Research Paper

Multi-centre Randomised Controlled Trial of a Smartphone-based Event Recorder Alongside Standard Care Versus Standard Care for Patients Presenting to the Emergency Department with Palpitations and Pre-syncope: The IPED (Investigation of Palpitations in the ED) study

Matthew J. Reed a,b,*, Neil R. Grubb c, Christopher C. Lang c, Rachel O’Brien a, Kirsty Simpson a, Mia Padarenga a, Alison Grant a, Sharon Tuck d, Liza Keating e, Frank Coffey f, Lucy Jones g, Tim Harris h, Gavin Lloyd i, James Gagg j, Jason E. Smith k, Tim Coats l

a Emergency Medicine Research Group Edinburgh (EMERGE), Department of Emergency Medicine, Royal Infirmary of Edinburgh, 51 Little France Crescent, Edinburgh, EH16 4SA, UK
b Edinburgh Acute Care, Usher Institute of Population Health Sciences and Informatics, College of Medicine and Veterinary Medicine, University of Edinburgh, The Chancellor’s Building, 49 Little France Crescent, Edinburgh EH16 4SB, UK
c Department of Cardiology, Royal Infirmary of Edinburgh, 51 Little France Crescent, Edinburgh EH16 4SA, UK
d Department of Emergency Medicine, Musgrove Park Hospital, Taunton & Somerset NHS Foundation Trust, Taunton TA1 5DA, UK
e Emergency Department, Royal Berkshire NHS Foundation Trust, Reading RG1 5AN, UK
f DREAM - Department of Research and Education in Emergency medicine, Acute medicine and Major trauma, Nottingham University Hospitals NHS Trust, Queen’s Medical Centre Derby Road, Nottingham, NG7 2UH, UK
 g Chesterfield Royal Hospital NHS Foundation Trust, Chesterfield Rd, Calow, Chesterfield S44 5BL, UK
h Barts Health NHS Trust, Whitechapel, London E1 1BB, UK
i Royal Devon and Exeter Hospital, Barrack Rd, Exeter EX2 5DW, UK
j Emergency Department, University Hospitals Plymouth NHS Trust, Plymouth PL6 8DH, UK
k Emergency Medicine Academic Group, Department of Cardiovascular Sciences, University of Leicester, University Road, Leicester LE1 7RH, UK
l Corresponding author at: Emergency Medicine Research Group Edinburgh (EMERGE), Department of Emergency Medicine, Royal Infirmary of Edinburgh, 51 Little France Crescent, Edinburgh EH16 4SA, UK

E-mail addresses: matthew.reed@nhslothian.scot.nhs.uk (M.J. Reed), Neil.Grubbd@nhslothian.scot.nhs.uk (N.R. Grubb), Chris.Lang@nhslothian.scot.nhs.uk (C.C. Lang), Rachel.O’Brien@nhslothian.scot.nhs.uk (R. O’Brien), Kirsty.Simpson@nhslothian.scot.nhs.uk (K. Simpson), Mia.Padarengaa@nhslothian.scot.nhs.uk (M. Padarenga), Alison.Grant@nhslothian.scot.nhs.uk (A. Grant), sharon.tuck@ed.ac.uk (S. Tuck), Liza.Keating@royalberkshire.nhs.uk (L. Keating), Frank.Coffey@nottingham.ac.uk (F. Coffey), ljones24@nhs.net (L. Jones), Tim.Harris@bartshealth.nhs.uk (T. Harris), gavin.lloyd@nhs.net (G. Lloyd), James.Gagg@tst.nhs.uk (J. Gagg), jasonesmith@nhs.net (J.E. Smith), tc61@leicester.ac.uk (T. Coats).

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ABSTRACT

Background: Patients with palpitations and pre-syncope commonly present to Emergency Departments (EDs) but underlying rhythm diagnosis is often not possible during the initial presentation. This trial compares the symptomatic rhythm detection rate of a smartphone-based event recorder (AliveCor) alongside standard care versus standard care alone, for participants presenting to the ED with palpitations and pre-syncope with no obvious cause evident at initial consultation.

Methods: Multi-centre open label, randomised controlled trial. Participants ≥16 years old presenting to 10 UK hospital EDs were included. Participants were randomised to either (a) intervention group; standard care plus the use of a smartphone-based event recorder or (b) control group; standard care alone. Primary endpoint was symptomatic rhythm detection rate at 90 days. Trial registration number NCT02783898 (ClinicalTrials.gov).

