Technoleg Iechyd Cymru
Health Technology Wales

Evidence Appraisal Report [1]

Smartphone based photoplethysmography for the detection and monitoring of atrial fibrillation

Appraisal summary

Why did Health Technology Wales (HTW) appraise this topic?

Atrial fibrillation (AF) is the most common form of arrhythmia, and if left uncontrolled, can lead to hospitalisation, and is associated with a range of serious health issues such as strokes and heart failure. More than 1.6 million people in the UK (BHF 2025), and more than 80,000 people in Wales have been diagnosed with atrial fibrillation (BHF 2024). In Wales, atrial fibrillation is a contributing factor to one in five strokes and there are approximately 15,000 people aged 65 years or older with undiagnosed atrial fibrillation in Wales (BHF 2024). AF has a broad impact on health services across both primary and secondary care. The development of smartphone-based screening and monitoring devices has the potential to increase screening coverage, improve clinical detection, and facilitate the monitoring of AF without the need for external and additional hardware.

What evidence did HTW find?

HTW researchers identified 11 observational studies (Brasier et al. 2019, Calvert et al. 2024, Fernstad et al. 2024, Gawałko et al. 2024, Gruwez et al. 2024a, Gruwez et al. 2024b, McManus et al. 2013, McManus et al. 2016, Mol et al. 2020, Proesmans et al. 2019, Rozen et al. 2018). The evidence included in this review suggests there are outcomes to support the effectiveness of photoplethysmography applications to detect AF in those suspected of having AF and/or under monitoring for AF, although the statistical significance of some outcomes were not reported and there are several limitations of the studies that are noted in this review. Outcomes reported in the evidence base included diagnostic accuracy outcomes which were reported across nine studies: sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), correctly classified rate, rate of no diagnosis, overall accuracy and atrial arrhythmia recurrence rate. Other outcomes included resource use (reported in two studies), environmental outcomes (reported in one study), patient compliance (reported in three studies), signal quality and technical failure (reported in five studies) changes to patient management (reported in one study), and adverse events (reported in one study).

[1] Cyfieithu dogfennau HTW wedi'u cyhoeddi o'r Saesneg i'r Gymraeg
Translation of published technical HTW documents from English into Welsh

One directly applicable economic analysis was identified which considered a retrospective analysis of UK patients using the FibriCheck smartphone app in comparison to 12-lead electrocardiogram (ECG) monitoring. The study showed that healthcare costs were significantly lower in patients managed with photoplethysmography (PPG). However, this estimation was based on the FibriCheck activation charge and the cost of ECG appointments only. In addition, the retrospective design of the analysis could introduce some bias due to differences in the characteristics of the intervention and comparator cohorts.

What was the outcome of HTW's appraisal?

Smartphone photoplethysmography (PPG) shows promise for the detection and monitoring of atrial fibrillation in adults with known or suspected atrial fibrillation, but the evidence is insufficient to support routine adoption.

The available evidence indicates that PPG applications have good diagnostic accuracy, and their use could potentially lead to a reduction in resource use and a faster diagnosis for some patients.

The evidence to support longer-term effectiveness and long-term resource use savings is limited and there is not enough evidence to support the cost effectiveness of smartphone PPG.

The Appraisal Panel strongly encourages further research generation in this area.

1. Purpose of the Evidence Appraisal Report

This report aims to identify and summarise evidence that addresses the following question: What is the clinical and cost effectiveness of smartphone based photoplethysmography for the detection and monitoring of atrial fibrillation among people with suspected or confirmed atrial fibrillation?

Evidence Appraisal Reports are based on rapid systematic literature searches, with the aim of identifying the best published evidence on the effectiveness and cost-effectiveness of health and social care technologies and models of care and support. Researchers critically evaluate this evidence. The draft Evidence Appraisal Report is reviewed by experts and by Health Technology Wales multidisciplinary advisory groups before publication.

2. Context

Atrial fibrillation (AF) is the most common form of arrhythmia and has a broad impact on all health services across primary and secondary care. It is a heart rhythm abnormality and is characterised by rapid and irregular beating of the atrial chambers of the heart resulting from structural and electrical causes. Arrhythmias can be self-limiting in their early stages and resolve without treatment but can also be progressive, meaning that intermittent atrial fibrillation can become persistent over time and abnormal rhythms can eventually become permanent and less amenable to treatment. The European Society of Cardiology (ESC) clinical practice guidelines outline four classifications of atrial fibrillation: first-diagnosed AF, paroxysmal AF, persistent AF and permanent AF (ESC 2024). Atrial fibrillation can be symptomatic, with people experiencing shortness of breath, or sensing that their heart rate is too fast, irregular, or is skipping beats. They may also experience chest pain and fatigue. If a person's heart rate remains rapid and uncontrolled, their health may deteriorate, and this could lead to hospitalisation.

Atrial fibrillation has a global prevalence of 2-4% and is expected to rise (Gruwez et al. 2024a). Atrial fibrillation is a major risk factor for strokes and is associated with higher morbidity and mortality (Bordignon et al. 2012). People with this condition are more than five times more likely to have a stroke (BHF 2025). Atrial fibrillation is more likely to occur in people with high blood pressure (hypertension), atherosclerosis or a heart valve problem (NHS 111 Wales 2025). Atrial fibrillation is also more common in older people, and men (NHS 111 Wales 2025). More than 1.6 million people in the UK (BHF 2025), and more than 80,000 people in Wales have been diagnosed with atrial fibrillation (BHF 2024). In Wales, atrial fibrillation is a contributing factor to one in five strokes and there are approximately 15,000 people aged 65 years or older with undiagnosed atrial fibrillation in Wales (BHF 2024).

3. Guidelines

3.1 ESC Guidelines for the management of atrial fibrillation

ESC clinical practice guidelines for the management of atrial fibrillation (updated in August 2024) set recommendations for heart rate control in people with AF (ESC 2024). Rate control therapy is recommended, as initial therapy in the acute setting, as an adjunct to rhythm control therapies, or as a sole treatment strategy to control heart rate and reduce symptoms. It is recommended that atrial fibrillation should be confirmed by an electrocardiogram (12-lead, multiple, or single leads) to establish the clinical diagnosis of AF, risk stratification and

treatment. The ESC state that the role of photoplethysmography technology for AF screening to assess AF burden and reduce stroke is still unclear.

The ESC also published an EHRA practical guide on how to use digital devices to detect and manage arrhythmias (Svennberg et al. 2022). The aim of the document was to provide practical guidance on the use of digital devices for arrhythmias (including early detection, management and implementation). The guide states that while 12-lead ECG is the gold standard for the diagnosis of arrhythmias, it is not always available and cannot diagnose paroxysmal arrhythmias if the recording is performed during asymptomatic periods. Digital devices that are ECG-based can overcome these limitations of availability according to the guide. The practical guide states that photoplethysmography (PPG) recordings may be of aid in symptomatic patients with a very low probability of symptoms that are being caused by arrhythmias to document a normal rhythm and normal heart rate. However, any arrhythmias detected using PPG recordings should be confirmed by a 12-lead ECG if possible or an ECG-based device when 12-lead ECG is not available, or the duration of arrhythmia does not allow an ECG-based recording.

3.2 Atrial fibrillation: diagnosis and management NICE guideline [NG196]

NG196 covers diagnosing and managing atrial fibrillation in adults (NICE 2021). For the detection and diagnosis of AF, the guideline recommends a 12-lead ECG if an irregular pulse is detected in people with suspected AF with or without symptoms [recommendation 1.1.2]. In people with suspected paroxysmal AF undetected by 12-lead ECG recording, NICE recommends the use of a 24-hour ambulatory ECG monitor if asymptomatic episodes are suspected, or symptomatic episodes are less than 24 hours apart. NICE also recommends the use an ambulatory ECG monitor, event recorder or other ECG technology for an appropriate period to detect atrial fibrillation if symptomatic episodes are more than 24 hours apart [recommendation 1.1.3]. For the management of people presenting acutely with atrial fibrillation, the guideline recommends conducting emergency electrical cardioversion, without delaying it to achieve anticoagulation, in people with life-threatening haemodynamic instability caused by new-onset AF [recommendation 1.8.1].

3.2.1 KardiaMobile for detecting atrial fibrillation NICE guidance [MTG64]

KardiaMobile, (an alternative to traditional ECG and PPG) is a portable ECG recorder for detecting AF which works alongside a smartphone device. It is a single-lead device and has two electrodes on the top surface. The person places two fingers on each electrode to record their ECG. NICE medical technologies guidance [MTG64] recommended KardiaMobile for the detection of AF for people with suspected paroxysmal AF, who present with symptoms such as palpitations and are referred for ambulatory ECG monitoring by a clinician (NICE 2022). The evidence showed that significantly more people had AF detected using the KardiaMobile single-lead device compared with a Holter monitor.

Information from the experts who contributed to this appraisal agreed that the use of KardiaMobile is increasing in some parts of Wales although it is more widely used in secondary care rather than primary care. Clinicians stated that they do not get the same level of specificity that is reported in the literature, although one expert highlighted that it has a much greater diagnostic yield than a Holter monitor.

4. Health technology

Photoplethysmography (PPG) signal analysis using smartphones, is a non-invasive and potentially cost-effective option for the screening and monitoring of AF (Brasier et al. 2019). PPG based applications use the light-emitting diode in cameras to measure pulsatile changes in light intensity that are reflected from a finger or face to distinguish AF from sinus rhythm (Gill et al. 2022).

For the purpose of this review, studies were only included if they evaluated the use of PPG in adults with known or suspected AF. Any type of screening study evaluating the use of PPG to screen for AF in the general or wider populations, including populations deemed at a higher risk of AF due to age or other conditions were excluded. For full inclusion and exclusion criteria, please see Appendix 2.

There are multiple applications reported across the evidence base using PPG for the detection and/or management of AF including: FibriCheck, Preventicus, Cardiio Rhythm, Pulse-Smart, Happitech, and CORAI which are detailed below.

This topic was proposed by Bieke Van Gorp at FibriCheck.

4.1 FibriCheck

FibriCheck (Qompium, Hasselt, Belgium) is CE marked as a class IIa medical device and has received clearance from the Food and Drug Administration (FDA). FibriCheck uses the camera of a smartphone to detect small changes in light absorption in the subcutaneous capillaries of the fingertip to measure cardiac rhythm. Data is automatically and securely transferred to the FibriCheck portal (web-based tool), allowing healthcare providers to gather remote insights into their clients' condition and guide clinical decisions.

In terms of how the app works in clinical practice, healthcare providers decide who uses FibriCheck, for how long. FibriCheck is prescribed to those eligible for monitoring at specific intervals. Information from the topic proposer explains that clinicians can provide access to the app remotely and is typically provided for 7 to 14 days but this is adjustable. The process involves healthcare providers explaining the application with instructions, people then independently download the FibriCheck app to self-monitor various health metrics, with results automatically analysed and shared via a portal to allow interpretation.

Calvert et al. (2024), Gawałko et al. (2024), Gruwez et al. (2024a), Gruwez et al. (2024b), and Proesmans et al. (2019) report relevant outcomes on FibriCheck.

4.2 Preventicus

Preventicus via the Heartbeats app is another PPG application for the screening, detection and monitoring of AF, although we have excluded studies evaluating the screening of the general population. It is CE marked as a class IIa medical device. The application works in the same way as FibriCheck (i.e., it uses PPG via the smartphone camera to distinguish AF from sinus rhythm). The app then generates a PPG report for the user and clinician/doctor. Brasier et al. (2019) reports diagnostic accuracy outcomes on the Preventicus application.

4.3 Cardiio Rhythm

Cardiio Rhythm measures heart rhythm through recording PPG from either the fingertip or the face without physical contact. Rozen et al. (2018) reports diagnostic accuracy outcomes on the Cardiio Rhythm application. This application is currently not CE marked as a medical device, and it is unclear whether the application is available for use in the UK.

4.4 Pulse-Smart

McManus et al. (2013) and McManus et al. (2016) evaluated the diagnostic accuracy of Pulse-Smart using an iPhone 4S camera directly on participants' right index or second finger for two minutes. This application is currently not CE marked as a medical device, and it is unclear whether the application is available for use in the UK. Information from the experts involved in the expert review process for this topic suggested that Pulse-Smart is designed for wellness purposes and is not intended to be used as a medical device. Additionally, users may be required to use an additional device, which would fall outside of the remit for this EAR.

4.5 Happitech

Mol et al. (2020) reports diagnostic accuracy outcomes and signal quality of a PPG algorithm developed by Happitech in adults diagnosed with AF who are admitted to hospital for elective electrical cardioversion. Happitech is CE marked as a class IIa medical device.

4.6 CORAI

Fernstad et al. (2024) published a prospective validation study on the diagnostic accuracy of the CORAI PPG software application (Corai Medicinteknik AB, Stockholm, Sweden) which is a Class IIb medical device that uses smartphones, such as the iOS (Apple iPhone) and Android operating systems. CORAI uses the built-in sensors of the smartphone to record a PPG measurement from the tip of a person's finger over the camera.

5. Effectiveness

We searched for evidence that could be used to answer the research question: What is the clinical and cost effectiveness of smartphone based photoplethysmography for the detection and management of atrial fibrillation?

For details on the methodology used to identify evidence for this report, refer to Appendix 1.

