# Mobile health applications for managing atrial fibrillation for healthcare professionals and patients: a systematic review

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#### **Aims**

A plethora of mobile health applications (m-health apps) to support healthcare are available for both patients and healthcare professionals (HCPs) but content and quality vary considerably and few have undergone formal assessment. The aim is to systematically review the literature on m-health apps for managing atrial fibrillation (AF) that examine the impact on knowledge of AF, patient and HCP behaviour, patients' quality-of-life, and user engagement.

# Methods and results

MEDLINE, EMBASE, CINAHL, and PsychInfo were searched from 1 January 2005 to 5 September 2019, with hand-searching of clinical trial registers and grey literature. Studies were eligible for inclusion if they reported changes in any of the following: (i) knowledge of AF; (ii) provider behaviour (e.g. guideline adherence); (iii) patient behaviour (e.g. medication adherence); (iv) patient quality-of-life; and (v) user engagement. Two reviewers independently assessed articles for eligibility. A narrative review was undertaken as included studies varied widely in their design, interventions, comparators, and outcomes. Seven studies were included; six m-health apps aimed at patients and one at HCPs. Mobile health apps ranged widely in design, features, and method of delivery. Four studies reported patient knowledge of AF; three demonstrated significant knowledge improvement post-intervention or compared to usual care. One study reported greater HCP adherence to oral anticoagulation guidelines after m-health app implementation. Two studies reported on patient medication adherence and quality-of-life; both showed improved quality-of-life post-intervention but only one observed increased adherence. Regarding user engagement, five studies reported patient perspectives on usability, three on acceptability, and one on feasibility; overall all m-health apps were rated positively.

#### **Conclusion**

Mobile health apps demonstrate improvements in patient knowledge, behaviour, and quality of life. Studies formally evaluating the impact of m-health on HCP behaviour are scarce and larger-scale studies with representative patient cohorts, appropriate comparators, and longer-term assessment of the impact of m-health apps are warranted.

#### **Keywords**

Mobile health • Apps • Atrial fibrillation • Management • Patients • Healthcare professionals • Systematic review

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# Introduction

The use of mobile health (m-health), primarily via smartphones, has the potential to allow wider dissemination of healthcare and could also support traditional healthcare delivery by promoting greater interaction between patients and healthcare professionals (HCPs). 1.2

Over the last decade there has been an explosion of m-health applications (m-health apps), with an estimated 3.7 billion downloaded globally between 2013 and 2017, including many for atrial fibrillation (AF) but very few have undergone formal assessment.<sup>4-6</sup> Hence, the magnitude and impact of m-health apps for AF, and the degree of patient and HCP engagement and acceptability, are currently unknown. Given that patients and HCPs can easily access these apps, it is important to have some sense of their scope and content, acceptability to users and additionally, to examine the purpose of, and outcomes of, app implementation and usage. To date, no systematic review has evaluated the impact of the variety of m-health apps currently available for patients with AF and HCPs who manage this condition. Therefore, the current review will systematically assess this literature to examine the impact on knowledge of AF, patient and HCP behaviour, patients' quality-of-life, and user engagement with the m-health app.

# **Methods**

This systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines.<sup>7</sup> A completed PRISMA checklist is provided in the Supplementary material online.

# Criteria for considering studies for the review

Studies carried out in any setting and designed to evaluate m-health apps were eligible for inclusion. We included primary research which evaluated the effects of any m-health app for AF which was designed to enhance patient and/or HCP education, improve communication between patients and HCPs, or to encourage active patient involvement in the management of their condition. All types of study designs were considered with the exception of purely qualitative studies. Ongoing studies were considered and are presented in a separate table. We excluded ehealth or m-health apps that only screened for or monitored AF, and remote monitoring of AF via electrocardiogram/implantable devices.

#### **Participants**

Adults (18 years and older) with AF and/or HCPs managing patients with AF were eligible for inclusion. Studies with mixed population groups which included patients with AF were also eligible for inclusion in this review, provided the majority were AF patients, and/or data regarding AF patients alone was available.

#### Interventions

Interventions designed to manage AF via the use of m-health apps (e.g. mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices) were eligible for inclusion.

#### **Comparators**

Any comparator or usual care (i.e. no intervention) could be included.

#### **Outcomes**

Studies were eligible for inclusion in the review if they reported changes in any of the following outcomes: (i) knowledge of AF (patient and/or HCP); (ii) HCP behaviour (e.g. adherence to AF management guidelines); (iii) patient behaviour (e.g. medication adherence); and (iv) patient quality-of-life. Studies were also eligible for inclusion if they reported only process outcomes, e.g. user engagement and perspectives on acceptability and usage patterns of the m-health app, but not if they were solely qualitative in nature.

#### **Search strategy**

The search strategy was developed by the research team. Medical Subject Headings and keywords such as AF, m-health, smartphone, mobile applications, etc. were used (see Supplementary material online, Table S1) to search bibliographic databases. MEDLINE, EMBASE, CINAHL, and Psychlnfo were searched from 1 January 2005 to 5 September 2019 for relevant studies. We restricted the publication date to the year 2005 onwards as m-health is a relatively new phenomenon, and also to capture only the more recent and relevant empirical research reflective of changes in clinical practice guidelines around stroke prevention for AF. There were no language restrictions. Availability of the full-text publication was a requirement.

Reference lists of included studies were manually searched. Additional unique records were identified through hand-searching trials registers [Cochrane Central Register of Controlled Trials, Clinical Trials (www.clin icaltrials.gov), and ISCTRN (www.isrctn.com/)] by entering key search terms (e.g. AF, m-health, smartphones) into the websites search function. Grey literature was addressed by contacting key opinion leaders for unpublished data. Search results were managed using Covidence.

