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

Authors

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ABSTRACT

Background: 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.

Objective: 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: 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: (1) Knowledge of AF; (2) Provider behaviour (e.g. guideline adherence); (3) Patient behaviour (e.g. medication adherence); (4) Patient quality-of-life; (5) 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.

Results: Seven studies were included; six m-health apps aimed at patients and one at HCPs. m-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: m-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.

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 2017,³ including many for atrial fibrillation (AF) but very few have undergone formal assessment.⁴⁻⁶ 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.⁷ A completed PRISMA checklist is provided in the supplementary material.

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 e-health or m-health apps that only screened for or monitored AF, and remote monitoring of AF via ECG/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 (PDAs), and other wireless devices etc.) 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: (1) Knowledge of AF (patient and/or HCP); (2) HCP behaviour (e.g. adherence to AF management guidelines); (3) Patient behaviour (e.g. medication adherence); (4) 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 atrial fibrillation, mobile health, smartphone, mobile applications, etc. were used (see **Supplementary Table 1**) to search bibliographic databases. MEDLINE, EMBASE, CINAHL, and PsychInfo 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.clinicaltrials.gov) and ISCTRN (www.isrctn.com/) by entering key search terms (e.g., atrial fibrillation, mobile health, smartphones etc.) 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 (DL/NM) 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 (JG).

Data extraction

Data were extracted by one reviewer (DL) and checked by another reviewer (JW). 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 (DL/JG) utilising the Cochrane risk of bias tool⁸ for randomised controlled trials and the Risk of bias tool for non-randomised studies,⁹ 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 on-going.^{10, 11} A full list of the excluded studies and the reason for exclusion are provided in the Supplementary materials (see **Supplementary Table 2**). No relevant studies were identified via hand-searching. As a result, seven studies^{4-6, 12-15} 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 209⁶ participants, with a total of 466 patients^{4-6, 12-14} (mean age ranged from 59¹⁴ to 71⁶ years; 50%¹³ to 67%⁵ male) and 10 HCPs (mean age 43.8 years; 30% men).¹⁵ Studies were conducted in Belgium (n=2),^{4, 5} China (n=1),⁶ Iran (n=1),¹⁵ Poland (n=1),¹² and the USA (n=2).^{13, 14} Six studies were m-health apps aimed at patients^{4-6, 12-14} all of whom had AF (not exclusively AF in one study¹²), with one targeting HCPs.¹⁵ Only one study⁶ had m-health apps directed at both patients and HCPs, but this study only reported outcome data for patients. The studies varied widely in design with one cluster-randomised pilot study;⁶ one prospective, randomised controlled trial;⁴ two before-and-after studies;^{12, 15} and three exploratory/feasibility pilot studies.^{5, 13, 14} Most studies had short follow-up periods, between

4-weeks^{13, 14} and 3-months,⁴⁻⁶ with only two studies following participants for longer (6-months¹⁵ and 1-year¹²).

Types of interventions

The interventions varied markedly in their design, features of the m-health app, and method of delivery (see **Table 1**). Three were delivered via an app on a mobile phone only,^{6, 12, 13} and four via mobile phone or tablet.^{4, 5, 14, 15} Two studies were patient education interventions,^{4, 12} two were patient behaviour change interventions utilising support and adherence apps,^{13, 14} two supported HCP behaviour change^{6, 15} although one of the two⁶ did not report the outcome data related to the HCP app, and two were multi-faceted apps incorporating patient behaviour change and education interventions.^{5, 6}

The one m-health app designed for HCPs (cardiologists) was a computerised decision-support system (CDSS) to help improve adherence to oral anticoagulation (OAC) guidelines, using an app to calculate the CHA₂DS₂-VASc, and HAS-BLED scores and to provide OAC treatment recommendations based on clinical guidelines.¹⁵

One study¹² 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.¹³ The mAF app⁶ included a patient version and a doctor version, containing clinical decision-support tools (CHA₂DS₂-VASc, HAS-BLED, SAME-TT₂R₂) linked to patient health records, patient educational materials (8 topics), and tools to engage and support patients in self-care (e.g., heart rate and blood pressure monitoring) and structured follow-up.

