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# A pilot study of a digital education program (INFORM-AF) for patients living with atrial fibrillation

Caleb Ferguson<sup>1,2,8\*</sup>, Fahad Shaikh<sup>1,2</sup>, Annie Downie<sup>3</sup>, Tonia Wilson<sup>3</sup>, Kaitlyn Griffin<sup>2</sup>, Sabine M. Allida<sup>1,2</sup>, Louise D. Hickman<sup>1</sup>, Beata V. Bajorek<sup>4,5,6</sup> and Rochelle Wynne<sup>1,7</sup>

## Abstract

**Background** There are many unmet educational needs for people living with atrial fibrillation (AF). Digital health offers promise; however, evidence is largely lacking. Hence, the objective of this study was to determine the system usability, feasibility, and efficacy of a digital education program (INFORM-AF) for patients living with atrial fibrillation on AF-related knowledge and quality of life.

**Methods** A pilot study was conducted. Patients diagnosed with AF were recruited from two metropolitan hospitals in Blacktown and Sutherland, New South Wales, Australia, following index hospitalisation. The INFORM-AF education program was delivered using the QStream™ digital platform directly to participants' smartphones over 6 weeks. Outcome measures included AF knowledge (JAKQ), AF quality of life (AFEQT) and system usability (SUS). Surveys were completed in-hospital at baseline and via phone at 6 weeks, 3, 6 and 12 months.

**Results** Thirty-two participants were enrolled, 2 were lost to follow up and 2 withdrew. 28 were included in the analyses. Mean age was 60 years (32–79 years), 56% female. There were significant improvements in AF knowledge (62% pre vs 73% post,  $p < 0.001$ ) and AF quality of life at 6 weeks ( $53.7 \pm 22.4$  pre and  $67.9 \pm 25.5$  post,  $p = 0.016$ ). Knowledge improvements were the greatest in the risk factor, symptom recognition, and when to seek assistance domains. System usability was excellent (mean 84 SUS score).

**Conclusions** The INFORM-AF education program demonstrated system usability and feasibility with improvements in AF knowledge and quality of life at 6 weeks, 3, 6 and 12 months. INFORM-AF will be evaluated in a larger clinical trial on outcomes including emergency department visits, hospitalisation, and healthcare utilisation.

**Trial registration** <https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=381531>.

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## Key messages

- The usability and feasibility of a digital education program (INFORM-AF) for people living with AF is unknown.

\*Correspondence:

Caleb Ferguson  
calebf@uow.edu.au

Full list of author information is available at the end of the article



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- Participants used the digital education program, and most completed the modules. Two dropped out and two were lost to follow up.
- It is feasible to conduct a digital health education program for people living with AF, although this cohort was younger.

**Keywords** Atrial fibrillation, Digital health, Spaced learning, Stroke prevention, Self-management, Patient education

## Introduction

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia [1]. The estimated global prevalence of AF is 60 million [2]. Future projections suggest a troubling trend, with estimations that prevalence will double by 2050. AF is a major risk factor for ischaemic stroke and heart failure and poses a significant economic burden associated with hospitalisation and emergency department visits [3]. Critical to reducing the burden of this growing pandemic is ensuring patients and their caregivers are equipped with adequate knowledge and skills to optimise self-management strategies. The 2018 Australian Heart Foundation/ Cardiac Society of Australia and New Zealand Guidelines for the diagnosis and management of AF recommend that an integrated care approach, including patient education and the use of eHealth tools and resources where available, should be adopted and delivered by multidisciplinary teams [4]. Furthermore, the guidelines strongly recommend that targeted patient education be provided throughout the continuum of AF management. However, the development and validation of AF educational resources have been poorly, to date [5].

