Participant Information Sheet

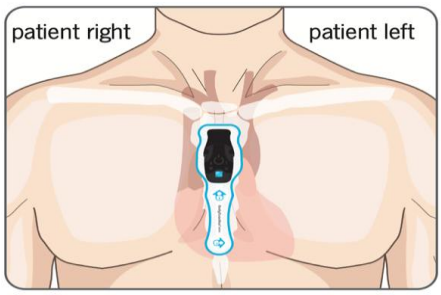
The ASPIRED Study

You are invited to take part in a research study. To help you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully before deciding whether you wish to take part. If there is anything that is not clear or if you would like more information, feel free to contact us.

What is the purpose of the study?

Syncope (sudden loss of consciousness also known as blackout or fainting) causes over 600,000 people to visit emergency departments every year in the UK. Often, by the time the patient is seen by the medical team, they have fully recovered making it hard to diagnose the underlying problem.

An extended mobile heart ECG monitoring device (see picture below) has been recently developed. This device can record your heartbeat and heart electrical rhythm tracing for up to 14 days. By recording your heartbeat and heart electrical rhythm after your attendance at the emergency department, we hope to have a better chance of diagnosing the underlying problem that caused you to visit the emergency department.



This study aims to discover whether by providing patients with a 14-day mobile heart ECG monitor, we can better diagnose and treat the cause of their sudden loss of consciousness and reduce the number of further episodes.

Why have I been invited to take part?

You have been asked to take part as you have come to the emergency department after experiencing a sudden loss of consciousness.

Do I have to take part?

No, it is up to you to decide whether to take part. If you do decide to take part, you will be given this information sheet to keep and will be asked to sign a consent form. If you agree to take part, you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

What will happen if I take part?

If you decide to take part, our research team will ask if you have any questions about the study. You may wish to take some time to decide whether to take part in the study but if you are still happy to take part, they will ask you to sign a consent form. You will be asked some questions, for example, about your day-to-day activities and our team will talk through how the device will be attached and operate. You will then be randomised (like a toss of a coin) to either receive the 14-day mobile heart monitoring device, or not. If you are randomised to

receive the extended mobile ECG monitoring device you will be shown how the device works. You will be required to either fit it yourself at home or be fitted with it in the hospital, which will take around 15 minutes. We would ask you to continuously wear the device for up to 14 days. It is the size of a watch face, is non-invasive, water-resistant and is discreet to wear. It continuously monitors the heart for up to 14 days including during sleep, in the shower, and during moderate exercise. It does not impact on activities of everyday life such as showering, swimming and other exercise, or your choice of clothes especially in warmer weather, as it sits comfortably underneath these. In the event of you having a sudden loss of consciousness/blackout or fainting whilst wearing the heart monitor you will be required to press the button on the heart monitor after the episode. You will also be required to complete a paper symptom diary to record when one of the episodes occurred. After wearing the device for 14 days, you will return it to the device manufacturer in a pre-paid envelope for interpretation. Your research team will receive the results of your ECG recording from the manufacturer and these results will be discussed with you during a future hospital appointment. You can view a short video describing how the 14-day mobile heart ECG monitor is fitted and is operated either by following this link: ASPIRED Study 14 day ECG monitor video – participants or via this QR code:

If you do wish to take some time to decide whether to take part in the study and have returned home or have been offered the opportunity to participate in the study after your hospital stay, you will be contacted by a member of the study team. If you are randomised to receive the extended mobile ECG monitoring device, you can either re-attend the hospital (travel expenses will be paid) for it to be fitted or it can be sent out to you and our study team will contact you to help you fit it yourself.

Half of people who are randomised will not receive the 14-day mobile heart ECG monitor and will be investigated as normal, which may include the use of a standard heart monitor. This will allow us to clearly see what the difference in diagnosis and treatment is for the two patient groups. Whether you are randomised to receive the heart monitor or not, the rest of your clinical care today will not change.