Hirschey and colleagues¹⁴ 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 app⁵ teamed up AF patients and their grandchildren and recorded performance of ‘healthy’ daily tasks, such as intake of OAC (non-vitamin K antagonist OAC, NOAC) 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 utilised 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.⁴

Types of comparators

One study compared the intervention to usual care only;⁶ one compared the app to standard care with internet access but no structured intervention, and standard care with no internet access;⁴ two were before-and-after studies,^{12, 15} and three studies did not have a comparison group.^{5, 13, 14} Usual care consisted of information from a cardiologist and booklets⁴, and consultation with a cardiologist.⁶

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 study¹⁵ reported on HCP behaviour, focussing 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 intervention¹² or compared to usual care^{4,6} (see **Table 1**). Desteghe et al⁵ reported a non-significant ($p=0.09$) increase in knowledge level from baseline to 3-months 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; $p<0.0001$).¹⁵

Two studies reported on patient adherence to medication.^{5,6} One⁶ reported a significant increase in drug adherence at 1- and 3-months in the intervention group (both $p<0.001$) measured using the Pharmacy Quality Alliance adherence measure, while the other study⁵ showed a reduction in adherence from 88.6% (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 al⁶ measured quality-of-life using the visual analogue scale of the EQ-5D¹⁶ and reported a significant improvement from baseline to 1-month and 3-months in the intervention group compared to usual care (all $p<0.05$). Desteghe⁴ assessed quality-of-life using the AFEQT.¹⁷ 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, 13, 14} with three assessing perspectives on acceptability,^{4, 6, 14} five on usability,^{4-6, 13, 14} and one on feasibility.⁶

Generally, patients found the m-health apps acceptable and usable. The two studies by Desteghe and colleagues^{4,5} employed the User Experience Questionnaire¹⁸ to assess patient engagement with the apps. The m-health app for tailored patient education rated positively on all aspects,⁴ whilst the Health Buddies app was rated positively only for clarity, novelty,

stimulation and attractiveness.⁵ Three studies^{4, 5, 14} reported some negative aspects of their m-health apps: software bugs reported by 7/12 (58%);¹⁴ 10% were unable to use the device;⁴ and 5/15 (33%) often encountered technical difficulties or problems.⁵

Risk of bias assessment

A summary of the risk of bias assessment is presented in **Table 2**, with more detailed explanation available in **Supplementary Table 3**. 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,^{5, 13, 14} the observational nature of the majority of the studies^{5, 13-15} and the lack of detail on the randomisation procedure⁶ or incomplete randomisation.⁴ 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.⁶ All included studies, with the exception of Sheibani et al¹⁵ 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^{4, 5, 15} and unclear in two.^{12, 13} The main issues were related to not defining the primary outcome and/or the timing of the primary endpoint. In the mAF app randomised controlled trial,⁶ 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 al¹⁴ did not provide follow-up data.

Excluded studies

Supplementary Table 2 summarises 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.¹²

On-going studies

Two protocol papers for ongoing studies were identified (see **Table 3**). One study¹¹ 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 CHA₂DS₂-VASc score ≥ 2 , in a cluster-randomised controlled trial 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 al⁶ 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 baseline¹² or patients

receiving usual care,^{4, 6} improved patient medication adherence⁶ and quality-of-life,^{4, 6} improved provider adherence to OAC guidelines¹⁵ 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 (≤ 15),^{5, 13-15} lack of a comparator group,^{5, 13, 14} lack of blinding for outcome assessors,^{4, 5, 12-15} imprecision or lack of definition of, and timing of, primary (and secondary) outcomes,^{5, 12-14} short follow-up periods for outcome evaluation (4-weeks¹⁴ to 3-months⁴⁻⁶), and incomplete reporting of outcome data.^{6, 14} 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),¹⁹ was 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 healthcare and everyday life does not negate the necessity for future m-health 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 mobile 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.²⁰

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 physicians¹⁵) whereas the other three^{5, 6, 14} were more complex. The Health Buddies app⁵ was an interactive game, involving patients' grandchildren, to support medication adherence; the mAF app⁶ patient-version focussed 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 app¹⁴ 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 on-going studies, one¹¹ has reported the results of the ABC-pathway supported by the mAFA II app on the primary outcome of a composite of stroke/thromboembolism, all-cause mortality, and rehospitalisation.²¹ 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 (HR): 0.39; 95% confidence interval (CI): 0.22 to 0.67; $p < 0.001$) compared to those receiving usual care ($n=1678$; mean age 70.0 years; 38% female).²¹ 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 on-going study, the AF-LITT,¹⁰ 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 inter-disciplinary HCPs in the design and refinement of the patient apps;^{4, 5, 13, 14} co-designing interventions with end-users is beneficial and effective.^{22, 23} Since the main goal of m-health is to support and maintain (healthy) behaviour change, utilising interdisciplinary teams, including psychologists and social scientists with expertise in behavioural change intervention development and implementation is essential.