5.1 Overview

HTW researchers identified 11 observational studies (Brasier et al. 2019, Calvert et al. 2024, Fernstad et al. 2024, Gawałko et al. 2024, Gruwez et al. 2024a, Gruwez et al. 2024b, McManus et al. 2013, McManus et al. 2016, Mol et al. 2020, Proesmans et al. 2019, Rozen et al. 2018). The evidence base included a mixture of prospective cohort studies, case control studies, cross over studies, and retrospective studies, all of which were either in primary or secondary care.

Of the 11 studies identified, eight studies included participants undergoing an interventional procedure (e.g. cardioversion or ablation) for AF (Calvert et al. 2024, Fernstad et al. 2024, Gruwez et al. 2024a, Gruwez et al. 2024b, McManus et al. 2013, McManus et al. 2016, Mol et al. 2020, Rozen et al. 2018). Of these, five studies recorded PPG measurements before and after an interventional procedure (Gruwez et al. 2024a, McManus et al. 2013, McManus et al. 2016, Mol et al. 2020, Rozen et al. 2018), rather than using the application for longer-term monitoring of AF. Although Gruwez et al. (2024a) instructed participants to perform a 'measurement set' of readings twice daily for four weeks both before and after an ablation procedure, overall results are reported. Two studies specifically evaluated the use of longer-term PPG monitoring during post-intervention follow up (Fernstad et al. 2024, Gruwez et al. 2024b). In Gruwez et al. (2024b), participants were instructed to perform FibriCheck PPG measurements twice daily (for 60 seconds) or whenever symptoms were perceived for one year. Each participant completed both conventional (3 outpatient appointments and 3 periods of 24 hours ECG Holter monitoring) and digital follow-up (using FibriCheck). In Fernstad et al. (2024), participants were instructed to measure one minute heart rhythm recordings twice daily for 30 days using the CORAI application alongside using KardiaMobile simultaneously. Calvert et al. (2024) also evaluated the use of FibriCheck for the monitoring of AF post-intervention (for elective direct current cardioversion, DCCV) although this was performed as a one-off measurement. Participants in the PPG group were instructed to take one, one minute PPG reading at 14 days post-DCCV.

Gawałko et al. (2024) also evaluated PPG for the remote management of AF with participants instructed to perform PPG recordings 3 times per day, and at time of any symptoms, one week prior to scheduled teleconsultations during the TeleCheck-AF project over three months. Participants in this study were recruited from an AF clinic, and it is unclear whether they had received an interventional treatment. The remaining two studies (Brasier et al. 2019, Proesmans et al. 2019) evaluated the use of PPG in participants with known AF through the examination of medical records, although Proesmans et al. (2019) included a 'convenience sample' of participants without a history of AF. The review did not identify any studies evaluating the use of PPG to detect AF in those with symptoms or suspected of having AF but who had not been diagnosed.

Five studies evaluated the use of the FibriCheck application (Calvert et al. 2024, Gawałko et al. 2024, Gruwez et al. 2024a, Gruwez et al. 2024b, Proesmans et al. 2019), two studies evaluated Pulse-Smart (McManus et al. 2013, McManus et al. 2016), one study evaluated Preventicus (Brasier et al. 2019), one study evaluated Cardiio Rhythm (Rozen et al. 2018), one study evaluated Happitech (Mol et al. 2020) and one study reported on the CORAI application (Fernstad et al. 2024). All primary studies were published between 2013 and 2024. One study was conducted in

Switzerland and Germany (Brasier et al. 2019), one study was conducted in Sweden (Fernstad et al. 2024), one study was in the UK (Calvert et al. 2024), two studies were based in the Netherlands (Gawałko et al. 2024, Mol et al. 2020), three were in Belgium (Gruwez et al. 2024a, Gruwez et al. 2024b, Proesmans et al. 2019) and three were based in the USA (McManus et al. 2013, McManus et al. 2016, Rozen et al. 2018). Ten studies were conducted in secondary care and one study was conducted in primary care.

Most of the evidence (N=7) compared a PPG application with a standard 12-lead ECG, although not all outcomes were prospectively compared to ECG measurements. Four studies compared a PPG application to a single-lead ECG (e.g., KardiaMobile) (Brasier et al. 2019, Fernstad et al. 2024, Gruwez et al. 2024a, Proesmans et al. 2019). The prevalence of AF or AFL (atrial flutter) varied considerably across the evidence base and ranged from 42% in Brasier et al. (2019) to 100% in six studies (Calvert et al. 2024, Fernstad et al. 2024, Gawałko et al. 2024, Gruwez et al. 2024a, McManus et al. 2013, Mol et al. 2020). The sample size in the primary studies ranged from 37 (Gawałko et al. 2024) to 592 (after exclusions) (Brasier et al. 2019). The average age of participants ranged from 61.9 years (Calvert et al. 2024) to 78 years (Brasier et al. 2019).

Outcomes reported in the evidence base included diagnostic accuracy outcomes: sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), correctly classified rate, rate of no diagnosis, overall accuracy, one-year atrial arrhythmia recurrence and detection of symptomatic atrial arrhythmia. Other outcomes included resource use, environmental outcomes, patience compliance, adverse events, signal quality, changes to patient management, and technical failure.

For fuller details on the study characteristics of studies included in this appraisal, see Appendix 5, Table A-1. For fuller details on the outcomes detailed below, see Table 1 and Table 2.

5.2 Diagnostic accuracy of photoplethysmography (PPG)

5.2.1 Smartphone PPG versus single-lead ECG

5.2.1.1 Studies including participants undergoing interventional procedures for AF (e.g., elective direct current cardioversion or ablation)

Two studies report diagnostic accuracy outcomes of PPG applications when compared with a single-lead ECG among participants undergoing an interventional procedure.

In their prospective validation study, Fernstad et al. (2024) ran the CORAI Heart Monitor PPG application simultaneously with a single-lead ECG recording (KardiaMobile) among 280 participants undergoing DCCV for persistent or recent onset of AF or AFL (atrial flutter). One minute heart rhythm recordings post-treatment were recorded twice daily for 30 days. Manual readings of the PPG recordings, compared with manually interpreted ECG recordings, had a sensitivity, specificity, PPV, NPV and overall accuracy of 97.7% [95% confidence interval [CI]: 97.3%–98.1%], 99.4% [95% CI: 99.3%–99.6%], 98.9% [95% CI: 98.7%–99.1%], 99.0% [95% CI: 98.8%–99.2%] and 98.9% [95% CI: 98.7%–99.1%] for both AF and AFL recordings and 99.0% [95% CI: 98.8%–99.2%], 99.7% [95% CI: 99.6%–99.8%], 99.2% [95% CI: 99.0%–99.5%], 99.2% [95% CI: 99.0%–99.5%], 99.5% [95% CI: 99.4%–99.6%] respectively, with AFL recordings excluded (p value, not reported [NR]).

Gruwez et al. (2024a) conducted a prospective validation study among 50 participants who were scheduled for AF ablation. Participants were instructed to perform a ‘measurement set’ twice daily, commencing four weeks prior to the ablation procedure and continuing four weeks after the procedure (total of eight weeks). The study reported the sensitivity of FibriCheck when compared to KardiaMobile (analysed by two cardiologists) to be 98.3% [95% CI: 96.7%–99.9%], a

specificity of 99.9% [95% CI: 99.8%–100.0%], a PPV of 99.6% [95% CI: 99.1%–100.0%] and a NPV of 99.6% [99.0%–100.0%], however the study does not report respective diagnostic accuracy outcomes for KardiaMobile.

5.2.1.2 Studies including participants with a history of AF

Brasier et al. (2019), conducted a case-control study among participants with a history of AF as identified from medical records. The study reports the diagnostic accuracy of Preventicus for the detection of AF versus KardiaMobile (single lead ECG analysed by two cardiologists) based on 1-minute, 3-minute and 5-minute PPG analyses. Sensitivity for the PPG cohort was reported as 90% [95% CI: 86%-93%] based on 1-minute PPG analysis versus 99.6% [95% CI: 97.9%–100%] for KardiaMobile (Brasier et al. 2019), although the statistical significance was not reported. The sensitivity values of the PPG cohort increased slightly for the 3-minute and 5-minute analyses, although this was not prospectively compared with KardiaMobile. For the 3-minute analysis the sensitivity for the PPG cohort was 91.3% [95% CI: 86.5%–94.7%] and 91.5% [95% CI: 85.9%–95.4%] for the 5-minute PPG analysis (p value, NR). Brasier et al. (2019) reported the specificity of the PPG cohort as 99% [95% CI: 98%–100%] versus 97.8% for KardiaMobile based on 1-minute PPG analysis although the statistical significance was not reported (Brasier et al. 2019).

Brasier et al. (2019) reported the correctly classified rate (CCR) and the percentage of no diagnosis due to unsuitable readings or poor signal quality. For the PPG cohort, the CCR was reported as 88.8 [95% CI, NR] based on 1-minute PPG analysis versus 82.2 (95% CI: NR) for KardiaMobile (Brasier et al. 2019), although the statistical significance was not reported. The CCR for the 3-minute analysis was 77.6 and 60.9 for the 5-minute analysis, although this was not prospectively compared with KardiaMobile. The percentage of no diagnosis for the 1-minute analysis was 6.7% for the PPG cohort, versus 18.8% for KardiaMobile. The percentage of no diagnosis increased in the PPG cohort in the 3-minute analysis (13%) and the 5-minute analysis (32.2%).

Proesmans et al. (2019) conducted a prospective cohort study of FibriCheck in people aged 65 years or older with AF, although a convenience sample was also included (n=79/223) which included people without AF. Participants were instructed to record 3 consecutive PPG measurements which lasted one minute. The reference standard was a 12-lead ECG. The sensitivity was 96% [95% CI: 89%–99%] versus 95% [95% CI: 88%–98%] for single-lead ECG, the specificity was 97% [95% CI: 91%–99%] for FibriCheck versus 97% [95% CI: 91%–99%] for single-lead ECG. The PPV was 95.6% [95% CI: NR] for FibriCheck (after insufficient quality readings were excluded) versus 95.7% for single-lead ECG (p value, NR). The NPV was 96.6% [95% CI: NR] for FibriCheck versus 95.7% [95% CI: NR] for single-lead ECG (p value, NR) and the overall accuracy was reported as 96.1% for FibriCheck versus 95.7% for single-lead ECG.

5.2.2 Smartphone PPG versus 12-lead ECG and/or Holter monitor

5.2.2.1 Studies including participants undergoing interventional procedures for AF (e.g., elective direct current cardioversion or ablation)

Five studies report diagnostic accuracy outcomes of PPG applications when compared with a 12-lead ECG among participants undergoing an interventional procedure (Gruwez et al. 2024b, McManus et al. 2016, McManus et al. 2013, Mol et al. 2020, Rozen et al. 2018).

Gruwez et al. (2024b) compared atrial arrhythmia recurrence after ablation using digital follow-up (FibriCheck) alongside conventional ECG-based follow-up and 24-hour Holter monitoring. Participants were instructed to perform PPG measurements twice daily (for 60 seconds) or

whenever symptoms were perceived for one year. Measurements categorised as AF by the application algorithm were subsequently reviewed by a medical technician.

McManus et al. (2016) and (McManus et al. 2013) included participants with AF scheduled to undergo elective cardioversion at the University of Massachusetts Medical Centre (UMMC) whereby two-minute pulse-recordings were obtained before and after cardioversion. Mol et al. (2020) included participants with AF who were admitted to OLVG Hospital (Amsterdam, The Netherlands) for elective DCCV. PPG recordings were obtained directly before and after cardioversion using an iPhone 8. Rozen et al. (2018) recruited participants with a diagnosis of AF who were scheduled for DCCV. The PPG recording lasted 20 seconds, conducted 3 times daily before and the DCCV procedure (total of one minute before, one minute after).

Sensitivity values across the studies were 96% [95% CI: NR] for Pulse-Smart (assumed) (McManus et al. 2013), 97% [95% CI: NR] for Pulse-Smart (McManus et al. 2016), 93.1% [95% CI: 86.9%–97.2%] for FibriCheck (Rozen et al. 2018), 94.1% [95% CI: 71.3%–99.8%] for FibriCheck in (Gruwez et al. 2024b) and 98.1% [95% CI: 93.4%–99.8%) when excluding low confidence recordings] for Happitech (Mol et al. 2020). Specificity values reported across the studies were 98% [95% CI: NR] for Pulse-Smart (assumed) (McManus et al. 2013) 94% [95% CI: NR] (McManus et al. 2016) for Pulse-Smart, 98.1% [95% CI: 93.2%–99.8%] (when excluding low confidence recordings) for Happitech (Mol et al. 2020), and 90.9% [95% CI: 82.9%–96%] for Cardiio rhythm (Rozen et al. 2018), although the statistical significance of the above values were not reported. The PPV reported in Rozen et al. (2018) for Cardiio Rhythm was 92.2% [95% CI: 85.8%–95.8%) and the NPV as 92% [95% CI: 94.8%–95.9%] although the statistical significance of the above values were not reported. The NPV for FibriCheck was 98.3% [95% CI: 90.9%–99.9%] reported in (Gruwez et al. 2024b). The overall accuracy values for Pulse-Smart were 96.7 (McManus et al. 2013) and 95.1 (McManus et al. 2016).

