

Mobile health applications for the detection of atrial fibrillation: a systematic review

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Aims	Atrial fibrillation (AF) is the most common sustained arrhythmia and an important risk factor for stroke and heart failure. We aimed to conduct a systematic review of the literature and summarize the performance of mobile health (mHealth) devices in diagnosing and screening for AF.
Methods and results	We conducted a systematic search of MEDLINE, Embase, and the Cochrane Central Register of Controlled Trials. Forty-three studies met the inclusion criteria and were divided into two groups: 28 studies aimed at validating smart devices for AF diagnosis, and 15 studies used smart devices to screen for AF. Evaluated technologies included smartphones, with photoplethysmographic (PPG) pulse waveform measurement or accelerometer sensors, smart-bands, external electrodes that can provide a smartphone single-lead electrocardiogram (iECG), such as AliveCor, Zenicor and MyDiagnostick, and earlobe monitor. The accuracy of these devices depended on the technology and the population, AliveCor and smartphone PPG sensors being the most frequent systems analysed. The iECG provided by AliveCor demonstrated a sensitivity and specificity between 66.7% and 98.5% and 99.4% and 99.0%, respectively. The PPG sensors detected AF with a sensitivity of 85.0–100% and a specificity of 93.5–99.0%. The incidence of newly diagnosed arrhythmia ranged from 0.12% in a healthy population to 8% among hospitalized patients.
Conclusion	Although the evidence for clinical effectiveness is limited, these devices may be useful in detecting AF. While mHealth is growing in popularity, its clinical, economic, and policy implications merit further investigation. More head-to-head comparisons between mHealth and medical devices are needed to establish their comparative effectiveness.
Keywords	Atrial fibrillation • Telemonitoring • Mobile health • Wearable devices • Systematic review

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Introduction

The prevalence of atrial fibrillation (AF) is increasing, estimated at 1% of the population and 5% among those aged >65 years.¹ Untreated AF accounts for 15% of all strokes and is independently associated with heart failure, cognitive impairment, and death.² Atrial fibrillation manifestations can range from asymptomatic to highly symptomatic and can negatively affect patients' quality of life if left untreated.³ Early diagnosis of AF may have several benefits, including the potential for individualized risk factor evaluation and modification, ablation for symptomatic individuals, and anticoagulation, which can reduce the risk of stroke and mortality by \sim 65% and 25%, respectively.⁴ Smartphones, tablet computers, and their applications (apps) have become ubiquitous across the globe. Mobile health (mHealth) technology characterized by portability, instantaneous access, and direct communication allows for faster transfer of physiologic parameters and patient-reported symptoms to healthcare providers, and has the potential to revolutionize clinical care in a cost-efficient manner.⁵ Recent studies have shown that the use of mHealth apps has a positive impact on health-related behaviours and clinical health outcomes.⁶ The current mobile devices to diagnose AF can be divided into five types: smartphones, smartbands or smartwatches, earlobe sensors, and handheld electrocardiogram (ECG) devices such as MyDiagnostick or Zenicor (Figure 1). These devices present potential compared to conventional monitoring systems. They are accessible, non-invasive, safe, and easy to use for patients. However, the effectiveness of these devices in reliably diagnosing paroxysmal AF (PAF) and screening for AF is unclear. Advances in wearable technology

and algorithms may yield practical options to determine AF burden and help stratify stroke risk.^{7,8} Here, we aimed to conduct a systematic review of the literature and summarize the performance of mHealth devices in diagnosing and screening for AF.

Methods

Search strategy

We used the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement to guide this review. We systematically searched MEDLINE, Embase, and the Cochrane Central Register of Controlled Trials for articles published from 1 January 2012 to 30 September 2019, inclusive. Search strategy and details of databases searched are available in Supplementary material online, *Appendix 1*.

Eligibility criteria

We included randomized controlled trials (RCTs), non-randomized trials, case-control, cohort or cross-sectional studies reporting the effectiveness of mHealth devices in detecting the primary outcome of AF detection among adults \geq 18 years. We also included studies that reported the cost of the intervention or clinical endpoints related to AF. We included published conference abstracts if demographic and outcome data were available. We excluded studies that did not meet inclusion criteria or those that only included routine methods of cardiac monitoring (pacemaker, implantable loop recorders, event recorders, and inpatient telemetry). Although the 12-lead ECG is still the gold standard method to diagnose AF, pacemaker and implantable cardioverter-defibrillator electrograms and cardiac telemetry monitoring are also well-validated tools



Figure I Types of wearable systems. PPG, photoplethysmography.

to detect AF. Therefore, those studies comparing mHealth devices with routine methods of cardiac monitoring were also included in this review. Since the recommendations for screening for AF in patients with prior ischaemic stroke differs substantially from general population, we excluded studies screening for AF in post-stroke patients.

Study eligibility

We assessed studies for inclusion according to the latest version of the PRISMA statement (www.prisma-statement.org).⁹ Manuscripts that met inclusion criteria on the basis of title and abstract review were reviewed in full to confirm eligibility.

Data extraction

A pair of reviewers independently abstracted each article (CRLP, RCA). We extracted data regarding publication date, source, corresponding author and country, study design, number and clinical characteristics of individuals assessed, category of mHealth device and method for AF detection, sensitivity, specificity, positive predictive values (PPVs), and negative predictive values (NPVs) for each test, newly diagnosed AF in screening studies, percentage of patients with newly diagnosed AF who received oral anticoagulation (OAC), monitoring time (single point in time or period of recording) if available, and the incremental cost-effectiveness and clinical outcomes if provided.

Data synthesis

We presented descriptive data as counts and percentages for categorical variables and mean (standard deviation) or median (interquartile range) for continuous variables. We presented sensitivity, specificity, PPV, and NPV as percentages with 95% confidence intervals when provided.