#### Study selection

Two reviewers (D.A.L./N.M.) independently screened the titles and abstracts against the search criteria. The full texts of all potentially relevant articles were retrieved and independently assessed by both reviewers. Disagreements were resolved through discussion and assessment by a third reviewer (J.G.).

#### **Data extraction**

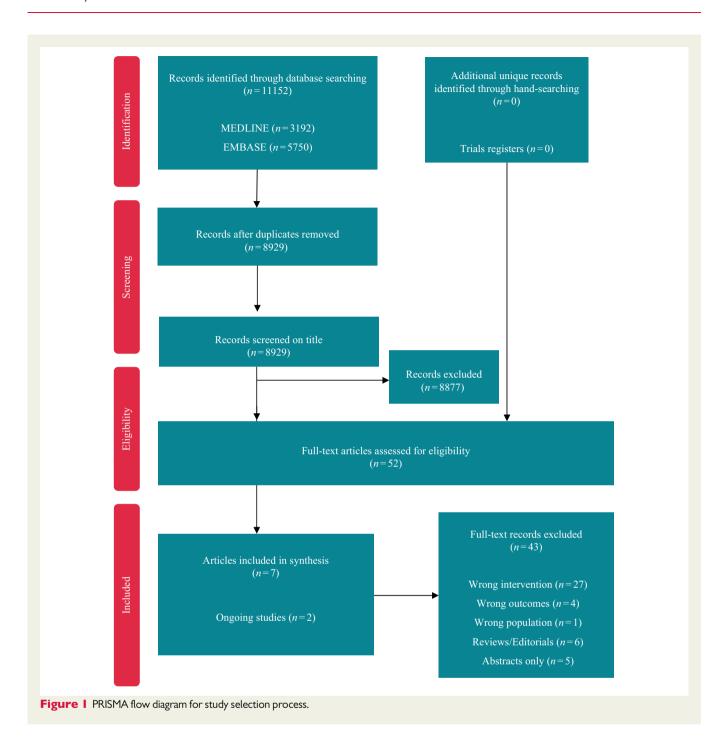
Data were extracted by one reviewer (D.A.L.) and checked by another reviewer (J.C.W.). The following information was extracted: (i) authors, year, country; (ii) study aim; (iii) study characteristics (study design and sample size); (iv) participant characteristics (age, sex, ethnicity, comorbidities); (v) intervention (type of m-health delivery, features of the app/m-health, duration, frequency, providers, target users, follow-up points); (vi) comparator(s) (usual care, description of usual care, no intervention); and (vii) outcomes [patients' and/or HCP's knowledge of AF, HCP behaviour (e.g. adherence to AF management guidelines), patient behaviour (e.g. medication adherence), patient quality-of-life, and user engagement and perspectives on acceptability].

#### Risk of bias assessment

Assessment of risk of bias in individual studies was undertaken independently by two reviewers (D.A.L./J.G.) utilizing the Cochrane risk of bias tool<sup>8</sup> for randomized controlled trials (RCTs) and the risk of bias tool for non-randomized studies,<sup>9</sup> as appropriate.

#### **Data synthesis**

Given that the included studies varied widely in their design, interventions, comparators, and outcomes, no synthesis was undertaken and we report a narrative review.



# **Results**

The searches identified 11 152 citations (see *Figure* 1). After removal of duplicates (n = 2223), the titles and abstracts of 8929 articles were independently assessed by two reviewers. Of these, 52 were deemed to be potentially relevant and were assessed for eligibility in their full text; 43 were excluded and 2 studies were ongoing. <sup>10,11</sup> A full list of the excluded studies and the reason for exclusion are provided in the Supplementary material online, *Table* S2. No relevant studies were identified via hand-searching. As a result, seven studies <sup>4–6,12–15</sup> were included (see *Table* 1).

# **Characteristics of the included studies**

The included studies were published between 2017 and 2019 and comprised between  $10^{13,15}$  and  $209^6$  participants, with a total of 466 patients<sup>4–6,12–14</sup> (mean age ranged from  $59^{14}$  to  $71^6$  years;  $50\%^{13}$  to  $67\%^5$  male) and 10 HCPs (mean age 43.8 years; 30% men). <sup>15</sup> Studies were conducted in Belgium (n=2), <sup>4,5</sup> China (n=1), <sup>6</sup> Iran (n=1), <sup>15</sup> Poland (n=1), <sup>12</sup> and the USA (n=2). <sup>13,14</sup> Six studies were m-health apps aimed at patients <sup>4–6,12–14</sup> all of whom had AF (not exclusively AF in one study <sup>12</sup>), with one targeting HCPs. <sup>15</sup> Only one study <sup>6</sup> had m-health apps directed at both patients and HCPs, but this study only

