

# Remote Patient Monitoring Study

Run by



**NHS**  
**West Essex**  
**Clinical Commissioning Group**



PATIENT INFORMATION LEAFLET



DATE

21 OCTOBER 2020



# PURPOSE OF THE STUDY

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The NHS is keen to improve the way it looks after all of us.

We know that recognising quickly if a person's health is deteriorating gives doctors a chance to intervene early and stop problems getting worse. That can make treatment more effective and means patients can recover better. Often it even avoids admissions or urgent visits to hospital.

In this research study we are testing if we can find out really early when someone is becoming ill and may need medical help. We are testing if taking regular health measurements can give us this information. These measurements will be taken using electronic devices, such as thermometers and blood pressure monitors that connect to the internet.

Once we have measurements from a large number of people, scientists will look at them to see if they can use the information to spot when treatment from a doctor would have been beneficial. We will use all the information we receive to write a report on how the NHS can improve patient care by using these types of electronic medical devices.

This study is being paid for by the NHS and it is being run by your local NHS organisation, West Essex Clinical Commissioning Group (CCG). L2S2 is a private company that West Essex CCG are paying to provide the electronic medical devices, securely store and analyse the data, and write up the results. West Essex CCG, the NHS Health Research Authority and the East of England – Essex Research Ethics Committee have reviewed and approved the study design.



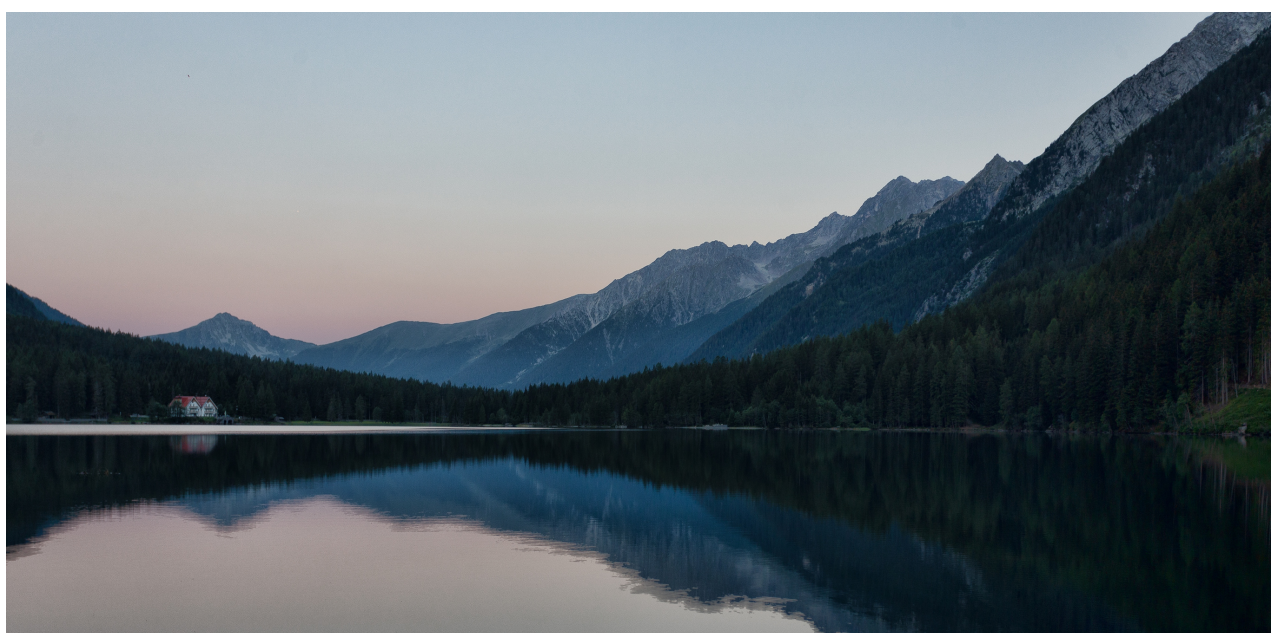
# WHY HAVE YOU BEEN ASKED TO TAKE PART?