Findings: Two hundred forty-three participants were recruited over an 18-month period. A symptomatic rhythm was detected at 90 days in 69 (n = 124; 55.6%; 95% CI 46.9–64.4%) participants in the intervention group versus 11 (n = 116; 9.5%; 95% CI 4.2–14.8%) in the control group (RR 5.9, 95% CI 3.3–10.5; p < 0.0001). Mean time to symptomatic rhythm detection in the intervention group was 9.5 days (SD 16.1, range 0–83) versus 42.9 days (SD 16.0, range 12–83; p < 0.0001) in the control group. The commonest symptomatic rhythms detected were sinus rhythm, sinus tachycardia and ectopic beats. A symptomatic cardiac arrhythmia was detected at 90 days in 11 (n = 116; 9.5%; 95% CI 3.3–10.5%) participants in the intervention group versus 1 (n = 116; 0.9%; 95% CI 0.0–2.5%) in the control group (RR 10.3, 95% CI 1.3–78.5; p = 0.006).

Interpretation: Use of a smartphone-based event recorder increased the number of patients in whom an ECG was captured during symptoms over five-fold to more than 55% at 90 days. This safe, non-invasive and easy to use

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device should be considered part of on-going care to all patients presenting acutely with unexplained palpitations or pre-syncope.

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Research in Context

Evidence Before This Study

Palpitations and pre-syncope are together responsible for 300,000 annual Emergency Department (ED) attendances in the United Kingdom (UK) alone. Diagnosis of the underlying rhythm is difficult as many patients are fully recovered by the time of attendance, and examination and presenting ECG are commonly normal. Palpitations are typically intermittent, and a diagnosis can only be made through establishing a symptom–rhythm correlation. There have been few studies investigating the use of smartphone-based event recorders; none have been randomised trials and none have studied acute or ED populations. Most previous research in this area has focused on primary and secondary prevention of stroke through the detection of atrial fibrillation.

Added Value of Study

This trial sought to clarify whether there is any benefit to adding a smartphone-based electrocardiogram (ECG) monitoring event recorder to standard care. The trial recruited patients presenting to the ED with palpitations and pre-syncope and no obvious cause in the ED. The principal outcome measure was the rate of detection of the underlying symptomatic rhythm at 90 days. This study shows that use of a smartphone-based event recorder increased the number of patients in whom an ECG was captured during symptoms over five-fold to more than 55% at 90 days. These are clinically significant rhythms as they diagnose the underlying cause of the patient’s symptoms. The smartphone-based event recorder also increased the number of patients diagnosed with cardiac arrhythmia.

Implications of All the Available Evidence

A smartphone-based event recorder should be considered as part of on-going care for all patients presenting acutely to EDs with unexplained palpitations or pre-syncope. It is safe, non-invasive, easy to use and far more efficient at diagnosing the underlying cause of the patient’s symptoms than current standard care, which in the healthcare system studied does not serve this patient group well.

1. Background

Palpitations (the noticeable pounding, fluttering or irregular beating of the heart) and pre-syncope (the sense of impending loss of consciousness) are together responsible for 1% of Emergency Department (ED) attendances and are clinically significant rhythms as they diagnose the underlying cause of the patient’s symptoms. The smartphone-based event recorder also increased the number of patients diagnosed with cardiac arrhythmia.

2. Methods

2.1. Design

Multi-centre open label randomised controlled trial in EDs and Acute Medical Units (AMU) of 10 tertiary and district general hospitals in the UK. A favourable ethical opinion was obtained from the South East Scotland Research Ethics Committee 02 (REC reference: 16/SS/0074) and from the HRA.
2.2. Participants

Participants aged 16 years or over presenting with an episode of palpitations or pre-syncope and whose underlying ECG rhythm during these episodes remains undiagnosed after ED assessment. Written consent was obtained from all participants.

Table 1 shows inclusion and exclusion criteria.

3. Randomisation

Participants were equally distributed between the two study groups. To balance site-level characteristics and ensure investigators could not predict the group allocation of the next-to-be enrolled patient, randomisation was by permuted block randomisation by site. Sealed opaque envelopes containing either ‘Standard Care plus Device’ or ‘Standard Care’ cards were prepared by a central administrator not involved in the study. Blocks were randomly labelled using random number generation with site-specific study participation numbers and sent to each local study team. Participants eligible for inclusion were randomised by the local study team by taking the next lowest consecutively numbered sealed opaque envelope.