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First author, year, country, reference	Study aim	Study population	Study design	App	Features of the app	Outcomes	Results	Conclusion
Balsam 2019, Poland <sup>12</sup> Effectiveness of 3D OCULUS study movie in teachin NCT03104231 aptients about c quences of AF all pharmacological stroke preventic	Effectiveness of 3D movie in teaching patients about consequences of AF and pharmacological stroke prevention	5 ∑	Prospective, single centre (hospital), before-and-after study linclusion criteria: aged >18 years Exclusion criteria: dementia August 2016 Questionnaire at baseline, immediately after viewing movie, 1 week and 1 year later Follow-up: immediate, 1 week, and 1 year	Oculus glasses and smart- phone with 3D movie describing risk of AF VR-3D movie available on Google Play and Appstore Version for men https://www.youtube.com/ watch! v=5WFxq_ m884 Version for women https://www.youtube.com/ watch! v=58i7LxBBv0g	Virtual reality headset (oculus glasses) and smartphone with 3D movie Information on risk of stroke and use of OAC to reduce stroke	Patient knowledge: (i) stroke consequence of AF; (ii) drugs may reduce stroke risk; (iii) OAC reduces stroke risk Usefulness of 3D movie to deliver information	Knowledge that stroke was con- 3D movie was an effective sequence of AF.  Before movie 22/100 (22.0%); Immediately after movie 83/100  7 days later 74/94 (78.7%)  7 days later 74/94 (78.7%)  8 consequences of AF  and role of OAC in  7 days later 74/94 (78.7%)  8 consequences of AF  and role of OAC in  8 rowledge about the  and role of OAC in  8 rowledge that drugs may re-  reported  duce stroke risk:  1 week later: 94/94 (100%);  P < 0.0001  1 year: 88/90 (96.7%)  1 week later: 90/94 (95.7%)  1 week later: 90/94 (95.2%):  1 year later: 89/90 (92.2%); all P  < 0.0001  1 usefulness: 99/100 (99%) stated  1 usefulness: 99/100 (99%) stated	3D movie was an effective tool in transferring frowledge about the consequences of AF and role of OAC in stroke prevention Negative aspects of mhealth apps not reported
Hirschey 2018, USA <sup>14</sup>	Hirschey 2018, USA <sup>14</sup> Perceived usability and usefulness of mobile app designed to support self-care and treatment adherence for AF patients prescribed NOACs	12 AF pts Mean age: 59y (range 37– 67y); 7 (58.3%) men; 100% Caucasian Mean AF duration: 6y (range 1–15y; 11/12 (92%) symptomatic; 11/12 had college or greater level education n = 16 enrolled; 12 completed study	Exploratory pilot study: naturalistic app use; surveys (in-person at baseline, then by post); 5 × 30 min semi-structured weekly interviews to examine patients' perceptions and everyday use of the app 4-week study with 5 visits total Recruitment September 2016 to April 2017 Purposive sampling of AF patients on NOACs, identified by clinician from 1 hospital Participants reviewed app features at different time-points and rated usability and usefulness over last week	ploratory pilot study:  Afib connect mobile app  autauralistic app use:  auravey (in-person at 10S) platforms baseline, then by post);  5 × 30 min semi-struct.  6 minated videos:  6 medication adherence and strucker. patients of plinary team (clinicians, plinary team)  7 medication eview.  7 medication adherence adiation rewiner and ausability and usefulness  8 mobile phone camera different study and usefulness  9 minated videos;  10 mon Af (medication sprinary team)  10 mon Af (medication and study sin on of app. Feedback diary mobile phone camera time-points and rated study and usefulness)	AFib guide: introduction to AF through text and animated videos; Library: detailed information on AF (medication, procedure options, medication adherence, and stroke risk) AF episode tracker: patient-generated for physician review AF trigger tracker: patient-generated for physician review AF trigger tracker: patient-generated for physician review AF trigger tracker: patient-generated for physician rewiew AF trigger tracker: patient-generated for physician rewiew Heart News. StopAFib.org, AHA Medication reminder and diary Heart rate monitor: using mobile phone camera	App usability, satisfaction, and usefulness	p p nav- ssign ss easy as easy rted sried sried of the of the ing pport r apps	Needs more research in larger, more diverse AF sample App broadly useful and effective in supporting patient self-care and medication adherence Software bugs reported by 7/12 (58%)
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	Desteghe 2018,	Effectiveness of an online tailored education platform to inform AF patients undergoing DCCV or PVI	120 AF pts requiring DCCV or PVI Mean (SD) age: 68.0y (10.2); 78 (65%) male	is statisfaction assead on 5-point ert statisfaction are returned upon for 4 eks state on 5-point arended question of a gain ertarly hospin and an analysis on criteria; consect is AF patients under gaplanned DCCV PM in a gain ertarly hospin on criteria; consect is AF patients under gaplanned DCCV PM in a gain ertarly or phy, (i.e. deafness) imment, inability to do Dutch and not the stop provide writts with internet accepted (i) and on the stop on a gain of a gain on a gain of a and on week post-proce-refrict on a gain of a and on a gain on a gain of a and on a gain of a and on a gain on a gain of a and access to the line tools a consider a thospital on, 6 and 12 must be a farmed and a saedline at hospital on, 6 and 12 must be a farmed and a saedline at hospital on, 6 and 12 must be a farmed a gain on, 6 and 12 must be a farmed a saedline at hospital con, 6 and 12 must be a farmed a considered a farmed a saedline at hospital con, 6 and 12 must be a farmed a considered a farmed a saedline at hospital con, 6 and 12 must be a farmed a considered a farmed a saedline at hospital con, 6 and 12 must be a farmed a considered a farmed a consider	On-line patient education (general AF information, OAC and procedure-related information) developed by 3 experienced cardiologists based on hospital brochures and patient websites (AFA, EHRA, AHA, Alliance for Aging Research) Education provided by text, images and movies. Fact boxes highlighted key educational messages	Patients had unique log-in and could visit site whenever they wanted On-line platform recorded how many times each patient visited platform, length of time viewing content, and which topics were viewed topics were viewed	Patient knowledge: measured by JAKO Patient Ool: measured by AFEQT Patient experience/opinions: measured by UEQ	Patient knowledge: Group 1 on-line tailored education group: significantly improved knowledge by end of hospitalization (75.0% IQR 6.6.7–85.0; P = 0.001) Knowledge persisted at 6 weeks (77.5% IQR 6.5.0–85.0; P = 0.001) and 12 weeks (80.0% IQR 70.0–90.0; P < 0.001) after procedure for access: no improvement in excess: no improvement between baseline and time of hospitalization (65.0% IQR 5.00–73.8; P = 1.00). Significant improvement between baseline and 6-week post-procedure (P = 0.016) and between hospitalization and 6-week post-procedure (P = 0.016). Significant improvement over course of study (P = 0.248) Group 3 Standard care only: no crease in overall AFEQT score in both on-line groups 6- and 12-week post-procedure to baseline and at hospitalization Group 3: no significant difference in overall AFEQT score over time (P = 0.082) Usability: on-line platform rated positively on all aspects	Small study Those without compatible device significantly older, had lower educational level and higher risk of stroke and bleeding 10% sample unable to use device

