**Participant Information Sheet**

**Study Title**:

Investigation of the use and acceptability of digital remote monitoring for older people living in the community.

**ERGO number:** 71011 **IRAS number:** 311512 **Sponsor**: University of Southampton

**Chief Investigator**: Dr Nicola Andrews

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**You are invited to take part in this research study**

* To help you decide whether to take part it is important that you understand why the research is being done and what it will involve.
* Please read the following information carefully.
* Please ask questions if anything is not clear or you would like more information before you decide. Our contact details are above.
* You may like to discuss it with others. However, it is up to you to decide whether to take part.
* If you are happy to participate you will be asked to sign a consent form.

**What is the study about?**

The study will explore the use of two different approaches to digital remote monitoring used to identify changes in health or care needs. These are:

1. Monitoring using sensors to detect changes in daily activity; and
2. Monitoring of signs (such as oxygen levels) and symptoms of health conditions.

The study will investigate how acceptable these are for older people living with frailty. Frailty is a health condition related to the ageing process in which multiple body systems gradually lose their in-built reserves.

We are a research team working across two organisations:

1. the National Institute for Health Research (NIHR) Applied Research Collaboration (ARC) Wessex; and
2. the Wessex Academic Health Science Network (AHSN).

The study is part of the NHS Insights Prioritisation Programme, funded by NHS England. This aims to evaluate changes that have happened during the pandemic.

Due to the ageing population, it is a national priority to develop services that meet the needs of people living with frailty. Across Dorset, Hampshire and the Isle of Wight services that support care at home are being developed. Digital remote monitoring is one way to deliver this care. Its use has increased through the pandemic. Yet, there is a lack of knowledge about whether this is acceptable and suitable for people with frailty or their family and informal caregivers. There is minimal previous research in this area.

We wish to understand how older people use these services and how these services affect their family or informal caregivers. We wish to hear about the experiences of older people using these services and the experiences of their family or informal caregivers. We also want to check that people are treated equally.

**Why have I been asked to take part?**

You have been asked to take part because you are either a family member or provide informal care to an older person who is using or has recently used a digital remote monitoring service.

The health or social care organisation providing the digital remote monitoring service have identified you as a main informal caregiver. This organisation agreed to send this information about the study to you on our behalf.

We would like to include in the study between 4 and 8 individuals providing informal care to users of each of the two types of digital remote monitoring.

**What will happen to me if I take part?**

If you take part, we will ask you questions about your experience of the digital remote monitoring used by the person you care for. This will be in an interview. However, I f you will find it difficult to take part in an interview, we can offer the option to complete a questionnaire instead.

For interviews:

* You can choose whether the interview takes place: Face-to-face at your home; Over the telephone; or Online using Microsoft Teams. The face-to-face option will only be available if you live in the Wessex locality.
* The researcher who will interview you will arrange this at a time that suits you. It should take no more than 1 hour. You can have a break in this time if needed.
* We will audio-record the interview to capture your answers in full. Online interview recording includes video, but you can turn your camera off.

For questionnaires:

* You can complete this online or on paper. The questionnaire will take up to 45 minutes to complete. You need to complete the online questionnaire in one go as you cannot save it as you are going along.

We will analyse information from all interviews and questionnaires looking for common themes.

**Are there any benefits of my taking part?**

You will not receive any direct benefits.

However, we will share the findings with local health and social care organisations. This may lead to service changes that benefit you and/or the person you care for in the future.

**Are there any risks involved?**

We do not expect that taking part in this study will cause you distress. However, if you feel uncomfortable, we can end the interview early. If you require support after taking part in the study, you can contact the research team.

**What data will be collected?**

The data that will be collected are:

* Contact details including name, telephone number, email and/or postal address.
* Information about your experience of digital remote monitoring.
* The following personal data, so that we can compare responses from people with different characteristics:
  + Your age bracket (44 or under; 45–64; 65-84; 85+).
  + Your ethnicity.
  + Your relationship with the person you care for.
  + Where you live in relation to the person you care for (live with or approximate usual journey time)
  + The age bracket of the person you are caring for (65-74; 75-84; 85+).
  + Whether the person you care for has a diagnosis of dementia or cognitive impairment.