4. Procedures

The local direct care team screened and identified potential participants using ED or the AMU triage information and clinical or electronic records. Potentially eligible participants were assessed for study inclusion by the attending clinician. If the potential participant fulfilled the study eligibility criteria, they were given a Participant Information Sheet. Afterwards, if agreeable, written consent was taken. Participants were allocated either (a) INTERVENTION group; standard care plus the use of a smartphone-based event recorder or (b) CONTROL group; standard care, depending on study envelope allocation. All intervention group participants were given an AliveCor Heart Monitor and trained in the use of the device and app in the ED or AMU by the research team. Control group participants received no other intervention. Participants in both groups were admitted, referred or discharged by the treating clinician according to current local hospital protocols. Participants in both groups were followed up at 90 days through hospital records (as per local protocol). GP records were also asked to complete a standardised written questionnaire. They also received a follow-up telephone call from the local study team enquiring about symptoms and contact with medical services. Participants were also asked about satisfaction and compliance.

If a participant allocated to the intervention group had an episode of palpitations or pre-syncope and was able to record an AliveCor Heart Monitor ECG during the episode, the participant emailed the ECG at a convenient time to the secure (nhs.net) email address of the coordinating Edinburgh research team. This email included a Portable Document Format (pdf) file attachment of the ECG tracing along with the participant’s AliveCor app login (which was their study number; no identifiable participant data left the local site).

The AliveCor app rhythm analysis algorithm automatically reported any ECG recorded as Normal, Atrial Fibrillation or Unclassified. The duty Consultant Emergency Physician at the coordinating Edinburgh centre along with a trial team Emergency Physician reviewed the ECG. The central study team contacted the local study team to arrange follow-up if required. In cases of disagreement, the central cardiology team were contacted for further opinion.

If specialist follow-up of the ECG tracing was not required, the local study team wrote to the participant informing them and asked them to arrange follow-up with their general practitioner (GP) who was also contacted with the report. Participants continued to record ECGs for the duration of the study period, but the participant and GP were not contacted again if participants recorded further ECGs that similarly did not require specialist follow-up.

If the participant’s ECG recorded a serious cardiac arrhythmia, i.e.,

- ventricular tachyarrhythmia
- complete or 3rd degree heart block
- second degree heart block type II (assumed to be symptomatic given the participant had chosen to record an ECG during the episode)
- pause > 6 s
- symptomatic bradycardia < 40 beats/min

during the study period, the central study team contacted the local study team who alerted the participant immediately by telephone, and referred them urgently to their local ED or cardiac electrophysiology service (as per local protocol).

Participants were asked to use a participant symptom diary to record any symptoms and include time and date, type of symptom and whether they were able to record an ECG during the symptoms. They returned this diary to the local study team along with the participant satisfaction and compliance questionnaire, and smartphone-based event recorder at the end of the 90 days in a pre-paid stamped, addressed envelope. Participants failing to do this were reminded by phone. Participant study information identified by study number alone, was collected on a paper Case Report Form and then entered into a specially designed password protected online accessed secure database (REDCAP; http://www.project-redcap.org), the server of which was held within the University of Edinburgh. The primary outcome was assessed by each local study team.

5. Outcomes

5.1. Primary Outcome

1. Symptomatic rhythm detection rate of a smartphone-based event recorder for symptomatic rhythm detection at 90 days versus standard care.

A ‘symptomatic rhythm’ will be any ECG rhythm recorded during an episode of palpitations or pre-syncope allowing symptom–rhythm correlation. This can be either via the AliveCor Heart Monitor ECG or through standard care.

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Table 1: Inclusion and exclusion criteria.

| Inclusion criteria were: |
|-------------------------|
| 1. Participant aged 16 years or over. |
| 2. Participant presenting with an episode of palpitations or pre-syncope with no obvious cause. |
| 3. Participant’s underlying ECG rhythm during these episodes remains undiagnosed after clinical assessment. |

| Exclusion criteria were: |
|-------------------------|
| 1. Prior diagnostic ECG. |
| 2. Palpitations or pre-syncope present during an admission ECG. |
| 3. Frequent episodes (i.e. at least once a day). |
| 4. Participants under 16 years of age. |
| 5. Previous participation in the study. |
| 6. Alcohol/illicit drugs/seizure/stroke/transient ischaemic attack/head trauma/-hypoglycaemia as presumptive cause. |
| 7. Inability or unwilling to give informed consent. |
| 8. Participants with recent (i.e., within 3 months) myocardial infarction, severe heart failure (New York Heart Association class 4) or unstable angina. |
| 9. Participants unwilling or unable to use the AliveCor Heart Monitor and AliveECG app. |
| 10. Participants without a compatible smartphone or tablet. |
| 11. Participants with cardiac pacemakers or other implanted electronic devices. |
| 12. No telephone number for follow-up. |
| 13. Participant in custody. |
*Other reasons for participant not being recruited:

| Reason                                                   | Count |
|----------------------------------------------------------|-------|
| Outside working hours                                    | 509   |
| Alcohol or recreational drug use                         | 19    |
| Deemed inappropriate to approach                         | 6     |
| Non-local resident so unable to arrange follow-up if required | 9     |
| Anxiety driven palpitations                               | 7     |
| Other illness believed to be causing symptoms             | 43    |
| Discharged before approach                                | 48    |