Fable   Continued First author, year, Study	inued Study aim	Study population	Study design	App	Features of the app	Outcomes	Results	Conclusion
Shelbani 2017, Iran <sup>15</sup>	Effect of CDSS on improving adherence to anticoagulation guidelines for AF	10 cardiologists managing  n = 373 newly diagnosed  AF pts  10 cardiologists [7 (70%) fe- male]  Mean age 43.89  (range 33-58y)  Perience: 11.2y  (range 3-32y)	Group 3: at hospitalization and 3 months only Interrupted times series design (before-and-after design)  Setting: offices of 10 cardiologists  OAC guideline adherence assessed fortnightly from January 2016 to January 2017;  6 months before and 6 months after intervention  Inclusion criteria: newly diagnosed AF patients Exclusion criteria: mechantical heart valve, severe mittal valve disease, any other reason for recurrent venous thromboembolism)  Convenience sampling for cardiologists Follow-up; 6-month post-	CDSS designed for anticoagulant management of AF installed on cardiologist smartphone/tablet	CDSS designed for antico- App calculated CHA <sub>2</sub> DS <sub>2</sub> - Provider adherence to agulant management of VASc score and HAS- OAC guidelines for AF installed on cardiol- BLED score, gave treat- ogist smartphone/ ment recommendations based on latest to the tions based on latest AHA/ACC guidelines	Provider adherence to OAC guidelines for AF	Before intervention (January– June 2016): 48% (n = 217: 21 excluded due to missing data) Post-intervention (July 2016-Jan 2017): 65.5% (n = 207, 25 ex- cluded due to missing data- significant increase in guidelinea- adherent OAC prescription post-intervention (P < 0.0001)	CDSS improved adherence to guidelines for OAC for AF by reducing guideline complexity, simplifying risk calculation, and providing interpretation of risk scores Negative aspects of m-health apps not reported
Guo 2017, China <sup>6</sup> ChiCTR-1OR- 17010436	Evaluation of patients' knowledge, QoL, medication adherence, QAC satisfaction, and usability, feasibility, and acceptability of mAFA app	n=209 pts MAFA: n=113 Mean (SD) age 67.4; 57.3% male Usual care: n = 96 Mean (SD) age 70.9y; 55.2% male	Cluster-randomized pilot study. 2 hospitals in China China Recruitment 1 January to 1 May 2017 Inclusion criteria: aged ≥18; confirmed AF (ECG or 24 h Holter) Exclusion criteria: <18); valvular AF: unable to provide written informed consent follow-up: 1 and 3 months	mAFA Clinican version Patient version	Clinical decision-support Patient knowledge (11-ite tools (CHA <sub>2</sub> DS <sub>2</sub> -VASc AF knowledge question and HAS-BLED, SAMe.  T <sub>2</sub> R <sub>2</sub> ), educational are Hendriks et al., T <sub>3</sub> R <sub>2</sub> ), educational and refrare protocols and structured follow-ence measure); up volvement strategies Drug adherence (Pharma with self-care protocols Quality Alliance adherand structured follow-ence measure); up OAC satisfaction (Anti-Included PHR OAC recommended based clini-App experience usability, cal guidelines; pts with feasibility, and accept-HAS-BLED ≥ 3 flagged ability of mAFA assess for FU art month self-support items	Patient knowledge (11-item AF knowledge question-naire Hendriks et al., 2013). Quality-of-life (EQ-5D-Y); Drug adherence (Pharmacy Quality Alliance adherence measure); OAC satisfaction (Anti-Clot Treatment Scale) All assessed at baseline, 1 and 3 months App experience: usability, feasibility, and acceptability of mAFA assessed at 1 month	Patient knowledge (11-irem Patient knowledge: mAFA signif- Significant improvements AF knowledge question- icantly improved knowledge, in patient knowledge, nather Hendriks et al., vs. UC (all P < 0.05) aquality-of-life, drug advance, and reduction Quality-of-life (EQ-5D-Y); creased in mAFA am vs. UC in OAC burden with Drug adherence (Pharmacy at baseline (86.5 vs. 71.3), 1 mAFA vs. UC Quality Alliance adhermonth (87.6 vs. 70.1) and 3 most (90%) rated app as ence measure); month (87.6 vs. 70.1) and 3 most (90%) rated app as ence measure); nonth (87.2 vs. 69.9) (all P easy, user friendly, ed.Clot Treatment Scale) Drug adherence: mAFA vs. UC. Negative aspects of mand 3 months (11): P = 0.870]; 1 month [0] reported app as a fullity of mAFA assessed and (all P < 0.05); mAFA pts reported significantly more OAC burden (all P < 0.05); mAFA pts reported app as reported significantly more OAC burden (all P < 0.04); month on only (P = 0.013).	Significant improvements in patient knowledge, quality-of-life, drug adherence, and reduction in OAC burden with mAFA vs. UC  Most (90%) rated app as easy, user friendly, helpful  Negative aspects of mhealth apps not reported
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Second	First author, year, country, reference	Study aim	Study population	esign	Арр	Features of the app	Outcomes	Results	Conclusion
Plea study to assess that a start of the standing your desaching your cases and some and treatment was propertive feasibility point Health Buddies App 100 Health Buddies and and treatment mean of the Health Buddies aged 5–15 study genderfolder and and treatment mean of the Health Buddies are occup, or occupated in Bedgium.  Af pass and 50 jage 60-52 study other and and treatment mean or occupation and treatment mean of the Health Buddies or circuites Act on the season of the Health Buddies are occup, or occupated in Bedgium.  NOAC population and or computer with income aged 5–15 years having a season or occupated with income aged 5–15 years having a season or occupated by the season or occupated and occupated or occupated by the season occupated	Ghanbari 2017, USA <sup>1</sup>	<sup>3</sup> Assess usability and feasibility of a mobile application to assess symptoms in patients with AF	n = 10 pts with PAF or persistent AF Age (NR) 5 (50%) women; PAF 50%	Pilot, feasibility study Inclusion criteria: >21y; AF dagnosis; stable medical regime for ≥30 days prior to study.  Exclusion criteria: asymptomatic AF; psychiatric or neurological disorders; dementia, cancer, drug/alcohol abuse; life expectancy <1 year; pregnancy; existing implantable cardiac rhythm devices and neuro-stimulators  Semi-structured phone interview at 4 week Follow-up; 4 week	miAfib Mobile app (iPhone only) to assess AF symptoms and positive/negative affect affect www.miAfib.com to assist mobile app set-up and for study details	_	⊃ ō	was easy, user friendly, helpful Users found app easy to use (4.75 ± 0.46), intended to use it in the future (4.37 ± 1.06) and found it easy to integrate into daily routine (4.5 ± 1.07)	Pts found app easy to use and would consider using app in the future Need larger study to determine feasibility in a diverse group of AF patients  Small sample size Negative aspects of melath apps not reported
	Desteghe 2017,	Pilot study to assess the feasibility and usability of the Health Buddies app in AF patients		Prospective feasibility pilot study 1 hospital in Belgium, recruited as out-pt. or in-pt. Inclusion criteria: AF, on an NOAC, grandchild aged 5-15 years, having a tablet, mobile phone or computer with internet access Exclusion criteria: enrolled in other studies; non-Dutch speaking Study conducted October 2015-August 2016 Participants had to use the app for 3 months Follow-up: 3 months	Health Buddies App	App co-developed with pts, grandchildren and parents in 2 workshops Patient contract: take NOAC daily; other health challenges Grandchild contract: daily healthy challenge (eating fruit, brushing teeth twice daily) Rewards to completing daily challenges (gaming) Goal to complete as many challenges as possible in 3 months. Reward at end trip or fun activity NOAC stock with a refill reminder and communication with HCP	A A G		Small sample; selected sample (only 15 participated); no control pated); no control soroup Patients evaluated the educational aspect of this app as a capital gain 5/15 (33%) often had technical difficulties with app

