RESILIENT Participant Information Sheet

Study Title: Predictive approaches in managing people with long-term conditions at risk of dementia: from remote monitoring data to digital biomarkers, a feasibility study.

Overview

You are invited to take part in a research study involving people with long-term health conditions and the people who support them.

There are multiple factors that can influence a person's risk of developing dementia including medical, lifestyle and environmental factors. Research has shown that having multiple long-term health conditions is one factor that may increase an individual's risk of developing dementia, if poorly managed. It is important to highlight that having risk factors does not mean that someone will go on to develop dementia but does mean that their risk is increased.

Our two-year study will investigate the feasibility of using health data generated from in-home devices and questionnaires to create algorithms that could help predict health deterioration.

In this study we will use information provided by you and your medical records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will follow all privacy rules. At the end of the study we will save some of the data in case we need to check it and/or for future research. We will make sure no-one can work out who you are from the reports we write.

In future, we hope to use the results from this study to design a larger scale trial that will investigate whether this type of data can help you and your clinician make better, more informed decisions about your healthcare.

This information sheet explains more about the study and how you will be involved.

Contents

What is the purpose of the study?

The RESILIENT study is the result of many years of collaboration and research developing and optimising in-home monitoring systems to support people living with dementia. We now want to expand and explore the possible benefits of remote health monitoring for people with long-term health conditions and the people who support them.

Our objective is to evaluate the feasibility of using in-home devices to remotely monitor the health of individuals aged 65 years and over, who have two or more long-term conditions. The data collected from the devices and questionnaires over the course of the study will be used to explore whether it is possible, in the future, to predict health deterioration before it occurs.

We will also work with your usual care team to explore the feasibility of using the data from the devices and questionnaires to generate health reports that may help with decision making.

Furthermore, we would like to explore the possibility of using data to support carer wellbeing. Therefore, we are inviting study partners who live with participants to try the devices and complete questionnaires.

Why have I been chosen?

You have two or more long-term health conditions, **or** you live with and support someone who has two or more long-term health conditions.

What will happen if I take part?

One of our research assistants will contact you to book a convenient time to visit you at your home. During the visit, we will go through this participant information sheet with you, answer any questions you may have and ask for your written consent to take part. After gaining your consent, we will go through several questionnaires looking at your health, memory and wellbeing.

We will then support you to set up the devices that we will provide free of charge for the duration of the study. This visit should take about 2 hours.

We encourage you to use the devices as described on the next page. This will help us identify changes in your health if they occur. We do not expect you to make any lifestyle changes during this study.

What devices are used in the study?

Smart Watch

We will ask you to wear the smart watch every day. The smart watch will continuously measure your heart rate and activity levels (e.g. step count).

The watch can be worn during all your activities i.e., showering, playing sport, sleeping. You are welcome to remove the watch at any time if it becomes uncomfortable.

Digital Weighing Scales

We will ask you to weigh yourself using the smart scales at least once a week. There are two types of scales: one type measures weight and hydration levels and the other, provided to those with a pacemaker, only measures weight.

Sleep Mat

The sleep mat will be placed under your mattress where you sleep. The sleep mat will record your time spent in bed, sleep quality and heart rate while you sleep. The sleep mat will collect this data automatically and can stay under your mattress for the length of the study.

Who is providing the devices and the app?

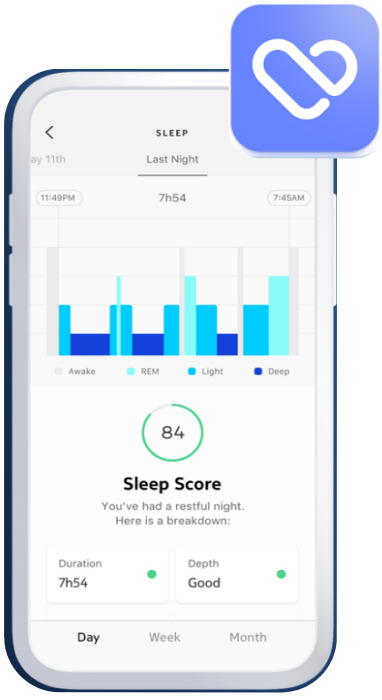
The devices and the app have been purchased from a company called ‘Withings’. Withings is a supplier for the study and does not hold any influence over the results or devices we have chosen.

Can I see my health readings?

Yes, during the first visit we will support you to set up the Health Mate app on your smartphone or smart tablet. We can provide a smart tablet if you do not have one or prefer not to use your own.

The app is free to download from the app store. We will set up a secure email and password for you to use this app.

Once set up, you will be able to use this app to view the health data collected by the devices. This includes your sleep quality (from the sleep mat), weight (from the scales), heart rate and activity levels (from the watch). You are free to use the app to view your health readings as often as you would like to.



It is important to note:

This study does not replace your normal healthcare. If you are feeling unwell or concerned about your health, please seek medical assistance from your GP or emergency services.

Summary health reports

A health report will be generated using the data collected from the devices and questionnaires. This will be sent to you and your care team at the Hub for review. The report will be sent weekly but the frequency might change during the study depending on your and your care team's needs. This report may highlight changes in your health which the Hub care team will follow-up with you if needed.

Research Visits

Every three months, we will ask you some questions about your health, memory and wellbeing. This may be in person, over the phone or online using a link sent to you by email. Each visit will be booked in advance at a convenient time.

