CI: Prof Andrew Farmer
Research Team Contact: 01865 231448

VIABLE

PARTICIPANT INFORMATION SHEET

Remote monitoring in virtual wards for acutely unwell patients being managed and treated on an ambulatory care pathway: feasibility study

We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information and if anything is not clear, or if you would like more information, please ask us.

What is the purpose of the study?

The NHS is using virtual wards to look after patients at home. When at home patients are regularly called and visited by doctors and nurses. We have developed a system that uses monitoring devices that will be used by the patient. The devices will automatically take important health measurements (such as pulse, and blood oxygen level), and report them to the NHS team. The NHS team can use these measurements to help them decide what's best for their patient. Before the NHS can use this system, we need to check that it works reliably. This study will help us determine whether we can consistently collect and report these measurements. It will also check how patients found the devices; whether they were easy to use and comfortable to wear. After this study we plan to do more research into how this system could work and how we can make it most useful for the NHS and their patients.

Why have I been invited?

We are looking for patients who have visited the Oxford University Hospitals Ambulatory Assessment Unit, have been determined to be acutely unwell and will be cared for via the Hospital at Home virtual ward. We will recruit 35 patients in total.

Do I have to take part?

No! Taking part is entirely voluntary. If you change your mind, you can withdraw from the study at any time without giving a reason. Withdrawing from the study will not affect the care you would normally receive from the NHS.

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

To take part in this study we will ask you to wear/use some home monitoring devices. These devices will monitor your health while you are being looked after by the NHS Hospital at Home team.

These devices are:

1. a vital-sign chest patch (to measure pulse and breathing rate)
2. a pulse oximeter (to measure oxygen levels in blood)
3. a blood pressure monitor
4. a thermometer (to measure your temperature)

You will also be provided with a tablet computer (and charger) that will receive data automatically from the chest patch and the pulse oximeter. You will be given an anti-adhesive wipe to help you remove the vital-sign chest patch at the end of monitoring period (maximum 7 days) and a participant diary where you will record the measurements.

We will attach the vital-sign chest patch to you while you are in hospital and give the other devices to you to take them home. Measurements and readings from the vital-sign chest patch and the pulse oximeter will automatically be sent to the NHS Hospital at Home team via a tablet computer we will give you. You will wear the chest patch for the duration of the monitoring period (usually less than a week), and you will be asked to use the pulse oximeter ~6 times a day (it takes about 1 minute to use). We will also ask you to use the blood pressure monitor and a thermometer a couple of times each day and note down the results in a participant diary we will give you. Your health will usually be monitored for the duration of your care by the Hospital at Home team. This is usually less than a week, but we might monitor you for up to a maximum of 7 days if you have an extended stay. During the monitoring you will be able to contact the research team should you have any issues with the devices or questions about the study. The research team may contact you during the monitoring to make sure the devices are working properly or to check how you are getting on.

After the monitoring has ended:

- We will contact you to arrange for the monitoring equipment to be collected from you and to make sure you have removed the chest patch with the anti-adhesive wipe.
- A member of our research team will phone you one to four weeks after the end of monitoring to ask you how you found the experience and what you thought of the monitoring devices.
- Six months after you joined the study, we will collect some information from your hospital records about whether you have been back to hospital in the last six months, whether you have seen your GP in that time and how was your health. You will not need to do anything or be contacted for this; we will collect this information directly from the hospital.

What should I consider?

- You may not take part if you are pregnant.
- You will be able to undergo all your prescribed treatments and medications whilst also taking part in this study.
- You will be able to take part in most other research studies at the same time as this study. If you are involved in other research that requires you to wear additional monitoring devices please speak with a member of our research team as it may not be appropriate for you to take part whilst already being monitored.
- Before enrolling you in the study we will check you have a suitable mobile phone network at your address. This is to ensure that the data from the monitoring devices can be sent back to your NHS care team. If you do not have a good mobile phone signal you may not be able to take part in this study.
- You will have to perform your measurements with the monitoring devices a few times a day. In total this should not take more than approximately 15 min per day.

Are there any possible disadvantages or risks from taking part?