Findings from our foundational exploratory qualitative study of AF patients, clinicians, and expert key stakeholders identified unmet needs in the provision of quality AF education to support self-management [6]. The study emphasised the importance of implementing a range of modern educational strategies focused on tailored information, which contrasts with brochure-based approaches to providing AF education. This led to the development of INFORM-AF, a co-designed, evidence-based education program that will be delivered through a spaced education digital platform called QStream™. Spaced education is a pedagogical approach widely used in health curricula for patients and clinicians that employs spaced repeated testing to deliver small amounts of educational content, whilst simultaneously testing users' understanding of the content. This microlearning approach to learning has been found to not only increase knowledge but also promote knowledge retention for up to 24 months [7]. A recent review of AF-related mHealth self-management apps found a lack of underpinning behaviour change

techniques (BCTs), poor app quality and that no app had been evaluated in a clinical trial. Highlighting the need to clinically validate mHealth interventions that address evidence-based behaviour change theoretical approaches to support AF self-management [8].

## Aim

This study aims to determine the system usability, feasibility, and efficacy of a digital education program (INFORM-AF) for patients living with atrial fibrillation on AF-related knowledge and quality of life.

## Methods

### Study design and setting

The study was a prospective, pre-post, pilot study conducted at two metropolitan hospitals in Sydney (Blacktown and Sutherland Hospitals), Australia. Blacktown Hospital is approx. 500-bed hospital 35kms west of central Sydney, serving a large diverse population, further Sutherland Hospital is a 375-bed hospital in the South-east of Sydney, located 30kms south of Sydney. Both hospitals are metropolitan teaching hospitals with in-patient CCUs and cardiology wards and outpatient cardiac rehabilitation services.

The study is reported following the CONSORT 2010 statement: extension to randomised pilot and feasibility trials [9]. Study findings have been previously presented at the 2023 European Society of Cardiology ACNAP Conference in Edinburgh and reported through published abstract [10].

### Ethical considerations

Ethics approval was received from the Western Sydney Local Health District Human Research Ethics Committee (2021/ETH00122). Written informed consent to participate was obtained from all of the participants in the study. Written informed consent was obtained from the participants for publication of this article and any accompanying tables/images. A copy of the written consent is available for review by the Editor of this journal.

### Participants

A convenience sampling strategy was used. Potential participants were identified by the research nurse (between May 2021 and Jan 2022), through daily

screening of admissions in the Cardiology Services of the participating hospitals. Recruitment was delayed due to COVID-19 lockdowns and a cessation of all non-COVID-19-related clinical research across the health system. Patients aged >18 years with a confirmed (primary or secondary) diagnosis of AF, detected on electrocardiogram (ECG) <12 months or at index presentation or admission, living within the catchment area of the participating hospitals, and who owned a smartphone were eligible to participate. The exclusion criteria were as follows: i) absence of ECG documentation of AF; ii) have end-stage heart failure defined as a left ventricular ejection fraction <20% or New York Heart Association Class IV; iii) have had cardiac surgery <2 months before index presentation or admission; iv) terminal malignancy; v) end-stage renal dysfunction defined as a history of dialysis or Stage 3 chronic kidney disease; vi) documented thyrotoxicosis or acute pneumonia; vii) poor English language literacy; viii) living in a residential aged care facility; ix) unable to independently use a smartphone device and x) unable to provide informed consent.