m-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.²⁴⁻²⁶ Of the studies included in this systematic review, only one⁵ 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),^{5, 13, 14} which are known to be effective for health promotion and secondary prevention.^{27, 28}

CONCLUSION

Mobile health technology can be utilised 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.

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Conflicts of interest:

DL has received investigator-initiated educational grants from Bristol-Myers Squibb (BMS); has been a speaker for Boehringer Ingelheim and BMS/Pfizer; and consulted for BMS, Boehringer Ingelheim and Daiichi-Sankyo. She is a co-author of one of the included studies (Guo et al 2017). MF has been a speaker/consultant for BMS/Pfizer, Medtronic, Abbott, Boston Scientific. E.G.C. has received honoraria as speaker/consultant from Medtronic International Trading Sarl, Merck & Co., Inc., and Novartis. PD has been a speaker for Abbott, Boehringer Ingelheim, Biotronik and Medtronic; and served in the advisory board for Boehringer Ingelheim. TP has served as a consultant for Bayer and Pfizer (no fees).

None to declare: NM, JG, JW, RL, CW.

Figure 1: PRISMA flow diagram for study selection process

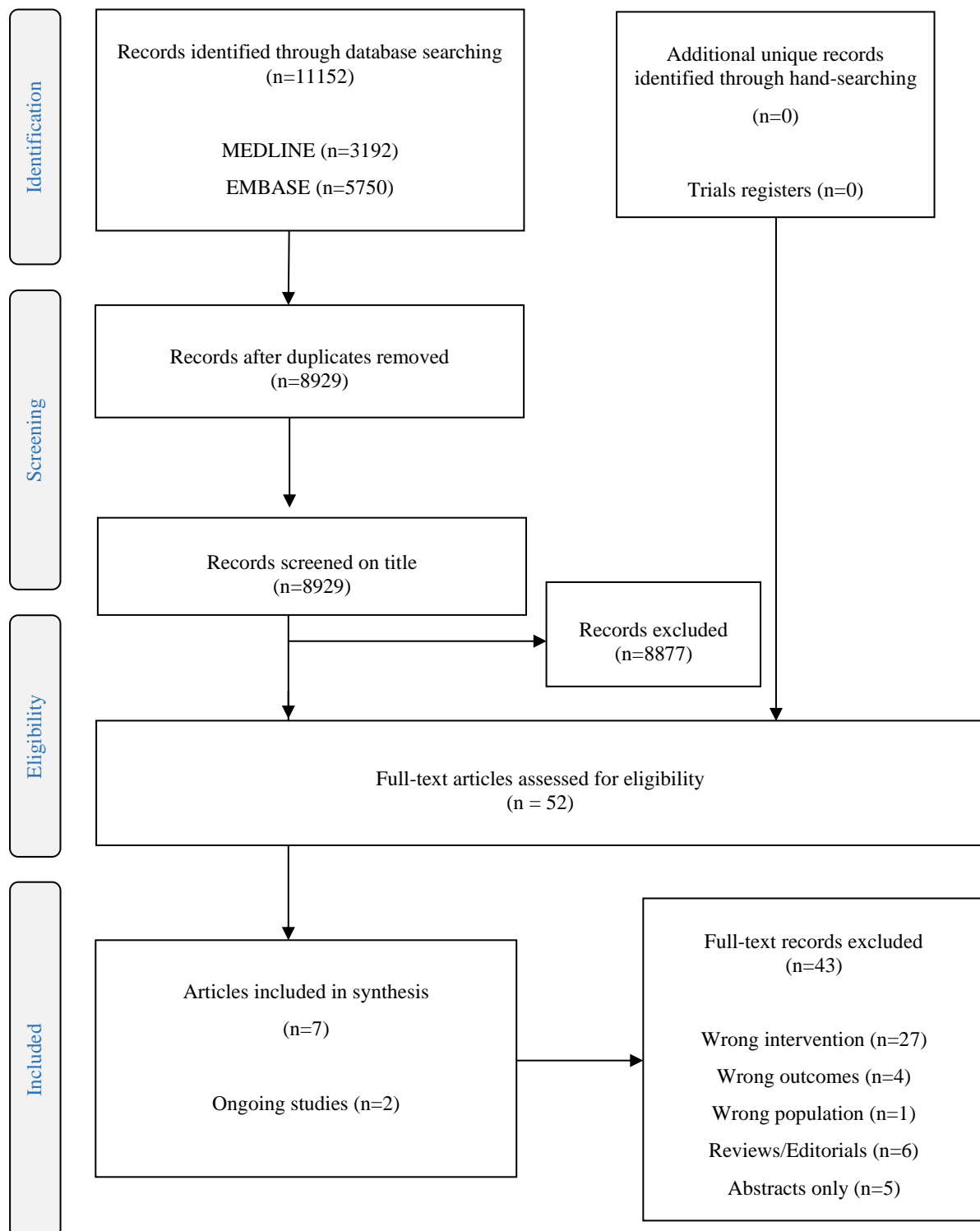


Table 1: Summary of the included studies

First author, year, country, reference	Study aim	Study population	Study design	App	Features of the App	Outcomes	Results	Conclusion
Balsam 2019, Poland ¹² OCULUS study NCT03104231	Effectiveness of 3D movie in teaching patients about consequences of AF and pharmacological stroke prevention	100 consecutive, hospitalised pts Mean (SD) age: 63y (15); 38% women, 62% history of AF	Prospective, single centre (hospital), before-&-after study <i>Inclusion criteria:</i> aged >18 years <i>Exclusion criteria:</i> dementia Recruitment April 2016 to 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 smartphone 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_m88ds Version for women https://www.youtube.com/watch?v=S8i7LxBBv0g	Virtual reality headset (oculus glasses) and smartphone with 3D movie Information on risk of stroke and use of OAC to reduce stroke	Patient knowledge: (1) stroke consequence of AF; (2) drugs may reduce stroke risk; (3) OAC reduces stroke risk Usefulness of 3D movie to deliver information	Knowledge that stroke was consequence of AF: Before movie 22/100 (22.0%); Immediately after movie 83/100 (93%); 7-days later 74/94 (78.7%) 1 year 64/90 (71.1%); all p<0.0001 Knowledge that drugs may reduce stroke risk: Before: 83/94 (88.3%) Immediately after: 1-week later: 94/94 (100%); p<0.0001 1 year: 87/90 (96.7%) (p=0.02) Knowledge that OAC reduces stroke risk: Before: 66/94 (70.2%) 1-week later: 90/94 (95.7%) 1-year later: 83/90 (92.2%); all p<0.0001 Usefulness: 99/100 (99%) stated useful tool to increase awareness of consequences of AF	3D movie was an effective tool in transferring knowledge about the consequences of AF and role of OAC in stroke prevention Negative aspects of m-health apps not reported
Hirschey 2018, USA ¹⁴	Perceived usability and usefulness of mobile app designed	12 AF pts	Exploratory pilot study: naturalistic app use; surveys (in-person at baseline, then	AFib Connect mobile app (Android & iPhone iOS) platforms	AFib guide: introduction to AF	App usability, satisfaction, and usefulness	Usability improvement: app navigation (3 themes); clarity of app instructions	Needs more research in larger, more diverse AF sample