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First author, year, Study aim country, reference	Study aim	Study population	Study design	Арр	Features of the app Outcomes	Outcomes	Results	Conclusion
					on clarity (1.500), novelty		on clarity (1.500), novelty	velty
							(0.942) and stimulation	uc
							(0.923) and attractive	suess
							(0.859). Efficiency (0.3	577)
							and dependability (0.481) re-	481) re-
							ceived neutral rating	

port system; DCCV, direct current cardioversion; ECG, electrocardiogram; EHRA, European Heart Rhythm Association; FU, follow-up; HCP, healthcare professional; IQR, interquartile range; JAKO, Jessa Atrial Fibrillation Questionnaine; Evaluation of QualiTy of life questionnaire; AHA, American Heart Association; CDSS, computerized decision-supmAFA, Mobile Atrial Fibrillation App; NOAC, non-vitamin K antagonist oral anticoagulatr, NR, not reported; OAC, oral anticoagulation; pts, pariony partial fibrillation; PHR, personal health record; PVI, pulmonary vein iso-ACC, American College of Cardiology; AF, atrial fibrillation; AFA, Atrial Fibrillation Association; AFEQT, Atrial Fibrillation Experience Questionnaire; y, years. usual care; UEQ, User Data on clinician version of the app not reported in this paper standard deviation, UC, SD, quality of life; lation; QoL,

reported outcome data for patients. The studies varied widely in design with one cluster-randomized pilot study;<sup>6</sup> one prospective, RCT;<sup>4</sup> two before-and-after studies;<sup>12,15</sup> and three exploratory/feasibility pilot studies.<sup>5,13,14</sup> Most studies had short follow-up periods, between 4 weeks<sup>13,14</sup> and 3 months,<sup>4–6</sup> with only two studies following participants for longer (6 months<sup>15</sup> and 1 year<sup>12</sup>).

# Types of interventions

The interventions varied markedly in their design, features of the mhealth app, and method of delivery (see *Table 1*). Three were delivered via an app on a mobile phone only,<sup>6,12,13</sup> and four via mobile phone or tablet. <sup>4,5,14,15</sup> Two studies were patient education interventions, <sup>4,12</sup> two were patient behaviour change interventions utilizing support and adherence apps, <sup>13,14</sup> two supported HCP behaviour change <sup>6,15</sup> although one of the two <sup>6</sup> did not report the outcome data related to the HCP app, and two were multi-faceted apps incorporating patient behaviour change and education interventions. <sup>5,6</sup>

The one m-health app designed for HCPs (cardiologists) was a computerized decision-support system to help improve adherence to oral anticoagulation (OAC) guidelines, using an app to calculate the CHA $_2$ DS $_2$ -VASc and HAS-BLED scores and to provide OAC treatment recommendations based on clinical guidelines. <sup>15</sup>

One study<sup>12</sup> used oculus glasses (virtual reality headset) and a smartphone to deliver patient education on risk of stroke and use of OAC for stroke prevention via a 3D movie, while another, the miAfib app, assessed AF symptoms and mood throughout the day.<sup>13</sup> The mAF app<sup>6</sup> included a patient version and a doctor version, containing clinical decision-support tools (CHA<sub>2</sub>DS<sub>2</sub>-VASc, HAS-BLED, SAMe-TT<sub>2</sub>R<sub>2</sub>) linked to patient health records, patient educational materials (eight topics), and tools to engage and support patients in self-care (e.g. heart rate and blood pressure monitoring) and structured follow-up.