In their non-inferiority analysis, Gruwez et al. (2024b) found a statistically significant increase in the one-year atrial arrhythmia recurrence after the ablation blanking period when compared with conventional follow-up (38.5% versus 17.7% [odds ratio, OR], 3.4; 95% CI: 1.7%–7.1%; p=0.001). Gruwez et al. (2024b) also found an increased detection rate of symptomatic atrial arrhythmia up to one year after ablation when compared with using Holter monitoring and ECG alone [31.1% versus 14.6% [OR], 3.1; 95% CI: 1.4%–6.7%, p=0.005]. The authors concluded that FibriCheck (digital follow-up) was found to be non-inferior. A subsequent superiority analysis demonstrated that more atrial arrhythmia detections were found with digital follow-up when compared with conventional follow-up.

5.3 Resource use

In their prospective case crossover study, Gawałko et al. (2024) report changes in resource use between a conventional care approach involving face to face consultations in people with known AF and the TeleCheck-AF programme which used FibriCheck as part of the tele-consultation programme. Participants collected PPG recordings three times per day, and at time of any symptoms, one week prior to scheduled teleconsultation. Treating physicians or AF nurses evaluated measurements before consultation. Reductions were found in the number of face-to-face consultations (7 versus 35, p<0.001), the number of ECGs (12 versus 42, p<0.001) and Holter monitors used (7 versus 25, p<0.001). Authors also report a decrease in the length/duration of consultations in the TeleCheck-AF programme versus the conventional approach (five minutes [two minutes for the FibriCheck evaluation and three minutes for teleconsultation] versus 20 minutes).

Gawałko et al. (2024) did not find a statistically significant difference in the number of emergency department visits observed between the conventional and TeleCheck-AF intervention approaches (5 versus 9, p=0.33). The TeleCheck-AF programme was initiated during the COVID-19

pandemic, which may have impacted healthcare utilisation. Additionally, the comparative standard care programme may not be representative of standard practice in NHS Wales.

Calvert et al. (2024) conducted a retrospective single centre cohort study on FibriCheck in people who have undergone DCCV. Participants in the PPG group were instructed to take one, one minute PPG reading at 14 days post-DCCV, to coincide with the standard timing of ECG follow up. Using remote monitoring via photoplethysmography, people who would normally require an ECG benefit from spending less time travelling to appointments and may also avoid parking charges (Calvert et al. 2024). The reduction in travel also has environmental benefits by reducing CO2 emissions (Calvert et al. 2024). A reduction in travel time for participants was observed in the FibriCheck intervention group when compared with 12-lead ECG. The total estimated participant travel time was 1240 minutes versus 9935 in the ECG group (Calvert et al. 2024) and the median participant travel time was 0 in the PPG group and 38 minutes in the ECG group ($p<0.001$) (Calvert et al. 2024).

5.4 Environmental outcomes

Calvert et al. (2024) reported a reduction in the total estimated carbon emissions was found in the FibriCheck arm when compared to using a traditional 12-lead ECG (110kg versus 940kg), along with a reduction in the estimated median carbon emissions (0 versus 2.32kg, $p<0.001$).

5.5 Patient compliance

Gruwez et al. (2024b) reported patient compliance during follow-up using FibriCheck when compared with conventional follow-up and found a lower level of compliance (78.2% for FibriCheck versus 92.6% for conventional follow-up) although the statistical significance of this outcome is unknown. Participants in Gruwez et al. (2024b) were instructed to perform PPG measurements for 60 seconds twice per day for one year.

Gruwez et al. (2024a) instructed participants to perform PPG measurements twice per day for eight weeks, where the mean compliance of FibriCheck was 69.8% and the median compliance was 82.1% although this outcome was not compared to a single-lead ECG.

Calvert et al. (2024) did not find a statistically significant difference in the level of compliance using FibriCheck compared with using ECG (89.4% versus 89.8% respectively, $p>0.999$). Participants in Calvert et al. (2024) performed a single recording at 14 days post DCCV procedure.

McManus et al. (2016) conducted a usability assessment of Pulse-Smart, referenced in section 8. Gawałko et al. (2021), Gawałko et al. (2023) and van Mourik et al. (2025) report patient and centre experiences of using the Tele-Check-AF project for the management of AF during the COVID-19 pandemic, referenced in section 8.

5.6 Signal quality and technical failure

5.6.1 Studies including participants undergoing interventional procedures for AF (e.g., elective direct current cardioversion or ablation)

Gruwez et al. (2024a) report the percentage of FibriCheck PPG readings of good quality on the first attempt (89.5%), when compared with KardiaMobile (93.2%) ($p<0.001$). After repeated measurements, this value increase to 96.6% for PPG readings and 95.1% of KardiaMobile readings.

Fernstad et al. (2024) report the percentage of CORAI PPG readings labelled as insufficient quality when compared simultaneously with single-lead ECG readings (PPG, 3.1% versus single-lead ECG, 4.9%; p<0.001)

Gruwez et al. (2024b) reported that 1663 out of 39,895 PPG measurements were labelled insufficient quality (4.2%), although this was not comparable with the Holter monitoring or ECG.

Mol et al. (2020) reported the percentage of high, medium and low signal quality of PPG recordings made by the Happitech application which were 93%, 5.6% and 1.4% respectively (p=0.72), although these were non-comparative results.

Calvert et al. (2024) reported 11.8% of participants in the PPG arm (FibriCheck) required a subsequent ECG reading, of which 12 of these cases were due to participants failing to utilise the application and in 10 of these cases, this was due to a technical failure of the application.

Gawałko et al. (2024) did not report outcomes relating to signal quality or technical failure, however, authors note that the quality of PPG signals can be impacted by several factors such as lighting, differing skin pigmentations, conditions such as eczema, low skin temperature, and tattoos. Additionally, intermittent recordings, rather than continuous monitoring could potentially miss asymptomatic and short arrythmia episodes.

5.6.2 Signal quality and technical failures in studies including participants with a history of AF

Some of the diagnostic accuracy outcomes reported in this EAR were after insufficient quality readings were excluded from the analysis. In Brasier et al. (2019), 672 patients were initially recruited although 80 were excluded, leaving 592 patients in the final analysis. Authors report that this was mainly due to insufficient readings from Preventicus and KardiaMobile. Out of the 80 patients that were excluded, 62 of these patients were excluded due to signal quality (44 PPG readings, and 18 KardiaMobile readings). Authors report that this was partly due to the study using a trial version of the algorithm and the automated signal quality check was deactivated to prevent bias. Proesmans et al. (2019) reported three different diagnostic accuracy outcomes of FibriCheck depending on whether insufficient quality readings were excluded, categorised as sinus rhythm or categorised as possible AF. The values reported in this EAR exclude insufficient quality readings where they are reported. For fuller details on outcomes, see Table 1 and Table 2.

5.7 Adverse events

Calvert et al. (2024) report no adverse events in the PPG arm, although participants with bradyarrhythmia were ordered a subsequent 12-lead ECG. Authors note that only 1 of 32 participants with concern for bradyarrhythmia required admission for pacemaker implant due to junctional bradycardia.

5.8 Quality of life outcomes

HTW researchers did not identify any quality-of-life outcomes reported across any of the included studies.

5.9 Changes to patient management

Gawałko et al. (2024) reported changes to patient management because of the integration of the TeleCheck-AF programme. Physician reported data found that four patients (11%) had their rhythm control medications adjusted, six (16%) patients were subsequently scheduled for an electrical cardioversion and changes in rate control medication was seen in one patient and they were then scheduled for pulmonary vein isolation. In 59% of patients who used FibriCheck, a teleconsultation was scheduled as a follow-up appointment, and in 32% of patients, FibriCheck was requested again, however, this was mostly in patients in whom AF was detected during the initial teleconsultation.

Table 1 – Diagnostic accuracy outcomes

Reference, type of study, application intervention and comparator	Participants	Results		Comments
Studies including participants undergoing interventional treatment for AF (e.g., elective direct current cardioversion or ablation)				
Studies using PPG for the longer-term monitoring of AF post interventional procedure				
Gruwez et al. (2024b) – one prospective non-randomised study (DIGITOTAL) Intervention: FibriCheck Reference standard: conventional follow up (three outpatient appointments and three periods of 24 hours ECG Holter monitoring, with intermittent 12-lead ECG)	N=97 (39,895 PPG measurements) N=92 completed 12 month follow up People who have had AF ablation.	**Sensitivity:** 94.1% [95% CI: 71.3%– 99.8%] **NPV:** 98.3% [95% CI: 90.9%–99.9%] **Non-Inferiority analysis:** Detection of symptomatic atrial arrhythmia up to one year after ablation: PPG: 31.3% (30/96 patients) with digital follow-up (OR, 3.1; 95% CI, 1.4%–6.7%). Holter monitor and ECG: 14.6% (14/96 patients) with conventional follow-up		P value, NR. Participants were instructed to perform PPG measurements twice daily (for 60 seconds) or whenever symptoms were perceived for one year. Measurements categorised as AF by the application algorithm were subsequently reviewed by a medical technician.
Fernstad et al. (2024) – one prospective non-randomised validation study (SMARTBEATS) Intervention: CORAI Reference standard: KardiaMobile (measured simultaneously) (analysed by two cardiologists).	N=280 (18005 heart rhythm registrations using simultaneous PPG and ECG recordings). Adults undergoing DCCV for persistent or recent onset of AF or AFL.	Diagnosing AF or AFL **Sensitivity:** PPG: 97.7% [95% CI: 97.3%–98.1%] **Specificity:** PPG: 99.4% [95% CI: 99.3%–99.6%] **PPV:** PPG: 98.9% [95% CI: 98.7%–99.1%] **NPV:** PPG: 99.0% [95% CI: 98.8%–99.2%] **Overall accuracy:** PPG: 98.9% [95% CI: 98.7%–99.1%]	Diagnosing AF (AFL readings excluded) **Sensitivity:** PPG: 99.0% [95% CI: 98.8%–99.2%] **Specificity:** PPG: 99.7% [95% CI: 99.6%–99.8%] **PPV:** PPG: 99.2% [95% CI: 99.0%–99.5%] **NPV:** PPG: 99.2% [95% CI: 99.0%–99.5%] **Overall accuracy:** PPG: 99.5% [95% CI: 99.4%–99.6%]	P value, NR. 1-min heart rhythm recordings post-treatment were recorded twice daily for 30 days. Participants recorded both types of measurements simultaneously by placing a fingertip over the camera lens of an iPhone 7 and at the same time placing other fingers from both hands on the electrodes of the KardiaMobile device.

Reference, type of study, application intervention and comparator	Participants	Results	Comments
Studies where participants recorded PPG measurements before and after an interventional procedure			
McManus et al. (2013) – one prospective cohort study Intervention: Pulse-Smart (assumed to be an older version of the application) Reference standard: 12-lead ECG	N=76 People with known persistent AF scheduled for cardioversion.	**Sensitivity:** 96.1% [95% CI: NR] **Specificity:** 97.5% [95% CI: NR] **Overall accuracy:** 96.7% [95% CI: NR]	P value, NR. PPG recording lasted two minutes before and after cardioversion. Number of recordings, NR
McManus et al. (2016) – one case prospective cohort single centre study Intervention: Pulse-Smart Reference standard: 12-lead ECG	N=121 (219 recordings) Diagnostic accuracy outcomes on AF include 98 participants. People with known AF scheduled for cardioversion.	**Sensitivity:** 97% [95% CI: NR] **Specificity:** 93.5% [95% CI: NR] **Overall accuracy:** 95.1% [95% CI: NR]	P value, NR. PPG recording lasted two minutes before and after cardioversion.
Mol et al. (2020) - one case–control cross-sectional study Intervention: Happitech Reference standard: 12-lead ECG	N=149 pre-elective electrical cardioversion (ECV). 41 participants were excluded post-ECV due to participants no longer being eligible. People with AF admitted to hospital for ECV.	**Sensitivity:** Including low confidence recordings: 96.3% [95% CI 90.8%–99.0%] Excluding low confidence recordings: 98.1% [95% CI: 93.4%–99.8%] **Specificity:** Including low confidence recordings: 93.5% [95% CI: 87.1%–97.4%] Excluding low confidence readings: 98.1% [95% CI: 93.2%–99.8%]	P value, NR. PPG recording lasted 90 seconds before and after ECV. Number of recordings, NR
Rozen et al. (2018) – one prospective single centre case control study. Intervention: Cardiio Rhythm	N=98 Pre-CV, n=97 Post-CV, n=92	**Sensitivity:** 93.1% [95% CI: 86.9%–97.2%] **Specificity:** 90.9% [95% CI 82.9%–96%] **PPV:** 92.2% [95% CI: 85.8%–95.8%]	P value, NR.