Risk of bias

We assessed risk of bias according to the Grading of Recommendations Assessment, Development and Evaluation (short GRADE). We assessed observational studies for risk of bias using the Newcastle-Ottawa Scale (NOS) for non-randomized studies. The NOS quality scale contains eight items partitioned into three categories (selection, comparability, and outcome); a maximum of one star is allocated to a high-quality study for each of selection and outcome and a maximum of two stars for comparability, giving an overall maximum of nine stars.¹⁰ We used a modified NOS scale to assess cross-sectional studies, using 3 categories (selection, comparability, and outcome) and a maximum of 10 stars.¹¹ The main advantages of this scale are that it is easy to use, considers many of the important elements that have empirically been shown to correlate with bias; and has known reliability and external validity. $^{12}\ensuremath{\,\text{We}}$ considered studies to be high quality if they had six or more stars in the NOS scale or seven stars in the modified NOS scale.^{13,14} Supplementary material online, Appendix 2 presents the risk of bias table.

Description of technology

Smartphone

There are three methods of using a smartphone to detect and monitor AF.

The first method uses a downloadable application and existing smartphone hardware, and relies on smartphone camera photoplethysmographic (PPG) pulse waveform measurement. Photoplethysmographic measures the blood volume changes through the skin capillary bed optically by illuminating the skin with a light-emitting diode and measuring the changes in light absorption.¹⁵

Changes in blood volume are synchronous with the heart beats, such synchrony is manifested by the concordance of inter-beat intervals (RR intervals). In a PPG signal, AF is manifested as varying pulse-topulse intervals and pulse morphologies. Multiple smartphone apps to detect AF exist. One of them is FibriCheck, which was cleared by the Food and Drug Administration (FDA) in September 2018.¹⁶

The second method uses a pair of external electrodes that communicate with an application downloaded to the phone; AliveCor heart monitor represents an example of this kind of devices. It is a smartphone-dependent device that converts the electrical signals from fingertips into ultrasound signals; these signals are then transmitted to the smartphone and a single-lead electrocardiogram (iECG) is recorded. Importantly, Kardiomobile 6L was recently released by AliveCor, which was cleared by the FDA in May 2019. Like the singlelead Kardia, the 6L has two sensors on top for left and right hand contact. In addition, there is a third on the bottom which can be put on a left knee or ankle. The combination of these sensors and contact points yield the six classic frontal leads of a full 12-lead ECG.¹⁷

The third method is based on mechanocardiography principles. The approach is also smartphone-based, but the acquisition of the heart signal is made in an alternative way. The patient lies down in a supine position and the smartphone is placed on the chest of the patient. The mechanical cardiac activity is recorded with accelerometers and gyroscopes, registering the tiny cardiogenic micromovements of the patient's chest for signal acquisition.¹⁸

Wrist-worn wearables

Heart rate sensors on the majority of wrist-worn devices, including the Apple Watch (Apple Inc.), utilize PPG. The Apple Watch records a tachogram (which is a plot of the time between heartbeats) and then applies its proprietary algorithm to determine pulse irregularity and thus AF. The Apple Watch algorithm received FDA clearance for the consumer market. An iECG can be recorded through a circuit between the detector on the watch back and the digital crown. The first smartwatch accessory cleared by the FDA for detection of AF via its ability to record a single-lead ECG signal was the Kardia Band. It utilizes a paired iPhone and Apple Watch to function. Finally, another smartwatch ECG technology cleared by the FDA is Verily's study watch, which is only intended for research purposes.¹⁹

Other devices

It is possible to detect rhythms with a pulsatile facial PPG signal obtained by the smartphone camera; no physical contact is used. PPG technology can also be used by devices on the ear lobe to assess rhythm. Other solution, like MyDiagnostick, similar to AliveCor in functionality, is a rodlike device with two electrodes on the endings. While holding the device, it will flash on the rhythm of the detected heartbeat. Time and date stamped stored ECGs can be made available by returning the MyDiagnostick to the physician, who can connect it to a web-portal (USB connection to internet-enabled PC). Zenicor is a handheld ECG device with which patients register their iECG themselves by placing their thumbs on two electrodes for 30 s. It automatically transmits the encrypted recording to a password-protected database.²⁰ Technology description is summarized in Figure 2.





Results

Study characteristics

The PRISMA flow chart of our included studies is shown in *Figure 3*. Our initial search strategy identified 246 studies, with another nine identified through other sources. We identified 189 potentially eligible full-text studies for review, of which we included 43 studies that met inclusion criteria in our systematic review.

Studies design

Of the 43 studies included, 28 studies aimed at *validating* smart devices for AF diagnosis, while the remainder 15 studies used smart devices to screen for AF diagnosis (*Figures 4 and 5*).

Validation of smart devices in the detection of known atrial fibrillation

Studies design

The review included 14 studies with a single set of inclusion criteria (cohort studies),^{21–34} nine studies with two sets of inclusion criteria (case–control studies).^{35–44} One of the case–control studies grouped participants into those with known sustained AF, those with other non-AF arrhythmias and those in sinus rhythm.⁴⁴ There were four studies of unclear design.^{45–48}

Population and setting

Population and setting of validation studies are summarized in *Table 1*.

Type of device

The type of device and the gold standard reference used in validation studies are summarized in *Table 1*.

Diagnostic accuracy

The accuracy of devices for arrhythmia detection depended on the technology used and the population evaluated. The PPG sensors found in smartphones detected AF with a sensitivity of 95.0-97.6% and a specificity of 95.0-99.6% in a 70 years old Chinese population.²¹ The AliveCor device had a sensitivity from 64.5% to 98.5% and a specificity from 97.5% to 98.0%, depending on the algorithm employed for detection.^{24,46,48} MyDiagnostick had a sensitivity from 81.8% to 94% and a specificity from 94.2% to 93% among cardiac ward³² and primary care patients,³⁷ respectively. The accelerometer and gyroscope based algorithms showed sensitivities of between 94% and 95%, specificities of 96% with a global accuracy of 97.0%.^{35,41} The diagnostic accuracy of smartbands and smartwatches was variable among studies depending on the different algorithms utilized, populations studied, and the testing conditions (most of the good quality data will be acquired when subjects are sleeping or sitting still). Sensitivity and specificity of smartbands were found to be in a range between 75.4% and 97.0% and 94% and 100%, respectively,^{22,43} while smartwatches



Figure 3 PRISMA flow chart of included studies. AF, atrial fibrillation; mHealth, mobile health.

showed a sensitivity 67.7–100% and a specificity of 67.6–98% (Take-home figure).^{33,42} The characteristics and diagnostic accuracy of different studies are summarized in *Table 1*.