Hirschey et al. <sup>14</sup> developed an app for patients' use on smartphones or tablets, to provide information on AF and OAC via text and animated videos, with a log for patients to record AF episodes and related notes, triggers for AF, medication and appointment reminders, heart rate monitor, and health-related news feed.

The Health Buddies app<sup>5</sup> teamed up AF patients and their grand-children and recorded performance of 'healthy' daily tasks, such as intake of OAC (non-vitamin K antagonist OAC) and heart rate monitoring for the AF patients (grandparents) and eating fruit or brushing teeth twice a day for the 'buddies' (grandchildren). The app rewarded performance of these daily tasks with access to educational quizzes for the patients and educational games for the grandchildren. Completion of daily tasks for a 3-month period was rewarded with a joint trip or fun activity for the grandparents and grandchildren. Another study by the same research group utilized an on-line tailored education platform on AF and procedure-related information for patients undergoing pulmonary vein isolation or electrical cardioversion, accessed using a unique log-in.<sup>4</sup>

# Types of comparators

One study compared the intervention to usual care only;<sup>6</sup> one compared the app to standard care with internet access but no structured intervention, and standard care with no internet access; <sup>4</sup> two were before-and-after studies, <sup>12,15</sup> and three studies did not have a

comparison group. <sup>5,13,14</sup> Usual care consisted of information from a cardiologist and booklets, <sup>4</sup> and consultation with a cardiologist. <sup>6</sup>

# **Types of outcomes**

Four studies reported on patient knowledge of AF, $^{4-6,12}$  with only one reporting patient knowledge of OAC. $^{12}$  No study reported on the knowledge of HCPs. Only one study $^{15}$  reported on HCP behaviour, focusing on adherence to OAC guidelines. Three of the four studies that examined the impact of m-health apps on patient knowledge demonstrated a significant improvement on knowledge of AF and/or OAC after the intervention $^{12}$  or compared to usual care $^{4,6}$  (see *Table 1*). Desteghe et al. $^5$  reported a non-significant (P=0.09) increase in knowledge level from baseline to 3-month post-intervention. The only study that reported the effect of the m-health app on HCP behaviour showed a significant improvement in guideline-adherent OAC treatment following the intervention (48% pre-intervention vs. 65.5% post-intervention; P<0.0001).

Two studies reported on patient adherence to medication.  $^{5,6}$  One  $^6$  reported a significant increase in drug adherence at 1 month and 3 months in the intervention group (both P < 0.001) measured using the Pharmacy Quality Alliance adherence measure, while the other study  $^5$  showed a reduction in adherence from 88.6% [standard deviation (SD) 15.4%] to 81.8% (SD 18.7%) measured using an electronic medication monitor.

Two studies reported on patient's quality-of-life.  $^{4.6}$  Guo et  $al.^6$  measured quality-of-life using the visual analogue scale of the EQ-5D<sup>16</sup> and reported a significant improvement from baseline to 1 month and 3 months in the intervention group compared to usual care (all P < 0.05). Desteghe et  $al.^4$  assessed quality-of-life using the AFEQT. This demonstrated significant improvements at 6 and 12 weeks post-procedure compared to baseline in the m-health app group and the comparator who had access to the internet, but not in the usual care group.

Five studies investigated user engagement with the m-health app,4–6<sup>13,14</sup> with three assessing perspectives on acceptability,<sup>4,6,14</sup> five on usability,<sup>4–6,13,14</sup> and one on feasibility.<sup>6</sup> Generally, patients found the m-health apps acceptable and usable. The two studies by Desteghe *et al.*<sup>4,5</sup> employed the User Experience Questionnaire<sup>18</sup> to assess patient engagement with the apps. The m-health app for tailored patient education rated positively on all aspects,<sup>4</sup> while the Health Buddies app was rated positively only for clarity, novelty, stimulation, and attractiveness.<sup>5</sup> Three studies<sup>4,5,14</sup> reported some negative aspects of their m-health apps: software bugs reported by 7/12 (58%);<sup>14</sup> 10% were unable to use the device;<sup>4</sup> and 5/15 (33%) often encountered technical difficulties or problems.<sup>5</sup>

#### Risk of bias assessment

A summary of the risk of bias assessment is presented in *Table 2*, with more detailed explanation available in Supplementary material online, *Table S3*. Overall, most of the included studies had high or unclear risk of bias in relation to participant selection due to highly selected and often small sample sizes, <sup>5,13,14</sup> the observational nature of the majority of the studies, <sup>5,13–15</sup> and the lack of detail on the randomization procedure<sup>6</sup> or incomplete randomization. <sup>4</sup> Due to the nature of the interventions it was not possible to blind the participants or personnel to the treatment allocation, and outcome assessors were only blinded in one study. <sup>6</sup> All included studies, with the exception of

Sheibani *et al.*<sup>15</sup> had a high or unclear risk of selective reporting bias. The degree of incomplete data reporting (attrition bias) varied and was low in three studies <sup>4,5,15</sup> and unclear in two.<sup>12,13</sup> The main issues were related to not defining the primary outcome and/or the timing of the primary endpoint. In the mAF app RCT, <sup>6</sup> 42/113 (37.2%) people in the intervention group did not provide 3-month follow-up data compared to complete follow-up data in the usual care group and 4/16 (25%) of people enrolled in the study by Hirschey *et al.*<sup>14</sup> did not provide follow-up data.