All the monitoring devices have been approved for use in the UK and will be used in accordance with their intended purpose. None of the devices are considered invasive and they should not cause any harm to the user through normal use.

There are a few things you should consider:

- Some people may find blood pressure monitoring be uncomfortable or even painful at times.
- Some people may find the adhesive on the chest patch can cause mild skin irritation. If you know you are particularly susceptible to rashes or skin irritation this may not be suitable for you. Please speak to a member of the research team if you believe this applies to you.

What are the possible benefits of taking part?

We hope that having your monitoring data available to your NHS care team will help them provide you with more targeted care and may make their visits and phone calls to you more efficient. This kind of monitoring might be beneficial for some patients and their NHS care teams.

Will my taking part in the study be kept confidential?

Yes. We endeavour to maintain participant confidentiality throughout the course of the study. All study records will be identified by a unique study ID. We will use your phone number, address, and email address (if you have provided one) where this is necessary to contact you, and your name and medical records number will be used by members of the NHS Hospital at Home team to identify data coming from your home monitoring devices. Data retrieved from your medical records via the OUH data warehouse will be held securely by the research group's data safe haven that has been approved for use by OUH.

Confidentiality will be maintained as far as it is possible, unless you tell us something which implies that you or someone you mention might be in significant danger of harm. In this case, we would have to inform the relevant agencies, but we would discuss it with you first**.** Responsible members of the University of Oxford and OUH NHS Trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

What will happen to my data?

UK General Data protection regulation (UK GDPR) requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the sponsor for this study, based in the United Kingdom, is the data controller and is responsible for looking after your information and using it properly.

We will be using information from you, and your medical records (which will be accessed directly and via the OUH data warehouse), in order to undertake this study and will use the minimum personally identifiable information possible. We will keep identifiable information about you for less than 3 months after the study has finished as we prepare the study for archive. This excludes any research documents with personal information, such as consent forms, which will be held securely at the University of Oxford for 5 years after the end of the study. The OUH Hospital at Home team will have access to your monitoring device data as part of this research. Research data collected and stored after the study ends will be de-identified (the link with the unique study ID code will be broken) and may also be shared online with other researchers in a data repository after the study results are published. After the study is finished, the anonymised data will be archived for 5 years at the University of Oxford.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights.You can find out more about how we use your information by contacting virtualhdu@ndcn.ox.ac.uk.

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

Participation in research is voluntary and you may change your mind at a later stage without giving a reason. Withdrawing from the study will not affect the NHS care you receive.

If you withdraw from the study, we will ask you:

1. If we can keep the data, we have already collected from you,
2. If we can collect any more data from you (without contacting you),
3. If you would like us to destroy all the data collected from you up to that point.

At the time of withdrawal we will arrange for all the study equipment to be collected from you.

What happens at the end of the study?

- We intend to report the results of this study on our website and by publishing the findings in academic journals. The results may also be discussed at relevant conferences.
- Participants will not be identified in any report or publication placed in the public domain.
- At the end of your participation we will write to you with details of where you can access our findings online.

What if there is a problem?

- If you have a concern about any aspect of this study, please speak with the research team. They will do their best to answer your questions.
- The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.
- NHS indemnity operates in respect of the clinical treatment which is provided.
- If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact Prof Andrew Farmer at andrew.farmer@phc.ox.ac.uk or phone 01865 289280.You may also contact the University of Oxford Research Governance, Ethics & Assurance Team (RGEA) office on 01865 616480, or, email RGEA.complaints@admin.ox.ac.uk.
- The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study. If you wish to contact the PALS team please contact **01865 221473** or PALS@ouh.nhs.uk.

How have patients and the public been involved in this study?

Service users, including former patients and their family members, have advised our research group on an ongoing basis for many years. We use their perspectives and experience to guide our study procedures and help us focus our research.

Who is organising and funding the study?

This research is organised and sponsored by the University of Oxford. This research is funded by the NIHR Oxford Biomedical Research Centre under the Digital Health from Hospital to Home theme.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by London - Camden & Kings Cross Research Ethics Committee.

Further information and contact details:

Please contact the VIABLE research team on 01865 231448 for further information.

Thank you for considering taking part.