Type of device

The type of device and the gold standard reference used in screening studies are summarized in *Table 2*.

Use of smart devices to screen for atrial fibrillation

Studies design

Six studies were prospective observational cohort studies $^{49-54}$ six were cross-sectional and $^{55-60}$ three studies were designed as RCTs. $^{61-63}$

Population and setting

Population and settings of the included screening studies are summarized in *Table 2*.

Main outcome measures

The incidence of newly diagnosed AF varied according to the characteristics of the screened population, ranging from 0.12%, in healthy community-dwelling citizens⁵⁵ to 8% in a Kenyan inpatient cohort with an increased risk of AF.⁵⁰ The study comparing the diagnostic performance of a smartphone PPG application and the AliveCor device showed higher sensitivity of PPG than AliveCor (92.9% vs. 71.4%) with comparable specificity (97.7% vs. 99.4%), lower PPV (53.1% vs. 76.9%) and similar NPV (99.8% vs. 99.2%) relative to AliveCor.⁵¹ Interestingly; in the Huawei Heart Study (HHS) automatic periodic measurements were more likely to identify episodes of AF compared to patient triggered events (37.0% vs. 7.5%).⁵⁴ Similar data were found in the STROKESTOP study, where new AF



was found in 3.0% and intermittent ECG screening increased the prevalence of AF in the screened population by 33% (Table 2). 61

Clinical outcomes

Only eight studies reported information regarding AF management, showing an incremented use of OAC among the screened population (*Table 3*).^{49,54,58–63} Among the participants in the STROKESTOP study, OAC therapy was started in 93% of the patients with newly diagnosed AF.⁶¹ In the Apple Heart Study (AHS), the notification subgroup (i.e. the group notified of an irregular pulse) was more likely to start receiving warfarin (2.2% vs. 0.1%), direct oral anticoagulant (22% vs. 0.3%) or aspirin (36% vs. 14%). Of the 404 notified participants who reported new AF, 24% reported undergoing cardioversion, 3% received an implantable loop recorder, 20% started antiarrhythmic therapy, and 18% underwent catheter ablation.⁵³

Cost-effectiveness of screening for atrial fibrillation using mobile health

Four studies provided data regarding costs.^{32,40,60,63} A costeffectiveness simulation based on the screening results and timeinvestment measurements was performed in Belgium, accounting for cost of staff, hospital, and screening with iECG provided by AliveCor; patients had a mean CHA2DS2-VASc score of 3.90 and hospitalized mainly for elective coronary revascularization or acute coronary syndrome, electrophysiological examination, heart failure or device implantation. The cost per preventable stroke to identify one new AF patient was reported as €7535 and €1916 at cardiology and geriatrics wards, respectively.⁴⁰ An Australian study reported that screening 1000 pharmacy customers aged >65 years (mean 76 years; 44% male, 7% with prior stroke, and mean CHADS-VASc 3.3) with AliveCor had an incremental cost-effectiveness of \$AUD 5988 per quality-adjusted life year (QALY) and \$AUD 30 481 for the prevention of one stroke.⁶⁰ Halcox et al.⁶³ showed a cost per AF diagnosis of \$10780 using AliveCor (£8255) in persons aged ≥65 years with a CHADS-VASc score ≥ 2 free from AF. The STROKESTOP screening programme estimated a cost of €4164 per QALY and €6583 per avoided stroke in this 75- and 76-year-old Swedish population. Based on this analysis, screening of 1000 individuals resulted in 263 fewer patient-years with undetected AF, 8 fewer strokes, 11 more life-years, and 12 more QALYs.⁶¹

Risk of bias

Six studies (19%) were at high risk of bias due to absence of a comparison group and absence of data on attrition rate. Most studies were non-randomized and recruited selected patients at risk of stroke (defined as CHADS-VASc \geq 1), as in Chan et al.^{51,52} The assessment of



cardiac rhythm was blinded in just three studies.^{32,37,42} Six studies did not provide information about baseline characteristics of the enrolled population.^{27,35,36,39,46,47} Only two studies provided the calculation of the sample size.^{25,37} Seven studies (22%) were at low risk of bias.

Discussion

In this review of 43 studies (>680 000 patients), we show that the use of mHealth devices is feasible and reliable for the detection of AF. The performance of these devices in detecting AF depends on the characteristics of the population being studied, their risk of developing AF, and the technology used to detect AF. There are limited head-to-head comparisons between medical devices, so their comparative effectiveness within any given population is unclear. The only direct comparison between automated PPG and AliveCor algorithms in real-life conditions found that the smartphone PPG algorithm had the greatest sensitivity, with the highest NPV to exclude AF, while automated AliveCor algorithm had the greatest specificity and PPV to rule in this condition.⁵¹ The lower specificity achieved by PPG algorithm may be explained by finger movement artefacts that can affect the detection algorithm, leading to a reduction in specificity when the smartphone application is used outside the clinic. The lower sensitivity of AliveCor algorithm was a surprising finding and was attributed to the use of the most updated version of the application. Nonetheless, a benefit of using ECG-based systems to screen for AF is having the option to overread the ECG tracings, which can help a clinician rule in or rule out AF.

Our findings are important given the limitations of current methods for AF detection. Pulse palpation can result in greater falsepositive cases by falsely assigning a diagnosis of AF to patients with transient pulse irregularities (e.g. ventricular or atrial ectopy). The use of 12-lead ECG for screening purposes is limited by its lack of portability. Continuous Holter monitoring is commonly used in clinical practice but disadvantages of this technology include cost, the need for skin electrodes with artefacts resembling cardiac arrhythmias, and a limited screening duration of 24–48 h.

A national screening programme for AF is likely to represent a cost-effective use of resources. Systematic opportunistic screening is more likely to be cost-effective than systematic population screening.⁶⁴ Mobile health devices offer a feasible option for mass screening of AF in diverse settings as they are user-friendly, leadless, and widely used by the general population. Screening is suggested as one strategy to increase AF detection rates and start OAC early. Atrial fibrillation detection has the potential to support behavioural changes that address risk factors, expedite treatment of AF, and avoid complications (e.g. heart failure or stroke).

