ESC CONFERENCE HOTLINE PRESENTATION

Immediate Ambulatory ECG Monitoring in Syncope

Results of the British Heart Foundation Funded ASPIRED Multicentre Randomised Controlled Trial

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British Heart Foundation

Declaration of Interest

- Research contracts : Professor Matt Reed is supported by an NHS Research Scotland Career Researcher Clinician award.
- Others : Boston Scientific Cardiac Diagnostics, Inc. (formally Preventice Solutions, Inc.) provided the BodyGuardian Mini 14-day ambulatory heart monitor. Boston Scientific (formally Preventice Solutions) had no other involvement in the study.

THE CLINICAL CHALLENGE IN SYNCOPE

Context

High patient volume

- Millions of global ED syncope attendances annually.

Diagnostic difficulty

- **~50% of patients** are discharged from the ED with an unexplained cause.
- Many will be benign, some will have cardiac cause.

Need for symptom-ECG correlation

- Poor diagnostic yield of standard clinical care.

Serious outcomes

- Clinically important pathology identified in **~7% of patients** within one month of ED attendance.
- **~1% of patients** die within one month of ED attendance.

Evidence for early cardiac monitoring

Evidence suggests arrhythmia detection is highest when cardiac monitoring is initiated early, ideally at the index ED visit.

TRIAL OBJECTIVE

Hypothesis

To determine whether immediate, continuous, prolonged cardiac rhythm monitoring, applied during the initial clinical presentation, could improve outcomes.

Primary outcome

Self-reported syncope episodes at 1 year.

Secondary outcomes

Clinically significant cardiac arrhythmias and time to detection.

Death from any cause.

Symptomatic syncope.

Hospital admission and duration.

Diagnostic tests and therapeutic interventions.

Patient satisfaction.

TRIAL METHODOLOGY OVERVIEW

Design

Population

Adults (16+ years) presenting to **45 UK NHS Emergency Departments** with syncope that remained unexplained after assessment.

Randomisation 1 : 1 within 72 hours

Intervention: Immediate 14-day continuous ambulatory ECG patch monitor fitted in the ED or shortly afterwards.

Standard Care: Usual local management.

Patient follow-up

- Patients tracked over 1 year using text/email/phone follow-up conducted every 4 weeks.
- Medical record review at 1 year.

TRIAL METHODOLOGY OVERVIEW

Design

Inclusion

- Syncope unexplained after ED assessment
- Aged ≥16 years
- Patient has capacity
- Resident in local health board so will not be lost to medical record follow up
- <5 self-reported episodes of syncope in the previous month

Exclusion

- Obvious underlying cause after ED assessment, including
- Features of vasovagal syncope
- Arrhythmia on ECG as likely cause
- Symptomatic postural drop ≥20 mmHg
- Previous recruitment
- Patient in custody or prison