Reference, type of study, application intervention and comparator	Participants	Results	Comments
Reference standard: 12-lead ECG	People with a diagnosis of AF and scheduled for cardioversion.	**NPV:** 92% [95% CI 94.8%–95.9%]	PPG recording lasted 20 seconds, conducted three times before and after procedure (total of one minute before, one minute after). At least one set of PPG recordings were obtained from all but one participant.
Gruwez et al. (2024a) - one prospective validation study (RELATION PPG) Intervention: FibriCheck Reference standard: KardiaMobile (analysed by two blinded cardiologists)	N=50 (n=3407 measurement sets) People with paroxysmal or persistent AF scheduled for ablation.	**Sensitivity:** 98.3% [95% CI: 96.7%–99.9%] Bradycardia group: 60 bpm, 85.2% significantly lower than in normal HR: 60–100 bpm, 99.0% and tachycardia >100 bpm, 98.7% p<0.001 **Specificity:** 99.9% [95% CI: 99.8%–100.0%] No significant difference between heart rate zones No significant difference in rhythm classification before versus after ablation **PPV:** 99.6% [95% CI: 99.1%–100.0%] **NPV:** 99.6% [95% CI: 99.0%–100.0%]	Authors note that clinicians utilising PPG for rhythm analysis should be aware that AF is more frequently missed in bradycardia (i.e. the sensitivity decreases in low heart rates) Participants were instructed to perform a 'measurement set' twice daily, commencing four weeks prior to the ablation procedure and continuing four weeks after the procedure (total eight weeks). One set included an ECG first, followed by PPG, concluding with a second ECG.
Studies including participants with a history of AF			
Brasier et al. (2019) – one case control multi-centre study (DETECT AF PRO) Intervention: Preventicus Reference standard: iECG by KardiaMobile, AliveCor (analysed by two cardiologists).	N=592 (after exclusions due to insufficient PPG/iECG signal quality). People in hospital with a history of AF as identified in medical records.	**Sensitivity:** 1-minute PPG analysis: 89.9% [95% CI: 85.5%–93.4%] iECG: 99.6% [95% CI: 97.9%–100%] 3-minute PPG analysis: 91.3% [95% CI: 86.5%–94.7%] iECG: NR 5-minute PPG analysis: 91.5% [95% CI: 85.9%–95.4%] iECG: NR	P value, NR. 5-minute PPG recordings were taken No diagnosis - Values relate to readings where no diagnosis was possible due to poor signal quality.

Reference, type of study, application intervention and comparator	Participants	Results	Comments
		Specificity: 1-minute PPG analysis: 99.1% [95% CI: 97.5%–99.8%] 3-minute PPG analysis: 98.7% [95% CI: 96.7%–99.6%] 5-minute PPG analysis: 99.6% [95% CI: 97.8%–100%] iECG: 97.8% [95% CI: 95.3%–99.2%] iECG: NR iECG: NR **Correctly classified rate:** 1-minute PPG analysis: CCR: 88.8 3-minute PPG analysis: CCR: 77.6 5-minute PPG analysis: CCR: 60.9 iECG: 82.23 iECG: NR iECG: NR **No diagnosis** 1-minute PPG analysis: No diagnosis (%): 6.7 3-minute PPG analysis: No diagnosis (%): 13 5-minute PPG analysis: No diagnosis (%): 32.2 iECG: 18.8 iECG: NR iECG: NR	
Proesmans et al. (2019) – one prospective cohort multi-centre study Intervention: FibriCheck Comparator: Single-lead ECG	N=223 After exclusions of insufficient quality readings: PPG, N=207 ECG, N=210 Participants (>65 years) with known paroxysmal or persistent AF	**Sensitivity:** PPG: 95.6% [95% CI: 95% CI: 89%–99%] Single-lead ECG: 94.7% (95% CI: 95% CI: 88%–98%) **Specificity:** PPG: 96.6% [95% CI: 91%–99%] Single-lead ECG: 96.6% [95% CI: 91%–99%]	P value, NR. PPG recording lasted one minute, and participants independently performed three consecutive measurements.

Reference, type of study, application intervention and comparator	Participants	Results	Comments
Reference standard: 12-lead ECG	identified from medical records. Supplemented with a convenience sample of people without AF (n=79).	**PPV:** PPG: 95.6% [95% CI: NR) Single-lead ECG: 95.7% [95% CI: NR] **NPV:** PPG: 96.6% [95% CI: NR] Single-lead ECG: 95.7% [95% CI: NR] **Overall accuracy:** PPG: 96.1% [95% CI: NR] Single-lead ECG: 95.7% [95% CI: NR]	Values reported here are readings shown after insufficient quality readings were excluded.

Abbreviations: AF, atrial fibrillation; bpm, beats per minute; CI, confidence interval; DCCV, direct current cardioversion; ECG, electrocardiogram; ECV, electric cardioversion; iECG, single-lead ECG; N, total number of participants; NPV, negative predictive value; NR, not reported; OR, odds ratio; PPG, photoplethysmography; PPV, positive predictive value

Table 2 – Other outcomes

Outcome	Evidence source(s)	Number of participants	Intervention details	Absolute/relative effect	Comments
Resource use					
Studies using PPG for the remote monitoring of participants with a history of AF					
Number of face-to-face consultations (n)	Gawałko et al. (2024) One prospective case-crossover analysis	N=37 Participants with diagnosed AF.	TeleCheck-AF programme using FibriCheck app (teleconsultation supported by app-based heart rate/rhythm monitoring) Participants recorded PPG measurements three times per day, one week before they were scheduled for tele-consultation. Comparator: conventional approach (DBC care products) 35 face-to-face consultations and 0 teleconsultations.	TeleCheck-AF: 7 Conventional approach: 35 (decrease of 80%, p<0.001)	Limitations associated with a case-crossover analysis such as a lack of control of within-person confounding TeleCheck-AF was initiated during the COVID-19 pandemic, which may have impacted healthcare utilisation.
Duration of consultations (face-to-face versus teleconsultation) (minutes)				TeleCheck-AF: 2.0 [95% CI: 0.8–2.8] for FibriCheck evaluation and 3.0 [95% CI: 0.5–6.0] for teleconsultation. Conventional approach: 20 (decrease duration of 75%)	
Number of ECGs used (n)				TeleCheck-AF: 12 Conventional approach: 42 (decrease of 71%, p<0.001)	
Number of Holter monitors used (n)				TeleCheck-AF: 7 Conventional approach: 25 (decrease of 72%, p<0.001)	
Number of emergency department visits (n)				TeleCheck-AF: 9 visits Conventional approach: 5 visits P=0.33	
Studies using PPG for the monitoring of AF post interventional procedure					
Median patient travel time (minutes)	Calvert et al. (2024) One retrospective cohort study	Baseline: Intervention (PPG) N=220 Baseline: 12-lead ECG N=196	Intervention: FibriCheck follow-up (PPG cohort) Comparator: Traditional 2-week 12-lead ECG follow-up (ECG cohort).	PPG: 0 [95% CI: 0–0] ECG: 38 [95% CI: 30–71] P<0.001	Findings based on a retrospective analysis and thus, intervention not prospectively compared to ECG.
Total estimated patient travel time (minutes)				PPG: 1240 ECG: 9935 P value, NR.	

Outcome	Evidence source(s)	Number of participants	Intervention details	Absolute/relative effect	Comments
			Participants in the PPG group were instructed to take one, one minute PPG reading at 14 days post-DCCV.		
Environmental outcomes					
Studies using PPG for the monitoring of AF post interventional procedure					
Total estimated carbon emissions (kg)	Calvert et al. (2024) One retrospective cohort study	Baseline: Intervention (PPG) N=220 Baseline: 12-lead ECG N=196	Intervention: FibriCheck follow-up (PPG cohort) Comparator: Traditional 2-week 12-lead ECG follow-up (ECG cohort). Participants in the PPG group were instructed to take one, one minute PPG reading at 14 days post-DCCV.	PPG: 110 ECG: 940	Findings based on a retrospective analysis and thus, intervention not prospectively compared to ECG
Median estimated carbon emissions (kg)				PPG: 0 [95% CI: 0–0] ECG: 2.32 [95% CI: 1.8–6.5] P<0.001	
Patient compliance					
Studies using PPG for the monitoring of AF post interventional procedure					
Patient compliance	Calvert et al. (2024) One retrospective cohort study	PPG cohort N=246 ECG cohort N=214	Intervention: FibriCheck follow-up (PPG cohort) Comparator: Traditional 2-week 12-lead ECG follow-up (ECG cohort). Participants in the PPG group were instructed to take one, one minute PPG reading at 14 days post-DCCV.	PPG: 89.4% ECG: 89.8% P>0.999	Not statistically significant

Outcome	Evidence source(s)	Number of participants	Intervention details	Absolute/relative effect	Comments
Studies where participants recorded PPG measurements before and after an interventional procedure					
Patient compliance	Gruwez et al. (2024a) One prospective validation study	PPG: N=112 People with paroxysmal or persistent AF.	Intervention: FibriCheck Participants recorded measurements twice daily for eight weeks (four weeks before and four weeks after procedure).	Mean compliance: 69.8% (78.14/112) Median compliance: 82.1%	For this outcome, results were not prospectively compared to the reference standard.
Studies using PPG for the longer-term monitoring of AF post interventional procedure					
Patient compliance	Gruwez et al. (2024b) One prospective non-randomised study	N=96	Intervention: FibriCheck Participants recorded measurements twice daily for 60 seconds for one year.	PPG: 78.2% Conventional follow-up: 92.6%	All participants were followed up with both conventional and digital follow-up.
Changes to patient management					
Studies using PPG for the remote monitoring of participants with a history of AF					
Adjustment to rhythm control medications	Gawałko et al. (2024) One prospective case-crossover analysis	N=37 Participants with diagnosed AF.	TeleCheck-AF programme using FibriCheck app Participants recorded PPG measurements three times per day, one week before they were scheduled for tele-consultation. Comparator: conventional approach (DBC care products) 35 face-to-face	4 patients (11%)	Limitations associated with a case-crossover analysis such as a lack of control of within-person confounding TeleCheck-AF was initiated during the COVID-19 pandemic, which may have impacted healthcare utilisation.
Number of patients subsequently scheduled for an electrical cardioversion				6 patients (16%)	
Changes in rate control medication and subsequently scheduled for pulmonary vein isolation				1 patient (3%)	
Teleconsultation scheduled as a follow-				59% of patients	

Outcome	Evidence source(s)	Number of participants	Intervention details	Absolute/relative effect			Comments
up appointment because of FibriCheck			consultations and 0 teleconsultations.				
Signal quality and technical failure							
Studies using PPG for the monitoring of AF post interventional procedure							
Number of participants requiring subsequent ECG	Calvert et al. (2024) One retrospective cohort study	PPG cohort N=246 ECG cohort N=214	Intervention: FibriCheck	PPG: n=29 (11.8%)			Participants in the PPG group were instructed to take one, one minute PPG reading at 14 days post-DCCV.
Studies where participants recorded PPG measurements before and after an interventional procedure							
Frequency of good quality readings	Gruwez et al. (2024a) - one prospective validation study	N=50 People with paroxysmal or persistent AF.	Intervention: FibriCheck	First attempt PPG readings of good quality: 89.5% (3497/3907) iECG readings of good quality: 93.2%, (3600/3863) p<0.001	Repeated measurements PPG readings of good quality: 96.6% (3776/3907) iECG readings of good quality: 95.1% (3673/3863)		The reported performance metrics apply to measurements of sufficient quality for analysis (referred to as good quality)
Signal quality of PPG	Mol et al. (2020) one case–control cross-sectional study	N=149 (after exclusions due to participants no longer being eligible) Adults admitted to hospital for elective electrical cardioversion (ECV).	Intervention: Happitech	High signal quality: 93% 201/216 recordings (SR 100, AF 101)	Medium signal quality: 5.6% 12/216 recordings (SR 7, AF 5)	Low signal quality: 1.4% 3/216 recordings (SR 1, AF 2)	P=0.72 For this outcome, results were not prospectively compared to the reference standard.