Challenges with use of mobile health to detect atrial fibrillation

The sensitivity and specificity of these mobile devices is a major concern. Ultimately, ECG confirmation is mandated by guidelines for the diagnosis of AF. Therefore, transmission of the PPG waveform would not really help to confirm an AF diagnosis if a 12-lead ECG or ECG-



Take-home figure Summary of findings for mHealth apps in atrial fibrillation detection. AF, atrial fibrillation; iECG, single-lead electrocardiogram; PPG, photoplethysmographic.

based device is not available. Consequently, many patients with PAF would be missed. Similarly, if only patients with persistent AF are included, they will be easier to be diagnosed by monitoring, falsely elevating the sensitivity, since accurately detecting a long-standing arrhythmia is not the same as accurately detecting 'bursts'. Besides, the performance in AF detection may be limited by the intrinsic accuracy of the automated algorithm. In one study assessing Kardia Mobile, 28% of recordings were unclassified by the algorithm.²⁴ Of these unclassified recordings, only 8% were non-interpretable by the physician. In another study, 3.7% of the samples were excluded from the statistical analysis due to poor device fitting, technical malfunction, or too short recording length.³⁶ Including those uninterpretable data in the analysis would probably result in lower sensitivity and specificity values. The main concern is the rate of false positives when it comes to using the app in a low-risk healthy population (i.e. 52% of the people in the AHS were under age 40). Since PPV and NPV largely depend on the prevalence of AF in the population tested, even given an accurate test, the sheer number of falsepositive results may be too high, with the consequent stress for patients, unnecessary tests, and costs for the society. In the AHS, only 2161 (0.52%) of the included patients received a notification of irregular pulse and just 450 (20.8%) eventually wore and returned an ECG patch. Of these, 153 (34%) had AF detected. But of the 293 015 in the study who did not receive a notification and completed the end-of-study survey, 3070 said they had received a new diagnosis of AF. Since only subjects who had a positive trigger on the iWatch were evaluated further, sensitivity cannot be determined at all. Another important limitation in the AHS and HHS is that the percentage of people who dropped out was high and full follow-up was low. In the HHS, 0.23% of the monitored patients had suspected AF and 38% of those suspected of having AF were unable to be followed up. In the AHS, close to 30% of participants were lost to follow-up. This represents a potential compliance bias that may affect the conclusions about the true frequency of AF. In addition, obtaining long-term participant commitment and compliance may become a greater challenge if consent is performed electronically.

The widespread adoption of a screening programme with wearable devices can also lead to measurement burden, over-diagnosis, and overtreatment, and studies demonstrating clinical benefit are largely pending. Identifying those at higher risk of AF is a reasonable way to boost the pre-test. A recent study showed that N-terminal Btype natriuretic peptide-stratified systematic screening for AF may be useful to select patients at highest risk of stroke, with a number needed to screen to diagnose 1 AF of 38.⁶²

Technical limitations of mobile health device

Photoplethysmographic monitoring apps are sensitive to errors caused by finger pressure, skin tone, user movement, and bright

reference	Category of mHealth	Country, setting, number in analysis	Type of study	Number of signals and filter	Age (years), mean	Gold standard	PPV (%) (95% CI)	NPV (%) (95% CI)	Sensitivity (%) (95% Cl)	Specificity (%) (95% CI)	Quality assessment
Yan et al. ²¹	Smartphone (PPG signal)	China, inpatients, 217	Cohort	512 samples Filter: 0.7–4.0 H ₇	70.3 ± 13.9	12-lead ECG	92 (84–96)	97 (93–99)	96 (91–98)	95 (87–98)	9
McManus et al. ²⁸	Smartphone (PPG signal)	USA, 76 patients scheduled for CV	Cohort	Not provided	65.3 ± 11.6	12-lead ECG	Not provided	Not provided	96.2	97.5	ę
Lee et al. ³⁰	Smartphone (PPG signal)	USA, 25 patients scheduled for CV	Cohort	Not provided	58±13.6	Not provided	Not provided	Not provided	97.6	9.66	Ŷ
Rozen et al. ³⁴	Smartphone (PPG signal)	USA, 97 patients scheduled for CV	Cohort	Not provided	67.7 ± 10.5	12-lead ECG	92.2 (85.8–95.8)	92 (94.8–95.9)	93.1 (86.9–97.2)	90.9 (82.9–96)	4
Brasier et al. ³⁸	Smartphone PPG	Switzerland and Germany, inpa- tient settings, 248 AF and 344 SR pratients	Case- control	Not provided	7 8 ± 13	Mobile iECG	Not provided	Not provided	91.5 (85.9–95.4)	99.6 (97.8–100)	v
Krivoshei et al. ⁴⁰	Smartphone (PPG signal)	Switzerland, inpa- tient and outpa- tient settings, 40 AF and 40 SR patients	Case- control	Filter: 0.5–7 Hz	80±8 ^a	12-lead ECG	Not provided	Not provided	95	5	v
McManus et al. ⁴⁵	Smartphone (PPG signal)	USA, inpatient set- tings, 98 AF, 15 PAC, 15 PVC, and 91 SR patients	Unsure	Not provided	65.9 ± 11.2^{a}	12-lead ECG	Not provided	Not provided	97	93.5	Ŋ
Schack et al. ⁴⁷	Smartphone (PPG signal)	Germany and Netherlands, in- patient settings, number of par- ticipants not provided	Unsure	Filter: 0.5–4 Hz	Not provided	Not provided	Not provided	Not provided	85 (65–100)	100 (99–100)	m