	to support self-care and treatment adherence for AF patients prescribed NOACs	<p>Mean age: 59y (range 37-67y); 7 (58.3%) men; 100% Caucasian</p> <p>Mean AF duration: 6y (range 1-15y); 11/12 (92%) symptomatic; 11/12 had college or greater level education</p> <p>n=16 enrolled; 12 completed study</p>	<p>by post); 5 x 30 min semi-structured weekly interviews to examine patients' perceptions and everyday use of the app</p> <p>4-week study with 5 visits total</p> <p>Recruitment September 2016 to April 2017</p> <p>Purposive sampling of AF patients on NOACs, identified by clinician from 1 hospital</p> <p>Participants reviewed app features at different time-points and rated usability and usefulness over last week</p> <p>Patient satisfaction assessed on 5-point Likert scale, yes/no and open-ended questions</p> <p>Follow-up: weekly for 4-weeks</p>	<p>App developed based on semi-structured interviews and usability data from clinicians (n=9) and patients</p> <p>Developed by interdisciplinary team (clinicians, qualitative researchers, & user experience designers)</p> <p>Usability testing conducted with clinicians and patients using first version of app. Feedback incorporated into design of version two, which was used for this study</p>	<p>through text & animated videos;</p> <p>Library: detailed information on AF (medication, procedure options, medication adherence & stroke risk)</p> <p>AF Episode Tracker: Patient-generated for physician review</p> <p>AF Trigger Tracker: Patient-generated</p> <p>AF News Feed: American Heart News, StopAFib.org, AHA</p> <p>Medication reminder & diary</p> <p>Heart rate monitor: using mobile phone camera</p> <p>Appointment reminder</p>		<p>and design intent; software bugs</p> <p>12/12 (100%) agreed somewhat or strongly that app was easy to use; only 1/12 reported needing to ask for help when using App;</p> <p>App satisfaction: 92% reported being satisfied/very satisfied with the app</p> <p>Perceptions of app usefulness (3 variables): core needs of the patient segment; patient workflow while managing AFib; app's ability to support the patient's evolving needs</p> <p>10/12 somewhat or strongly agreed that the AFib app acted and felt like other apps they had used before</p>	<p>App broadly useful and effective in supporting patient self-care and medication adherence</p> <p>Software bugs reported by 7/12 (58%)</p>
Desteghe 2018, Belgium ⁴	Effectiveness of an on-line tailored education platform to inform AF patients undergoing DCCV or PVI	<p>120 AF pts. requiring DCCV or PVI</p> <p>Mean (SD) age: 68.0y (10.2); 78 (65%) male</p>	<p>Prospective, randomised controlled trial at 1 Belgian tertiary hospital</p> <p><i>Inclusion criteria:</i> consecutive AF patients undergoing planned DCCV or PVI</p>	On-line patient education (general AF information, OAC & procedure-related information) developed by 3 experienced cardiologists/electro-	<p>Patients had unique log-in and could visit site whenever they wanted</p> <p>On-line platform recorded how</p>	Patient knowledge: measured by JAKQ	<p>Patient knowledge: <u>Group 1</u> on-line tailored education group: significantly improved knowledge by end of hospitalisation (75.0% IQR 66.7-85.0; p=0.001)</p>	<p>Small study</p> <p>Those without compatible device significantly older, had lower educational</p>