Outcome	Evidence source(s)	Number of participants	Intervention details	Absolute/relative effect	Comments
Studies using PPG for the longer-term monitoring of AF post interventional procedure					
Percentage of PPG readings labelled as insufficient quality	Gruwez et al. (2024b) – one prospective non-randomised study	N=96 (39,895 PPG measurements) People who have had AF ablation during the inclusion period from January to April 2022.	Intervention: FibriCheck	1663 out of 39,895 were labelled insufficient quality (4.2%)	Outcome not compared with Holter monitor or ECG P value, NR.
Percentage of PPG readings labelled as insufficient quality	Fernstad et al. (2024) – one prospective non-randomised validation study (SMARTBEATS)	N=280 (18005 heart rhythm registrations using simultaneous PPG and ECG recordings) Adults undergoing DCCV for persistent or recent onset of AF or AFL.	Intervention: CORAI	PPG: 3.1% (561/18005) Single-lead ECG: 4.9% (882/18005)	P<0.001

Abbreviations: AF, atrial fibrillation; CV, cardioversion; DBC, 'diagnosebehandelcombinatie (DBC) care; DCCV, direct current cardioversion; ECG, electrocardiogram; iECG, single-lead ECG; N, total number of participants; NPV, negative predictive value; NR, not reported; PPG, photoplethysmography; PPV, positive predictive value; SR, sinus rhythm

5.10 Ongoing studies

Table 3 – Summary of ongoing systematic reviews

Study information	Status	Research question and outcome measures
Title: Accuracy and efficiency of smartphone applications to detect atrial fibrillation: an update diagnostic meta-analysis **Author:** A. M. Junior, B. C. d. Oliveira and I. O. F. Barbosa **Accession Number:** CRD42024526899 **Registration:** https://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42024526899 **Country:** Brazil	**Anticipated or actual start date:** 21 March 2024 **Anticipated completion date:** 31 December 2024	**Review question:** The accuracy and effectiveness of smartphone apps in detecting atrial fibrillation Purpose: to conduct a comprehensive assessment of the existing literature **Population:** Any participant using a smartphone application for the detection or diagnosis of atrial fibrillation. **Intervention:** Any kind of smartphone application designed to detect atrial fibrillation. **Comparator:** ECG **Primary outcome measures:** Validation of the use of photoplethysmography signals against ECG; sensitivity, specificity, area under the receiver operator curve, positive/negative predictive values, or other relevant measure. **Secondary outcome measure:** NR
Abbreviations: ECG, electrocardiogram; NR, not reported		

Table 4 – Summary of ongoing primary studies

Study information	Status	Research question and outcome measures
Registration: NCT04300270 https://clinicaltrials.gov/study/NCT04300270 **Country:** Sweden **Target recruitment**: 480 participants **Follow-up:** 30 days	Recruiting **Last updated:** 10/10/2024 **Estimated study completion:** 01/2025	**Title:** Validation of a Novel Smartphone based Photoplethysmographic Method for Ambulatory Heart Rhythm Monitoring in Connection to Treatment of Atrial Fibrillation with Direct Current Cardioversion **Population:** People undergoing direct current cardioversion for treatment of atrial fibrillation or atrial flutter at Danderyd University Hospital. **Intervention:** Smartphone PPG recordings **Comparator:** Alivecor KardiaMobile iECG **Primary outcome measure:** Sensitivity, specificity, positive predictive value, negative predictive value, receiver operating characteristic (ROC) curve analysis. **Secondary outcome measure:** Odds ratio, Actual compared to expected number of recordings. Proportion of recordings with interpretable signal quality. Correlation between heart rhythm perceived by the participant (dichotomized into sinus rhythm or atrial fibrillation) and actual rhythm recorded on handheld ECG (dichotomized in the same way), expressed as correlation coefficient R and Cohen's kappa.
Abbreviations: ECG, electrocardiogram; iECG, single-lead ECG		

5.11 Certainty of the evidence

Based on the available evidence, there are no randomised controlled trials assessing the effectiveness of photoplethysmography in this setting in the NHS and/or UK. Some of the outcomes detailed in this rapid review were non-comparative and authors did not assess or report statistical significance.

We did not include any studies where PPG was used to diagnose AF in symptomatic patients suspected of having AF. All studies evaluated the use of PPG In participants with diagnosed AF. The potential use of PPG in screening for AF in wider or at-risk populations, and the use of PPG monitoring in paroxysmal versus permanent AF was not assessed in this review.

Information from the manufacturer of FibriCheck suggests the application works across the six different Fitzpatrick skin types, however, we did not find any evidence that reported data for different skin types across participants and thus, whether the applications could diagnose AF irrespective of skin colour is unclear.

Some declarations of interests were reported across the primary studies including Brasier et al. (2019), Mol et al. (2020), Rozen et al. (2018) and Fernstad et al. (2024).

Using the JBI checklists for cohort studies (Moola et al. 2020) and diagnostic accuracy studies (Campbell et al. 2020) for reference, several limitations were noted:

- Calvert et al. (2024) in their retrospective review, details a short follow-up time of two weeks post DCCV procedure and their analysis is based on assumptions.
- Gawałko et al. (2024) conducted a prospective case-cross over analysis of the TeleCheck-AF programme where FibriCheck was used as part of a wider teleconsultation programme. It was rolled out during the COVID-19 pandemic to minimise social contact. Authors note this may have impacted healthcare utilisation.
- Studies did not use randomisation when allocating participants to interventions, although Gruwez et al. (2024a) and Fernstad et al. (2024) reported blinding in their data extraction.
- It is unclear from the papers whether any strategies were taken to deal with any confounding factors.
- The usage instructions to participants and number of recordings taken varied across the studies and applications used, which could potentially affect detection rates.
- In Gruwez et al. (2024b), participants were followed up using conventional and digital follow-up using FibriCheck and thus, each patient served as their own control.

6. Cost effectiveness

6.1 Economic literature review

Appendix 4 summarises the selection of articles for inclusion in the evidence review. The titles and abstracts of 3,193 records identified in the search for this research question were screened and two records were deemed potentially relevant to the economic evidence review. The full texts of these studies were reviewed against the inclusion/exclusion criteria. One study (Gawałko et al. 2024) was excluded because it considered resource use only. The remaining study (Calvert et al. 2024) was included and is summarised in the table below.

Calvert et al. (2024) reported the results of a retrospective analysis of patients attending a DCCV follow-up service using data extracted from electronic patient records. The analysis considered a remote rhythm monitoring service using the FibriCheck smartphone app (PPG cohort) in comparison to traditional 12-lead ECG monitoring at two weeks follow-up (ECG cohort). The study estimated differences in healthcare costs, patient costs, patient compliance and experience, travel time and environmental impact.

Healthcare costs were estimated based on the FibriCheck activation charge (£32) and the cost of ECG appointments (£135). No other healthcare costs appear to have been considered in the analysis. Estimated healthcare costs were found to be significantly lower in patients managed with PPG. The total healthcare cost for the PPG cohort was £11,787 while the total cost for the ECG cohort was £29,025, equating to a cost saving of £17,238.

The study was deemed to be directly applicable as it considered the UK NHS perspective. However, note that the analysis includes some costs which are outside the typical NHS perspective (such as travel and parking costs). We have focused primarily on the reporting of healthcare costs. The study was generally considered to be of high quality, but some potentially serious limitations were noted. Most notably, the retrospective design of the analysis could introduce some bias due to differences in the characteristics of the intervention and comparator cohorts. This includes differences in the selection of patients receiving each strategy as patients with some clinical concerns (such as bradyarrhythmia) would be advised to use ECG. Furthermore, the reported patient characteristics showed that there was a statistically significant difference in age between the analysed groups with younger patients in the PPG cohort. The narrow selection of healthcare resources included in the estimation of healthcare costs was a further limitation.

Table 5 – Summary of included economic study: Calvert et al. 2024

Study details	Study population and design	Data sources	Results	Quality assessment
Author and year: Calvert et al. 2024 **Country:** United Kingdom (UK) **Type of economic analysis:** Cost analysis **Perspective:** Multiple perspectives considered including healthcare and environmental. **Currency:** UK pound sterling (£) **Price year:** Not reported. Presumed to be 2023 prices based on costs reported. **Time horizon:** Study covered a period of 29 months (between May 2020 and October 2022). **Discounting:**	**Population:** Patients attending a direct current cardioversion (DCCV) follow-up service in Liverpool. 416 patients were included in the study. They underwent 461 acutely successful DCCV procedures (246 in the intervention arm and 215 in comparator arm). Patients with acutely unsuccessful DCCV were excluded from the analysis. Patients using rhythm monitoring methods other than the intervention and comparator (listed below) were also excluded. This includes patients using their own smart wearable or having implantable device interrogation. **Intervention:** Remote rhythm monitoring service using the FibriCheck smartphone app and associated telemedicine portal (PPG cohort). Patients either self-installed the app on their smartphone or were assisted by a nurse. Patients were also provided	**Source of baseline and effectiveness data:** The retrospective analysis was the key source of data in the analysis. Effectiveness was not a key consideration in the analysis. The analysis did not consider the accuracy of each strategy, patient quality of life or long-term health outcomes. However, the analysis did include an analysis of rhythm at follow-up. Arrhythmia detection rates were found to be generally similar between arms. Atrial flutter was more common in the ECG arm, but this largely reflects the patients selected for each strategy. As PPG cannot reliably differentiate regular arrhythmias from sinus rhythm, patients with known flutter were preferred for ECG follow-up. Safety outcomes were also analysed but again these largely reflect patients selected for each strategy as ECG was preferred in instances where there was a clinical concern (such as bradyarrhythmia). No adverse safety events were noted in the PPG arm. **Source of resource use and cost data:** The source of healthcare costs was not reported.	**Results** **Healthcare costs** Mean cost per patient PPG arm: £47.91 (± £43.62) ECG arm: £135 (± £0.00) P<0.001 Total cost for cohort PPG arm: £11,787 ECG arm: £29,025 Estimated saving of £17,238 **Patient costs (travel and parking)** Total cost for cohort PPG: £177 ECG: £1,316 **Carbon emissions (based on travel to centre)** Total for cohort PPG: 110 kg ECG: 940 kg	**Applicability** Directly applicable to the UK NHS context. However, note that the analysis includes some costs which are outside the typical NHS perspective (such as travel and parking costs). Therefore, while patient costs and carbon emissions are included for completeness, our focus is primarily on the healthcare costs. **Limitations** The study has some potentially serious limitations. • Potential for bias due to the retrospective nature of analysis. This includes differences in the selection of patients receiving each strategy. As noted, patients with some clinical concerns (such as bradyarrhythmia) would be advised to use ECG. • Potential bias was also shown in the reported patient characteristics in each cohort. Most notably, there was a statistically significant difference in age between the analysed groups with younger patients in the PPG group. • The source of healthcare costs was not reported. It is therefore unclear whether all cost

Study details	Study population and design	Data sources	Results	Quality assessment
Not reported. Presumed that no discounting was applied. **Potential conflict of interest:** Four authors reported potential conflicts of interest These were based on the receipt of research grants, consultancy or speaker fees from Boston Scientific, Medtronic, BMS/Pfizer, Boehringer Ingelheim, Daiichi Sankyo, Biosense Webster, Itamar, Philips, Imricor and Biotronik.	with a contact number in case they required further support to use the app or advice regarding their symptoms. Patients were advised to perform a single one-minute rhythm recording at 14 days post-DCCV, to coincide with the standard timing of the ECG follow-up. **Comparator:** Traditional 12-lead ECG monitoring at two weeks follow-up (ECG cohort). **Study design** Retrospective analysis of patients attending the DCCV follow-up service using data extracted from electronic patient records. Patients in the PPG and ECG cohort were compared considering estimated differences in healthcare costs, patient costs, patient compliance and experience, travel time and environmental impact. The decision on which monitoring strategy to use was made by the cardiac specialist nurse in conjunction with the patient.	It was reported that FibriCheck activation would cost £32 while the cost of a 12-lead ECG appointment was £135. In those instances where patients assigned to FibriCheck subsequently needed an ECG, both costs were applied. This scenario occurred in 29 patients (11.8%). In 12 cases, this was due to issues downloading or using the app. In 10 cases, this was due to technical failures with the app. In the remaining seven cases, the FibriCheck result was inconclusive (ECG subsequently showed AF in two cases, atrial flutter in one case and sinus rhythm in four cases). Note that healthcare costs appear to have been estimated based on the use of FibriCheck and ECG appointments only. Medication use and adjustments were reported in the study, but they do not appear to have been included in the cost analysis. However, this would have made minimal impact as there were no statistically significant differences between groups. Patient costs were estimated based on travel and parking costs. These costs were applied to patients having an ECG appointment. No travel or parking costs were applied to patients successfully using FibriCheck. Travel distance to the healthcare centre was estimated using the patient's postcode. For patients living outside the local area, it was assumed that the distance to their local centre would be five		aspects were included. Most notably, it is unclear whether the cost of FibriCheck is based only on the cost of the app. If so, the total cost is likely to be underestimated as the study notes the possibility of nurses providing assistance with the app and subsequent support provided by phone. • The study did not consider the provision of smartphones for patients who would otherwise be unable to use the app. This cost would need to be considered if evaluating the service for potential roll-out across the NHS. • Total healthcare costs for each strategy would be underestimated as the analysis only considered ECG appointments and the use of FibriCheck. Subsequent resource use, including medication was not considered. • The environmental impact was selectively considered based only on carbon emissions associated with travel. The carbon cost of providing the FibriCheck service was not considered. • Study is based on the experience of a single centre using FibriCheck. The findings may not be generalisable to

Study details	Study population and design	Data sources	Results	Quality assessment
	Patients were offered both options if appropriate and a choice could be made based on patient preference. However, there are scenarios where the use of PPG would be inappropriate and therefore ECG would be advised instead. This includes patients with bradyarrhythmia or where there is a need to check the QT-interval when starting antiarrhythmic drugs.	miles. Travel costs were estimated assuming a 50-mpg diesel car at a fuel price of £1.63 per litre (equivalent to £0.15 per mile). Parking costs were estimated to be £3.60 based on the minimum spend at the healthcare centre. Environmental impact was calculated based on estimated carbon emissions due to travelling to the centre. An average diesel car was estimated to produce 0.23 kgCO2 per mile. This was multiplied by the estimated miles travelled for each patient. Note that in those instances where patients did not attend a scheduled ECG appointment, the healthcare cost was still applied. However, travel, parking and environmental costs were not applied as the journey was not made.		other apps or to other DCCV patients treated in different centres.

Abbreviations: EQ-5D, EuroQol five-dimensions questionnaire; ICER, incremental cost-effectiveness ratio; NA, not applicable; NR, not reported; QALY, quality-adjusted life year; RCT, randomised controlled trial; RR, risk ratio

6.2 HTW cost utility analysis

We considered developing an economic model to estimate the cost effectiveness of PPG in two scenarios. The first scenario was the use of PPG as part of initial diagnosis in people with suspected AF and the second scenario was PPG monitoring in people with confirmed AF. However, after consultation with experts, it was determined that the evidence base was insufficient to be used as the basis for an economic evaluation in either scenario.