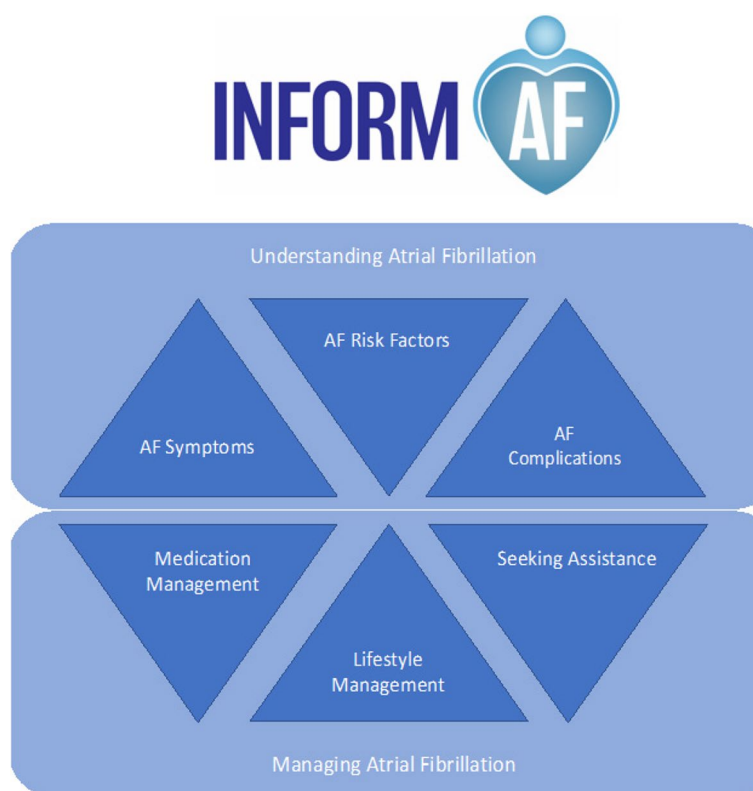
#### Sample size

We aimed to enrol a total of 30 participants in this pilot study. This study uses a feasibility trial sample size, as

determined by Lancaster & Thabane [11]. This sample size was selected to pilot this intervention, as it was unknown if participants would engage with, or complete the intervention. The study aimed to recruit 30 participants in the intervention arm, accounting for 25% attrition rate [12]. The estimated sample size was guided by the range reported in an audit of pilot trials [13].

#### Description of the intervention

INFORM-AF, a co-designed, theory-driven Qstream™ delivered educational intervention. The INFORM-AF educational program consisted of a series of six interactive case studies delivered through the QStream™ spaced digital platform. The key topics were identified as priority areas for education by patients with AF, clinicians, and key stakeholders in a previous study and through existing literature [6]. The case studies were created for the purposes of the study. Consumer input was obtained from people with lived experience to seek advice on topic areas. Two themes were covered by the intervention: 'Understanding Atrial Fibrillation' and 'Managing Atrial Fibrillation.' This included 6 topics: (1) AF symptoms; (2) AF risk factors; (3) AF complications; (4) Managing Medications; (5) Lifestyle Management; and (6) Engaging with your health provider. Refer to Fig. 1 for the program



**Fig. 1** INFORM-AF case study content areas

content. Each of the modules follows the same format. The user is provided with a short case scenario, a question, and multiple-choice responses. Once the question is answered, the user is provided with instant feedback and the correct response, some feedback, and a take-home message. This is accompanied by further information and additional resources, such as multimedia and reference materials. Participants were quizzed on the following six questions:

1. Is atrial fibrillation always accompanied by symptoms?
2. What are the main risk factors for atrial fibrillation?
3. What are the consequences of atrial fibrillation?
4. When should I take my anticoagulant?
5. Can key lifestyle modifications help patients with atrial fibrillation?
6. Should Paul go to the general practitioner or emergency room each time he feels atrial fibrillation?

Automated delivery of the 6 case scenarios followed a standardised spaced algorithm: (a) two questions per delivery, every 2 days; b) questions answered incorrectly were repeated after 7 days, and questions answered correctly were repeated after 13 days; (c) two consecutive correct answers were required to retire a question, and a maximum of three attempts were provided before retiring a question. Cases were retired once the participant correctly answered a question on two consecutive occasions. This novel intervention combined: (a) authentic