For the first phase of the study, we are including people living in the Uttlesford area who are over the age of 65 and have two or more chronic health problems or are frail.

Your GP has selected you based on your medical history and has invited you on our behalf. No information about you has been or will be passed from your GP to the Research Team until you agree to take part in the study.

Please note:

- You do not have to take part in this study if you do not want to.
- The NHS will not treat you any differently if you decide not to take part.
- If you start the study, you can choose not to finish it.





# WHAT WILL HAPPEN IF YOU TAKE PART?

*We will answer your questions and confirm your consent*



If you agree to take part in this study after you have read all the information provided here, you should complete the enclosed consent form and return it to your GP practice in the envelope provided. You are welcome to speak to a friend, relative or carer before you decide to take part.

If you have read all the information provided and would still like to ask more questions, you should call The Clinical Research Network on XXXXX. The Clinical Research Network support lots of research studies like this one in the UK and will be able to answer any questions you have. They can also take your consent over the telephone if you are happy to take part, which means you will not need to post your consent form back to your GP practice. The Clinical Research Network will need to take some personal details from you in order to do this and they will ask you if that is ok when you call.

If you do not want to take part, you do not have to, and you do not need to let us know. If we do not receive your consent form within two weeks, we will assume you do not want to take part and you will not be contacted again regarding this study.

**If you are willing to take part, please complete and return your consent form within one week of receiving this invitation.**

The consent form will be used to show that the study has been properly explained to you and that you have agreed to take part. Each statement on the form has a box next to it for you to write your initials if you agree to it. This is important as we must confirm that you have read, understood and given your permission for us to do all things listed.





# WHAT WILL HAPPEN IF YOU TAKE PART?

The consent form will ask you to confirm that:

- You have read and understood all the information about the study and have had all your questions answered satisfactorily
- Taking part is voluntary and you can stop taking part at any time without this affecting your medical care or legal rights in any way
- Members of the Research Team will read relevant sections of your medical history and that you give permission for the Research Team to access this information
- You understand that the information collected about you will be used to support other research in the future and may be shared anonymously with other researchers
- You agree for your GP to be involved in this study and that necessary information about you will be exchanged between your GP and the Research Team
- You understand the information held by L2S2 Ltd may be used to contact you or provide information about your health status
- You agree to take part in the study





# CONTACT BY A MEMBER OF THE RESEARCH TEAM

*You will be contacted by a member of the Research Team*



Due to Covid-19 we will not ask you to attend any face to face appointments or meet with the Research Team in person at any point during the study. We are committed to making sure you are not exposed to the virus at any point as a result of taking part and have designed the study very carefully so that you can participate safely and remotely from the comfort of your own home.

To do this this, we will only contact you by phone, email and via the Reassure App that will be used as part of the study.

Once you have provided your consent to take part a member of the Research Team will telephone you to talk through the study and get you set up, ready to start.

During your initial phone call, the Health Research Assistant will:

- Check that you are still happy to take part in the study
- Speak with you about the study and carry out safety checks before starting, such as making sure you are not allergic to any of the materials used in the medical devices being given to you
- Discuss the medical devices that will be given to you and make sure you are completely happy to use them. If you are not, they will not be sent to you and you will not be asked to use them.
- Explain how often you will need to take your health measurements
- Confirm your address so that the medical devices and equipment can be sent to you by post



# THE EQUIPMENT FOR THE STUDY

*You will be sent the medical devices and  
equipment by post*



You will be sent electronic medical devices and a mobile phone to use at home during the study. The medical devices you are given will depend on your current health, for example you might be given a blood pressure monitor, a thermometer or a peak flow meter.

We will only use officially approved medical devices to take the readings and we will use a copy of your health record from your GP to work out the types of readings we should take from you.