Fig. 1. Study recruitment diagram.
5.2. Secondary Outcomes

1. Symptomatic rhythm detection rate of a smartphone-based event recorder for cardiac arrhythmia detection at 90 days versus standard care.
2. Time to detection of symptomatic rhythm using a smartphone-based event recorder versus standard care.
3. Time to detection of symptomatic cardiac arrhythmia (rhythm that is not sinus rhythm/sinus tachycardia/ectopic beats) using a smartphone-based event recorder versus standard care.
4. Number of participants treated or (planned for treatment) for cardiac arrhythmia in participants using a smartphone-based event recorder versus standard care.
5. Participant satisfaction and monitor compliance.
6. Cost-effectiveness analysis.
7. Serious outcomes at 90 days: all cause death and major adverse cardiac events [MACE] (myocardial infarction, life-threatening arrhythmia, insertion of a pacemaker or internal cardiac defibrillator, insertion of pacing wire).

Table 2
Baseline characteristics of study population.

|                          | Intervention n = 125 | Control n = 117 | Total n = 242 |
|--------------------------|----------------------|----------------|---------------|
| Gender: Male             | 51 (40.8)            | 54 (46.2)      | 105 (43.4)    |
| Age in years/mean (SD)   | 40.0 (14.0)          | 39.1 (13.5)    | 39.6 (13.8)   |
| History of presenting episode |                      |                |               |
| Palpitations             | 110 (88.0)           | 109 (93.2)     | 219 (90.5)    |
| Pre-syncope              | 15 (12.0)            | 8 (6.8)        | 23 (9.5)      |
| 1 min or less            | 19 (15.2)            | 19 (16.2)      | 38 (15.7)     |
| 10 min or less           | 31 (24.8)            | 37 (31.6)      | 68 (28.1)     |
| Estimated length of presenting (last) episode |                    |                |               |
| 1 h or less              | 27 (21.6)            | 27 (23.1)      | 54 (22.3)     |
| More than 1 h            | 48 (38.4)            | 34 (29.1)      | 82 (33.9)     |
| Anxious                  | 52 (41.6)            | 50 (42.7)      | 102 (42.1)    |
| Arm or neck pain or tingling | 34 (27.2)          | 33 (28.2)      | 67 (27.7)     |
| Chest pain or pressure   | 51 (40.8)            | 52 (44.4)      | 103 (42.6)    |
| Dizziness                | 62 (49.6)            | 56 (47.9)      | 118 (48.8)    |
| Faint/Light headed        | 73 (58.4)            | 61 (52.1)      | 134 (55.4)    |
| Pounding                 | 55 (44.0)            | 56 (47.9)      | 111 (45.9)    |
| Fluttering               | 42 (33.6)            | 38 (32.5)      | 80 (33.1)     |
| Short of breath          | 51 (40.8)            | 49 (41.9)      | 100 (41.3)    |
| Fast/Racing heart        | 77 (61.6)            | 68 (58.1)      | 145 (59.9)    |
| Skipped/missed heartbeat(s) | 33 (26.4)           | 27 (23.1)      | 60 (24.8)     |
| Irregular heart beating  | 36 (28.8)            | 40 (34.2)      | 76 (31.4)     |
| Never had before         | 29 (23.4)            | 29 (24.8)      | 58 (24.1)     |
| Yearly (or even less frequent) | 16 (19.9)         | 27 (23.1)      | 43 (18.7)     |
| Monthly                  | 27 (21.8)            | 25 (21.4)      | 52 (21.6)     |
| Weekly                   | 29 (23.4)            | 21 (17.9)      | 50 (20.7)     |
| More than once a week    | 104 (84.6)           | 94/116 (80.1)  | 198 (82.8)    |
| Gradually                | 19 (15.4)            | 22/116 (19.0)  | 41 (17.2)     |
| Suddenly                 | 48 (39.7)            | 47 (40.9)      | 95 (40.3)     |
| Gradually                | 73 (60.3)            | 68 (59.1)      | 141 (59.7)    |
| Participant able to end the attacks? | 19 (15.4)        | 14 (12.0)      | 33 (13.8)     |
| Recent alcohol use?      | 11 (8.8)             | 16 (13.7)      | 27 (11.2)     |
| Recent cocaine or amphetamine use? | 1 (0.8)        | 0 (0.0)        | 1 (0.4)       |
| Recent (last 7 days) febrile illness? | 9 (7.2)           | 8 (6.8)        | 17 (7.0)      |
| Past medical history     |                       |                |               |
| Previous or known hypertension/ischaeimic/coronary/valvular heart disease/failure | Yes (14 (11.3) | 20 (17.1) | 34 (14.1) |
| Previous or known anaemia or thyrotoxicosis | Yes (4) | 3 (2.6) | (2.9) |
5.3. Assessment of Safety and Adverse Events