			<p><i>Exclusion criteria:</i> <18 years, severe mental (i.e. dementia) or physical (i.e. deafness) impairment, inability to read Dutch and not able to provide written informed consent</p> <p>Those with internet access allocated to: Group 1 on-line education (n=35); or Group 2 standard care with on-line access (n=36)</p> <p>Those without computer/tablet/smartphone (Group 3) received (3) standard care (n=49)</p> <p>JAKQ completed 1-3 weeks prior to hospitalisation, at hospitalisation and 6 and/or 12-week post-procedure</p> <p>Standard care included information from cardiologist and specific and general information booklets</p> <p>Only those in Group 1 received access to the on-line tools</p> <p>Follow-up: Groups 1 and 2 at baseline, at hospitalisation, 6- and 12-months later</p> <p>Group 3: at hospitalisation and 3-months only</p>	<p>physiologists based on hospital brochures & patient websites (AFA, EHRA, AHA, Alliance for Aging Research)</p> <p>Education provided by text, images and movies. Fact boxes highlighted key educational messages</p>	<p>many times each patient visited platform, length of time viewing content and which topics were viewed</p>	<p>Patient QoL: measured by AFEQT</p> <p>Patient experience/opinions: measured by UEQ</p>	<p>Knowledge persisted at 6-weeks (77.5% IQR 65.0-85.0; p=0.010) and 12-weeks (80.0% IQR 70.0-90.0; p<0.001) after procedure</p> <p>Group 2 standard care with on-line access: No improvement in overall knowledge between baseline and time of hospitalisation (65.0% IQR 50.0-73.8; p=1.00). Significant improvement between baseline and 6-week post-procedure (p=0.010) and between hospitalisation and 6-week post-procedure (p=0.016)</p> <p>Group 3 Standard care only: No knowledge improvement over course of study (p=0.248)</p> <p>Quality of life: Significant increase in overall AFEQT score in both on-line groups 6- and 12-weeks post-procedure compared to baseline and at hospitalisation</p> <p>Group 3: no significant difference in overall AFEQT score over time (p=0.082)</p> <p>Usability: on-line platform rated positively on all aspects</p>	<p>level and higher risk of stroke and bleeding</p> <p>10% sample unable to use device</p>
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Sheibani 2017, Iran ¹⁵	Effect of computerised decision support system (CDSS) on improving adherence to anticoagulation guidelines for AF	<p>10 cardiologists managing n=373 newly diagnosed AF pts</p> <p>10 cardiologists (7 (70%) female) Mean age 43.8y (range 33-58y)</p> <p>Mean length professional experience: 11.2y (range 3-32y)</p>	<p>Interrupted times series design (before-&-after design) Setting: offices of 10 cardiologists</p> <p>OAC guideline adherence assessed fortnightly from January 2016 to January 2017; 6-months before and 6-months after intervention</p> <p><i>Inclusion criteria:</i> newly diagnosed AF patients</p> <p><i>Exclusion criteria:</i> mechanical heart valve, severe mitral valve disease, any other reason for requiring anticoagulation (history of recent or recurrent venous thromboembolism)</p> <p>Convenience sampling for cardiologists</p> <p>Follow-up: 6-months post-intervention only</p>	CDSS designed for anticoagulant management of AF installed on cardiologist smartphone/tablet	App calculated CHA ₂ DS ₂ -VASc score and HAS-BLED score, gave treatment recommendations based on latest AHA/ACC guidelines	Provider adherence to OAC guidelines for AF	<p>Before intervention (Jan-June 2016): 48% (n=212; 21 excluded due to missing data)</p> <p>Post-intervention (July 2016-Jan 2017): 65.5% (n=207; 25 excluded due to missing data)</p> <p>Significant increase in guideline-adherent OAC prescription post-intervention (p<0.0001)</p>	<p>CDSS improved adherence to guidelines for OAC for AF by reducing guideline complexity, simplifying risk calculation, and providing interpretation of risk scores</p> <p>Negative aspects of m-health apps not reported</p>
Guo 2017, China ⁶ ChiCTR-IOR-17010436	Evaluation of patients' knowledge, QoL, medication adherence, OAC satisfaction, and usability, feasibility and acceptability of mAFA app	<p>n=209 pts mAFA: n=113 Mean (SD) age 67.4; 57.5% male</p> <p>Usual care: n=96 Mean (SD) age 70.9y; 55.2% male</p>	<p>Cluster randomised pilot study, 2 hospitals in China</p> <p>Recruitment 1 January to 1 May 2017</p> <p><i>Inclusion criteria:</i> aged ≥18; confirmed AF (ECG or 24-hr Holter)</p> <p><i>Exclusion criteria:</i> <18y; valvular AF; unable to</p>	<p>Mobile Atrial Fibrillation App (mAFA)</p> <p>Clinician version*</p> <p>Patient version</p>	Clinical decision-support tools (CHA ₂ DS ₂ -VASc and HAS-BLED, SAME-TT ₂ R ₂), educational materials, patient involvement strategies with self-care protocols and structured follow-up	<p>Patient knowledge (11-item AF knowledge questionnaire Hendriks et al, 2013);</p> <p>Quality-of-life (EQ-5D-Y);</p> <p>Drug adherence (Pharmacy</p>	<p>Patient knowledge: mAFA significantly improved knowledge vs. UC (all p<0.05)</p> <p>Quality of life: Significantly increased in mAFA arm vs. UC at baseline (86.5 vs. 71.3), 1- (87.6 vs. 70.1) and 3-months (87.2 vs. 69.9) (all p<0.05)</p>	<p>Significant improvements in patient knowledge, quality-of-life, drug adherence, and reduction in OAC burden with mAFA vs. UC</p> <p>Most (90%) rated app as easy, user friendly, helpful</p>

