ISRCTN10278811 https://doi.org/10.1186/ISRCTN10278811

# Ambulatory ECG monitor versus standard care in acute unexplained syncope (sudden loss of consciousness also known as blackout or fainting)

**Submission date**
25/03/2022

**Recruitment status**
No longer recruiting

**Registration date**
19/04/2022

**Overall study status**
Ongoing

**Last Edited**
23/04/2025

**Condition category**
Signs and Symptoms

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

## Plain English summary of protocol

Background and study aims
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. A mobile heart ECG monitoring device has recently been developed (BodyGuardian Mini; Preventice Solutions). This device can record the patient's heartbeat and heart electrical rhythm tracing for up to 14 days. By wearing the mobile heart monitor after attendance at the Emergency Department there may be a better chance of finding an underlying problem that caused the blackout. This study aims to recruit people who, after investigation at the Emergency Department a cause hasn't been found for their episode of blackout. The goal is to discover if by providing patients with a 14-day mobile heart ECG monitor, doctors can better diagnose and treat the cause of a sudden loss of consciousness and reduce the number of further episodes and their potential serious consequences (i.e. injury, anxiety, poor quality of life and on rare occasions, death), reduce hospital admissions, reduce overall health costs and increase quality of life. At the moment it is not known how long patients who have this type of monitor should be monitored for, so this study will also answer this question.

Who can participate?
Adults aged 16 years or older who attend hospital following a blackout, and after initial assessment it is still unclear what caused the blackout.

What does the study involve?
Participants are allocated to one of two groups. One group will be fitted with the mobile heart monitor to wear for 14 days and will also receive standard care which may mean being referred to a specialist clinic in the hospital. The other group will not be given the heart monitor but will receive standard care which may include the use of a standard heart monitor and being referred to a specialist clinic in the hospital. Everyone who takes part in the study will be contacted once a month for 2 years either by text, email or phone call to complete a very brief questionnaire

comprising of two questions. Participants will also be asked to complete a quality-of-life questionnaire when they start the study and in 1 and 2 years' time asking how they are feeling and about day-to-day activities. Finally in 1 years' time participants will be asked to complete a satisfaction questionnaire.

What are the possible benefits and risks of participating?
For the group allocated to wear the 14-day mobile heart ECG monitor, there is the possibility that the researchers may find a heart-related problem that may not have been detected otherwise. This information would be shared with the Specialist team at the hospital to arrange appropriate further tests and treatments as necessary. Otherwise, there are no direct benefits to taking part in this study, but the results from this study might help to improve the healthcare of patients in the future.

Where is the study run from?
University of Edinburgh and NHS Lothian (UK)

When is the study starting and how long is it expected to run for?
August 2021 to June 2026

Who is funding the study?
British Heart Foundation (UK)

Who is the main contact?
1. Dr Matthew Reed - Chief Investigator
mattreed@ed.ac.uk
2. Lynn Dinsmore - Trial Manager
Lynn.Dinsmore@ed.ac.uk

### Study website
https://www.ed.ac.uk/usher/edinburgh-clinical-trials/our-studies/all-current-studies/aspired-study

# Contact information

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Principal Investigator

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### Type(s)
Scientific

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## Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number
304917

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
CPMS 52042, Protocol Number AC21115, IRAS 304917

# Study information

### Scientific Title
Multi-centre open-label randomised controlled trial of immediate enhanced ambulatory ECG monitoring versus standard monitoring in acute unexplained syncope patients: the ASPIRED study.

### Acronym
ASPIRED

### Study objectives
To determine whether the immediate application of enhanced mobile heart monitoring will decrease the number of episodes of blackouts at 1 year compared to standard care monitoring in patients attending hospital with acute unexplained blackouts.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 29/11/2021, South East Scotland Research Ethics Committee 01 (2nd Floor, Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG, UK; +44 (0)131 536 9000; sandra.wyllie@nhslothian.scot.nhs.uk), ref: 21/SS/0073

### Study design
Multi-centre open-label randomized controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Diagnostic

### Participant information sheet
https://www.ed.ac.uk/usher/edinburgh-clinical-trials/our-studies/all-current-studies/aspired-study

### Health condition(s) or problem(s) studied
Early diagnosis of patients presenting to Emergency Departments with undiagnosed syncope (blackouts).