#### **Excluded studies**

Supplementary material online, *Table S2* summarizes the 43 excluded studies. Most [27/43 (62.8%)] studies were excluded as they were not an m-health intervention, four (4/43) reported outcomes which were outside the scope of the review, one (1/43) focused on a population without AF, one (1/43) was a systematic review, one (1/43) was a narrative review, three (3/43) were editorials, and one (1/43) was a protocol for a systematic review. Five (5/43) were abstracts, four with no full-text available and one with full-text which was one of the included studies.<sup>12</sup>

## **Ongoing studies**

Two protocol papers for ongoing studies were identified (see Table 3). One study  $^{11}$  is testing an upgraded version of the mAF app,  $^6$  incorporating the ABC (Avoid stroke, Better symptom management, and Cardiovascular and other comorbidities management) pathway compared to usual care in 3660 AF patients with CHA $_2$ DS $_2$ -VASc score  $\geq \! 2$ , in a cluster-RCT in China. The second study, the Atrial Fibrillation health Literacy Information Technology Trial (AF-LITT)  $^{10}$  is a pilot RCT, exploring a 30-day smartphone intervention, based on an embodied conversational agent and the AliveCor Kardia device, compared to standard care (a symptom and adherence journal), in 180 AF patients receiving OAC, in the USA.

## Discussion

We have reported a systematic review of studies that have evaluated the impact of m-health apps for the management of AF on patient and HCP knowledge and behaviour, patient quality-of-life, and user engagement with the app. Despite the abundance of m-health apps available for healthcare, and AF specifically, only seven studies were eligible for inclusion in our systematic review. Of these, six were patient m-health apps. 4-6,12-14 Although the study by Guo et al.6 reported both a patient and HCP version, outcome data was only presented relating to patient knowledge, behaviour, quality-of-life, and app experience. Notwithstanding the disparity in the design, features, and delivery of the m-health interventions, overall the various apps improved patient knowledge on AF and OAC compared to baseline 12 or patients receiving usual care, 4,6 improved patient medication adherence<sup>6</sup> and quality-of-life, <sup>4,6</sup> improved provider adherence to OAC guidelines<sup>15</sup> and were positively rated for user engagement and acceptability. 4-6,13,14

However, many of the studies had limitations including very small sample sizes ( $\leq$ 15), <sup>5,13–15</sup> lack of a comparator group, <sup>5,13,14</sup> lack of blinding for outcome assessors, <sup>4,5,12–15</sup> imprecision or lack of definition of, and timing of, primary (and secondary) outcomes, <sup>5,12–14</sup> short follow-up periods for outcome evaluation (4 weeks<sup>14</sup> to 3

Randomized control	led trials (ass	essed by Cochra	ane Risk of Bias	tool <sup>8</sup> )			
Study	Selection bia	as	Reporting bias	Performance bias	Detection bias	Attrition bia	s Other bias
Author (year)	Random sequence generation	Allocation concealment	Selective reporting	Blinding participants and personnel	Blinding outcome assessors	Incomplete outcome data	Other sources of bias
Desteghe et al. (2018) <sup>4</sup>	High	High	Unclear	High	Unclear	Low	Unclear
Guo et al. (2017) <sup>6</sup>	Unclear	Unclear	Unclear	High	Low	High	Unclear
		and consid confoundir	eration of on one one one one one one one one of one of the one of		outcome d ssessments	lata	reporting
Balsam et al. (2019) <sup>12</sup>	Low	Unclear		ow H	ligh L	Jnclear	High
Hirschey et al. (2018) <sup>14</sup>	High	High	H	ligh U	Jnclear	High I	High
Sheibani et <i>al</i> . (2017) <sup>15</sup>	Unclear	Low		ow H	ligh L	.ow	Low
Ghanbari et al. (2017) <sup>13</sup>	High	High		ow L	Jnclear L	Jnclear	Unclear
		High		ow L	Jnclear L	.ow	Unclear

months<sup>4–6</sup>), and incomplete reporting of outcome data.<sup>6,14</sup> This review has highlighted the need for larger, more comprehensive primary data collection studies with appropriate control groups, in diverse and representative AF patients, with longer-term follow-up, strategies to reduce attrition and ensure as complete as possible follow-up data, and more studies formally assessing the impact of m-health interventions on HCP knowledge and guideline-adherent AF management.

A commentary on two European Society of Cardiology-endorsed apps, MyAF (Patient version) and AFManager (HCP version), <sup>19</sup> were identified in our searches. However, these apps have yet to be formally tested for impact on patient and HCP knowledge and behaviour and were therefore not eligible for inclusion in this review. The rapid integration and upscaling of mobile and e-technology in health-care and everyday life does not negate the necessity for future mhealth apps to demonstrate evidence of positive impacts on the outcomes they claim to support, to enable confidence in the end-user in their effectiveness and applicability.

The promise of m-health is to make health education and health-related resources accessible regardless of health literacy. Reading ability plays a vital part in health literacy. Therefore, it is mandatory to introduce health apps that are not only scientifically validated but also written at reading-grade levels not exceeding national standard recommendations.<sup>20</sup>

All included studies used essentially stand-alone m-health apps, rather than apps as part of an intervention package, although the complexity and content of the apps varied. Four studies 4,12,13,15 used the app to focus on delivery of one element (i.e. patient education, 4,12 patient self-monitoring and reporting of AF symptoms and mood, 13 and stroke and bleeding risk assessment and OAC recommendation for physicians 15) whereas the other three 5,6,14 were more complex. The Health Buddies app 5 was an interactive game, involving patients' grand-children, to support medication adherence; the mAF app 6 patient

version focused on education but also incorporated patient self-support items, self-monitoring of heart rate and blood pressure, and feedback on treatment; while the AFib Connect app<sup>14</sup> included education, plus self-monitoring of heart rate, AF episodes and triggers, medication and appointment reminders, and a heart health-related news feed. These apps, as part of an intervention package, may be more, or less, effective than when used as the sole intervention; however, it is important to identify the active component(s) of interventions.