You will also be provided with a mobile phone. It does not have lots of different functions on it like a modern mobile phone. For example, you cannot use it to make telephone calls or search the internet. It will only be able to do the following things:

- It will automatically send the readings from the medical device(s) over the internet to us so we can analyse them for the study.
- It will allow us to send you messages asking you to do things, like take another reading.
- We will also use it to ask you some general questions like 'How you are feeling today?'.





# LIST OF DEVICES BEING USED IN THE STUDY



Home Hub



Thermometer



Blood Pressure



Blood Sugar



Blood Oxygen



Peak Flow



Scales



ECG



Urine Ketostix





# HOW TO USE THE EQUIPMENT

## *Explaining how to use the equipment to take your health readings*

Step by step instructions on how to use the medical devices to take your health measurements will be included in the Reassure App on the mobile phone we provide you. You will also be sent printed instructions so you can refer to it without using the mobile phone and you will be able to phone a member of the Research Team to ask questions and get extra support at any time if you need it.

The medical devices and mobile phone are designed to be very easy to use but we are testing this as part of the study, so you will be encouraged to tell a Health Research Assistant if you find using any of the equipment difficult.

The medical devices are connected to the internet. This means we can record your readings easily and analyse them later. It also means that readings are sent from the medical devices to the research team automatically.





# PARTICIPATING IN THE STUDY

*You will take your own health measurements at home every day*

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The health readings you take at home each day will provide the Research Team with the information they need to complete the study. The Research Team will explain when and how you should use the medical devices to take your health readings during your initial telephone call, but it is likely that this will be once a day every day.

Every time you take health readings you will need to:

- Answer two or three short questions on the mobile phone to tell us how you are feeling.
- Take the health readings we have asked you to take using the medical devices at the planned times.
- Occasionally take extra readings if you are asked to do so.

You will also need to keep the mobile phone charged. We will explain you how to do this and will send you reminders on the mobile phone when it needs to be done or if the battery is running low.

**We will not be analysing your health readings to monitor your health directly during the study so it is REALLY IMPORTANT that you contact your doctor as usual if you feel unwell or think that you need medical attention.**

Don't worry if you forget to take a health measurement. You will be reminded to take them by the Research Team, by a message sent to the mobile phone, but it doesn't matter if you forget to take a health measurement.



# CONTACT DURING THE STUDY

*We will call you regularly throughout the study*

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Everyone will be called by a Health Research Assistant twice a week during the study to make sure they are getting on well with taking their health measurements and are happy to continue taking part in the study. This will also be an opportunity for you to ask questions, raise any concerns you might have and talk in general about how you are finding the study.

This research study is purely observational, and the Research Team will not be monitoring your health during the study. The data collected will be looked at some time after it is collected and so it would not be possible to intervene if the data showed you might be unwell. The Research Team will not be able to give you medical advice over the telephone, so if you feel unwell you should either contact your doctor as usual, call NHS 111 or dial 999 if it is a medical emergency.

All information will be kept confidential, unless you tell us something that indicates there is a risk of harm to you or others.

If you would like more information about the study or help to decide whether to take part, please call the West Essex Study Team at L2S2 on 01223 234550 if you want more information about the study or need help at any point. You can leave a message for Dr Philip Gaffney, or email [WECCG@L2S2.com](mailto:WECCG@L2S2.com), they will arrange for the right person to speak to you.

For general information about research in healthcare, please visit this link:  
<https://www.gov.uk/guidance/good-clinical-practice-for-clinical-trials>

To join the study call: XXX



# FREQUENTLY ASKED QUESTIONS

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## How long will you need to take part for?

We would like you to take part in the study for twelve weeks (three months). We might ask you to take part for longer if you are happy to do so but we will discuss this with you at the end of the first twelve weeks. You will not be asked to take part long than twenty four weeks (six months) in total.

If you become unwell unexpectedly and you need urgent treatment either in hospital or from your GP, we will need to ask you to stop being part of the study.

If you change your mind about taking part in the study, we will only keep anonymised measurements we have taken for you up to the point when you stop, and we will anonymise your medical history. This means it can no longer be linked to you.