In the case of PPG as part of initial diagnosis, the primary concern was the lack of evidence reliably demonstrating the accuracy of PPG technologies against comparator technologies. As noted above, the evidence review did not identify any studies evaluating the use of PPG to detect AF in those with symptoms/suspected of having AF but who had not been diagnosed. Therefore, it would not be possible to reliably estimate the cost effectiveness of PPG technologies in this scenario.

The key concern for an analysis on the use of PPG for monitoring patients with known AF was the lack of long-term evidence on patient management and outcomes. The existing economic analysis by Calvert et al. (2024) shows the potential for cost savings when adopting a PPG monitoring strategy. However, effectiveness was not a key consideration in the analysis as it did not consider the accuracy of each strategy, patient quality of life or long-term health outcomes. To fully consider cost effectiveness within a cost-utility framework, these effectiveness aspects would need to be incorporated. Unfortunately, it was determined that it would not be possible to reliably quantify these aspects given the current evidence base.

7. Organisational considerations

- Clinicians who contributed to the expert review process raised concerns about the two different populations being considered in this EAR (i.e., detecting atrial fibrillation in patients suspected of having AF versus the monitoring people who have a confirmed diagnosis of atrial fibrillation) and suggested they should be considered separately.
- Experts agreed that the evidence base is limited and there is a lack of data to support longer term outcomes. Experts also note that the included studies have methodological concerns and relatively small sample sizes.
- During expert review, there were concerns around rolling out PPG applications for the detection of atrial fibrillation on a larger scale, especially among patients who present with no symptoms. One expert noted this should be on a patient-by-patient basis and workflow could become a challenge.
- Experts note that the burden of AF increases with age, and therefore the technology could be targeted to certain age groups. The scope of the current review included participants with suspected AF or the monitoring of those with confirmed AF and as such, did not include studies assessing the use of the technology as a screening tool in wider populations
- Concerns were also raised about the payment of PPG applications and who would manage the large amounts of data produced.
- One expert also noted that patients often buy these devices or applications such as FibriCheck themselves before asking healthcare professionals which creates large amounts of data to be reviewed.
- Experts agreed that PPG applications seem to work among people with darker skin tones and FibriCheck has undergone FDA clearance and has subsequently been validated across different skin tones. However, clinicians predict that it would be dependent on the device, lights of different wavelengths, their analytical algorithms and signal filtering, and whether different smartphones are used.

8. Patient, carer, and family considerations

HTW collaborated with Cardiomyopathy UK to run a survey of patients to gather their experiences of atrial fibrillation (AF) and their views and opinions of smartphone-based apps to manage their condition.

Additionally, four studies reporting patient experiences were found during the clinical evidence literature search.

8.1 Patient survey with Cardiomyopathy UK

HTW produced a survey to gather patient experiences with AF, current methods patients use to manage their condition, and their experiences with, or view and opinions on, smartphone-based apps to help manage the condition. The survey was shared with Cardiomyopathy UK's research network for patients and ran for a month online. Seven responses were received.

8.1.1 Living with AF and impacts on quality of life

Patients reported living with AF from periods of two to twenty-one years. A diagnosis can come as a 'shock'. Symptoms patients experience because of AF include breathlessness, tiredness, anxiety, embarrassment, constant worry about palpitations, disruptions to work, sport and leisure activities, voluntary and social activities and physical activities. Patients described needing to be 'always on alert' as palpitations can occur at any time and 'seem to happen when I least expect it'. Patients report this as 'stressful'.

During palpitations, patients advise they cannot function normally and need to manage the palpitation by sitting down and resting. Some patients use meditation until the palpation has stopped.

> *"I'm always on alert for an irregular heart beat which is stressful. When it happens I can't function properly and have to sit down and try to meditate."*

> *"It stopped me from doing my normal work role, I was not allowed to continue with my sports or my volunteering as an RNLI lifeboat. crew. My hill walking was curtailed as well. It makes me breathless when encountering steeper inclines or after a couple of flights of stairs."*

AF is often associated with other heart conditions. In addition to AF, some patients also reported having total heart failure, ventricular tachycardia (VT) and hypertrophic obstructive cardiomyopathy (HOCM). Some reported that their AF was the result of surgery for other conditions.

> *"I'm on lots of medication anyway and now have to take AF meds which have nasty side effects. I'm tired and dizzy and worry about having a cardiac arrest as a result of having an inherited condition which required surgery which left me with AF."*

8.1.2 Managing AF

Patients advise using medication to help manage their AF, however there are challenges associated with this. Patients describe difficulties getting the correct type and dosage of medication. Side effects from sustained use of blood thinning medications are also a serious concern for patients and they advise that these side effects have an impact on daily life. Patients report experiences with bleeding and bruising and feeling cold in extremities. In more severe cases, patients link the bleeding associated with AF medication to further heart complications. This causes patients to experience distress and a constant concern that their condition will worsen.

> *"It took time to ascertain the correct medication dosage to slow my heartbeat to a manageable level and caused me worry over my future."*

> *"He [husband] also had several bleeds due to blood thinners. One of which was a gastric bleed & finally a stroke which killed him. He had always bled quite easily & I feel his clotting times should have been monitored."*

For some patients who reach stability, there are less impacts and, once they understand their abilities and the limitations that come with them, less need for monitoring and additional support. But for others, there is the constant worry and stress of the condition worsening and leading to stroke. Patients reported that they need to avoid alcohol, overeating, dehydration, physical exertion and stress in work and personal lives. They also advise that it can be difficult to get others to take their condition, and the impacts it can have, seriously.

> *"It's a constant worry for me"*

8.1.3 Use of smartphone apps to monitor AF

None of the patients who responded to the survey had experience of using smartphone apps to help manage their AF. Of the seven, only two had previously heard of such apps.

When asked their opinion on the potential benefits of these apps to patients with AF, three patients responded that they could see benefits, two stated that they didn't know and one responded with some scepticism, stating that 'if you have AF you hardly need an app to let you know about it as symptoms are there'. Due to their unfamiliarity with the apps and their purpose, patient responses questioned if they could be used to give a pre-warning in live time of an oncoming episode or linked with other technologies, such as implantable cardioverter defibrillators (ICDs). This highlights the need to ensure that technologies are properly explained to patients before their introduction. It also highlights patients' preferences for more streamlined approaches where a single technology combines multiple functions, over the use of several technologies each with a defined role.

When asked what they view as important support for people living with AF, patients responded that they could benefit from having clotting time assays, more information on diet and exercise and other alternatives to medication to re-establish normal sinus rhythm. Patients were keen to stress the importance of further research into managing AF and noted how technologies, such as apps, could be the way forward in this area.

8.2 Patient experiences from the clinical literature

Five studies containing patient experiences with smartphone apps to monitor AF were found during the clinical evidence sift.

McManus et al. (2016) conducted a useability questionnaire with their patient sample. Patients reported that the app from this study was "easy" or "very easy to use" (63%) and patients felt that the app could be "important" or "very important" (88%) to them if it could determine their heart rhythm. Patients predominantly reported that app use was "reassuring," "improved my general well-being," and could fit "very well" into their daily life. Patients from this study found the app more useful than other health or heart rhythm devices. They found the app "reassuring to general sense of well-being," and made them more "conscious of their health".

However, the authors note that design of an app for AF detection would need to be built toward older persons. Although smartphone use is increasingly common in seniors, they note that research indicates physical difficulties, sceptical attitudes and difficulty leaning new technologies are barriers in this population, but that once they adopt new technologies, these often become integral to their lives.

Similarly, Lamberigts et al. (2021) found that most of their patient sample reported that using FibriCheck after discharge from hospital was reassuring and made them feel safer, although three of their patient sample reported mild to severe stress associated with taking measurement during the use of the app.

Gawałko et al. (2021) noted how the patients from their sample agreed that the FibriCheck app was easy to use and install. The app gave patients a safe feeling due to being in constant heart rate and rhythm control. More than half of the patients agreed or that they would like to use the FibriCheck app in the future. They also found the automated reminders useful.

In their follow-up study, Gawałko et al. (2023) looked at patient motivation and adherence to using the FibriCheck app. They noted that patients could over or under report episodes of AF due to uncertainties around symptoms or a desire to 'compensate' for low-event days. This highlights the importance of condition education if patients are to use apps correctly. Where patients were supported to use of tools like apps (from specialised AF clinics), adherence, motivation and correct use improved. Older patients were shown to have higher motivation to consistent and good use of the app, as were those with a lack of co-morbidities (specifically diabetes, which may mask AF symptoms), female patients and those with previous AF.

Lastly, van Mourik et al. (2025) considered patient experiences with a TeleCheck-AF approach, which links a PPG-based smartphone application with subsequent tele-consultations in dedicated AF outpatient clinics. This would allow patients with AF to remote on-demand rate and rhythm assessment. In this study, the app Fibricheck was used in conjunction with structured teleconsultation and AF management. The authors found that patients were overall very positive about the PPG app for regular care. Patients found the application easy to use, the instructions were clear and accessible, and only a minority of the patients asked family or close friends for help with the initial installation. All participants were willing to use the PPG-based smartphone application again in the future and would recommend the use of this application to other patients. Patients were asked to make a recording three times a day for at least one week, and they found it easy to incorporate into their daily routine and advised that it was time-savings and cost-effectiveness compared to attending a healthcare setting for monitoring. Patients found it favourable that they were able to perform self- monitoring and that they were provided with direct results.

From the comments received through the survey conducted with Cardiomyopathy UK, this approach would be welcomed by patients and may meet patient expectations for how PPG

technologies can best be utilised for patient identified needs by linking them in with tele-consultations and live time monitoring and reporting.

8.3 Summary

AF is a complex condition that can leave patients with significant challenges to daily life. While some patients achieve stability through medication, that medication can pose a risk to patients ongoing health. The use of smartphone-based apps to monitor AF can aid patients by providing reassurance and support to those who experience worry about their condition and the stress and negative impacts associated with that worry. While patients from clinical trials report good experiences with apps, the importance of educating patients in symptom recognition and understating their condition is essential if patients are to use these apps correctly. From the sample of patients surveyed outside of clinical trials, some can see the potential benefits of using apps to monitor AF while others express some concern around it potentially increasing patient stress and its relevance to those who have reached stability using medication.

Patients show great interest in the potential for PPG apps to be combined with teleconsultations to provide a streamlined approach to remote monitoring with on demand reporting that can be used to improve patient lives in real time.

9. Conclusions

This evidence review summarised published evidence on the effectiveness and cost effectiveness of smartphone-based use of the photoplethysmography for the management of atrial fibrillation. The literature search identified 11 primary studies reported in the clinical effectiveness section of this review (Brasier et al. 2019, Calvert et al. 2024, Fernstad et al. 2024, Gawałko et al. 2024, Gruwez et al. 2024a, Gruwez et al. 2024b, McManus et al. 2013, McManus et al. 2016, Mol et al. 2020, Proesmans et al. 2019, Rozen et al. 2018).

The evidence included in this review suggests there are outcomes to support the effectiveness of photoplethysmography applications to detect AF, although the statistical significance of some outcomes were not reported and there appears to be some overlap in participant data across some studies. Additionally, there were several variables that could have impacted the results such as: the use of several smartphone types and models, the type of application and algorithm used, participant characteristics and prior health conditions, care setting, and choice of comparator.

Outcomes included diagnostic accuracy outcomes, resource use, environmental outcomes, patient compliance, changes to patient management, signal quality, technical failure and adverse events. Sensitivity and/or specificity was reported in nine out of 11 studies, whereas overall accuracy was reported in five studies. The sensitivity values for PPG applications ranged from 89.9% for Preventicus compared with 99.6% for KardiaMobile (Brasier et al. 2019) to 99% for CORAI reported by Fernstad et al. (2024). The specificity values range from 90% in Rozen et al. (2018) for Cardiio Rhythm to 99.9% reported in Gruwez et al. (2024a) for FibriCheck. Overall accuracy values ranged from 95.1% for Pulse-Smart reported in McManus et al. (2016) to 96.7% in McManus et al. (2013) and 99.5% for CORAI when diagnosing AF (Fernstad et al. 2024). Additionally, Fernstad et al. (2024) reported that 3.1% of PPG readings (using CORAI) were labelled as insufficient quality compared with 4.9% of single-lead ECG readings ($p<0.001$). No statistically significant outcomes were found to demonstrate differences in patient compliance using PPG applications versus ECG.

Reductions in travel times were observed (p, NR), along with a 70% statistically significant reduction in the number of ECGs and Holter monitors used because of using FibriCheck instead of conventional monitoring (without use of Holter monitor), and an 80% reduction in the number and duration of face-to-face consultations was observed. A reduction in the total estimated carbon emissions was found in the FibriCheck arm when compared to using a traditional 12-lead ECG (p, NR), along with a reduction in the estimated median carbon emissions ($p<0.001$).

HTW researchers did not identify any quality-of-life outcomes.

Evidence from an economic analysis based on a retrospective analysis of UK patients showed that healthcare costs were significantly lower in patients managed with PPG compared to 12-lead ECG monitoring. However, this estimation was based on the FibriCheck activation charge and the cost of ECG appointments only. In addition, retrospective design of the analysis could introduce some bias due to differences in the characteristics of the intervention and comparator cohorts.