Of the two ongoing studies, one 11 has reported the results of the ABC pathway supported by the Mobile Atrial Fibrillation App (mAFA) Il app on the primary outcome of a composite of stroke/thromboembolism, all-cause mortality, and rehospitalization.<sup>21</sup> Among the 1646 patients receiving the mAFA II-supported intervention (mean age 67.0 years; 38% female), the rate of the composite endpoint was significantly lower (1.9% vs. 6.0%; hazard ratio 0.39; 95% confidence interval 0.22-0.67; P < 0.001) compared to those receiving usual care  $(n = 1678; \text{ mean age } 70.0 \text{ years}; 38\% \text{ female}).^{21} \text{ However, the impact}$ of the m-health supported intervention on patient and HCP behaviour, patient knowledge, and quality-of-life is yet to be reported. The other ongoing study, the AF-LITT, <sup>10</sup> a pilot RCT of 180 AF patients receiving OAC, examining the impact of an embodied conversational agent and the AliveCor Kardia device for 30 days on health-related quality of life and self-reported adherence to OAC and app experience (patient and physician), is also still to report its findings.

It is encouraging that several of the included studies involved contributions from patients and interdisciplinary HCPs in the design and refinement of the patient apps;<sup>4,5,13,14</sup>co-designing interventions with end-users is beneficial and effective.<sup>22,23</sup> Since the main goal of mhealth is to support and maintain (healthy) behaviour change, utilizing interdisciplinary teams, including psychologists and social scientists with expertise in behavioural change intervention development and implementation is essential.

Table 3 S	Summary of ongoing	studies of mobile health interventions	for atrial fibrillation management
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First author, year, country, reference, trial registration number	Study aim	Study design	Study population	Арр	Features of the app	Outcomes
Guo 2019, China <sup>11</sup> ChiCTR-OOC- 17014138	To investigate the effectiveness of an integrated care approach to AF management, supported by mobile health technology	Prospective cluster- RCT (40 sites) Intervention vs. usual care Follow-up: 1 year	Adult AF patients with CHA2DS2- VASc score ≥2 N = 3660	mAFA II	Smartphone app Upgraded version of mAF app <sup>6</sup> Clinical decision-support tools (CHA <sub>2</sub> DS <sub>2</sub> -VASc and HAS-BLED, SAMe-TT <sub>2</sub> R <sub>2</sub> ), guideline-based treatment recommendations, educational materials, patient involvement strategies with self-care protocols and structured follow-up, to support implementation of ABC pathway	Primary: composite of stroke and thromboembolism, ACM, and rehospitalization Secondary: incidence of AF in 2 weeks; change in proportion continuing OAC; cost-effectiveness; QALY
Guhl 2017, USA <sup>10</sup> NCT03093558	To evaluate the efficacy of the ECA/ Kardia intervention to improve HRQoL and OAC adherence and implementation into a larger multi-centre RCT	Pilot RCT Novel smartphone- based intervention to address patient experience of AF Intervention: 30-day smart- phone-based ECA and Kardia Standard care: symptom and adherence journal	N = 180 AF patients receiving OAC	AF-LITT	Embodied conversational agent and AliveCor Kardia monitor	Primary: HRQoL Self-reported adherence to OAC Secondary: patient acceptability, usage levels, and acceptability to referring physicians

ABC, Avoid stroke, Better symptom management, and Cardiovascular and other comorbidities management; AF, atrial fibrillation; AF-LITT, Atrial Fibrillation health Literacy Information Technology Trial; ECA, Embodied Conversational Agent; HRQoL, health-related quality of life; mAFA, Mobile Atrial Fibrillation App; OAC, oral anticoagulation; PPG, photoplethysmography; QALY, quality-adjusted life years; RCT, randomized controlled trial.

Mobile health apps that include gamification features such as prizes, rewards, feedback on performance, competition, and social connectivity, have been shown to foster patient engagement and support adoption of healthy behaviours. <sup>24–26</sup> Of the studies included in this systematic review, only one <sup>5</sup> included gamification strategies within their app, such as rewards and communication with HCPs. However, several of the apps included self-regulatory behaviour change techniques, such as feedback and monitoring (including self-monitoring), <sup>5,13,14</sup> which are known to be effective for health promotion and secondary prevention. <sup>27,28</sup>

## **Conclusion**

Mobile health technology can be utilized to support the management of AF, and apps which have been formally evaluated demonstrate

improvements in patient knowledge of AF and OAC, medication adherence, and quality-of-life, and greater guideline-adherent OAC management by cardiologists. However, there is a dearth of studies formally evaluating the impact of m-health on HCP behaviour. Larger-scale studies with representative patient cohorts, appropriate comparators, and longer-term assessment of the impact (both potential benefits and harms) of m-health in this field are warranted.

# Supplementary material

Supplementary material is available at *Europace* online.

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for Boehringer Ingelheim and BMS/Pfizer; and consulted for BMS/Pfizer, Boehringer Ingelheim, and Daiichi-Sankyo. She is a co-author of one of the included studies (Guo et al. 2017). M.M.F. has been a speaker/consultant for BMS/Pfizer, Medtronic, Abbott, and Boston Scientific. E.G.C. has received honoraria as speaker/consultant from Medtronic International Trading Sarl, Merck & Co., Inc., and Novartis. P.D. has been a speaker for Abbott, Boehringer Ingelheim, Biotronik, and Medtronic; and served in the advisory board for Boehringer Ingelheim. T.S.P. has served as a consultant for Bayer and Pfizer (no fees). All other authors declared no conflict of interest.

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