TRIAL METHODOLOGY OVERVIEW

Design

14 days of ambulatory ECG monitoring

FDA approved Boston Scientific BodyGuardian Mini chosen

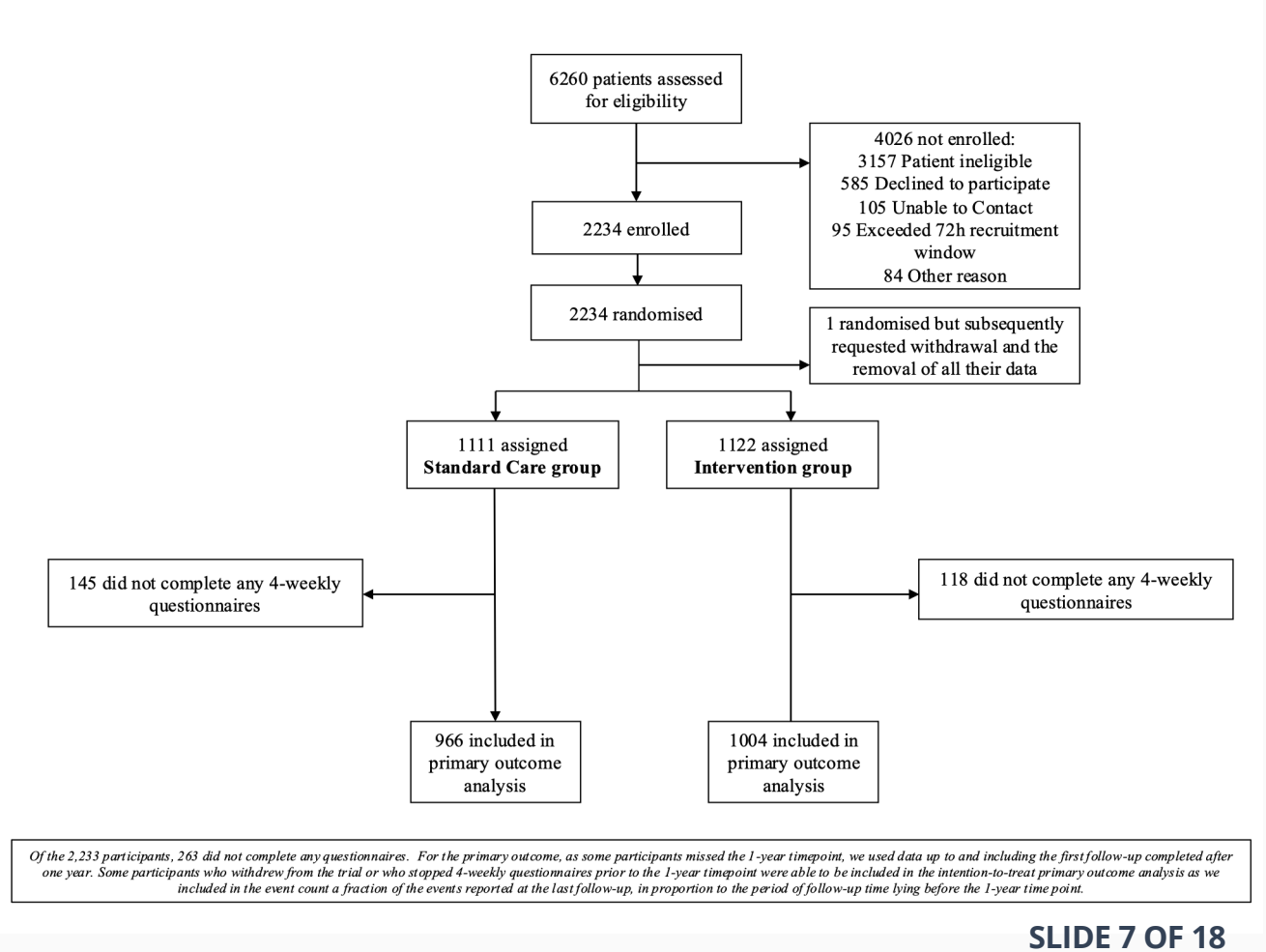
Statistical power

Powered to detect a **6% absolute reduction** in 1-year syncope recurrence (from 40% in standard care to 34% in the intervention group).

Boston Scientific provided the BodyGuardian Mini 14-day ambulatory heart monitor. Boston Scientific had no other involvement in the study.

FLOW OF PARTICIPANTS THROUGH THE TRIAL

- **2234 participants** randomised across 45 hospitals.
- **72%** of eligible patients recruited.
- **1970 participants (88%)** had one-year primary outcome data.
- **2180 participants (98%)** had one-year follow-up data (e.g. mortality).



BASELINE CHARACTERISTICS

Patient Characteristic	Standard Care (N=1111)	Intervention (N=1122)
Mean age (years/SD)	58.3 ± 19.7	58.3 ± 19.8
Male sex, n (%)	570 (51.3%)	594 (52.9%)
Previous syncope, n (%)	487 (43.8%)	522 (46.7%)
>1 episode in past year	262 (53.8%)	278 (53.8%)
Coronary Artery Disease	88 (7.9%)	95 (8.5%)
Admitted to hospital, n (%)	436 (39.2)	442 (39.5)

Baseline Insights

- Cohorts well-balanced.
- Typical for syncope studies.
- Almost 50% women.
- ~40% of patients in both groups required hospital admission.
- High burden of disease (almost 50% had previous syncope).

PRIMARY OUTCOME RESULTS

Primary Endpoint

No difference in self-reported syncope episodes

Mean self-reported syncope episodes at 1 year:
1.37 in monitoring group vs **1.58** in standard care.

0.89

INCIDENCE RATE RATIO (IRR)

95% CI: 0.68 to 1.18

p = 0.42 (not significant)

- This result is highly robust across all sensitivity analyses, including multiple imputation models.
- Recurrence rates lower than modeled; 28.0% (Intervention) vs 28.6% (Standard Care) at 1 year.
- Significant disease burden recruited.