Do I have to take part?

No, if you decide not to take part, this will in no way affect your rights or the care you receive.

You are also free to withdraw your participation at any time, without giving us a reason. If you choose to withdraw, your decision will not compromise your rights or the standard of care you receive. At the point of withdrawal, no further information will be collected by the devices and they will be removed from your home.

The data that has been collected up to the point of your decision to withdraw will still form part of the data analysed at the end of the project.

How will this benefit me?

There will be no direct benefit to you. However, the healthcare team at your Hub service may contact you if they identify a health reading outside your normal range in the health report.

Are there any risks/disadvantages?

Your participation in the study is strictly confidential and the risk of identifiable information being unintentionally disclosed is extremely low.

Further supporting information & FAQ's

Who will have access to my data?

The data that you provide will be kept strictly confidential. You will be assigned a unique identification (ID) number which is used to identify your data.

Withings will have access to pseudonymised data generated by your use of the devices. As will all technical devices connected to the internet, there will be a unique identifier (known as your IP address) that will be available to them. Withings is subject to data protection regulations and have a legal duty to protect personal data. We ask that you do not add any identifiable information to the app or change any of the privacy or security settings. We will create dummy accounts and will use unidentifiable research email addresses during account set up.

Study documents will be stored in a locked filing cabinet in the Research and Development Department at Surrey and Borders Partnership NHS Foundation Trust. An electronic copy of this will be kept on a password protected computer file.

Your anonymised data may also be shared with other researchers to support other research studies and used in further data analysis. We will not store personally identifiable information such as your name and address with your questionnaire data so your answers cannot be linked back to you. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

How will we use information about you?

We will need to use information from you and your health records for this research project.

Identifiable information will include your:

- Name
- NHS number
- Contact details

Approved individuals from Surrey and Borders Partnership NHS Foundation Trust and Imperial College 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, NHS number, or contact details. Your data will be assigned a code number which will be used instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. Any results we publish, will be written in a way that ensures no-one can work out that you took part in the study.

What are my rights and choices about the data you hold on me?

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. If you would like to stop taking part in the research study, we will continue to collect data from your health record for the duration of the study. If you would not like us to do this, then please let us know.

If you agree to participate in the study, you can give permission for your anonymised data to be stored by Imperial University for the use in future research. Other organisations, such as Academic Institutions or Charities, can apply to access this data. All applications will have to evidence that their research has undergone ethical review prior to any data being shared. To safeguard your rights, we will use the minimum personally identifiable information possible.

Will my General Practitioner (GP) be informed?

Yes, it is routine practice to inform your GP that you are taking part in a research study. Your GP will be provided with details of the study. If something is found during the research visit that could be relevant to your health, the research team will alert you and your GP so it can be followed up.

What will you do with my personal information when the research study stops?

Surrey and Borders Partnership NHS Foundation Trust will be responsible for retaining anonymised and non-anonymised data from this study for a minimum of 10 years after the study end and must obtain the permission of the Chief Investigator (Professor Ramin Nilforooshan) if they wish to delete or archive data.

What will happen to the results of the research study?

The results of this research will guide future research studies and may be used in future clinical research applications, published in scientific journals and/or may be presented at a conference. You will not be identified in the results or publication report unless you have given your consent for this.

Who is organising and funding the research?

This research study is being sponsored by Surrey and Borders Partnership NHS Foundation Trust. It is funded by the Engineering and Physical Sciences Research Council (EPSRC) and National Institute for Health and Care Research (NIHR).

Who has reviewed the research?

This study has been reviewed and approved by the London – Surrey Borders Research Ethics Committee and the Health Research Authority, and registered on the IRAS system (integrated research application system) reference number 321104.

Will I have to travel as part of the study?

We do not predict that you will need to travel for this study as all visits will happen at your home or over the phone, However, if required, we will reimburse any travel expenses that occur as a result of your participation.

What happens if I go on holiday during the study or wish to take a break from using the devices?

Please contact the research team if you have an upcoming holiday or would like a break from the devices. This is so we can adjust the summary reports accordingly. You can take a break from using one or more of the devices at any time.

What if something goes wrong?

Should you become injured as a result of your participation in the study you should contact us straight away as you may be eligible for compensation. The study is covered by a no-fault compensation policy underwritten by the Newline Group.

Contact Details

Who can I contact if I have questions or concerns about the study?

You can contact one of the researchers or the chief investigator if you have any questions or concerns about the study. This could include questions about the data captured in the app or by the devices.

Chief Investigator: Dr Ramin Nilforooshan – 01372 216 584

Research team: Please call 01372 216 596

Who can I contact if I have a problem with the devices?

If you experience any difficulty with the devices during the study, please contact us by emailing research@sabp.nhs.uk, putting RESILIENT in the subject line, or call 01372 216 596.

Need further details on how we use the information we keep about you?

If you need further details about how we use the information we keep about you, please ask a member of the research team. Alternatively, you can contact Surrey and Borders Partnership NHS Foundation Trust's Data Protection Officer at: dpo@sabp.nhs.uk. You can also find more information in this online leaflet: http://www.hra.nhs.uk/patientdataandresearch

What if I am unhappy and wish to make a complaint?

If you remain unhappy and wish to complain formally, you can contact:

Patient Advice and Liaison Service (PALS)

Call: 01372 216 202

Email: rxx.palsandcomplaintssabp@nhs.net