Once a month for 2 years, we will contact you either by text, email, or phone call (whichever you prefer) to complete a very brief questionnaire comprising of two questions; you will be asked whether you have had any further episodes of sudden loss of consciousness, and the number of visits to your GP for any reason (but we won't be asking what these visits were for). You will also be asked to complete a quality-of-life questionnaire today and in one and two years asking how you are feeling, and about your day-to-day activities. Finally in one years' time you will be asked to complete a satisfaction questionnaire. A member of your local research team will also collect information relating to the research from your hospital records over the two years of your participation.

When you are taking part in this study, your data will be stored securely and in alignment with the General Data Protection Regulations and confidentially agreements. Your data will be viewed by permitted colleagues only from your local hospital team, Edinburgh Clinical Trials Unit and individuals from the trial sponsor and regulated authorities. We will seek permission from you for your local study team to hold your identifiable data for up to 15 years before it is destroyed. This is in case we wish to contact you in future to invite you to take part in future ethically approved studies looking at your health in 5-15 years from now. This is optional. If you do not wish to consent to this, your participation in this study is not affected.

Today	Monthly
All Participants: Sign a Consent Form Complete a Questionnaire	**All Participants:** Complete a monthly questionnaire by text, email, or phone call for 2 years Complete a yearly questionnaire by post or email for 2 years
Half (50%) of Participants: Receive the mobile ECG heart monitoring to wear continuously for 14 days	

What are the possible benefits of taking part?

If you are randomised to test the 14-day mobile heart ECG monitor, there is the possibility that we may find a heart-related problem that may not have been detected otherwise. This information will be shared with your clinical team to arrange appropriate further tests and treatments as necessary. Otherwise, there are no direct benefits to you taking part in this study, but the results from this study might help to improve the healthcare of patients in the future.

What are the possible disadvantages of taking part?

No significant risks have been identified with either wearing or not wearing the 14-day heart monitor. There is a very small risk of minor skin irritation from the 14-day heart monitor which will settle on removal of the patch. Should this happen your study team can provide you with adhesive strips suitable for sensitive skin.

It is possible that the monitor may reveal an incidental health problem that you or your doctor is unaware of. In this situation you would then be seen in a hospital clinic by a specialist doctor who will arrange appropriate further tests and treatments as necessary.

All participants are required to complete a monthly questionnaire over the phone/text/email once a month for 2 years. This questionnaire is likely to take no longer than three minutes to complete every month.

What if there are any problems?

If you have a concern about any aspect of this study, please contact **Rachel O'Brien, Tel: 0131 242 3867** who will do their best to answer your questions.

In the unlikely event that something goes 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 NHS Lothian but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

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

You are free to withdraw from the trial at any time. The reasons you give for this will be recorded, but you do not need to give a reason if you do not wish to do so. Data collected up until that point may still be used to inform the study unless you specifically ask for that data not to be used.

What happens when the study is finished?

When the study is finished, anonymised data will be stored by the Edinburgh Clinical Trials Unit (ECTU). No identifiable data will be passed to the device manufacturer who will only have details of your study number. All study documentation will be kept for a minimum of 3 years. Anonymised data may be used in future studies which have relevant permissions in place. You will be asked if you agree for identifiable data to be stored by your local study team for up to 15 years in order that it may be used for future ethically approved studies. This

is in case we wish to contact you in future to take part in future ethically approved studies looking at your health in 5-15 years from now. You can opt out of this without affecting your trial participation.

Will my taking part be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage.

If you are part of the group receiving the 14-day mobile heart monitoring device you will return the ECG device to the manufacturer (Preventice Solutions uk) who will interpret your ECG recording and provide a report to your research team. To protect your personal details Preventice UK will only receive your unique study ID number.

We will use a third party text message provider to send your 4 weekly text message. This provider has been approved for us to use by the study Sponsor and NHS Lothian Information Governance. To protect your personal information when we contact you 4 weekly by text message we will not use your name and ask that you do not send personal details in response to this text message.