## Are there any risks from taking part?

We have set up this study very carefully. The risks of harm to you are the same as or less than the risk for you of using any normal sort of electronic equipment at home. We are using official medical devices that are safe for anyone to use and have been carefully tested so that they should not be able to harm you.

## Will taking part affect your medical treatment?

This study is purely about research and analysing readings from a large number of people. Your medical treatment will not be affected as a result of the study and the study will not be used to diagnose any new medical conditions.

You should continue to take any medication you are on as normal and continue to attend any health care appointments as planned.





# FREQUENTLY ASKED QUESTIONS

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## Will the care you receive from the NHS change after the study?

No, the care you receive will not change in the immediate future. The NHS may decide to make changes after it has seen the results of this study. However, any changes are likely to take several years to be put in place.

## What will happen after the study ends?

At the end of the study we will write a report for West Essex CCG with our findings and our recommendations for how this new technology could be used to improve NHS services. You will not be mentioned personally in any report, and it will not be possible to find out that you were involved in the study from the study report.

Within three months after the end of the study we will send you a report with our findings.

If you have been given medical devices to use, you will be allowed to keep them at the end of the study.

## Reimbursements and benefits

You will not be given any money or gifts to take part in this research study.

It is probable that you will not benefit yourself from taking part in this study. We hope that people in the future with similar health problems will receive better treatment earlier, helping them live longer happier lives. You will have helped to make this happen because you took part in this study.

It is possible that an organisation might benefit commercially from the results of the study because any improved healthcare process that results from this research could be set up and run by a profit-making enterprise. If this happens, you will not benefit financially in any way.



# ADDITIONAL INFORMATION

## Complaints

If you have any problems during the study or you wish to make a complaint, please call L2S2 on 01223 234550.

The researchers will answer your questions and direct you to appropriate person in charge of this study to address your concerns or complaint.

If you remain unhappy and wish to escalate your complaint further, please email Dr Philip Gaffney at [WECCG@L2S2.com](mailto:WECCG@L2S2.com) or write to use at 2a Oakington Business Park, Dry Drayton Road, Oakington, Cambridge, England, CB24 3DQ.

You can also escalate your complaint to West Essex Clinical Commissioning Group in the following ways:  
Telephone 01992 566122/6123 Freephone: 0800 7833396  
(Monday to Friday 10:00am-4:00pm, we have a confidential voicemail available.

If you leave us a message we will call you back the next working day) or email [weccg.comments@nhs.net](mailto:weccg.comments@nhs.net)

## If you are harmed during the study

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against West Essex Clinical Commissioning Group but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

If you are harmed during the research, you should report it to West Essex Clinical Commissioning Group in the following ways:  
Telephone 01992 566122/6123 Freephone: 0800 7833396  
(Monday to Friday 10:00am-4:00pm, we have a confidential voicemail available. If you leave us a message we will call you back the next working day) or email [weccg.comments@nhs.net](mailto:weccg.comments@nhs.net)



# ADDITIONAL INFORMATION

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## How will we use information about you?

We will need to use information from your care home manager and your GP for this research project. This information will include your:

- Initials
- NHS number
- Name
- Contact details
- Medical history

We will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Some of your information may be sent to a company called Feebris to assist with this research. They must follow our rules about keeping your information safe.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

## What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from your GP. If you do not want this to happen, tell us and we will stop.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.



# ADDITIONAL INFORMATION

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/](http://www.hra.nhs.uk/information-about-patients/)
- a leaflet available from: [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch)
- by asking one of the Research Team
- by sending an email to [WECCG@L2S2.com](mailto:WECCG@L2S2.com)
- by ringing L2S2 on 01223 234550 or by ringing West Essex CCG on 01992 566122/6123 Freephone: 0800 7833396 and asking to speak to the Data Protection Officer

L2S2 is audited on a regular basis by NHS Digital and other professional audit organisations. (BSI accredit L2S2 to ISO 27001 and ISO 13485).

These are data security and medical quality standards. These audits ensure that L2S2 meet the legal requirements necessary for them to undertake this research study.



## reassure