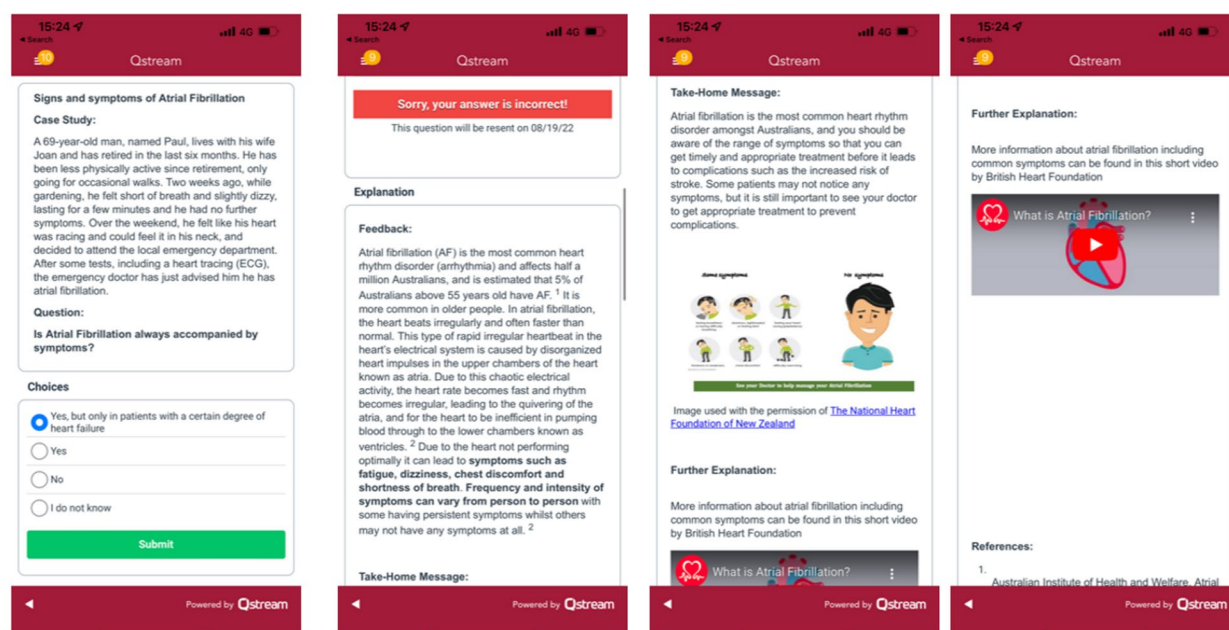
case-based anticoagulation learning scenarios; (b) real-time audit and feedback; and (c) online links to evidence-based learning materials. Refer to Fig. 2 for a sample QStream case study question with immediate feedback and rich resources.

### Sample INFORM-AF case study question with immediate feedback and rich media resources

Once consented, participants were asked to download the application on their smartphone device and sign up for the QStream application with the help of the study nurse. Participants received the case studies through pop-up notifications (by default) which could be accessed in their own time. The time commitment to answering the case studies was approximately 5–10 min every second day of the week. However, participants could read and interact with the additional resources provided which took approximately 30 min to an hour of their time per week. The education program took 6 weeks to complete.

### Outcome measures

All participants were assessed at baseline face-to-face and followed up at 6 weeks, 3, 6, and 12 months over the phone. Age, gender, language spoken at home, length of smartphone ownership, and highest level of education were collected at baseline. AF-related knowledge and quality of life were measured at baseline and at 6 weeks, 3, 6, and 12 months. AF-related knowledge was assessed using the Jessa Atrial Fibrillation Knowledge Questionnaire (JAKQ). JAKQ is a brief, complete, and valid



**Fig. 2** Example INFORM-AF scenario

AF-specific knowledge questionnaire that can be used in daily practice to assess patients’ insight into their condition. It could be used as a tool for individually tailored patient education. The 16-item, JAKQ comprises 8 questions about AF in general, 5 questions about oral anticoagulation (OAC) therapy, and either 3 questions about vitamin K antagonists (VKA) or non-vitamin K antagonist oral anticoagulants (NOAC) [14]. A higher score indicates better AF-related knowledge.