Serious outcomes were routinely collected as part of the study. The only adverse events recorded were those directly related to the use of the smartphone-based event recorder and application.

5.4. Statistical Methods

5.4.1. Sample Size

Using a symptomatic rhythm detection rate at 90 days of 25% [4] versus standard care (10%), we estimated that 110 participants in each group would have 80% power to determine an absolute 15 percentage point improvement in symptomatic rhythm detection. We aimed to recruit an extra 10% in each group to allow for drop out (i.e., 121 participants in each group).

5.4.2. Analysis

Descriptive analysis of participants are presented split by allocated study group. Baseline to 90-day change in diagnostic yield between the two study groups was analysed using comparison of proportions tests. Additional comparison of proportions tests were used to compare further categorical binary variables between study groups (where expected counts were small the p-value from the Fisher's test was used instead). Categorical variables were compared using a $\chi^2$ test (and $Y^2$ test for trend if appropriate). Log-rank tests and Kaplan–Meier curves were used to examine if the smartphone recorder had an effect on the time to detection of symptomatic rhythm and symptomatic cardiac arrhythmia separately up to 90 days versus standard care. All participants were analysed on an intention to treat basis. Statistical significance was determined as $p < 0.05$ for all outcomes with an acknowledgment of increased type I error risk in the secondary outcomes not considered in the power calculation.

5.4.2.1. Economic Analysis. Overall and median healthcare utilisation costs (primary/community/secondary care and intervention costs) were calculated for both groups. The costing scope included primary care, secondary care and community NHS costs obtained from 2016/17 NHS reference cost data. A Mann–Whitney test was used to examine the overall cost-effectiveness between the smartphone-based event recorder and standard care. Healthcare utilisation costs per symptomatic

Table 3
Examination findings, initial ECG and management.