SECONDARY OUTCOMES: ARRHYTHMIA DETECTION

Diagnostic Yield

DEFINITIONS OF CLINICALLY SIGNIFICANT CARDIAC ARRHYTHMIAS	
Serious cardiac arrhythmias **(Clinically significant whether symptomatic or asymptomatic)**	**Clinically significant** **(only if symptomatic)**
Ventricular Fibrillation (VF)	Second degree AV heart block Mobitz type I
Ventricular Tachycardia (VT) ≥120 beats per minute (bpm) for ≥30 seconds	Sinus pause ≥2.5 seconds when awake or ≥4 seconds at night (but <6 seconds)
VT ≥120 bpm for <30 seconds (≥4 beats)	Bradycardia <40 bpm for <30 seconds
Complete or 3rd degree heart block	Sick sinus syndrome with alternating sinus bradycardia and tachycardia
Second degree atrioventricular (AV) heart block Mobitz type II	Junctional / idioventricular rhythm ≥30 seconds in duration
Pause ≥6 seconds	Supraventricular tachycardia >100 bpm ≥30 seconds in duration
Sinus bradycardia <30 bpm	Atrial flutter/fibrillation with ventricular rate >100 bpm or <60 bpm ≥30 seconds in duration
Bradycardia <40 bpm for ≥30 seconds	New Atrial flutter/fibrillation ≥30 seconds in duration

SECONDARY OUTCOMES: ARRHYTHMIA DETECTION

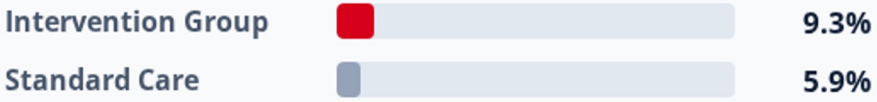
Diagnostic Yield

Clinically Significant Arrhythmia (Serious/Symptomatic)

OR: 2.95 (95% CI: 2.28 to 3.81)

Symptomatic Arrhythmia at 1 Year

OR: 1.66 (95% CI: 1.20 to 2.31)



Accelerated diagnosis

The 14-day ECG patch also identified clinically significant cardiac arrhythmias significantly sooner

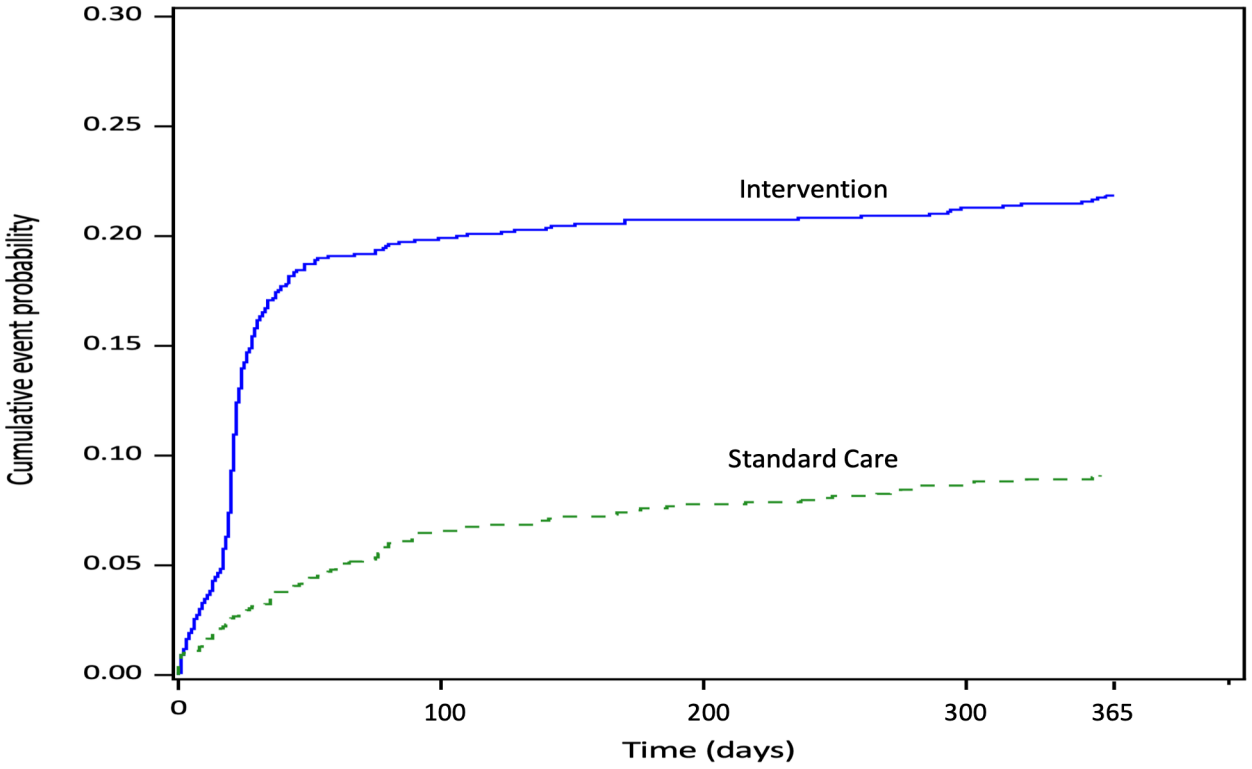
Median days to diagnosis

22.0 days vs 54.5 days

ODDS RATIO 0.35 (95% CI: 0.28 TO 0.44)