10. Contributors

This topic was proposed by Bieke Van Gorp at FibriCheck.

The HTW staff involved in producing this report were:

- C Bowles, Health Services Researcher - Effectiveness author
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- M Prettyjohns, Principal Researcher and Health Economist – Cost effectiveness author
- R Miller, Senior Health Economist – Cost effectiveness quality assurance
- E Hasler, Information Specialist – Literature search & information management
- A Evans, Patient and Public Involvement (PPI) Manager – PPI author
- R Shepherd, Project Manager – Project Management

The HTW Assessment Group advised on methodology throughout the scoping and development of the report.

We are grateful to the following subject experts, who also contributed to this appraisal:

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Subject experts contributed to this appraisal by commenting on a draft of this report, and in some cases providing other advice to HTW's staff and decision-making groups. All contributions from reviewers were considered by HTW's Assessment Group and actioned accordingly. However, subject experts had no role in authorship or editorial control, and the views expressed are those of Health Technology Wales.

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Appendix 1 – Evidence review methods

We searched for evidence that could be used to answer the review question: What is the clinical and cost effectiveness of smartphone based photoplethysmography for the detection and management of atrial fibrillation?

The criteria used to select evidence for the appraisal are outlined in Appendix 2. These criteria were developed following comments from the Health Technology Wales (HTW) Assessment Group and UK experts.

The systematic search followed HTW's standard rapid review methodology. A search was undertaken of Medline, Embase, CINAHL, KSR Evidence, Cochrane Library, and the International Network of Agencies for Health Technology Assessment (INAHTA) HTA database. Additionally, searches were conducted of key websites and clinical trials registries. The searches were carried out in November 2024 with an update search of Medline, Embase, CINAHL, KSR Evidence, Cochrane Library, and INAHTA HTA database conducted on 13 March 2025. At the same time as the update search, forward citation tracking of the included studies used within this review was conducted in Scopus.

Appendix 3 gives details of the search strategy used for Medline. Search strategies for other databases are available on request.

Appendix 4 summarises the selection of articles for inclusion in the review.

Appendix 2 – Inclusion and exclusion criteria for evidence included in the review

	Inclusion criteria	Exclusion criteria
Population	Adults with known or suspected atrial fibrillation	General screening for AF/general population
Intervention	Mobile phone-based use of the photoplethysmography only (smartphone application/s without additional hardware)	Photoplethysmography not using smartphone camera (e.g., wearable smart devices/smart watches or clip on sensors).
Comparison/ Comparators	Single lead ECG (e.g., KardiaMobile) in previously established pathways, or 12-lead, multiple leads 24-hour Holter monitor (for AF management)	Non-comparative evidence
Outcome measures	Diagnostic accuracy outcomes: sensitivity, specificity, PPV, NPV Resource use (e.g., hospital stays, re-admissions, healthcare utilisation, reduction in travel times, reduced number of appointments) Changes in patient management (such as earlier initiation of preventative treatment for strokes) Health related QoL PPI outcomes e.g., patient satisfaction Adverse events or technical failure of device/application. E.g., worse survival using application Economic outcomes Environmental outcomes	
Study design	We will prioritise the following study types, in the order listed: • Systematic reviews of randomised controlled trials. • Randomised controlled trials. • Non-randomised comparative trials. • Single-arm (no control group) trials that report any relevant outcome. We will only include evidence from "lower priority" sources where this is not reported by a "higher priority" source. This could be because higher priority evidence: • Does not cover all relevant populations • Does not compare the technology of interest to all relevant comparators • Does not cover all outcomes of interest • Reports over short-term follow-up periods, and longer follow-up data is required to facilitate decision making. Where relevant and well-conducted systematic reviews exist, we will use these by: • Reporting or adapting their reported outcome measures where these are fully relevant to the scope of our review, and appropriate synthesis methods have been used • Using these reviews as a source of potentially relevant studies where the review cannot be used as a source of outcome data We will prioritise systematic reviews in terms of the sources of evidence they include, using the order described above.	

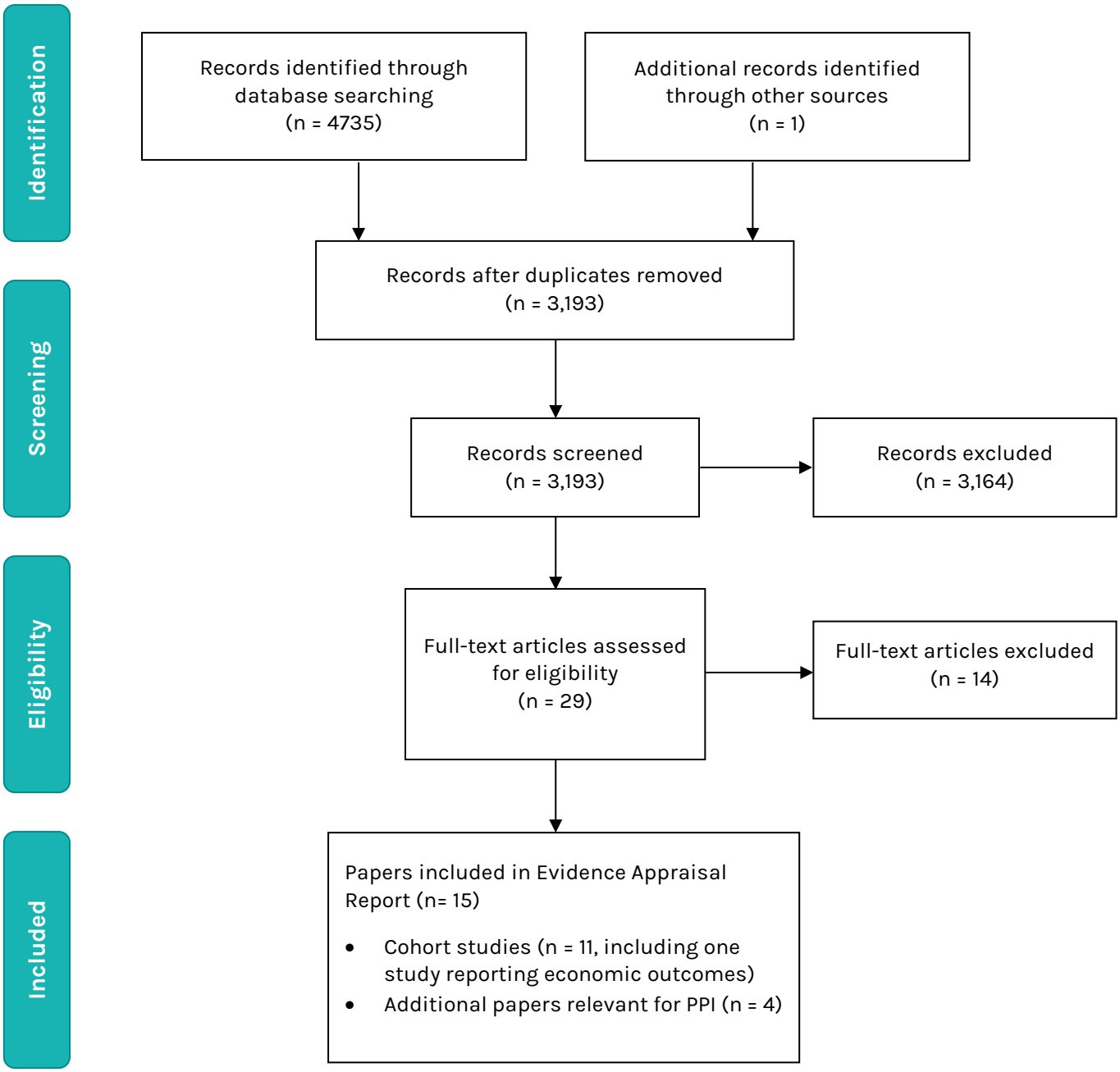
	Inclusion criteria	Exclusion criteria
Search limits	N/A	
Language limits	English language only	
Publication status	We will include evidence from studies that are published in full. We will only include evidence from conference abstracts if there are critical gaps in the fully published evidence. We will include details of any ongoing trials that have a planned completion or reporting date within 24 months of the date searches are carried out. We will only include trials of a design that is likely to add to the existing evidence in terms of certainty; for example, if we report evidence from randomised controlled trials in the EAR, we will only report details of ongoing trials if they also use a randomised design.	
Subgroup analysis	Where the evidence allows, we will report outcomes separately according to list any factors identified as potentially influential on outcomes such as: • disease stage/risk classification • place in treatment pathway	

Appendix 3 – Medline strategy

Ovid MEDLINE(R) ALL 1946 to March 12, 2025		
Atrial fibrillation		
1	exp Atrial Fibrillation/	77490
2	((atrial or atria or atrium or auricular) adj3 fibrillat*).tw,kf.	106461
3	(AF or A-fib or Afib).tw,kf.	61271
4	Atrial Flutter/	6548
5	(atrial adj1 flutter*).tw,kf.	7503
6	((abnormal or irregular) adj1 (heart or cardi*) adj1 rhythm*).tw,kf.	482
7	or/1-6	141922
Photoplethysmography		
8	Photoplethysmography/	3115
9	(photop?lethysmogra* or photo-p?lethysmogra* or "photo p?lethysmogra*").tw,kf.	5565
10	(photo* adj3 p?lethysmogra*).tw,kf.	352
11	PPG*.kw.	494
12	(PPG* adj3 (based or signal or photo*)).tw,kf.	2751
13	((PPG* or p?lethysmogra*) adj3 finger*).tw,kf.	627
14	or/8-13	7129
Set combination: atrial fibrillation AND photoplethysmography		
15	7 and 14	289
Smartphone/mobile applications		
16	*Cell Phone/	7686
17	Smartphone/	11302
18	Mobile Applications/	14433
19	((smartphone* or smart phone* or smart-phone* or mobilephone* or mobile phone* or mobile-phone* or cellphone* or cell phone* or cell-phone*) adj3 (app* or camera* or finger* or detect* or monitor* or wireless*)).tw,kf.	15380
20	(smartphone based or smartphone-based).tw,kf.	4627
21	(smartphone* or smart phone* or smart-phone* or mobilephone* or mobile phone* or mobile-phone* or cellphone* or cell phone* or cell-phone*).tw,kf.	49324
22	video camera*.tw,kf.	4075
23	((smart or mobile or digital) adj1 (health* or technolog* or device*)).tw,kf.	41946
24	(mobile health or mhealth or m-health or ehealth or e-health).tw,kf.	28974
25	(digital adj3 (based or application* or intervention* or program*)).tw,kf.	17055
26	mobile app*.tw,kf.	13220
27	(app or apps).tw,kf.	53398
28	or/16-27	150963
Set combination: atrial fibrillation AND smartphone/mobile applications		
29	7 and 28	864
Broader heart terminology		
30	*Heart/	104978
31	Heart Rate/	180524
32	*Cardiovascular Diseases/	142179
33	exp *Arrhythmias, Cardiac/	194426
34	exp Arrhythmias, Cardiac/cl, di [Classification, Diagnosis]	57590
35	((heart or cardi*) adj1 (rate* or rhythm* or output* or signal* or activit*)).tw,kf.	249985
36	arrhythmia*.tw,kf.	113954
37	or/30-36	767162
Set combination: heart AND smartphone/mobile applications AND photoplethysmography		
38	14 and 28 and 37	337
Additional mop-up searching		

39	(fibricheck* or cardiiorhythm* or cardiio-rhythm* or cardiio rhythm* or pulsesmart* or pulse-smart* or pulse smart*).mp.	19
40	((remote* heart* adj (rate or rhythm) adj3 monitor*) or (remote* monitor* adj3 heart* adj (rate or rhythm))).ti.	10
41	((smartphone* or smart phone* or smart-phone*) and (photop?lethysmogra* or photo-p?lethysmogra* or "photo p?lethysmogra*")).ti.	47
Final set combination, plus filters		
42	or/15,29,38-41	1261
43	limit 42 to english language	1237
44	exp Animals/ not Humans/	5316086
45	(baboon*1 or bovine*1 or canine*1 or cat*1 or chimpanzee*1 or cow*1 or dog*1 or feline*1 or goat*1 or hens or macque*1 or mice or monkey*1 or (mouse adj2 model*1) or murine*1 or ovine or pig*1 or porcine or (non-human adj2 primate*1) or sheep or rabbit*1 or rat or rats or rattus or rhesus or rodent*1 or zebrafish).ti.	2246461
46	44 or 45	5746046
47	43 not 46	1226