### Interventions

Participants will be randomised, 1:1, between the two study arms. Randomisation will be performed using a web-based randomisation service to ensure allocation concealment. The allocation sequence will be created by a database programmer using computer-generated pseudo-random numbers. Stratification by site will be used to ensure balanced randomisation.

Participants randomised to the intervention arm will be fitted with a 14-day ambulatory heart monitor (Preventice BodyGuardian Mini) applied by the study team as soon after ED attendance and randomisation as possible. The participant will wear the ambulatory ECG monitor for a maximum of 14 days after which they will remove the monitor and return it to Preventice UK for reporting by an ECG technician. The ECG report will be shared with the local study team.

Participants in both control and intervention arms will receive standard care which will include all care usually given to unexplained syncope patients at each participating site along with some form of standard care monitoring such as but not limited to wired inpatient telemetry, Holter style monitoring or implantable loop recorder.

All participants will be followed up for 2 years from randomisation through hospital records, questionnaires and participant-reported events.

Participants will be contacted at monthly intervals throughout the study follow-up by automated text or email (participant preference) with a link to a brief web-based questionnaire. Those who are unable to access digital forms of communication will receive phone calls. Participants will also be contacted at 1 and 2 years to complete a quality-of-life questionnaire. The participants' involvement in the study will cease at 2 years.

### Intervention Type
Device

### Phase
Not Applicable

### Drug/device/biological/vaccine name(s)
Boston Scientific Cardiac Diagnostics BodyGuardian Mini Ambulatory ECG Monitor

### Primary outcome measure
Number of self-reported episodes of syncope at 1 year. Participants will be contacted at monthly intervals throughout the study follow-up which will last for 2 years, by automated text or email (participant preference) with a link to a brief web-based questionnaire asking for the number of syncope events experienced since their last response and how many of these they attended hospital for. Those who are unable to access digital forms of communication will receive phone calls.

### Secondary outcome measures
1. Within trial cost-effectiveness (cost per syncope avoided and cost per quality-adjusted life-year [QALY] gained), and lifetime cost per QALY at (a) 1 year and (b) 2 years measured by NHS resource utilisation data and EQ-5D-5L questionnaires.
2. Number of self-reported episodes of syncope at (a) 90 days and (b) 2 years, those identified in the medical records at (c) 90 days, (d) 1 year and (e) 2 years, and syncope recurrence rate at (f) 90 days, (g) 1 year and (h) 2 years measured from 4 weekly patient brief questionnaire and extraction of NHS resource utilisation data.
3. Index presentation hospital (a) admission rate and (b) duration of hospital stay measured

using NHS resource utilisation data at 90 days 1 year and 2 years.
4. Patient satisfaction measured using a patient questionnaire at 1 year
5. Clinically significant cardiac dysrhythmia (serious and/or symptomatic cardiac dysrhythmia at (a) 90 days, (b) 1 year and (c) 2 years measured from NHS resource utilisation data.
6. (a) 30-day, (b) 1-year and (c) 2-year all-cause death as recorded from NHS resource utilisation data
7. Detection of diagnostic ECG/symptom correlation (symptomatic) at (a) 90 days, (b) 1 year and (c) 2 years measured from NHS resource utilisation data and participant self-reported 4 weekly brief questionnaires.
8. Time to detect clinically significant cardiac dysrhythmia (i.e. time to clinician being aware) measured from NHS resource utilisation data at 90 days, 1 year and 2 years. For the intervention group data from the ambulatory ECG monitoring report which will be provided at the end of the 14-day monitoring period.
9. In the intervention group, the duration of enhanced ambulatory ECG monitoring required to detect clinically significant cardiac dysrhythmia measured using data from the ambulatory ECG monitoring report at 90 days
10. Number and type of diagnostic tests and therapeutic interventions at (a) 1 year and (b) 2 years measured from the NHS resource utilisation extraction data

