Improving discussions about resuscitation in COVID-19

Participant Information Sheet (PIS)

You are being invited to take part in the research study 'Improving discussions about resuscitation in COVID-19'. This participant information sheet explains why the research is being conducted and what it will involve. Please take time to read this 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 information.

What is the purpose of the research?

This research will find out how discussions about resuscitation can be improved for relatives and carers who had a discussion about resuscitation with a medical professional on behalf of a family member or relative during the COVID-19 pandemic.

Good communication around care at the end-of-life is important for relatives and carers, and can help when coping with bereavement. The issue of communication about resuscitation is especially important during the pandemic. COVID-19 has disrupted the usual way healthcare professionals communicate with relatives and carers because of, untimely, unexpected deaths and restrictions to face-to-face visiting. Complaints about resuscitation communication are common. This is distressing for patients and families and costly for the NHS.

Research is needed to explore how resuscitation discussions have been undertaken during COVID-19. The project will use relatives' and carers' experiences to inform policy makers and health care providers about what works well and what needs to be improved when discussing resuscitation in COVID-19.

Where will the research findings be published and shared?

We will share the findings in four ways:

1. A report for bereaved relatives and carers and the public
2. A formal report of the research findings for policy makers

3. At least one article in a peer-reviewed academic journal, which will be read by researchers and practitioners
4. Presentations about the research to the Department of Health and Social Care

It is important to note that the study team will not be able to pass judgement on the treatment that you or your relative received. Furthermore, the research team will not be able to provide support in resolving any complaints or grievances with NHS organisations beyond signposting to the NHS organisations' complaints office.

Who will conduct the research?

The research will be conducted by a team based at the University of Manchester and Newcastle University. The team includes Dr Michaela Hubmann, Dr Louise Tomkow, Dr Felicity Dewhurst, Professor Barbara Hanratty and Professor Chris Todd.

Who has reviewed the research project?

This project has been reviewed by The University of Manchester Research Ethics Committee (reference number 2021-11386-19227).

Who is funding the research project?

The project has been funded by the National Institute for Health Research (NIHR).

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

If you decide to take part, you will be asked to take part in an interview with one of the research team. Because of the current situation with COVID-19 restrictions, interviews will either be conducted using video conferencing software such as zoom/skype or over the phone. Zoom/skype interviews will record voice only. Audio recordings will be recorded via encrypted audio recording software either using the zoom software or an encrypted Dictaphone. If possible, we would prefer you to turn on your video feed, as this would make it easier for the research team to detect any signs of you becoming upset or distressed, however you can turn your video feed off if this makes you feel more comfortable.

The interviews will take place at your convenience at a time and date best suited for you.

Prior to starting the interview you will be asked to complete a consent form. This consent form can be signed by hand and returned by post, or you can add an electronic signature and return to the research team via email. If you would prefer the research team can talk you through this consent form before we interview you and we can record you giving your consent verbally. Interviews will last from 30 minutes to up to 2 hours. You will only be asked to take part in 1 interview. Everything that you tell us during the interview will be kept confidential.

The research team will ask specific questions we know, based on previous research, are important. This includes when and where discussions about resuscitation took place, and who led those discussions. The interviews will also provide you with time to discuss other factors important to you.

We know these conversations may cause distress. If you would find it comforting and supportive, we are happy for you to have another family member or friend to join the interview discussion. We will also provide you with the contact details of a bereavement support specialist who will be able to offer you an appointment after your interview. This is optional.

Will I be compensated for taking part?

You will not be paid or compensated for taking part in this research.

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

It is up to you to decide whether or not to take part. Participation is voluntary, please feel free to discuss the study with others first before deciding whether or not to take part. If, after you have read this sheet through, you would like more information about the research project, please contact Dr Louise Tomkow the researcher from the University of Manchester who is leading this research.

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 up to a month after being interviewed without giving a reason and without detriment to yourself. This does not affect your data protection rights. If you decide not to take part you do not need to do anything further.

The interview will be recorded using an audio recorder, transcribed and saved to a secure University of Manchester computer server. We want all participants to feel comfortable with the recording process and be aware that they are free to stop recording at any time.

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:

- Your contact details
- Your gender and ethnicity
- Your current occupation

Under what legal basis are you collecting this information?

We are collecting and storing this personal identifiable information in accordance with 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 audio recordings or transcripts.

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 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. All

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

Only the study team at The University of Manchester will have access to your personal information, and they will anonymise it as soon as possible. We will also anonymise any information you provide during your interview about your relative and the NHS organisation and staff who cared for them. Your name and any other identifying information will be removed and replaced with a random ID number. Only the research team will have access to the key that links this ID number to your personal information. Your consent form and contact details will be retained for 2 years and stored electronically on an encrypted computer at the University of Manchester; all paper copies of consent forms will be destroyed.

Anonymised data will be held for a minimum of five years after the study has been completed to allow us to publish our findings. The audio recordings of your interview will be destroyed once the interviews have been transcribed. The audio recordings will be transcribed by a University approved transcription service, following University protocol. All personal identifiable information will be removed from the final transcript. Your data will not be shared with anyone outside of the research team.

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.

In the unlikely event that you express concerns about self-harm or others coming to harm and the research team feel that there is a risk to you or others, the research team would provide immediate support. This would include breaking confidentiality in order to involve the relevant emergency services.

What if I have a complaint?

Minor complaints

If you have a minor complaint about this study then please contact the research team leader in the first instance:

Dr Louise Tomkow

louise.tomkow@manchester.ac.uk

Humanitarianism and Conflict Response Institute, Ellen Wilkinson Building, University of Manchester, Oxford Road, Manchester, M13 9PL

Formal complaints

If you wish to make a formal complaint or if you are not satisfied with the response you have gained from the researcher in the first instance, then please contact the Research Governance and Integrity Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PT, 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 Michaela Hubmann

michaela.hubmann@manchester.ac.uk

Division of Population Health, Health Services Research & Primary Care, The University of Manchester, Oxford Rd, Manchester, M13 9PL, UK