If there is a problem with your personal phone/device used to access the study questionnaire, the study Sponsor and NHS Lothian are not responsible for rectifying the issue or any resulting data loss.

How will we use information about you?
We will need to use information from you and from your medical records for this research project.

This information will include your:

- Hospital number, NHS number, Health and Care number, or Community Health Index (CHI) number (patients in Scotland only). The Community Health Index (CHI) is a population register, which is used in Scotland for health care purposes. The CHI number uniquely identifies a person on the index.
- Name.
- Contact details – address, telephone number and email address.
- GP details – to let your GP know that you are taking part in the study.

People 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. 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 central NHS records and your hospital. 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.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

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/
- our leaflet available from [**www.hra.nhs.uk/patientdataandresearch**
- by asking one of the research team
- by contacting the Data Protection Officer at either
    - University of Edinburgh. Email: dpo@ed.ac.uk or call 0131 651 4114
    - NHS Lothian: Lothian.DPO@nhs.net or call 0131 465 5444

What will happen to the results of the study?

This study will be written up as a publication for a medical journal and the team will aim to present the findings at relevant conferences. You will not be identifiable from any published results.

If you wish to see a copy of the results of the study you can email emerge@nhslothian.scot.nhs.uk. These will not be available until after the study has been completed.

Who is organising and funding the research?

This study has been organised by the University of Edinburgh and NHS Lothian and is funded by the British Heart Foundation.

Who has reviewed the study?

The study proposal has been reviewed by a team of patient representatives who have had personal experience of this condition.

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. A favourable ethical opinion has been obtained from South East Scotland Research Ethics Committee 01. NHS Management Approval has also been given.

Researcher Contact Details

If you have any further questions about the study please contact the EMERGE research team on Tel: 0131 242 1284.

Independent Contact Details

If you would like to discuss this study with someone independent of the study, please contact Professor Alasdair Gray (NHS Lothian) at emerge@nhslothian.scot.nhs.uk.

Complaints

If you wish to make a complaint about the study, please contact:
NHS Lothian Patient Experience Team, Waverley Gate, 2 – 4 Waterloo Place, Edinburgh, EH1 3EG
Tel: 0131 536 3370

CONSENT FORM
The ASPIRED Study

Participant ID: _____

Please **initial** box

1. I confirm that I have read and understand the information sheet (Version 7.0 30 08 2023) for the above study. I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care and/or legal rights being affected. ☐
3. I give permission for the research team to access my medical records for the purposes of this research study. ☐
4. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Sponsor (University of Edinburgh and NHS Lothian), from regulatory authorities or from the NHS organisation where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data and/or medical records. ☐
5. I give permission for my personal information (including name, address, date of birth, telephone number, email address and consent form) to be passed to the University of Edinburgh and Edinburgh Clinical Trials Unit (ECTU) for administration of the study. ☐
6. I give permission for my Community Health Index (CHI) number and/or my NHS number and/or my Health and Care number to be collected and passed to the University of Edinburgh and ECTU. ☐
7. I agree to my General Practitioner being informed of my participation in the study. ☐
8. I understand that data collected about me during the study may be converted to anonymised data. ☐
9. OPTIONAL: I agree to my identifiable data being stored by the local study team for up to 15 years in order that it may be used for future ethically approved studies. These studies may involve recontacting me, as well as accessing my routine electronic healthcare records (hospital and GP). Yes ☐ No ☐
10. I agree to my anonymised data being used in future studies. ☐
11. I understand that the data generated during this study may be used for future commercial development of products and I will not benefit financially from this. ☐
12. I agree to take part in the above study. ☐

Name of Person Giving Consent	Date	Signature
Name of Person Receiving Consent	Date	Signature
Name of Person Witnessing Consent (Required for phone consent only)	Date	Signature

1x original – into Site File; 1x copy – to Participant; 1x copy – into medical record