### Overall study start date
01/08/2021

### Completion date
24/06/2026

## Eligibility

### Key inclusion criteria
1. Syncope remains unexplained after initial ED/AMU assessment.
2. Aged ≥16 years
3. Patient has capacity
4. Local resident (i.e. resident within local health board so will not be lost to medical record follow up)
5. Less than five self-reported episodes of syncope in the previous month

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
16 Years

### Sex
Both

### Target number of participants
2,234

### Total final enrolment
2234

### Key exclusion criteria
1. Obvious underlying cause after assessment:
1.1. Features of vasovagal syncope AND absence of structural heart disease AND normal physical examination AND normal ECG
1.2. Dysrhythmia on pre-hospital or hospital ECG as likely cause of syncope
1.3. Postural hypotension (symptomatic postural drop >20 mmHg AND suggestive history)
1.4. Confirmed diagnosis of Pulmonary Embolus or Acute Myocardial Infarction
1.5. Radiological diagnosis or clinical signs/symptoms of cerebrovascular accident/transient ischemic attack or subarachnoid haemorrhage
1.6. Evidence of:
1.6.1. Haemorrhage
1.6.2. Alcohol or illicit drugs
1.6.3. Epileptic seizure
1.6.4. Hypoglycemia
1.6.5. Head trauma
1.6.6. Other obvious cause of syncope as presumptive cause of TLoC
2. Inability to consent
3. Previous recruitment into the study
4. Patient in custody or prison
5. Aged <16 years
6. Patient does not reside within local health board and will therefore be lost to medical record follow up
7. Five or more self-reported episodes of syncope in the previous 4 weeks

### Date of first enrolment
15/07/2022

### Date of final enrolment
24/06/2024

## Locations

### Countries of recruitment
England

Jersey

Scotland

United Kingdom

Wales

### Study participating centre
**Royal Infirmary of Edinburgh**
NHS Lothian

51 Little France Crescent
Edinburgh
United Kingdom
EH16 4SA

**Study participating centre**
**Taunton Hospital**
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

**Study participating centre**
**NHS Fife**
Hayfield House
Hayfield Road
Kirkcaldy
United Kingdom
KY2 5AH

**Study participating centre**
**Royal London Hospital**
Whitechapel
London
United Kingdom
E1 1FR

**Study participating centre**
**St George's Hospital**
Blackshaw Road
London
United Kingdom
SW17 0QT

**Study participating centre**
**Southampton General Hospital**
Tremona Road
Southampton
United Kingdom
SO16 6YD

**Study participating centre**
**Queen Elizabeth University Hospital**
1345 Govan Road
Glasgow
United Kingdom
G51 4TF

**Study participating centre**
**St Johns Hospital**
Howden West Road
Livingston
United Kingdom
EH54 6PP

**Study participating centre**
**Addenbrookes**
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

**Study participating centre**
**John Radcliffe Hospital**
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

**Study participating centre**
**Royal Berkshire Hospital**
Royal Berkshire Hospital
London Road
Reading
United Kingdom
RG1 5AN

**Study participating centre**

**Derriford Hospital**
Derriford Road
Derriford
Plymouth
United Kingdom
PL6 8DH

**Study participating centre**
**Northern General Hospital**
Northern General Hospital NHS Trust
C Floor, Huntsmnan Building
Herries Road
Sheffield
United Kingdom
S5 7AU

**Study participating centre**
**Royal Derby Hospital**
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

**Study participating centre**
**Jersey General hospital**
Gloucester Street
St Hellier
Jersey
JE1 3QS

**Study participating centre**
**Southmead Hospital**
Southmead Road
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Bristol
United Kingdom
BS10 5NB