AF-related quality of life was assessed using the Atrial Fibrillation Effect on Quality-of-Life Questionnaire (AFEQT). AFEQT is a novel, disease-specific health-related quality of life instrument explicitly developed for use as an outcome measure in clinical trials, as a tool for disease management, and as a potential marker of health care quality. It was developed with patient input and shown to be feasible, reliable, valid, and responsive to treatment [15–17]. This 20-item instrument evaluates key domains as follows: a 4-item Symptoms score, an 8-item Daily Activities score, a 6-item Treatment Concerns score, and a 2-item Treatment Satisfaction scale [17]. The first 3 of these domains can be grouped to form an overall score. A higher score indicates an improved quality of life. System usability was also measured using a 10-item System Usability Scale (SUS) at 6 weeks, 3, 6, and 12 months. The System Usability Scale (SUS) is the most widely used standardized questionnaire for the assessment of perceived usability [18]. It enables the evaluation of a wide variety of products and services, such as hardware, software, mobile devices, websites, and apps. It has five response options for respondents; from Strongly agree to Strongly disagree, a SUS score above 68 would be considered above average and anything below 68 is below average. Study data were collected and managed using Research Electronic Data Capture (REDCAP) [19, 20]. Permissions were obtained to use the AFEQT and JAKQ scores as outcome measures.

Analysis

Data were analysed using descriptive statistics, with outcomes assessed at 5 time points (baseline, 6 weeks, 3, 6, and 12 months). Summaries distributions of continuous baseline variables are presented as means and standard deviations. Categorical variables are presented as frequencies and percentages. Analyses were conducted using SPSS v22. A student t-test was used. All statistical tests were 2-tailed, and a *p*-value of <0.05 was considered statistically significant.

Results

Between May 2021 and January 2022, 32 participants were enrolled. Two were lost to follow-up (aged 55 – 70 years), two withdrew (aged 70 – 80 years), and 28 participants were included in the final analyses.

Table 1 Baseline characteristics

Characteristics	Total (n = 32)
Age, mean (SD) years	60 (10.7)
Gender (Male/Female) %	14 (43.8%)/ 18 (56.3%)
Language spoken at home, n (%)	
English	30 (93.7%)
Other	2 (6.25%)
Length of smartphone ownership, mean (SD) years	9.4 (5.4)
Highest Level of education, n (%)	
Postgraduate degree	2 (6.3%)
Bachelor's degree	8 (25.0%)
TAFE qualifications	9 (28.1%)
Secondary school	10 (31.3%)
Primary school	0 (0.0%)
Did not attend	0 (0.0%)
Prefer not to say	3 (9.4%)
AF-related knowledge (JAKQ) at baseline, mean (SD)	60.7 (13.1)
AF-related quality of life (AFEQT) at baseline, mean (SD)	53.2 (21.9)

Table 1 shows the baseline demographics, AF-related knowledge, and quality of life measurements of the 32 participants. The mean age was 60 years (32–79 years), with 56% female. Most participants spoke English at home (*n* = 30; 94%). Only two participants spoke another language at home i.e., Urdu and Hindi. The mean length of smartphone ownership was 9.4 years. One quarter (26.3%) has a bachelor’s degree or higher. AF-related knowledge was above average at baseline represented by the mean JAKQ score of 61.8 (13.1). The mean AFEQT score was 53.7 (22.4) at baseline suggesting moderate disability.

Effect on AF-related knowledge

The JAKQ scores significantly increased at 6 weeks (62% pre vs 71% post; *p* < 0.001), 3 months (73% post; *p* = 0.003), 6 months (73% post; *p* < 0.001) and 12 months (73% post; *p* < 0.001). Refer to Table 2 for change in scores for all time points.