			<p>provide written informed consent</p> <p>Follow-up: 1- and 3-months</p>		<p>Included personal health record (PHR)</p> <p>App calculated risk scores from PHR; OAC recommended based clinical guidelines; pts. with HAS-BLED ≥ 3 flagged for FU</p> <p>Patient educational program: 8 components with additional patient self-support items</p>	<p>Quality Alliance adherence measure);</p> <p>OAC satisfaction (Anti-Clot Treatment Scale)</p> <p>All assessed at baseline, 1- and 3-months.</p> <p>App experience: Usability, feasibility and acceptability of mAFA assessed at 1-month</p>	<p>Drug adherence: mAFA vs. UC: baseline (4 (4-11) vs. 4 (4-11); $p=0.870$); 1 month (0 (0-4) vs. 4 (0-11); $p<0.001$); 3 months 2 (0-4) vs. 4 (0-11); $p<0.001$)</p> <p>Anticoagulation satisfaction: UC expressed more OAC burden (all $p<0.05$); mAFA pts. reported significantly more OAC benefit at 1-month only ($p=0.013$)</p> <p>App usability: 90% reported app was easy, user friendly, helpful</p>	<p>Negative aspects of m-health apps not reported</p>
Ghanbari 2017, USA ¹³	Assess usability and feasibility of a mobile application to assess symptoms in patients with AF	<p>n=10 pts with PAF or persistent AF</p> <p>Age (NR)</p> <p>5 (50%) women; PAF 50%</p>	<p>Pilot, feasibility study</p> <p><i>Inclusion criteria:</i> >21y; AF diagnosis; stable medical regime for ≥ 30 days prior to study</p> <p><i>Exclusion criteria:</i> asymptomatic AF; psychiatric or neurological disorders; dementia, cancer, drug/alcohol abuse; life expectancy <1 year; pregnancy; existing implantable cardiac rhythm devices and neuro-stimulators</p> <p>Semi-structured phone interview at 4-week</p> <p>Follow-up: 4 weeks</p>	<p>miAfib</p> <p>Mobile app (iPhone only) to assess AF symptoms and positive/negative affect</p> <p>www.miAfib.com to assist mobile app set-up and for study details</p>	<p>Beta version of app tested extensively for user experience, data recording and transfer prior to release of final product to app store</p> <p>Users prompted via notifications to complete symptoms and affect assessment 4 times per day every 3 hours</p>	<p>User engagement and perspectives on acceptability</p> <p>Questionnaire on app usage and acceptance (5-point Likert scale)</p>	<p>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)</p>	<p>Pts found app easy to use and would consider using app in the future</p> <p>Need larger study to determine feasibility in a diverse group of AF patients</p> <p>Small sample size</p> <p>Negative aspects of m-health apps not reported</p>