| Examination                        | Intervention (n = 125) | Control (n = 117) | Total (n = 242) |
|------------------------------------|-----------------------|------------------|-----------------|
| Initial pulse at triage /bpm - mean (SD) | 85.3 (19.4)           | 83.0 (15.2)      | 84.2 (17.5)     |
|                                   | (n = 124)             | (n = 116)        | (n = 240)       |
| Initial systolic BP at triage /mmHg - mean (SD) | 139.0 (22.5)          | 139.0 (20.5)     | 139.0 (21.5)    |
|                                   | (n = 124)             | (n = 116)        | (n = 240)       |
| Initial diastolic BP at triage /mmHg - mean (SD) | 83.8 (12.7)           | 84.1 (13.6)      | 83.9 (13.1)     |
|                                   | (n = 124)             | (n = 116)        | (n = 240)       |
| First postural difference if present /mmHg - mean (SD) | 6.7 (7.6)             | 0.3 (0.8)        | 3.8 (6.3)       |
|                                   | (n = 7)               | (n = 6)          | (n = 13)        |
| Admissions ECG                    |                       |                  |                 |
| Rate /bpm - mean (SD)             | 78.8 (18.8)           | 77.5 (16.1)      | 78.2 (17.5)     |
|                                   | (n = 117)             | (n = 107)        | (n = 224)       |
| QRS axis - median (IQR)           | 79.0 (39.0– 88.0)     | 80.0 (42.0– 90.0) | 79.5 (40.5– 89.0) |
|                                   | (n = 125)             | (n = 114)        | (n = 239)       |
| QTc int /ms - mean (SD)           | 395.1 (88.7)          | 401.5 (47.3)     | 398.2 (70.6)    |
| Sinus rhythm                      | 123 (98.4)            | 117 (100.0)      | 240 (99.2)      |
| PR > 200 ms                       | 7 (5.6)               | 4 (3.4)          | 11 (4.5)        |
| Slow risk in the initial portion of the QRS | 0.0                   | 0.0              | 0.0             |
| Heart block?                      | 0.0                   | 0.0              | 0.0             |
| QRS duration ≥ 120 ms             |                       |                  |                 |
|                                   | 2 (n = 124)           | 3 (n = 116)      | 5 (n = 240)     |
|                                   | 118 (n = 124)         | 115 (n = 116)    | 233 (n = 240)   |
| Number of ventricular ectopics    | 0 (n = 124)           | 1 (n = 116)      | 5 (n = 240)     |
|                                   | 4 (n = 117)           | 0.0              | 0.0             |
|                                   | 0 (n = 240)           | 0.0              | 0.0             |
|                                   | 0 (n = 240)           | 0.0              | 0.0             |
|                                   | 0 (n = 240)           | 0.0              | 0.0             |
|                                   | 0 (n = 240)           | 0.0              | 0.0             |
|                                   | 0 (n = 240)           | 0.0              | 0.0             |
|                                   | 0 (n = 240)           | 0.0              | 0.0             |
|                                   | 0 (n = 240)           | 0.0              | 0.0             |
| ED clinician rating of likelihood of any underlying cardiac arrhythmia | 0 (n = 124)           | 1 (n = 116)      | 1 (n = 240)     |
|                                   | 5 (n = 240)           | 11 (n = 233)     | 11 (n = 241)    |
|                                   | 1 (n = 117)           | 11 (n = 230)     | 11 (n = 241)    |
|                                   | 5 (n = 239)           | 11 (n = 238)     | 11 (n = 240)    |
|                                   | 0 (n = 238)           | 0.0              | 0.0             |
|                                   | 0 (n = 238)           | 0.0              | 0.0             |
| Management                        |                       |                  |                 |
| Participant discharged from the ED/AMU | 117                   | 114              | 231             |
|                                   | 129                   | 132              | 30 (n = 230)    |
| If admitted then where?           |                       |                  |                 |
| Ward - Non monitored              | 3 (n = 8)             | 2 (n = 3)        | 5 (n = 11)      |
|                                   | 37.5                  | 66.7             | 45.5            |
| Ward - Monitored                  | 0 (n = 8)             | 0 (n = 3)        | 0 (n = 3)       |
| Coronary Care Unit                | 2 (n = 8)             | 1 (n = 3)        | 3 (n = 11)      |
| Direct to cardiology ward         | 3 (n = 8)             | 3 (n = 11)       | 27.3            |
| Reason(s) for admission?          |                       |                  |                 |
| Palpitation/pre-syncope investigation | 8 (n = 8)              | 2 (n = 3)        | 10 (n = 11)     |
| Other                             | 0 (n = 8)             | 0.0              | 1 (n = 11)      |
|                                   | 33.3                  | 1 (n = 11)       | 9.1             |
rhythm diagnosis were calculated for both groups using overall healthcare utilisation cost and number of patients with a symptomatic rhythm in each group. Analyses were performed in SAS 9.4 (SAS Institute, Cary NC). The sponsor deemed that a data monitoring committee was not required. This trial was registered at ClinicalTrials.gov (trial registration number NCT02783898), and the protocol published in Trials [26].

6. Results

Between 4 July 2016 and 9 January 2018, 243 participants were recruited to the study at 10 centres (Edinburgh 66 participants, 27.2%, Reading 57, 23.5%, Royal London 43, 17.7%, Exeter 24, 9.9%, Plymouth 15, 6.2%, Chesterfield 12, 4.9%, Leicester 12, 4.9%, Musgrove Park 5, 2.1%, Nottingham 5, 2.1%, Whips Cross 4, 1.6%). Fig. 1 details the study recruitment diagram, and Table 2 details the baseline characteristics of enrolled participants. One hundred twenty-six participants were allocated to the intervention group and 117 to the control group. Two hundred nineteen (90.5%) participants presented with palpitations or pre-syncope. One participant was removed from the study by the local study team after being randomised, as they did not meet the inclusion criteria. Baseline data were therefore collected on 125 participants in the intervention group and 117 in the control group. Participants ranged from 17 to 74 years of age with a mean age of 39.5 (SD 13.7). Table 3 details examination findings, initial ECG and management. One participant in each group was lost to follow-up leaving 124 participants available for analysis in the study group and 116 in the control group.

A symptomatic rhythm was detected at 90 days in 69 (n = 124; 55.6%; 95% CI 46.9–64.4%) participants in the intervention group versus 33 (25.2%; 95% CI 16.7–34.9%) participants in the control group (RR 5.9, 95% CI 3.3–10.5; p = 0.0001). A symptomatic cardiac arrhythmia was detected at 90 days in 11 (n = 116; 9.5%; 95% CI 4.2–14.8) in the control group versus 1 (0.8%; 95% CI 0.0–4.5) in the intervention group (RR 13.9, 95% CI 3.9–46.8; p = 0.006).