Overall proficiency in each domain based on % of correct responses was 75.66% at the initial attempt and 94.18% at the current attempt. Participants were the most proficient in questions about lifestyle (96.7%) and medication (93.5%) changes, AF complications (90.30%), AF risk factors, and exacerbations (78%) at the initial attempt. Knowledge improvements were the greatest in the symptom recognition (71.43%), and when to seek assistance (96.7%) domains. One hundred percent proficiency was able to be achieved in the



**Table 2** Change in AF-related knowledge and quality of life scores for all time points

Outcomes	Difference in scores from baseline	p-value
JAKQ (n = 28)		
6 weeks	9.4	< 0.001*
3 months	11	0.003*
6 months	10.9	< 0.001*
12 months	11.1	< 0.001*
AFEQT (n = 28)		
6 weeks	15.2	0.003*
3 months	16	0.002*
6 months	12.7	0.006*
12 months	14.2	0.016*

Legend: JAKQ Jessa Atrial Fibrillation Knowledge Questionnaire, AFEQT Atrial Fibrillation Effect on Quality-of-Life Questionnaire  
\* Statistical significance

domains of lifestyle changes, AF, and medications and managing complications, further > 95% proficiency was achieved in the domains of risk factors and when to seek assistance. Proficiency in the domain of symptom recognition was able to be nearly doubled following the intervention (40% pre vs 77% post). Engagement in the program was 90.9%, referring to participants commencement of modules. The improvement trend line represents the percentage of improvement. See Fig. 3.

Effect on AF-related quality of life

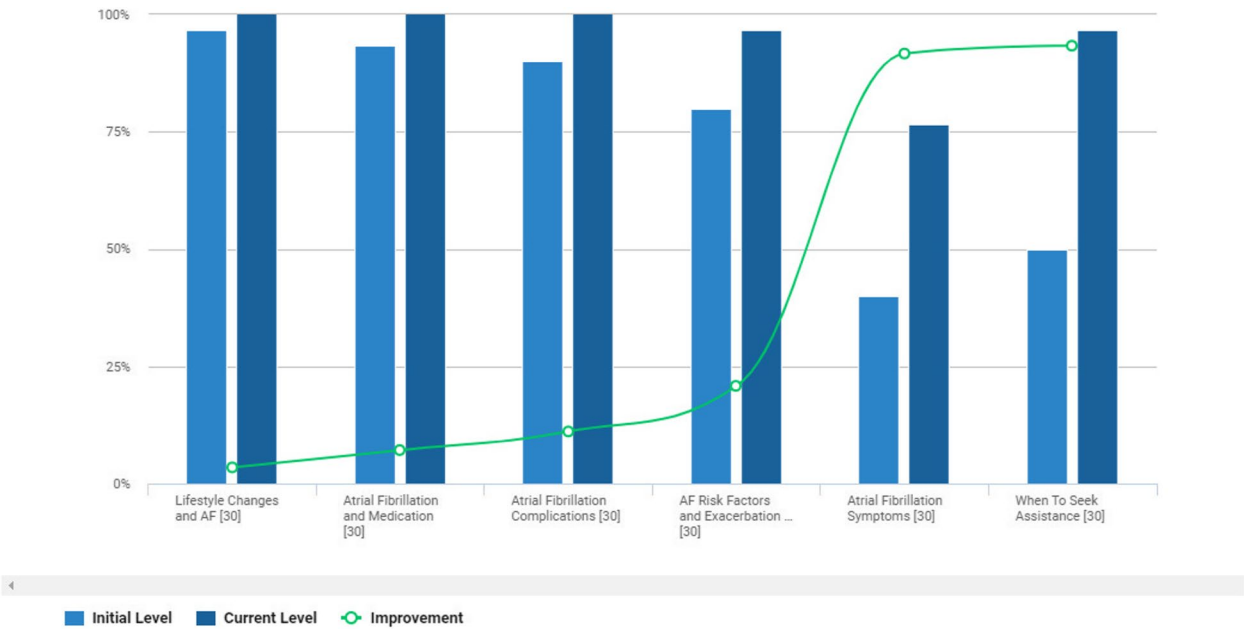
There were significant improvements to AFEQT scores at 6 weeks (54 pre and 69 post,  $p=0.003$ ), 3 months (70 post;  $p=0.002$ ), 6 months (66 post;  $p=0.006$ ), and 12 months (68 post;  $p=0.016$ ). Results have been previously graphically described in the published conference abstract available [10].