Table I Conti	inued										
Study reference	Category of mHealth	Country, setting, number in analysis	Type of study	Number of signals and filter	Age (years), mean	Gold standard	PPV (%) (95% Cl)	NPV (%) (95% Cl)	Sensitivity (%) (95% CI)	Specificity (%) (95% Cl)	Quality assessment
Poh et al. ³¹	Smartphone (PPG signal)	China, setting not provided, 1013 participants	Cohort	512 samples Filter: 0.48–12 H7	68.4 ± 12.2	12-lead ECG	87.5 (72.5–94.9)	100 (99.4–100)	100 (88–100)	(%6.69–99.9%)	4
Proesmans et al. ²⁵	Smartphone iECG and PPG signal (FihriChark)	Belgium, 223 primary care patients	Cohort	657 samples	77±8	12-lead ECG	- PPG: 95.6 - iECG: 95.7	- PPG: 96.6 - iECG: 95.7	- PPG: 96 (89–99) - iECG: 95 (88–98)	- PPG: 97 (91–99) - iECG: 97	4
Yan et al. ²²	(PPG signal)	China, cardiology wards, 51	Cohort	512 samples Filter: 0.48–12 H 7	69.4	12-lead ECG	87.5 (64.4–96.4)	97.1 (83.6–99.6)	93.3 (70.2–98.8)	94.4 (81.9–98.5)	2
Fan et <i>a</i> l. ²³	Smartband (PPG signal)	China, inpatients, 112	Cohort	Not provided	66.6 ± 13.2^{a}	12-lead ECG	99.6 (97.6–99.9)	96.2 (93.5–97.9)	95.4 (92–97.4)	99.7 (98–99.9)	ß
Bonomi et al. ⁴³	(PPG signal)	Netherlands, 20 patients sched- uled for CV and 40 patients pre- scribed a Holter: 120 healthy subjects	Case- control	Not provided	67.4 ± 12.1 ^b	12-lead ECG	99 (96–100)	57 (46-68)	97 (91–100)	100 (99–100)	Ŋ
Corino et al. ⁴⁴	Smartband (PPG signal)	as control group Italy, inpatient set- tings, 30 AF patients, 31 SR and 9 with	Case- control	Not provided	76±9ª	Not provided	Not provided	Not provided	75.4	96.3	4
Quer et al. ²⁷	Smartband (PPG signal)	other rhythms USA, 137 commu- nity subjects	Cohort	Not provided	Not provided	Not provided	Not provided	Not provided	96	96	m
Bumgarner et al. ²⁶	Smartwatch (PPG signal)	USA, 100 patients scheduled for CV	Cohort	169 samples	68±11	12-lead ECG	Not provided	Not provided	93 (86–99)	84 (73–95)	Ŀ
Hochstadt et al. ²⁹	Smartwatch (PPG signal)	lsrael, 20 patients hospitalized for AF	Cohort	18 608 measurements	74.1 ± 8.7	12-lead ECG	Not provided	Not provided	100	93.1	S
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Table I	

Study reference	Category of mHealth	Country, setting, number in analysis	Type of study	Number of signals and filter	Age (years), mean ± SD	Gold standard	PPV (%) (95% CI)	NPV (%) (95% CI)	Sensitivity (%) (95% CI)	Specificity (%) (95% CI)	Quality assessment
Tison et al. ³³	Smartwatch (PPG signal)	USA, 9750 ambu- latory patients	Cohort	Not provided	42 ± 12	12-lead ECG	CV cohort: 90.9Ambulatory cohort: 7.9	CV cohort: 97.8Ambulato- ry cohort: 98.1	CV cohort: 98Ambulatory cohort: 67.7	CV cohort: 90.2Ambulatory cohort: 67.6	m
Nemati et <i>al.</i> ³⁹	Smartwatch (PPG signal)	USA, inpatient and outpatient set- tings, 15 AF patients and 31 with other rhythms	Case- control	Filter: 0.2–10 Hz	Not provided	Telemetry monitoring	Not provided	Not provided	76	94	4
Dörr et al. ⁴²	Smartwatch (PPG signal)	Germany, inpa- tient settings, 237 AF and 271 SR patients	Case- control	Not provided	76.4±9.5	Mobile iECG	97.5 (93.7–99.3)	94.7 (90.1–97.3)	93.7 (89.8–96.4)	98.2 (95.8–99.4)	7
William et al. ²⁴	AliveCor	USA, 52 patients admitted for AAD initiation	Cohort	225 samples	68.1±26	12-lead ECG	Not provided	Not provided	96.6	94.1	4
Lau et <i>a</i> l. ⁴⁶	AliveCor	Australia, unclear setting, 39 AF and 70 SR patients	Unsure	300 samples	Not provided	12-lead ECG	Not provided	Not provided	98 (89–100)	97 (93–99)	Ŋ
Haberman et al. ⁴⁸	AliveCor	USA, 123 athletes, 128 healthy young adults, and 130 cardiol- ogy clinic patients	Unsure	Not provided	Cardiology patients: 59 ± 15 Young adults: 25 ± 2 Athletes: 35 ± 20	12-lead ECG	Not provided	Not provided	46	94	S
Desteghe et al. ³²	AliveCor and MyDiagnostick	Belgium, 125 patients in geri- atric wards and 320 in cardiol- ogy wards	Cohort	Not provided	GW: 83 ± 5.8CW: 68 ± 14.6	12/6-lead ECG	CW: - MyDiagnostick: 54.8- AliveCor: 56GW: - MyDiagnostick: 81.8- AliveCor: 88.9	CW:- MyDiagnostick: 94.6 - AliveCor: 91.9GW: - 96.1 - AliveCor: 94.4	CW:- MyDiagnostick 81.8- AliveCor: 54.5GW:- MyDiagnostick 89.5- AliveCor: 78.9	CW:- MyDiagnostick: 94.2- AliveCor: 97.5GW- MyDiagnostick: 95.7- AliveCor: 97.9	v