Appendix 4 – Flow diagram outlining selection of relevant evidence sources



Appendix 5 – Further details on primary studies

Table A1 – Study characteristics of primary studies

Reference	Study Design, Location	Comparator	Population/Setting	Outcomes	Comments
FibriCheck (CE marked as a class IIa medical device)					
Calvert et al. (2024)	Retrospective cohort study Single centre UK	12-lead ECG	• PPG for the monitoring of AF post interventional procedure • Secondary care, follow up post-DCCV 2 weeks • N=416 (total baseline participants, PPG, 220; ECG, 196) • N=246 (PPG follow-up, 2 weeks) • N=214 (ECG follow-up, 2 weeks) • People with diagnosed AF who have undergone direct current cardioversion (DCCV) from May 2020 to October 2022 • Exclusion criteria: People with acutely unsuccessful DCCV, utilising their own rhythm monitoring or having implantable device interrogation. • AF prevalence during study, 100% • Mean age, 61.9 (PPG), 66.4 (ECG)	• Annual healthcare expenditure • Annual travel time • Annual patient expenditure • Annual c02 emissions • Cost per patient • Median patient travel time • Patient compliance • PPG technical failures • Financial and environmental impact • Number of participants requiring subsequent ECG	The decision on which monitoring type to utilize post-DCCV was made by the cardiac specialist nurse who performed the DCCV at the time of the procedure, after discussion with the patient and offering them both options if appropriate. Participants in the PPG group were instructed to take one, 1 min PPG reading at 14 days post-DCCV, to coincide with the standard timing of ECG follow up. Unclear whether PPG waveforms were reviewed by healthcare professional. Several assumptions and/or estimations to demonstrate resource use/savings. Authors report few conflicts of interests and do not receive personal fees.
Gawałko et al. (2024)	Non-randomised prospective case-crossover study Maastricht University Medical	12-lead ECG as part of DBC care products (this included 35 face-to-face consultations)	• PPG for the monitoring of AF prior to interventional procedure/treatment • Secondary care, 3-month remote AF management • N=37 • People with diagnosed AF with a follow-up appointment at the AF clinic in 2020.	• Number of face-to-face consultations • Duration of consultations • Number of emergency departments visits	Study evaluated a wider TeleCheck-AF programme, using FibriCheck alongside a new mobile health infrastructure. TeleCheck-AF was initiated during the COVID-19 pandemic in the Netherlands, which may have impacted healthcare utilisation. DBC care products (referred to by authors as comprehensive packages of care activities and

Reference	Study Design, Location	Comparator	Population/Setting	Outcomes	Comments
	Centre and AF Clinic Netherlands		• One 3-month conventional DBC care product period from 2019 was compared with a 3-month TeleCheck-AF approach (January-December 2019 versus April-August 2020) • Exclusion criteria: AF ablation, pacemaker implantations and other invasive procedures. • AF prevalence during study, 100% • Median age, 68 years.	• ECG and Holter usage. • Changes in patient management/treatment • Patient experience, reported in section 8.	procedures) may not be typical of what people would receive as standard care for AF in the UK, and thus associated cost savings may be over-estimated when making generalisations to the NHS setting in the UK. Participants collected PPG recordings 3 times per day, and at time of any symptoms, 1 week prior to scheduled teleconsultation. Treating physicians or AF nurses evaluated measurements before consultation. Authors report no conflicts of interest.
Gruwez et al. (2024a)	Prospective blinded validation study RELATION PPG trial Single centre Belgium	KardiaMobile, Alivecor. single-lead ECG ECG analysed by two cardiologists.	• Participants recorded PPG measurements before and after an interventional procedure • Secondary care, before and 4 week follow up post-ablation • N=50 • People (>18 years) with diagnosed paroxysmal AF and persistent AF scheduled to undergo ablation • Exclusion criteria: people with a pacemaker • Data collection period one: 27 December 2022 to 7 February 2023 • Period two: 31 May 2023 to 13 July 2023 (split due to availability of ECG devices) • AF prevalence during study, 100% • Mean age, 63 years.	• Sensitivity • Specificity • PPV • NPV • Patient compliance • Technical failure/signal quality	Participants were instructed to perform a 'measurement set' twice daily, commencing 4 weeks prior to the ablation procedure and continuing 4 weeks after the procedure (total 8 weeks). One set included an ECG first, followed by PPG, concluding with a second ECG. A consistent ECG diagnosis between both ECG readings was, along with PPG data of sufficient quality, available in 3407 measurement sets. PPG waveforms were analysed by commercially available FC algorithm and attached labels of AF, sinus rhythm or insufficient quality. Authors declare no conflicts of interest.
Gruwez et al. (2024b)	Prospective non-randomised study	24-hour ECG Holter monitoring at 3, 6, and 12 months and	• PPG for the long-term monitoring of AF post interventional procedure • Secondary care, one year follow up post-ablation • N=96 (39,895 PPG measurements)	• Sensitivity • Negative predictive value • Compliance rate	Non-randomised singe centre study, with a follow-up of one year. Study conducted at same centre as Gruwez (2024a).

Reference	Study Design, Location	Comparator	Population/Setting	Outcomes	Comments
	DIGITOTAL study Single centre Belgium	intermittent 12-lead ECG	• N=92 completed one year of digital and conventional follow-up • People who have had AF ablation during the inclusion period from January to April 2022. • AF prevalence during study, unknown. • Mean age, 62 years.	• One-year atrial arrhythmia recurrence • Detection of symptomatic atrial arrhythmia • Percentage of insufficient quality readings	Each participant completed both conventional (3 outpatient appointments and 3 periods of 24 hours ECG Holter monitoring) and digital follow-up. Participants were instructed to perform PPG measurements twice daily (for 60 seconds) or whenever symptoms were perceived for one year. Measurements categorised as AF by the application algorithm were subsequently reviewed by a medical technician. Patients performed 39,895 PPG measurements between three and 12 months after AF ablation.
Proesmans et al. (2019)	Prospective cohort study Multi centre (n=17) Belgium	Single lead using ECG-bone (Interuniversity Micro-Electronics Center, IMEC) Reference gold standard 12-lead ECG	• People aged 65 years and above, with known paroxysmal or persistent AF identified from medical records, supplemented with convenience sample of people without AF, n=79 • Primary care (N=223, after exclusions due to active pacemaker pacing during measurements - a predefined exclusion criteria) • A PPG signal suitable for analysis was obtained for 92.8% of patients (207/223) • Patients with an active pacemaker rhythm were excluded • AF prevalence during study, 46% • Mean age, 77 years.	• Sensitivity • Specificity • PPV • NPV • Overall accuracy	Cohort was supplemented with a convenience sample of people without a reported history of AF. PPG recording lasted one minute, and participants independently performed three consecutive measurements. Single-lead ECG was obtained simultaneously with PPG measurement. Insufficient quality readings were excluded on the participant (rather than individual measurement) level. PPG and single-lead ECG waveforms were analysed by the FibriCheck AF algorithm. Authors declare no conflicts of interest.

Reference	Study Design, Location	Comparator	Population/Setting	Outcomes	Comments
Preventicus Heartbeats app (CE marked as a class IIa medical device)					
Brasier et al. (2019)	Case-control DETECT-AF PRO study Multi-centre (n=2) Switzerland and Germany	Mobile iECG by KardiaMobile by AliveCor – Interpreted by two cardiologists	• Participants with a history of AF • Secondary care • N=592; n=344 sinus rhythm group, n=248 AF group (after n=80 were excluded after enrolment mainly due to PPG/iECG signal quality) • Hospitalised patients with a history of AF as identified in medical records (>18 years; 14.2% <65 years) • Exclusion criteria: people without pacemaker or implanted defibrillator • AF prevalence during study, 42% • Median age, 78 years	• Sensitivity • Specificity • Percentage of no diagnosis • Correctly classified rate (CCR)	5-minute PPG recordings were taken, and outcomes reported in 1-minute, 3-minute, and 5-minute intervals. Age and sex matched patients without a history of AF in their medical records were recruited as potential matches for the comparator group. Authors reported some of the patients with a history of AF were likely to be in SR at the time of recruitment. The final allocation of the patients to the respective groups occurred after recruitment was closed and all was data analysed (blinded). PPG waveforms were analysed using the Heartbeats algorithm. Potential conflict of interest due to some authors having shares in Preventicus.
Cardiio Rhythm (Not CE marked)					
Rozen et al. (2018)	Prospective case-control Single centre USA	12-lead ECG– Interpreted by two cardiologists	• Participants recorded PPG measurements before and after an interventional procedure • Secondary care, n=98 recruited • Pre-CV, n=97 • Post-CV, n=92 • People (>18 years) with a diagnosis of AF who were scheduled for elective direct current cardioversion (DCCV) • AF prevalence during study, 90% • Mean age, 68 years	• Sensitivity • Specificity • PPV • NPV	PPG recording lasted 20 seconds, conducted 3 times daily before and after DCCV procedure (total of 1 minute before, 1 minute after). Recordings were labelled AF if at least 2 of the 3 recordings were sufficiently irregular. Five of 97 patients were excluded from the post-CV rhythm analysis, because of a baseline normal sinus rhythm (n=1), a contraindication to the procedure (n=3) and one participant left before the post-CV recordings took place. Authors report in n=3 cases a 12-lead ECG was not available, single-lead rhythm strips were used.

Reference	Study Design, Location	Comparator	Population/Setting	Outcomes	Comments
					PPG waveforms were analysed using CRMA algorithm. Two authors are employees and stakeholders of Cardiio Inc. One other author has a patent for the algorithm described in study.
Pulse-Smart (Not CE marked)					
McManus et al. (2016)	Prospective cohort study Single centre USA	12-lead ECG Interpreted by trained physicians	• Participants recorded PPG measurements before and after an interventional procedure • Secondary care • N=121 (219 recordings) • Mean age, 66 years People with diagnosis of AF scheduled to undergo cardioversion (n=98 (81%)), PACs (n=15), or PVCs (n=15) • Exclusion criteria: People with acutely unsuccessful cardioversion who did not convert to sinus rhythm post-cardioversion	• Overall accuracy (pre and post CV) • Sensitivity • Specificity • Usability assessment (reported in section 8)	Overlap of participant data from McManus et al. (2013) – includes an additional 55 participants (n=22 with AF). The study included participants who had different types of arrhythmia, but results reported are for AF participants only. PPG recording lasted 2 minutes before and after cardioversion. Details on any conflict of interests were not available.
McManus et al. (2013)*	Prospective cohort study Single centre USA	12-lead ECG Interpreted by trained physicians	• Participants recorded PPG measurements before and after an interventional procedure • Secondary care • N=76 • Mean age, 65 years. • Adults with known persistent AF scheduled to undergo cardioversion • Exclusion criteria: People with acutely unsuccessful cardioversion who did not convert to sinus rhythm post-cardioversion • AF prevalence during study, 100%	• Overall accuracy (pre and post CV) • Sensitivity • Specificity	PPG recording lasted 2 minutes before and after cardioversion. PPG waveforms were analysed by a statistical algorithm. Details on any conflict of interests were not available.

Reference	Study Design, Location	Comparator	Population/Setting	Outcomes	Comments
Happitech (CE marked as a class IIa medical device)					
Mol et al. (2020)	Case-control cross-sectional study Single centre Netherlands	12-lead ECG	• Participants recorded PPG measurements before and after an interventional procedure • Secondary care • N=149 pre-elective electrical cardioversion (ECV). Post-ECV n=41 excluded due to being unable to use PPG, ongoing infection, technical failure, unsuccessful ECV • Adults with AF admitted to hospital for elective electrical cardioversion (ECV) • Exclusion criteria: unable to use PPG, people with ongoing infection. • AF prevalence during study, 100% • Mean age, 69 years.	• Overall accuracy (pre and post ECV) • Sensitivity • Specificity • Signal quality	PPG recording lasted 90 seconds before and after ECV.. PPG waveforms were analysed using the Happitech artificial intelligence algorithm. Two authors are stakeholders of Happitech. One other author receives personal fees.
CORAI (Class IIb medical device)					
Fernstad et al. (2024)	Prospective validation study (SMARTBEATS) Single centre Sweden	Mobile iECG by KardiaMobile by AliveCor – Interpreted by two cardiologists (measured simultaneously with PPG)	• PPG for the long-term monitoring of AF post interventional procedure • Secondary care (ambulatory real-world setting) • N = 280 • Adults undergoing DCCV for persistent or recent onset of AF or AFL • Exclusion criteria: people with a cardiac implantable electronic device • AF or AFL prevalence during study, 100% • Median age: 69 years.	• Sensitivity • Specificity • PPV • NPV • Overall Accuracy • Signal quality	1-min heart rhythm recordings post-treatment were recorded twice daily for 30 days. A PPG report was automatically generated by the CORAI application, allowing a heart rhythm diagnosis to be determined through manual reading. Manual readings were made by two cardiology consultants with a third cardiologists in case of disagreement. Participants recorded both types of measurements simultaneously by placing a fingertip over the camera lens of an iPhone 7 and at the same time placing other fingers from both hands on the electrodes of the KardiaMobile device. First author of paper is the creator and founder of CORAI.

Reference	Study Design, Location	Comparator	Population/Setting	Outcomes	Comments
					Study was funded by VINNOVA (grant number 2019-01378) and by the Stockholm County Council.

Abbreviations: AF, atrial fibrillation; AFL, atrial flutter; CV, cardioversion; DBC, 'diagnosebehandelcombinatie (DBC) care; DCCV, direct current cardioversion; ECG, electrocardiogram; iECG, single-lead ECG; NPV, negative predictive value; NR, not reported; PACs, premature atrial contractions; PPG, photoplethysmography; PPV, positive predictive value; PVCs, premature ventricular contractions

*We assumed McManus et al. (2013) tested an older version of the PULSE-SMART application (this is because the authors used the same algorithm as the other PULSE-SMART study and cited the same methodological paper, however the newer version has a turning point ratio, referenced in McManus et al, 2016).