Desteghe 2017, Belgium ⁵	Pilot study to assess the feasibility and usability of the Health Buddies App in AF patients	<p>n=15 AF pts and n=20 grandchildren aged 5-15y</p> <p>AF pts.: Mean (SD) age 69.2y (3.7); 10 (67%) male; 6 (40%) had college or university education</p> <p>Grandchildren: Mean (SD) age 9.5y (3.0)</p> <p>Only 15/410 (3.7%) of NOAC population and 15/114 (13.2%) eligible participated</p>	<p>Prospective feasibility pilot study</p> <p>1 hospital in Belgium, recruited as out-pt. or in-pt.</p> <p><i>Inclusion criteria:</i> AF, on a NOAC, grandchild aged 5-15 years, having a tablet, mobile phone or computer with internet access</p> <p><i>Exclusion criteria:</i> enrolled in other studies; non-Dutch speaking</p> <p>Study conducted October 2015 to August 2016</p> <p>Participants had to use the App for 3 months</p> <p>Follow-up: 3-months</p>	Health Buddies App	<p>App co-developed with pts., grandchildren and parents in 2 workshops</p> <p>Patient contract: take NOAC daily; other health challenges.</p> <p>Grandchild contract: daily healthy challenge (eating fruit, brushing teeth twice daily)</p> <p>Rewards to completing daily challenges (gaming).</p> <p>Goal to complete as many challenges as possible in 3 months. Reward at end trip or fun activity</p> <p>NOAC stock with a refill reminder and communication with HCP</p>	<p>Patient knowledge on AF and treatment: measured by JAKQ baseline and 3-months</p> <p>Medication adherence: measured by MMAS-8 baseline and 3-months. MEMS and Helping Hand devices monitored medication adherence. Pill count at 3-months</p> <p>Motivation to use app: measured by number of log-ins</p> <p>App experience: measured by UEQ</p> <p>App satisfaction usability, content and effects of the Health Buddies app: questionnaire designed by</p>	<p>Patient knowledge on AF and treatment: JAKQ score improved but not significantly from 64.6% (SD 14.7) at baseline to 70.4% (SD 10.4) after 3 months (p=0.09)</p> <p>Medication adherence: Mean (SD) MMAS-8: at baseline 7.7 (0.6) and 7.4 (0.9) at end of study</p> <p>Electronic monitoring showed lower taking and regimen adherence than self-reported on app (taking adherence 88.6% (SD 15.4) and regime adherence 81.8% (SD 18.7). Pill count adherence 94.5% (SD 9.2)</p> <p>Motivation to use app: App use significantly decreased towards end of study in both pts (p=0.009) and grandchildren (p<0.001). 13/15 (87%) completed the 90-day contract</p> <p>Mean (SD) % of days using app significantly higher in pts vs. grandchildren (57.7% (SD 30.0) and 24.3% (SD 23.8), respectively; p=0.002)</p> <p>App experience: Rated positively on clarity (1.500), novelty (0.942) and stimulation (0.923)</p>	<p>Small sample; selected sample (only 15 participated); no control group</p> <p>Patients evaluated the educational aspect of this app as a capital gain</p> <p>5/15 (33%) often had technical difficulties with app</p>
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						study team gathered	and attractiveness (0.859). Efficiency (0.577) and dependability (0.481) received neutral rating	
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ACC, American College of Cardiology; AF, atrial fibrillation; AFA, Atrial Fibrillation Association; AFEQT, Atrial Fibrillation Evaluation of Quality of life questionnaire; AHA, American Heart Association; CDSS, computerised decision support system; DCCV, direct current cardioversion; ECG, electrocardiogram; EHRA, European Heart Rhythm Association; FU, follow-up; HCP, healthcare professional; IQR, interquartile range; JAKQ, Jessa Atrial Fibrillation Questionnaire; mAFA, Mobile Atrial Fibrillation App; NOAC, non-vitamin K antagonist oral anticoagulant; NR, not reported; OAC, oral anticoagulation; pts, patients; PAF, paroxysmal atrial fibrillation; PVI, pulmonary vein isolation; QoL, quality of life; SD, standard deviation, UC, usual care; UEQ, User Experience Questionnaire; y, years

*Data on clinician version of the app not reported in this paper

Table 2: Risk of bias assessment for included studies

Randomised controlled trials (assessed by Cochrane Risk of Bias tool ⁸)							
Study	Selection bias		Reporting bias	Performance bias	Detection bias	Attrition bias	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 (2018) ⁴	High	High	Unclear	High	Unclear	Low	Unclear
Guo (2017) ⁶	Unclear	Unclear	Unclear	High	Low	High	Unclear

Observational studies (assessed by Risk of Bias for non-randomised studies (RoBANS) tool ⁹)						
Study	Selection bias	Confounding variables	Performance bias	Detection bias	Attrition bias	Reporting bias
Author (year)		Inadequate confirmation and consideration of confounding variables	Inadequate measurements of exposure	Inadequate blinding of outcome assessments	Incomplete outcome data	Selective outcome reporting
Balsam 2019 ¹²	Low	Unclear	Low	High	Unclear	High
Hirschey 2018 ¹⁴	High	High	High	Unclear	High	High
Sheibani 2017 ¹⁵	Unclear	Low	Low	High	Low	Low
Ghanbari 2017 ¹³	High	High	Low	Unclear	Unclear	Unclear
Desteghe 2017 ⁵	High	High	Low	Unclear	Low	Unclear

Table 3: Summary of on-going studies of mobile health interventions for atrial fibrillation management

First author, year, country, reference, trial registration number	Study aim	Study design	Study population	App	Features of the App	Outcomes
Guo 2019, China ¹¹ 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 CHA ₂ DS ₂ -VASc score \geq 2 N=3660	Mobile Atrial Fibrillation App (mAFA) II	Smartphone app Upgraded version of mAF app ⁶ Clinical decision-support tools (CHA ₂ DS ₂ -VASc and HAS-BLED, SAME-TT ₂ R ₂), 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 rehospitalisation Secondary: incidence of AF in 2 weeks; change in proportion continuing OAC; cost-effectiveness; QALY
Guhl 2017, USA ¹⁰ 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 smartphone-based ECA and Kardia	N=180 AF patients receiving OAC	Atrial Fibrillation health Literacy Information Technology Trial (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

		Standard care: symptom and adherence journal				
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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, randomised controlled trial

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