Study	Catedony	Countru	Tune of	Number of	Are (vere)	Cold Cold	DDV (%)	NPV (%)	Cancitivity	Snacificity	Ouality
reference	of mHealth	setting, number in analysis	study	signals and filter	mean ± SD	standard	(95% CI)	(95% CI)	(%) (95% CI)	(%) (95% CI)	assessment
Vaes et <i>a</i> l. ³⁷	MyDiagnostick	Belgium, primary care settings, 103 and 88 SR	Case- control	Not provided	AF: 77 ± 8 SR: 71 ± 11	12-lead ECG	45 (24–68)	99 (97–100)	94 (87–98)	93 (85–97)	ъ
Lahdenoja et al. ³⁵	Accelerometer and gyroscope	patients Finland, 16 hospi- talized patients	Case- control	500 samples Filter: 1–45 Hz	AF: 71.45R: 31.4	12-lead ECG	100 (79.6–100)	95.8 (79.8–99.3)	93.8 (71.7–98.9)	100 (85.7–100)	Ŋ
Jaakkola et <i>a</i> l. ⁴¹	sensors Accelerometer and gyroscope	with AF and 23 healthy subjects Finland, inpatient settings, 150 AF	Case- control	Not provided	74.8 ±1.1	5-lead teleme- try ECG	96 (91.6–98.1)	95.4 (91–98)	95.3 (90.6–98.1)	96 (91.5–8.5)	Ŋ
Conroy et al. ³⁶	Earlobe sensor (PPG signal)	Device the second secon	Case- control	497 samples Filter: 0.5–5 Hz	AF: 64 ±11 SR: 38 ± 12	12-lead ECG	Not provided	Not provided	6.06	90.9	Ŷ
		CV and 46 healthy subjects									

Sensitivity, specificity, PPV, and NPV values are highlighted in light green. The category of mHealth is marked in a different couver account account account account accounts. The category of mHealth is marked in a different couver account account accounts. The category of mHealth is marked in a different couver account accounts. Allow contribution: CI, confidence interval: CV, cardiology wards: ECG, electrocardiogram; GV, geriatric wards; iECG, single-lead electrocardiogram; mHealth, mobile health; NPV, negative pre-dictive value; PAC, premature atrial complexes; PPG, photoplethysmographic; PPV, positive predictive value; PVC, premature ventricular complexes; RR, relative risk; SD, standard deviation; SR, sinus rhythm. ^a AF patients. ^bCohort of patients prescribed for a Holter.

Other of "beneficients NewCorr Comparity commonly wells most made by a cardiologist ing participants Reference dag R64:± 81 0.69 (054-0.08) Feans et ol "o NiweCor nonity-well. nosis made by a cardiologist 0.69 (054-0.08) Feans et ol "o NiweCor Keny-nimernal Prospective 12-lead ECG 543 ± 20.5 8(3-9) Chan et al." AliveCor Keny-nimernal Prospective 12-lead ECG 543 ± 20.5 8(3-9) Chan et al." AliveCor Reiners cohort 12-lead ECG 543 ± 20.5 8(3-9) Chan et al." AliveCor Prospective 12-lead ECG 543 ± 10.6 1.7 Solit et al." AliveCor Prospective 12-lead ECG 543 ± 10.6 1.7 Solit et al." AliveCor Prospective 12-lead ECG 67.8 ± 10.6 1.7 Solit et al." AliveCor Prospective 12-lead ECG 61.7 ± 13.4 0.8 Chan et al." AliveCor Prospective 12-lead ECG 61.7 ± 13.4 0.8 Chan et al."	Study eference	Category of mHealth	Country, set- ting, number in analysis	Type of study	Gold standard	Age (years), mean ± SD	Newly diag- nosed AF (%) (95% CI)	OAC initia- tion (%) ^a	Period of recording	Quality assessment
Exame terral medicine out:New CorRevenue out: medicine out:Prospective12-lead ECG543 ± 2058(3-9)Chan et al a dan inpa- ten dan inpa- 	Chan et al. ⁴⁹	AliveCor	China, 11574 healthy com- munity-dwell- ing narticinants	Prospective cohort	Reference diag- nosis made by a cardiologist	78.6 ± 8.1	0.69 (0.54–0.84)	23.6 (13.8–33.4)	Single time	m
Chan et d_1^{23} NiveCorChinaryProspective12-lead ECG $5/8\pm10.6$ 117Soni et d_1^{15} AliveCorcan are setting, contcolort $1.3 + 10.6$ 1.17 Soni et d_1^{15} AliveCorIndia, 2000Cross-sectionalUS-based cardiac 61.1 1.6 Danticipantsmunity-dwell-ogist diagnosis $0.8 + 10.6$ 1.7 1.6 Chan et d_1^{16} AliveCorIndia, 2000Cross-sectional $1.2 + 10.6$ 0.8 Dante d_1^{16} AliveCorChina, anbu- $0.8 + 10.6$ 0.8 India, 2000Cross-sectional $1.2 + 10.6$ 0.8 Dowres et d_1^{26} AliveCorChina, anbu- $0.8 + 10.6$ 0.8 Lowres et d_1^{29} AliveCorAustralia, ambu- $0.8 + 10.6$ $0.8 + 10.6$ Lowres et d_1^{29} AliveCorAustralia, ambu- $0.8 + 10.6$ $0.8 + 10.6$ Lowres et d_1^{29} AliveCorAustralia, 2476Cross-sectional $1.2 + 10.6$ Lowres et d_1^{29} AliveCorAustralia, 2476Cross-sectional $1.2 - 10.6$ Lowres et d_1^{20} AliveCorAustralia, 2476Cross-sectional $1.2 - 10.6$ Lowres et d_1^{20} AliveCorAust	evans et al. ⁵⁰	AliveCor	Kenya, internal Kenya, internal medicine, out- patients clinics, and an inpa- tient ward, 50	Prospective cohort	12-lead ECG	54.3 ± 20.5	8 (3–19)	Not provided	Single time	m
Soni et d_1^{55} AiveCorIndia, 200Cross-sectionalUS-based cardiac61.11.6healthy community-dwell- munity-dwell- ing participantsmunity-dwell- electrophysiol- ogist diagnosis64.7 \pm 13.40.8Chan et d_1^{56} AiveCorChina, 13 122Cross-sectional12-lead ECG64.7 \pm 13.40.8Lowres et d_1^{56} AiveCorAustralia, ambu-cian diagnosis63.7 \pm 13.40.8Lowres et d_1^{56} AiveCorAustralia, ambu-cian diagnosis1.5Corbard et d_1^{59} AiveCorAustralia, ambu-cian diagnosis1.5Orchard et d_1^{59} AiveCorAustralia, at-1.2-lead ECG78 \pm 10.8Participants at- tending theParticipants at-1.2-lead ECG78 \pm 10.8Participants at- tending theParticipants at-1.2-lead ECG78 \pm 10.8Participants at- tending theParticipants at-Participants at-1.2-lead ECG78 \pm 10.8Participants at- tending theParticipants at-Participants at-Participants at-Participants at-Participants at-Participants at- tending the <t< td=""><td>Chan et al.⁵²</td><td>AliveCor</td><td>China, primary care setting, 2052 participants</td><td>Prospective cohort</td><td>12-lead ECG</td><td>67.8 ± 10.6</td><td>1.17</td><td>Not provided</td><td>Single time</td><td>9</td></t<>	Chan et al. ⁵²	AliveCor	China, primary care setting, 2052 participants	Prospective cohort	12-lead ECG	67.8 ± 10.6	1.17	Not provided	Single time	9
Chan et d_1^{56} AliveCorChina, 13 122Cross-sectional12-lead ECG 6.7 ± 13.4 0.8healthy community-dwell- munity-dwell- ing participantsnunity-dwell- ing participants12-lead ECG 6.7 ± 13.4 0.8Lowres et d_1^{58} AliveCorNunity-dwell- ing participantsreating physi- cian diagnosis 69 ± 9 1.5Lowres et d_1^{58} AliveCorCross-sectionalTreating physi- cian diagnosis 69 ± 9 1.5Orchard et d_1^{59} AliveCorAustralia, 2476Cross-sectional1.2-lead ECG 78 ± 1 0.8Orchard et d_1^{59} AliveCorAustralia, 2476Cross-sectional1.2-lead ECG 78 ± 1 0.8Orchard et d_1^{59} AliveCorAustralia, 2476Cross-sectional1.2-lead ECG 78 ± 1 0.8Dichard et d_1^{59}	òoni et <i>a</i> l. ⁵⁵	AliveCor	India, 2000 healthy com- munity-dwell- ing participants	Cross-sectional	US-based cardiac electrophysiol- ogist diagnosis	61.1	1.6	Not provided	Three times over a 5-day period	Ŷ
Lowres et $al.^{58}$ AliveCor Australia, ambu- Cross-sectional Treating physi- 69 ± 9 1.5 diagnosis post-cardiac cian diagnosis post-cardiac surgery, 42 post-cardiac surgery, 42 patients Orchard et $al.^{59}$ AliveCor Australia, 2476 Cross-sectional 12-lead ECG 78 ± 1 0.8 patients attending the practice during the flu-vaccina-	Chan et al. ⁵⁶	AliveCor	China, 13 122 healthy com- munity-dwell- ing particioants	Cross-sectional	12-lead ECG	64.7 ± 13.4	0.8	Not provided	Single time	Ŷ
Orchard et al. ⁵⁹ AliveCor Australia, 2476 Cross-sectional 12-lead ECG 78±1 0.8 participants at- tending the practice during the the flu-vaccina-	.owres et al. ⁵⁸	AliveCor	Australia, ambu- latory patients post-cardiac surgery, 42 patients	Cross-sectional	Treating physi- cian diagnosis	6 1 9	1.	30%	Four times per day for 4 weeks	7
	Drchard et <i>al.⁵⁹</i>	AliveCor	Australia, 2476 participants at- tending the practice during the flu-vaccina-	Cross-sectional	12-lead ECG	78 ± 1	8. O	37.5%	Single time	4
Lowres et al. ⁶⁰ AliveCor Australia, 1000 Cross-sectional 12-lead ECG 76±7 1.5 (0.8–2.5) pharmacy customers	.owres et al. ⁶⁰	AliveCor	tion period Australia, 1000 pharmacy customers	Cross-sectional	12-lead ECG	76±7	1.5 (0.8–2.5)	60%	Single time	4

