funding the research project?

This project has been funded by Versus Arthritis.

What would my involvement be?

➢ What would I be asked to do if I took part?

If you would like to take part, you will be asked to complete a screening survey. The first part of the screening survey includes questions to make sure that you meet the study inclusion criteria. The second part of the screening survey includes questions to help ensure that we will capture shielding experiences from people across a wide range of situations and backgrounds. We will also ask you to share your contact details so that we can discuss your participation and send you relevant documents.

If we invite you to take part and you decide to do so, you will be asked to participate in a focus group. This would be a discussion with up to five other participants, with one or two members of the research team present to ask questions. Due to social distancing measures the focus group will take place over a video platform such as Zoom. Focus groups will be audio recorded, with the permission of everyone taking part, and we may also take brief notes. We will ask everyone taking part in a focus group to agree to treat as confidential any information that they hear from other participants during the group. After the focus group, the audio recording will be typed up (transcribed), checked, and then destroyed. Focus groups will last between 60 and 90 minutes. If you need to take a break, please just mention it to the researcher and the conversation can be paused at any time.

➢ Will I be compensated for taking part?

As a thank you for taking part we are offering a high street gift voucher worth £20 for those taking part in focus groups.

➢ What happens if I do not want to take part or if I change my mind?

The study is voluntary and it is up to you to decide whether or not to take part. Please just let a member of the research team know by email or telephone. If you do decide to take part you will be given this information sheet to keep and will be asked to provide verbal consent. Consent will be audio-recorded and stored for 5 years in line with The University of Manchester's research governance policy. If you decide to take part you are still free to withdraw at any time during the focus group without giving a reason and without detriment to yourself. The focus group will be audio recorded with your permission and permission of other members of the group. If you change your mind after the focus group, you can ask for your data to be withdrawn from the project for up to two weeks after the focus group date. 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". This information will help us to ensure that we involve a range of different people in our study. Specifically we will need to collect:

- Age category (18-25; 26-35; 36-45; 46-55; 56-65; 66-75; 75+)
- Gender you identify with (male; female; transgender; non-binary; prefer not to say)
- Ethnicity (free text; prefer not to say)
- Rural urban classification (City centre; city suburbs; town centre; town suburbs; large village (>2000); small village (<2000); Hamlet (<100); Isolated house/farm; prefer not to say)
- Geographical location (North East; North West; East Midlands; West Midlands; South Eastl East of England; South West; London; prefer not to say)
- Employment status (Employed, full-time; employed, part-time; self-employed; volunteer (unpaid work); student; not employed, looking for work; not employed, not looking for work; retired; prefer not to say)
- Musculoskeletal condition/arthritis diagnosis
- Whether or not you shielded
- Socio-economic status (first half postcode / prefer not to say)
- Contact details, including email address and telephone number
- Audio (sound) recordings of your answers during the focus group, and your verbal consent
- All recordings will be taken using a secure, encrypted audio recording device and will be stored on The University of Manchester's secure server.

➢ 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, including transcripts of audio recordings.

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.

- **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 the Data Controller for this project. This means that 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. The study team at The University of Manchester will have access to your personal information and they will anonymise it as soon as possible. Your name and any other identifying information will be removed and replaced with a random ID number. The research team will have access to the key that links this ID number to your personal information.

All researchers are trained with this in mind, and your data will be looked after in the following way:

- Focus groups will take place and be recorded in Zoom and your personal data will be processed by Zoom. This may mean that your personal data is transferred to a country outside of the European Economic Area, some of which have not yet been determined by the European Commission to have an adequate level of data protection. Appropriate legal mechanisms to ensure these transfers are compliant with the UK General Data Protection Regulation are in place. The recordings will be removed from the above third party platform and stored on University of Manchester managed file storage as soon as possible following the completion of data collection. See Further privacy information: https://zoom.us/privacy
- Audio-recordings of consent will be made and stored separately to audio recordings of focus groups.
- All audio-recordings will be downloaded onto secure University of Manchester research drives immediately following the focus group, and deleted.
- All focus groups will be transcribed by a University of Manchester approved supplier, 1st class Secretarial Services.
- All audio-recordings of focus groups will be deleted once transcribed and checked to preserve confidentiality.
- All transcriptions will be pseudonymised (all personal names and identifying information will be removed and your contribution will be given a unique ID code, which is linked to your personal data if needed). Any information relating to locations / healthcare facilities / other potential identifiers will be removed. Only the research team will have access to the key that links your contact data and ID code.
- All data will be held on secure research drives at the University of Manchester
- The research team at The University of Manchester will keep your information private and only accessible to the research team.
- In refining the research findings, we may share anonymous quotes or summaries of what you have said with our formally appointed patient and public involvement and engagement group; this would only be done linked to an ID number.
- In writing up reports and scientific papers we may use anonymous quotes or summaries of what you have said to demonstrate a research finding; this would only be done linked to an ID number.
- The audio-recorded consent, written contact details and transcripts of focus groups will be retained for 5 years

- Please also note that individuals from The University of Manchester 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. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

What if I have a complaint?

➢ **Contact details for complaints**

We do not anticipate that taking part in the study will cause you any problems and It is very unlikely that anything will go wrong, but if you have any worries, concerns or minor complaints you can inform a member of the research team first:

DR CHARLOTTE A SHARP, (Principal Investigator)

- **Email: Charlotte.sharp@manchester.ac.uk**

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, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 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 complain to the Information Commissioner's Office about complaints relating to your personal identifiable information Tel 0303 123 1113

Contact Details

If you have any queries about the study or if you are interested in taking part then please contact the researcher:

DR CHARLOTTE A SHARP, (Principal Investigator)

- **Email: Charlotte.sharp@manchester.ac.uk**

LYNN LAIDLAW (Patient contributor)

- **Email lynn.laidlaw@manchester.ac.uk**

JOYCE FOX (Patient contributor)

- **Email: joyce.fox@manchester.ac.uk**

Are there any additional considerations that I need to know about before deciding whether I should take part?

We realise that shielding and people's experiences of the COVID-19 pandemic have been challenging. Some people may find talking about their experiences upsetting but equally some people can find it very helpful. If you do find it upsetting and want to pause or stop completely, the researcher can stop the conversation and recording immediately. You can have as much time as you need until you feel ok to continue or, if you prefer, you can withdraw from the study and any data will be destroyed.

In the event that you feel distressed after the focus group, please contact one of the following organisations for support.

Mind

Lines are open Mon-Fri 9-6pm, except for bank holidays

Infoline:	0300123 3393
Text:	86463
Email:	info@mind.org.uk

Samaritans

National helpline: 116 123 (24 hours a day, 365 days a year, free to call, at any time, from any phone
Email: jo@samaritans.org

Manchester and Salford Samaritans

Address:	72-74 Oxford St, Manchester, M1 5NH.
Telephone:	116 123 free from any phone 0330 094 5717 (local call charges apply)

Versus Arthritis

National helpline: 0800 5200 520 (Monday to Friday, 9am-6pm).
Email: helpline@versusarthritis.org