The mean time to symptomatic rhythm detection in the intervention group was 9.5 days (SD 16.1, range 0–83) versus 42.9 days (SD 16.0, range 12–66) in the standard care group (p < 0.0001). Fig. 2 shows the Kaplan–Meier curve of proportion of participants undiagnosed versus time up to 90 days for the intervention and control groups. Commonest symptomatic rhythms detected were sinus rhythm (in 53 participants; 66.3%), sinus tachycardia (19; 23.8%) and ectopic beats (13; 16.3%). Some participants had more than one symptomatic rhythm recorded. Eighty participants had a symptomatic rhythm detected with 12 of these having a symptomatic cardiac arrhythmia (atrial fibrillation or flutter, SVT and sinus bradycardia) and 68 having sinus rhythm, sinus tachycardia or ectopics [Table 4]. There were four cases where the central cardiology team were required for further ECG opinion after review by both the central on call and trial team Emergency Physicians. Table 4 also details how the diagnosis was made in both groups.

The mean time to symptomatic cardiac arrhythmia detection in the intervention group was 9.9 days (SD 15.6, range 1–55) versus 48.0 days (1 participant) in the control group (p = 0.0004). Symptomatic cardiac arrhythmias were AF (8 intervention, 0 standard care), SVT (3 intervention, 0 standard care), sinus bradycardia (0 intervention, 1 standard care) and atrial flutter (1 intervention, 0 standard care).

Serious outcome at 90 days in the intervention group was 11 (8.9%) versus 2 (1.7%) in the control group (p = 0.02). At 90 days, 12 participants in the intervention group were subsequently undergoing (or planning to undergo) treatment for symptomatic cardiac arrhythmia versus 6 in the control group (p = 0.192). Table 5 details the results of the participant satisfaction and monitor compliance questionnaire. Eighty of 92 (87.0%) participants found the AliveCor monitor easy to use. There were more ED presentations (after index visit) due to palpitations/pre-syncope in the intervention group (12/124; 9.7%; 95% CI 4.5–14.9% with 1 or more non index ED presentations) compared to the control group (3/116; 2.6%; 95% CI 0.0–5.5%; p = 0.031). The only death in the study was in the intervention group in a participant known to have treated congenital structural heart disease whose death was thought unrelated to his initial presentation to the ED.

There was no difference in the number of participants with one or more inpatient hospital days (over all admissions) due to palpitations or pre-syncope in the intervention group (2; n = 122; 2 patients with no data; 1.6%; 95% CI 0.0–3.8%) compared to the control group (1; n = 116; 0.9%; 95% CI 0.0–2.5%; p = 0.999), number of outpatient presentations due to palpitations or pre-syncope (p = 0.058), number of GP visits (8.8% versus 4.8% in the intervention and control groups; p = 0.104). There were 68 participants who recorded the AliveCor monitor at home during the study period. Eighty of 92 (87.0%) participants found the AliveCor monitor easy to use. There were four cases where the central cardiology team were required for further ECG opinion after review by both the central on call and trial team Emergency Physicians. Table 4 also details how the diagnosis was made in both groups.

![Fig. 2. Kaplan–Meier curve showing number of participants undiagnosed (y axis) versus time up to 90 days (x axis) in both study groups.](image-url)
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with palpitations or near syncope the incorporation of a patient-underlying cause of the patient's symptoms. In patients presenting rhythm correlation rate over

group (£1395). Median overall healthcare utilisation cost (primary/commu-nity/secondary care and intervention costs) in the intervention group was £108 (IQR 99.0–2697) versus £0 in the standard care group (IQR 0–120.0, range 0–4161; p = 0.0001). Cost per symptomatic rhythm diagnosis was £921 less per patient per symptomatic rhythm in the intervention group (£474) compared to the control group (£1395).

7. Discussion

Use of a smartphone-based event recorder increases the symptom-rhythm correlation rate over five-fold at 90 days with a reduced cost per diagnosis. These are clinically significant rhythms as they diagnose the underlying cause of the patient's symptoms. In patients presenting with palpitations or near syncope the incorporation of a patient-activated detection device into routine practice may overcome some of the current difficulties in diagnosis caused by the normalisation of cardiac rhythm by the time the patient undergoes a clinical assessment. Given the frequency of patients presenting to the ED with palpitations and pre-syncope, our study findings suggest that a smartphone-based event recorder should be considered as part of on-going care of all patients presenting acutely with these symptoms.