We will store your contact details in a separate location to all other information you provide. We will anonymise all other data. A unique code will replace your name and we will label your data with this code. If you opt to receive the study report, we will keep your name and either email or postal address until the end of the study so we can send it to you. The study is due to be completed by the end of March 2023. We will destroy your contact details within 3 months of this date. If you do not wish to receive the report, we will only store your details until after your interview or return of your questionnaire.

**Will my participation be confidential?**

The research team and the University will keep your participation and the information we collect about you during the research strictly confidential. We will not tell the organisation providing the digital remote monitoring service if you take part. There are some exceptional situations when your confidentiality may be breached, such as if there is a safeguarding or safety concern, but this will be discussed with you first.

Responsible members of the University of Southampton may be given access to information about you. This could be for monitoring purposes and/or to carry out an audit of the study to ensure that the research meets regulatory requirements. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All these people have a duty to keep your information strictly confidential.

We will collect data electronically where possible. We will store all data in electronic format by scanning any paper records, then shredding the paper copy.

Audio-recordings will be typed into text (transcribed). We will securely transfer recordings to a third-party, university-approved transcriber or for online interviews will use the Microsoft Teams transcription facility. When transcription is complete, any identifying details will be removed, and recordings destroyed.

We will store all data on University or Wessex AHSN password protected and encrypted computer systems, backed up on secure platforms. We will also store data in an encrypted study-specific SharePoint on the University network to allow sharing of data between researchers from the AHSN and ARC. The University will store your anonymised data for 10 years after the end of the study. Wessex AHSN will store your anonymised data for 6 years. Data will then be securely destroyed.

**Do I have to take part?**

No, it is entirely up to you to decide whether to take part. If you decide you want to take part, please leave a message for the research team (023 8059 7983, [N.M.Andrews@soton.ac.uk](mailto:%20N.M.Andrews@soton.ac.uk)). We will then contact you to discuss the study further.

**What happens if I change my mind?**

You have the right to change your mind and withdraw from the study. You do not have to give a reason and it would not affect the care of the person you care for or your legal rights. However, it may not be possible to fully withdraw your data, as your data may not be linked to you once analysis has started. In this situation, the data will be used in the analysis, but no quotes will be used in any publications or reports.

If you decide you wish to withdraw you should contact us (023 8059 7983, [N.M.Andrews@soton.ac.uk](mailto:%20N.M.Andrews@soton.ac.uk)).

**What will happen to the findings of the research?**

We will not include any information that can directly identify you in reports or publications of the research findings. The findings may be supported by quotes taken from your answers, but these will be anonymised.

We will report key insights to local organisations during the study, so that these can be used to improve services as soon as possible. At the end of the study, we will write a report which we will circulate to local health and social care providers and NHS England. We will send you a study report if you wish to receive one. We will also seek publication in an academic journal and opportunities to share the findings at events with professional and public audiences.

We will place the anonymised transcript of your interview or your completed questionnaire in the University of Southampton data repository, with all data that could make you identifiable removed. This will make your data available for future academic research and learning. Sharing research data means it can be reused and analysed from different perspectives. This offers opportunities to increase the pace of research. It will not be available for non-academic research.

**Where can I get more information?**

If you want further information after reading this information sheet, please contact the research team (023 8059 7983, [N.M.Andrews@soton.ac.uk](mailto:%20N.M.Andrews@soton.ac.uk)).

**What happens if there is a problem?**

If you have a concern about any aspect of this study, you should speak to the research team. We will do our best to answer your questions.

If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, [rgoinfo@soton.ac.uk](mailto:rgoinfo@soton.ac.uk)).

**Data Protection Privacy Notice**

The University of Southampton conducts research to the highest standards of research integrity. As a publicly funded organisation, the University must ensure that it is in the public interest when we use personally identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, ‘Personal data’ means any information that relates to and is capable of identifying a living individual. The University’s data protection policy governing the use of personal data by the University can be found on its website (<https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page>).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at <http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf>

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University’s policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason (‘lawful basis’) to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the ‘Data Controller’ for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University’s data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University’s Data Protection Officer ([data.protection@soton.ac.uk](mailto:data.protection@soton.ac.uk)).

**Thank you**

Thank you for taking the time to read the information sheet and considering taking part in the research.