**Study participating centre**
**Glan Clwd Hospital**
Ysbyty Glan Clwydd

Bodelwyddan
Rhyl
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LL18 5UJ

**Study participating centre**
**Aberdeen Royal Infirmary**
Foresterhill Road
Aberdeen
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AB25 2ZN

**Study participating centre**
**St. Thomas's Hospital**
Westminster Bridge Road
London
United Kingdom
SE1 7EH

**Study participating centre**
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Crewe Road South
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EH4 2XU

**Study participating centre**
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TS19 8PE

**Study participating centre**
**Forth Valley Royal Hospital**
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**Study participating centre**
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CV2 2DX

**Study participating centre**
**Chesterfield Royal Hospital NHS Foundation Trust**
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**Study participating centre**
**Kettering General Hospital**
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NN16 8UZ

**Study participating centre**
**Warwick Hospital**
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**Study participating centre**
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**Study participating centre**

**North West Anglia NHS Foundation Trust**
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Peterborough
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PE3 9GZ

**Study participating centre**
**Milton Keynes General Hospital**
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MK6 5LD

**Study participating centre**
**Northumbria Specialist Emergency Care Hospital**
Northumbria Way
Cramlington
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NE23 6NZ

**Study participating centre**
**Epsom and St Helier University Hospitals NHS Trust**
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**Study participating centre**
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**Study participating centre**

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369 Fulham Road
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**Study participating centre**
**Royal Alexandra Hospital**
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United Kingdom
PA2 9PN

**Study participating centre**
**Hull Royal Infirmary**
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**Study participating centre**
**Salisbury District Hospital**
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**Study participating centre**
**William Harvey Hospital**
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Ashford
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TN24 0LZ

**Study participating centre**
**Lincoln County Hospital**
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**Study participating centre**
**Imperial College Healthcare NHS Trust**
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W2 1BL

**Study participating centre**
**Wrexham Maelor Hospital**
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Wrexham
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LL13 7TD

**Study participating centre**
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**Study participating centre**
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GL1 3NN

**Study participating centre**
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United Kingdom
M6 8HD

**Study participating centre**
**Queens Hospital**
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Burton-on-trent
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DE13 0RB

**Study participating centre**
**Kings College Hospital**
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SE5 8AB

**Study participating centre**
**University College London Hospitals NHS Foundation Trust**
250 Euston Road
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NW1 2PG

# Sponsor information

**Organisation**
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enquiries@accord.scot

**Sponsor type**

University/education

**Website**
http://accord.scot/

# Funder(s)

**Funder type**
Charity

**Funder Name**
British Heart Foundation

**Alternative Name(s)**
the_bhf, The British Heart Foundation, BHF

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Trusts, charities, foundations (both public and private)

**Location**
United Kingdom

# Results and Publications

**Publication and dissemination plan**
Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**
31/12/2026

**Individual participant data (IPD) sharing plan**
Anonymised study Individual participant data (IPD) and metadata generated and/or analysed during the current study will be available on request. In the first instance, email requests should be made via email to ECTUdatashare@ed.ac.uk. Study data and metadata will be available for as long as it has been retained. Once the completed application form has been received, a review panel will review the application form. The review panel will consider the following: Permissions listed in ASPIRED Ethics/Patient Information Sheet Consent Form (PISCF); Risk of identification; Risk of affecting ASPIRED study outcomes/data access embargo date; Stage of study; Requester evaluation (e.g. relationship to Chief Investigator, Edinburgh Clinical Trials Unit
etc); Scientific merit of proposed data use; Overlap with other study projects; and Permissions (i.e. ethical, information governance) in place for proposed data use.

## IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | | 23/02/2023 | 24/02/2023 | Yes | No |
| Other publications | Results from an embedded qualitative study focused on patient and healthcare professional usability and acceptability | 08/04/2025 | 23/04/2025 | Yes | No |