There are different potential ways of incorporating the technology into patient care, which may depend on the configuration of local healthcare systems. In this study the devices and instructions were given to patients in the ED by a researcher, but this could also be undertaken at a follow-up appointment with a specialist nurse or family practitioner, where there is less time pressure than in emergency care. In this study, the ECGs were transmitted for central analysis; however, an alternative approach may be for the patient to show, on their smartphone, any recorded ECGs at a follow-up appointment. This would reduce the need for the transfer of sensitive patient data and mean that a clinical system to respond to emailed ECGs would not be required. The AliveCor app rhythm analysis algorithm automatically reports any rhythms as they diagnose the cause of symptoms to the time I initially visited the Emergency ward. 80 patients had a subsequent ED attendance in the intervention group compared the control group. Whilst this number is small, it may be that the remote transmission of an ECG did not give the patient the immediate reassurance that they required. The psychology of patient interaction with 'smart' personal medical devices is an emerging field, and better understanding of patient/device interaction is likely to be important in realising the potential benefits of new technologies.
The patients found the monitor easy to use. This reinforces data from previous work in ED patients which showed that 74% found it acceptable to use a smartphone to monitor their health, 79% to use a medical device connecting to a smartphone to monitor their health, and 77% reported that they would feel confident to use such technology [27]. There is a concern that self-monitoring may lead to increased anxiety; however when the Arrhythmia Alliance [14] distributed AliveCor Heart Monitors to 1500 people of all ages, only one returned their monitor because it caused them to worry and check their heart rate too often.

We found that the commonest reason for a patient not to be able to participate was that they did not possess a smartphone. We did not record the age of non-participants, but it is likely that these were older patients. However, whilst smartphone ownership decreases with age our previous research shows 64% of those aged 50–75 and 30% over 75 years of age own a smartphone [27], and in the Arrhythmia Alliance study, older people were noted to be regular users of mobile technology and gave positive feedback about the system [14].

This study confirms previous evidence that most symptomatic rhythms in patients with palpitations or pre-syncope are benign [28]. Only 12 of 240 participants in the study experienced a symptomatic cardiac arrhythmia; the remaining 68 with symptomatic palpitations or pre-syncope were found to have sinus rhythm, sinus tachycardia or ectopic beats. Even in the absence of underlying arrhythmia, previously unexplained symptoms can cause anxiety and can have a significant impact on quality of life [29]. With such a low incidence of cardiac diagnoses in this population, it is perhaps appropriate that follow-up of these patients is in community care rather than in cardiology clinics (where currently these conditions account for up to one-fifth of all referrals) [30–33], with only patients diagnosed with a symptomatic cardiac arrhythmia being referred to specialist care.

This study suggests that the AliveCor technology performs effectively and safely. The randomised, prospective design with systematic data collection is a key strength of the study. Whilst there was a potential variation in standard care between sites, this element of pragmatic design ensures our findings are generalisable across all types of standard care in the UK National Health Service without compromising validity. Potential limitations of our study include a large proportion of recruitment occurring in office hours largely by research staff in research active hospitals and the use of a central ECG reading service not available in routine practice.

Only one type of device was studied and many similar devices are entering the market. We think that the results of this study will be generalisable across many forms of patient-activated, symptom-based home ECG recording devices. Subtle differences in design or incorporation into clinical workflow may have an influence on effectiveness, so novel devices should undergo clinical evaluation. It is also possible that patients choosing to take part in a study of new technology may be more motivated to use the device, and it may not perform as well in a non-study setting.

In summary, this study demonstrates the ability of a smartphone-based event recorder to improve clinical care and patient experience for those suffering undiagnosed palpitations and pre-syncope. These findings are likely to be generalisable from Emergency Medicine to General/Internal/Acute Medicine and General (Family) Practice in a broad range of developed healthcare systems. A safe, non-invasive and easy to use smartphone-based event recorder should be considered part of on-going care of all patients presenting acutely with unexplained palpitations or pre-syncope.

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Availability of Data and Material

The datasets generated and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing Interests

The authors declare that they have no competing interests and no financial interest in the device used in this study. AliveCor had no involvement in the study.

Authors’ Contributions

MR was responsible for the conception of the study. MR, NG, CL, ROB, KS and ST were responsible for the design of the study. ROB, MP, AG, MR, LK, FC, LJ, TH, GL, JG, JS and TC were responsible for acquisition of data, MR, ROB, NG, CL and ST were involved in data analysis and all authors were involved in interpretation of data, drafting the article and revising it critically for important intellectual content. All authors approved the final submitted version and agree to be accountable for all aspects of the work.

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