

This information sheet provides additional information on the CONTACT study and should be read in conjunction with the CONTACT Participant Summary and/or CONTACT Participant Interview.

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1. Why are we doing this study?

The coronavirus (COVID-19) pandemic has had a major impact across the UK. Care Homes, like yours, have had to make difficult choices to try and manage the spread and risk of people infected by COVID-19. This has had a significant impact on the wellbeing of residents of care homes, their friends and family, and the staff who care for them.

A potential way to reduce the spread of infections, such as COVID-19, is through "contact tracing". This is where people who test positive for an infection are contacted and asked who they have been in close contact with. This is difficult in care homes, as there are lots of people who come into contact with you every day, and it would very difficult to remember details of every contact.

If you have any questions please ask a CONTACT Researcher.

Name of Researcher: <INSERT>

Telephone: <INSERT>

Email: <INSERT>



Your care home has therefore agreed to take part in this study and use a contact tracing system as part of a new standard of care. Therefore everyone in the care home – residents, staff and visitor, will be asked to wear a small device on their wrist – similar to a watch – or as a small broach or on a keyring/lanyard (see pictures). The device will record all contacts between people who wear a device (device IDs only), and specific locations within the home. It could be used to know who has been in contact with who, where they were

when they made contact, and for how long. As part of this study, your care home will also collect some information about you to help with production of reports to help your home with infection management and prevention procedures.

If someone has a positive COVID-19 test then it will be possible to use information from the small devices to see who has been in contact with the person with COVID-19 infection. This information will be used to help put things in place to make the risk of infection to others smaller – this may include self-isolation of those exposed to risk of infection.

2. What are the advantages and risks of taking part?

We hope that this study will give us more information on how small, wearable devices can be used by care homes to make the risk of COVID-19 infection smaller.

We do not expect there will be any direct risks or disadvantage to taking part.

3. What information will you collect about me?

As part of the CONTACT study we are asking residents, staff and visitors to wear a device which will collect information about the contacts people have within the home. In addition to this information, we will also collect the following information about you:

Resident	Staff	Visitor
Device ID	Device ID	Device ID
Age	Age	Age
Gender	Gender	Gender
Ethnicity	COVID-19 testing	COVID-19 testing
Medical History	Job Role	Date and time of visit
Length of stay (from	Do you work in another	
study start date only)	care home? If so, name	
	of the other home(s).	
COVID-19 testing		
Your thoughts on wearing the device		

How will we collect this information?

We will ask staff at your care home involved in supporting delivery of the study for the information. They will give this to researchers working at the University of Leeds, either on a paper form or entered onto a secure computer system. This information will be provided in an anonymised format. The research team would not have any information that could lead to the identification of an individual.

The data from these sources will be sent via secure methods to the Clinical Trials Research Unit (CTRU) at the University of Leeds (where the study is being centrally coordinated) for processing and analysis.

Information from the wearable device will be automatically transferred to a secure computer system – no information is stored on the device. Again, this information is anonymous.

4. What information will be collected on the device?

Your device will collect the following details;

- Contact "event" (person and/or location)
- Date/Time of event and duration
- Signal strength (indication of proximity 2 metres distance)
- Battery life

These details will be linked to a device ID only with no personal details associated with the device. This anonymised information will automatically be transferred to a company called "MicroshareTM" – the makers of the devices,

who then automatically direct this information to the research team at the University of Leeds. Microshare do not keep any of this information – it is deleted immediately after being directed to the university.

Only staff supporting delivery of the study in your care home will know which device is allocated to you. Researchers at the University of Leeds will hold limited information (not your full name) about you to help your care home team link study information back to you (who you have come into contact with in the home).

5. What happens if I test positive for COVID19?

Residents: If you test positive for COVID-19 your care home will continue to look after you in the usual way as they would if you were not participating in the study.

Staff: If you test positive for COVID-19 your care home will ask you to follow usual procedures as they would do if you were not participating in the study.

Visitors: If you test positive for COVID-19 you should inform the care home. The care home will then ask you to follow usual procedures as they would do if you hadn't participated in the study.

In the event of a COVID positive test your care home will be able to request a detailed report of contacts linked to the person with the positive test from Researchers at the University of Leeds. Your care home will then take appropriate measures to limit transmission – these measures may include isolation of people who came into contact with the person with COVID-19 infection and therefore at risk of being exposed to infection. This information can also be shared with NHS Test and Trace contact tracing queries.

6. Will my information be kept confidential?

The University of Leeds is the sponsor for this study and is based in the United Kingdom. We will be using anonymised information from you and/or your records held within the home in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Leeds will put arrangements in place to keep the collected identifiable information about you for 5 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Most of the information needed for the study will be collected electronically (secure computer system) or on paper forms and sent (usually using standard Royal Mail post but in some cases by encrypted email) to the study team at the CTRU. You will be allocated a unique study number, which will be linked to the device you wear and the limited personal information we collect (age/gender/ethnicity). This unique identifier will be linked to a list held within your care home only.

Your data will be entered onto a secure database held at the CTRU. All access to data and databases will be restricted just to the staff who require access to process and analyse the data.

Your anonymised data may be used in future by the organisations involved in this research for evaluation, teaching and training purposes relating to the provision of NHS care and treatment and for academic and non-commercial research purposes.

How will my information be stored?

Information collected about you will be processed by a researchers at the University of Leeds and entered and stored on CTRU systems. Your limited personal information will only be accessed by the research team.

All the data collected will be securely stored for up to 5 years after the end of the study and then destroyed.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by contacting University of Leeds Data Protection Officer at dpo@leeds.ac.uk
- CTRU Privacy Notice is available to read at https://ctru.leeds.ac.uk/contact.

7. More information about taking part

What will happen if I do not want to carry on with the study?

You are free to stop wearing the device at any time without giving a reason.

If you did wish to stop wearing the device, you would need to tell a member of the care home team supporting the study delivery, who would collect the device from you. The device would then stop collecting information from you. Data already collected on you and your device will be included in the final study analysis.

What happens when the research stops?

Your help with this study is complete once you are asked to stop wearing your device.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to your care home manager. You can also contact the study team (contact details on first page) who will do their best to answer your questions. There are no special compensation arrangements in place for this study.

What happens if new information about the study becomes available?

Sometimes during the course of a study, new information becomes available. If this happens your care home will let you know about it and you can decide if you want to continue in the study.

We will also keep your care home updated regarding study progress via newsletters. If you wanted to speak to anyone in the study team at any point about your participation, please use the contact details on the first page of this information sheet.

What will happen to the results of the research study?

We hope that this study and associated wider project will help inform how contact tracing devices can be used within care homes to support infection control and prevention strategies. When the study is complete the results will be published in a medical journal and all care homes will be sent a summary of the results, but no individual participants will be identified.

Who is organising, funding and reviewing the research?

The study is being organised and supervised by the University of Leeds. It is funded by the Department of Health and Social Care. All research is looked at by an independent group of people called a Research Ethics Committee to protect the safety, rights, wellbeing, and dignity of those taking part. This study has been reviewed and approved by <INSERT> Research Ethics Committee.

What do I need to do now?

Please let us know if you would not like to take part in the study by informing a member of the care home team supporting delivery of the study.

If you are happy to take part you will be given a device to start wearing and your care home will collect information required for the study.

8. Questions?

If you have any questions or would like more information, please contact us using the contact details on page 1 of this information sheet.