Study reference	Category of mHealth	Country, set- ting, number in analysis	Type of study	Gold standard	Age (years), mean ± SD	Newly diag- nosed AF (%) (95% CI)	OAC initia- tion (%) ^a	Period of recording	Quality assessment
Halcox et <i>a</i> l. ⁶³	AliveCor	UK, primary care setting, 1001 narticinants	Two-arm RCT	Cardiologist diag- nosis/12-lead FCG/Holter	72.6±5.4	1.84	100%	Twice weekly over 12 months	ĸ
Chan et al. ⁵¹	Smartphone (PPG signal) and AliveCor	China, primary care setting, 1013 participants	Prospective cohort	iECG by AliveCor assessed by a cardiologist	68.4 ± 12.2	2.76	Not provided	Single time	ъ
Perez et al. ⁵³	Smartband (PPG signal)	USA, 419 297 healthy com- munity-dwell- ing Darticipants	Prospective cohort	ECG patch assessed by a cardiologist	41±13	0.17	Not provided	117 days	4
Guo et al. ⁵⁴	Smartband (PPG signal)	China, 187 912 healthy com- munity-dwell- ing participants	Prospective cohort	Clinical evalua - tion, ECG, or 24-h Holter	34.7 ± 11	0.12	High risk ^b : 79.6% Intermediate risk: 12.7% Low risk: 5.5%	14 days every 10 min	4
Verbrugge et al. ⁵⁷	Smartphone (PPG signal)	Belgium, 12.328 healthy com- munity-dwell- ing participants	Cross-sectional	12-lead ECG/ Holter	49±14	1.1	Not provided	7 days	4
Svennberg et al. ⁶¹	Zenicor	Sweden, 7173 healthy com- munity-dwell- ing participants	Two-arm RCT	12-lead ECG	76	3 (2.7–3.5)	3.7 (3.3-4.2)	2 weeks two times daily	
Kemp Gudmundsd- ottir et <i>a</i> l. ⁶²	Zenicor	Sweden, 6868 healthy com- munity-dwell- ing participants	Two-arm RCT	12-lead ECG	76	4.4	94.5	4 week four times daily	