Most patients (78%) did not have a clinically significant cardiac arrhythmia

DETECTION OF CLINICALLY SIGNIFICANT CARDIAC ARRHYTHMIAS



No. at risk					
Intervention	1095	873	863	854	845
Standard Care	1085	1003	980	965	958

2.95

ODDS RATIO (95% CI: 2.28 TO 3.81)

p = <0.001 (significant)

TREATMENTS

Interventions

Increased clinical interventions

	Intervention Group % (n)	Standard Care % (n)	Odds Ratio (95% CI)
Anti-arrhythmic drugs	10.8% (117)	7.3% (79)	1.47 (1.11 – 1.95) **Significant**
Pacemaker implantation	6.8% (74)	4.6% (50)	1.49 (1.04 – 2.13) **Significant**
Defibrillator Placement (ICD)	0.6% (7)	0.4% (4)	1.74 (0.51 to 5.97) **Non significant**

SECONDARY OUTCOME: 1-YEAR SURVIVAL

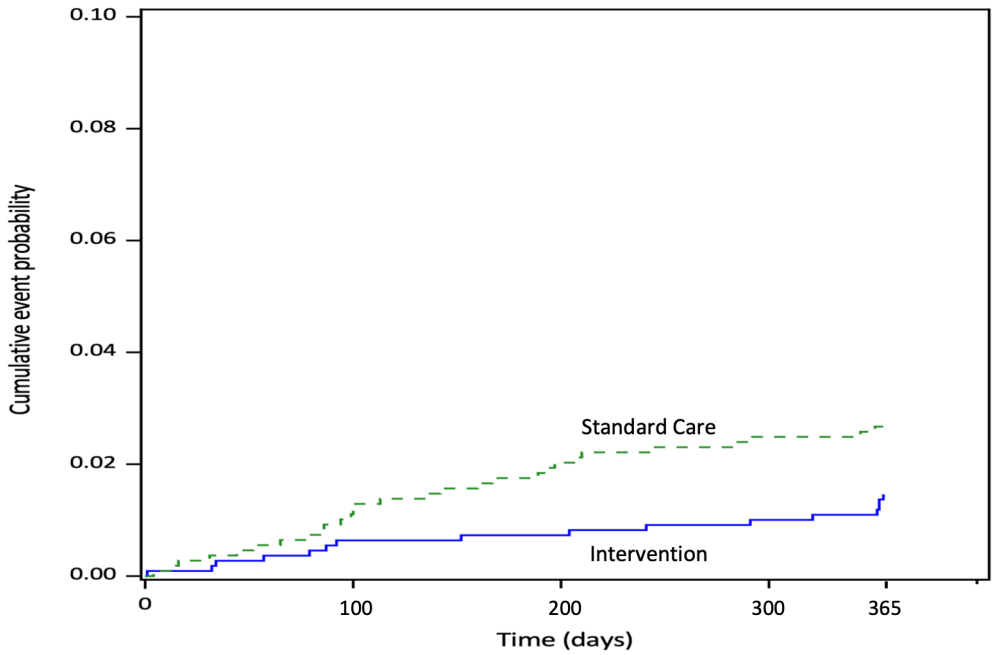
Clinical Signal

All-cause mortality at 12 months

2.9%
STANDARD CARE
(31/1085)

1.5%
INTERVENTION
(16/1095)

0.50
ODDS RATIO (95% CI: 0.27 TO 0.93)
p = 0.028 (significant)



No. at risk					
Intervention	1095	1088	1087	1084	1079
Standard Care	1085	1073	1063	1058	1055

SAFETY

Device safety profile

- **Low SAE Rates:** Only 1 serious adverse event occurred in each group (infected ILR in standard care, pacemaker hematoma in intervention).
- **Minor adverse reactions:** Mainly mild skin irritation due to the electrode adhesive in the patch group (49 total events).
- **Acceptability:** 91% reported that the patch monitor was easy to use.

CONCLUSIONS & CLINICAL IMPLICATIONS

ESC 2026

Primary endpoint

Applying 14-day ambulatory cardiac patch monitoring at index ED visit **did not reduce** patient-reported syncope episodes at one year.

Diagnosis

Early monitoring **more than doubled** arrhythmia diagnosis (22% vs 9%) and reduced time-to-detection (54.5 to 22.0 days).

Treatment

More patients received prompt targeted treatment (e.g. permanent pacing and anti-arrhythmic drugs)

Outcome

Provides a biologically plausible mechanism for our **1-year survival benefit** (2.9% vs 1.5%)

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Immediate Ambulatory Electrocardiographic Monitoring in Syncope

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Thank you

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ECTU Edinburgh Clinical Trials Unit

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Athena SWAN Silver Award

accord Academic and Clinical Central Office for Research and Development

NHS Lothian

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