System usability

System usability was excellent (mean 84), demonstrating excellent app usability across domains including effectiveness (can users achieve their objectiveness), efficacy (how much effort and resource is expended to achieve those objectives) and satisfaction (was the experience satisfactory).

Discussion

This pilot INFORM-AF study demonstrated the efficacy of a digital education programme that aimed to improve patient knowledge and AF-related quality of life. This pilot study demonstrates the potential clinical impact as seen in the significant improvements to AF quality of life and knowledge which were achieved at six weeks and sustained over 12 months of follow-up. The greatest gains in knowledge improvements were seen in the domains of risk factors, symptom recognition and when to seek assistance. Whilst our results are drawn from a small sample, this pilot study demonstrates good intervention usability, with measurable improvements in AF-related knowledge and AF-related



**Fig. 3** Proficiency by topic area. Legend: [30] refers to 30 participants, including those lost to follow-up

quality of life. These results are similar to other studies. There is a growing body of evidence, such as the 'ASK FOR IT' and mAF App trials, that shows enhancing patient education and patient involvement strategies can improve important clinical outcomes such as quality of life and drug adherence and decrease anxiety and depression [21, 22].

Studies to date have shown that structured education approaches improve the health of patients and decrease healthcare utilisation. Vinereanu and colleagues of the IMPACT-AF trial demonstrated that a multi-faceted, complex intervention increased the proportion of patients treated with oral anticoagulation [23]. This complex intervention was targeted at patients and clinicians including education, regular monitoring, and feedback via the use of educational brochures, web and video resources, and patient-provider engagement. Oral anticoagulant use increased in the intervention group from 68% (804 of 1184 patients) at baseline to 80% (943 of 1184 patients) at 1 year (difference 12%), whereas in the control group it increased from 64% (703 of 1092 patients) at baseline to 67% (732 of 1092 patients) at 1 year (difference 3%). Kaplan–Meier estimates showed a reduction in the secondary outcome of stroke in the intervention versus control groups (HR 0.48, 95% CI 0.23–0.99; log-rank  $p$  value = 0.0434) [23]. More recently, the home-based, personalised HELP-AF study reduced total unplanned hospitalisations by 26% (IRR 0.74; 95% CI 0.62–0.89;  $p$  = 0.001) when compared with standard care [24]. INFORM-AF differs to these other trials as it is uniquely delivered by a QStream digital platform which uses an evidence-based pedagogical approach to enhance both knowledge acquisition and retention [7]. The QStream™ platform is considered the most effective microlearning in businesses through it individualized learning approaches. The INFORM-AF pilot has demonstrated the value of increasing knowledge in health care, and the potential to achieve behaviour change and improve clinical outcomes.

There is an emerging body of evidence describing the effects of microlearning that are aligned with significant improvements in biomarkers. In a recent randomised controlled trial of 456 patients with type 2 diabetes, patients using QStream™ were presented with multiple-choice questions related to diabetes management, exercise, long-term diabetes complications, medication adherence, and nutrition as well as detailed explanations for the answers, a 'take-home message' and evidence-based patient resources via smartphone. HbA1c levels were evaluated at enrolment, 6 and 12 months after the QStream™ challenge. Patients who had the highest HbA1c levels before the QStream™ intervention (9% or more – an indication of high blood glucose and greater

risk of diabetes complications) saw the most dramatic drops in HbA1c over the 12 months [25].