Studies with newly diagnosed AF values above 2.5% are highlighted in light green and cells providing information about OAC initiation in or angentine with newly diagnosed AF values above 2.5% are highlighted in light green and cells providing information about OAC initiation in or angentine with newly diagnosed AF values above 2.5% are highlighted in light green and cells providing information about OAC initiation in or angentine with newly diagnosed AF values above 2.5% are highlighted in light green and cells providing information about OAC initiation in or angentine. The confidence interval: ECG, electrocardiogram: iECG, single-lead electrocardiogram: mHealth, mobile health; OAC, oral anticoagulation: PFG, photoplethysmographic; RCT, randomized controlled trial; SD, Standard deviation. after a strial fibrillation; CI, confidence interval; ECG, electrocardiogram: iECG, single-lead electrocardiogram; mHealth, mobile health; OAC, oral anticoagulation; PFG, photoplethysmographic; RCT, randomized controlled trial; SD, Standard deviation. after a string fibrillation; CI, confidence interval; ECG, electrocardiogram; iECG, single-lead electrocardiogram; mHealth, mobile health; OAC, oral anticoagulation; PFG, photoplethysmographic; RCT, randomized controlled trial; SD, Standard deviation. after a strict fibrillation; CI, confidence interval; ECG, electrocardiogram; after a strict and the strict and

ambient light, potentially leading to artificial measurements which might limit diagnostic accuracy if PPG recordings are collected in the ambulatory free-living setting. Tattoos can be a problem as they may block the light from penetrating the skin.⁶⁵ Extreme temperatures could result in peripheral vasoconstriction, impeding pulse recording, and performance of the application. Besides, a minority of studies provided information about the number of samples analysed or the filter used to smooth the tracings (*Table 1*). Furthermore, apps are not optimized to detect atrial flutter with a fixed atrioventricular conduction ratio and several algorithms were not designed to detect short episodes of AF (e.g. AHS).⁵³ On the other hand, the use of RR-interval variability analysis implies that atrial or ventricular extrasystoles might be misdiagnosed as AF.

Outside mHealth, artificial intelligence may improve diagnostic accuracy and boost the effectiveness of AF detection. A recent study demonstrated detection of AF by analysing facial PPG signals without physical contact using a smartphone camera and a pretrained deep convolutional neural network.⁶⁶ A recently presented wearable smart ring device with a deep learning algorithm detected AF with PPG monitoring signals, achieving a sensitivity, specificity, PPV, and NPV of 99.0%, 94.3%, 95.6%, and 98.7%, respectively.⁶⁷

Economic aspects

While studies have found that a screening strategy for AF with handheld devices may be cost-effective in hospitalized and ambulatory patients,^{32,60,63,68} comprehensive cost-effective analyses accounting for the costs of mass screening vs. savings from improved clinical outcomes have not been undertaken. Cost comparisons between mHealth devices and routine monitoring techniques such as Holter have not been described. Therefore, the overall cost-effectiveness of this technology is currently unclear.^{69,70}

Policy implications of mobile health development

The findings of this review have important policy implications at a population level. Our study provides evidence that screening of healthy, ambulatory patients can be low-yield, but that there may be benefit to screening older patients who are at risk for AF. The implications of accessible mHealth technologies on health care resource costs are unclear, and there are concerns related to privacy, data ownership, and implications on health care insurance plans. Policy should be driven by the evidence for safety, efficacy, and cost-effectiveness, and widespread adoption of digital health technology should be informed by rigorous studies and clinical validation in the real world before implementation in patient care.

Strengths and limitations

This is the first systematic review of studies evaluating the diagnostic performance of these mHealth devices in screening for and detecting AF. We used a comprehensive literature search strategy across multiple databases with no data restrictions. Nonetheless, several limitations should be noted. First, the variation in interventions, settings, and study designs precluded meta-analyses. Second, several studies did not provide sufficient data around the clinical characteristics of the selected population such as cardiovascular risk factors or CHADS-VASc scale (missing in 21 studies) which impact the

sensitivity and specificity of the technology in screening for AF. Third, the methodological quality of the primary studies was suboptimal and prone to bias as most were observational and guasi-experimental. Only a minority of studies (3/43) were RCTs, but this is not unusual in studies of health service and digital health interventions; for example, in a recent review of interventions that improved physician adherence to heart failure guidelines, only a minority of the studies (10/ 35) were RCTs.⁷¹ Fourth, screening studies did not distinguish between paroxysmal or persistent AF in the population analysed. As the clinical characteristics of these two groups are likely to be different, the performance of each test might differ in each population. Fifth, the technique used for screening has an impact in the detection of the arrhythmia, and short-term devices have different performance than long-term devices. Sixth, surface ECG is the cornerstone of the diagnosis of AF. Current guidelines advocate the confirmation of a possible diagnosis of AF with a surface 12 leads ECG.⁷²

Future considerations

While mHealth has the potential to change the paradigm of health care, its reliability and safety must be carefully assessed. Although the number of mHealth-related publications is growing gradually, the majority of the published evidence is limited to underpowered pilot data. Patient selection, technology, and control groups vary widely in different studies. Robust scientific evaluation through appropriately designed studies with clinical endpoints is critical for establishing the on-field effectiveness of mHealth initiatives. There is a need for highest-quality scientific data regarding the clinical effectiveness and cost-efficiency of AF screening in specific patient populations or settings before roll-out and implementation in patient care. The volume of data derived from long-term monitoring will offer opportunities and through big-data analysis and machine learning, meaningful trends and information can be extracted and turned into valuable knowledge.

Conclusions and relevance

Mobile health technologies can reliably screen for and detect AF but its performance varies with the patient population. While mHealth is growing in popularity, its clinical and cost-effectiveness are unclear and merit further investigation. Specifically, more head-to-head comparisons between mHealth and medical devices are needed to establish their comparative effectiveness.

Supplementary material

Supplementary material is available at Europace online.

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Conflict of interest: R.C.A. and M.A.M. are members of ESC e-cardiology working group. R.C.A. reports receiving speaker fees from Boston Scientific. All other authors declared no conflict of interest.

Data availability

The authors confirm that the data supporting the findings of this study are available within the article and/or its supplementary materials.

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