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**Phone Participant Information Sheet**

**The ASPIRED Study**

**Guidance for researchers**

This information sheet and consent form is only to be used for participants who are willing to provide verbal consent over the phone without receiving the full participant information sheet. The following text is provided as minimum information that should be provided to participants during the phone discussion.

Following consent all participants should be provided with a copy of the full participant information sheet and a copy of the consent pages from this information sheet.

Before using this phone participant information sheet, the researcher should confirm the following by initialling the following boxes:

1. The participant has been given the opportunity to attend hospital to

provide written informed consent in person

2. The participant has been given the opportunity to receive the full

information sheet prior to consent but is happy to proceed with only

verbal information before randomisation

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| We would like to invite you to take part in a research study. This short summary explains what the research is about. Before you decide if you wish to participate you need to understand why the research is being done, what it would involve and the potential disadvantages and benefits. |
| **What is the purpose of the study?** |
| Syncope (also known as blackout or fainting) causes over 600,000 people to visit an Emergency Department (ED) every year in the UK. Often, by the time the patient is seen, they have fully recovered making it hard to diagnose the underlying problem. An extended mobile heart ECG monitoring device has been recently developed that can record the hearts electrical rhythm for up to 14 days. This study aims to discover whether by providing patients with this 14-day mobile heart 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 invited to take part because you have come to the ED 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. |
| **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 and will ask you to sign a consent form. You will be asked some questions about your day-to-day activities and our team will talk through how the monitoring device will be attached and operate. You will then be randomised (like a toss of a coin) to either receive the monitoring device, or not. Half of people who are randomised will not receive the ECG monitoring device and will be investigated as normal, which may include the use of a standard heart monitor. Whether you are randomised to receive the heart monitor or not, the rest of your clinical care today will not change.  If you are randomised to receive the 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, 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 discreet to wear. It continuously monitors the heart for up to 14 days including during sleep, in the shower, and during 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. After wearing it for 14 days, you will return it to the device manufacturer in a pre-paid envelope for interpretation. The results will be discussed with you during a future hospital appointment.  If you are randomised to wear the heart monitor, you will be required to complete a paper diary to record any episodes of sudden loss of consciousness.  Once a month for 2 years, all participants will be contacted either by text, email, or phone call (whichever you prefer) to complete a very brief questionnaire comprising of two questions. This is likely to take no longer than three minutes to complete. Finally in one and two years’ time you will be asked to complete a short 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. 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. |
| **What are the possible benefits of taking part?** |
| If you are randomised to test the heart 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. 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. |
| **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. 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. |
| **Contact for further information:** |
| If you have any further questions about the study please contact the local research team on [contact details]. |

**CONSENT FORM**

**The ASPIRED Study**

**Participant ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  | Please **initial** box |
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| 1. I confirm that I have read and understand the short information sheet (Version 1.0 11 07 2022) information, ask questions and have had these questions answered satisfactorily. | ⬜ |
| 1. 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. | ⬜ |
| 1. I give permission for the research team to access my medical records for the purposes of this research study. | ⬜ |
| 1. 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. | ⬜ |
| 1. 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. | ⬜ |
| 1. I give permission for my Community Health Index (CHI) number/hospital number to be collected and passed to the University of Edinburgh and ECTU. | ⬜ |
| 1. I agree to my General Practitioner being informed of my participation in the study. | ⬜ |
| 1. I understand that data collected about me during the study may be converted to anonymised data. | ⬜ |
| 1. 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 ⬜ |
| 1. I agree to my anonymised data being used in future studies. | ⬜ |
| 1. 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. | ⬜ |
| 1. I agree to take part in the above study. | ⬜ |

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| Name of Person Giving Consent |  | Date |  | Signature |
| Name of Person Receiving Consent |  | Date |  | Signature |

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| --- | --- | --- | --- | --- |
| 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