### Strengths and limitations

The mean age of participants in INFORM-AF were generally young (mean 60 years), however this aligns with other AF studies (ASK FOR IT, mean 65 yrs, mAF trial 67 yrs, IMPACT-AF, 70 yrs) [21–23]. Yet, it is well-established that it is a condition with risk associated with advanced aging. Therefore, in future studies, it is important to increase the representation of older adults in AF education trials. Whilst AF-related knowledge is an important factor in improving medication adherence and self-care behaviours, it is well-established that these concepts are multi-faceted, and that improved knowledge alone, will not achieve improved adherence or self-care behaviour. Other factors, such as incentivisation, intervention dose, intensity, timing, repetition, nudges, and targeting family caregivers could be helpful considerations in education provision.

This study was a pilot study with a 12-month follow-up and a relatively small sample size ( $n$  = 28) and were younger participants (mean age 60 years). Therefore, results should be interpreted with caution. There is limited generalisability and further, adequately powered, robustly designed clinical trials in the context of atrial fibrillation are needed. Whilst there has been a rise in the development and uptake of digital education programs delivered via mHealth, they often lack strong educational theoretical underpinnings or sophistication in functionality. Future educational programs must be robustly evaluated to determine their effect on patient and health system-related outcomes. Whilst the study was conducted during COVID-19 and recruitment was delayed due to lockdowns and restrictions on clinical research, this had no deleterious impacts on the research or outcomes beyond delay.

### Future directions

Given the intervention's good usability, we plan to further evaluate the INFORM-AF education program through a prospective, randomised (1:1), open-label, blinded-endpoint multisite clinical trial. Important clinical outcomes will be assessed, including emergency department visits, hospitalisation, and healthcare utilisation. Study results are expected to be reported in 2025. Findings are expected to inform future clinical practice guideline recommendations for AF patient education [26].

### Conclusion

The prevalence of AF is increasing, alongside emergency department visits, hospitalisations and associated costs. Improving patient education is critical to provide

fundamental information and inform self-management practices for people living with AF. The INFORM-AF, a digital education program, demonstrated good system usability, significant improvements in AF knowledge and quality of life at 12 months, and the potential to achieve behaviour change through patient education and thus improve clinical outcomes. The INFORM-AF education program will now be evaluated through a phase 1 randomised controlled trial on outcomes including emergency department visits, hospitalisation, and healthcare utilisation. Findings may be helpful to inform future models of integrated AF management.

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#### Authors' contributions

Conception and design of the work; CF, BB, LH. Data acquisition and analysis; CF, FS, AD, TW, KG, RW. Interpretation of data; CF, SA, FS, RW. Drafting and revision of manuscript; CF, FS, AD, TW, KG, SA, LH, BB, RW

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#### Data availability

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

#### Declarations

##### Ethics approval and consent to participate

Ethics approval was received from the Western Sydney Local Health District Human Research Ethics Committee (2021/ETH00122). The study was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12621000421831). Written informed consent to participate was obtained from all of the participants in the study.

##### Consent for publication

Written informed consent was obtained from the participants for publication of this article and any accompanying tables/images. A copy of the written consent is available for review by the Editor of this journal.

##### Competing interests

The authors declare no competing interests.

##### Author details

<sup>1</sup>University of Wollongong, Wollongong, NSW, Australia. <sup>2</sup>Blacktown Hospital, Western Sydney Local Health District, Blacktown, NSW, Australia. <sup>3</sup>Sutherland Hospital, Southeast Sydney Local Health District, Sutherland, NSW, Australia. <sup>4</sup>University of Newcastle, Newcastle, NSW, Australia. <sup>5</sup>Hunter Medical Research Institute, Newcastle, NSW, Australia. <sup>6</sup>Hunter New England Local Health District, Melbourne, NSW, Australia. <sup>7</sup>Royal Melbourne Hospital, Melbourne, VIC, Australia. <sup>8</sup>Centre for Chronic & Complex Care Research, School of Nursing, University of Wollongong, Wollongong, NSW, Australia.

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