

Risk factor management of atrial fibrillation using mHealth: The Atrial Fibrillation – Helping Address Care with Remote Technology (AF-HEART) Pilot Study



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BACKGROUND Personalized treatment of atrial fibrillation (AF) risk factors using mHealth and telehealth may improve patient outcomes.

OBJECTIVE The purpose of this study was to assess the feasibility of the Atrial Fibrillation Helping Address Care with Remote Technology (AF-HEART) intervention on the following patient outcomes: (1) heart rhythm tracking; (2) weight, alcohol, blood pressure (BP), and sleep apnea reduction; (3) AF symptom reduction; and (4) quality-of-life (QOL) improvement.

METHODS A total of 20 patients with AF undergoing antiarrhythmic therapy, cardioversion, and/or catheter ablation were enrolled and followed for 6 months. The AF-HEART intervention included remote heart rhythm, weight, and BP tracking; televisits with a dietician focusing on AF risk factors; and referrals for sleep apnea and hypertension treatment.

RESULTS Patients transmitted a median of 181 rhythm recordings during the 6-month follow-up period. Patients lost an average of

3.5 kilograms at 6 months ($P = .005$). Patients had improved SF-12 scores ($P = .01$), AFSS score ($P = .01$), EQ-5D score ($P = .006$), and AFEQT Global Score ($P = .03$). There was significant correlation between weight loss and decrease in symptom severity ($r = -0.45$, $P = .05$), and between % weight loss and decrease in symptom severity ($r = -0.49$, $P = .03$).

CONCLUSION This study described the feasibility of the AF-HEART intervention for (1) consistent remote tracking of heart rhythm, weight, and BP; (2) achievement of weight loss; (3) reduction of symptoms; and (4) improvement in QOL. Expansion to a larger randomized study is planned.

KEYWORDS Atrial fibrillation; Risk factor management; Mobile health; Electrocardiogram; Obesity

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Introduction

Atrial fibrillation (AF) is a debilitating cardiac arrhythmia that affects an estimated 6 million Americans.^{1,2} AF is characterized by rapid, uncoordinated electrical activity of the atria and an irregular heartbeat rather than a regular contraction of the heart. Specifically, AF leads to symptoms including palpitations, shortness of breath, fatigue, and anxiety and is associated with worsened clinical outcomes including heart failure, stroke, and death.^{2–4} Additionally, AF contributes to diminished quality of life (QOL).^{3,5} Therapies widely

used in clinical practice to treat AF and its associated symptoms include antiarrhythmic therapy, cardioversion, and catheter ablation.^{3,6,7} In addition, researchers have demonstrated that the presence of coexisting AF risk factors such as increased weight, alcohol intake, sleep apnea, and hypertension significantly worsen clinical outcomes after therapy. Treatment of these risk factors also improves AF symptoms and outcomes, highlighting the need for improved risk factor management as part of overall care for AF patients.^{8–24}

Mobile health (mHealth) technology, which uses smartphones, watches, wearable and/or portable monitors, and health applications for patient care, has revolutionized health-care.^{25–27} The general public currently uses mHealth to monitor heart rate, heart rhythm, blood pressure, exercise, diet, alcohol intake, and sleep.^{28,29} Easy-to-use mHealth

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KEY FINDINGS

- In this pilot study of 20 patients, the authors describe the design of Atrial Fibrillation Helping Address Care with Remote Technology (AF-HEART), a multimodal intervention including heart rhythm tracking with Kardia, risk factor reduction of weight through telehealth visits, blood pressure monitoring, alcohol reduction, and sleep apnea reduction through referrals.
- Through the AF-HEART intervention, patients lost an average of 3.5 kilograms and recorded a median of 181 rhythm recordings.
- Using patient's own baseline as comparison, patients had significant improvement in symptoms related to atrial fibrillation and in quality of life.

technologies such as the Apple Watch are already widely integrated into the lives of U.S. adults, 59% of whom report using an mHealth device/application to monitor their health.^{30,31} Thus, mHealth can be harnessed to promote patient-driven cardiac risk reduction and symptom self-management, including those related to AF.^{32,33} This strategy therefore holds the promise to help improve outcomes in AF patients, including risk factor reduction, symptoms, and QOL.

While previous trials have focused on the individual AF risk factors of increased weight,^{8,24,34,35} alcohol use,^{18,19} sleep apnea,^{20,36} and hypertension,^{37–39} these risk factors often coexist and need to be managed concurrently.⁴⁰ By incorporating burgeoning technology of wristband and smart device electrocardiogram (ECG) technology, the Atrial Fibrillation Helping Address Care with Remote Technology (AF-HEART) study was a pilot study that assessed AF risk factor interventions on weight, alcohol use, sleep apnea, and hypertension, facilitated by mHealth and telehealth technology. This study assessed a combined risk factor mHealth-based intervention in a group of patients utilizing a rhythm-control strategy for AF management, with the goal to improve AF risk factors, symptoms, and QOL. Specifically, we hypothesized that the AF-HEART m-Health intervention would (1) be feasible, (2) improve risk factor-based outcomes including weight loss, (3) decrease AF-related symptom severity, and (4) improve QOL.

Methods/design

The AF-HEART study was a single-center pilot study designed to assess feasibility of risk factor management facilitated by mHealth and telehealth during rhythm control of AF. The study was conducted at Columbia University Irving Medical Center, whose Institutional Review Board approved this study (IRB-AAAR3990). Patients were identified from the Division of Cardiology and completed informed consent prior to enrollment. The research reported in this paper adhered to the Helsinki Declaration as revised in 2013.

STUDY INCLUSION (N=20)

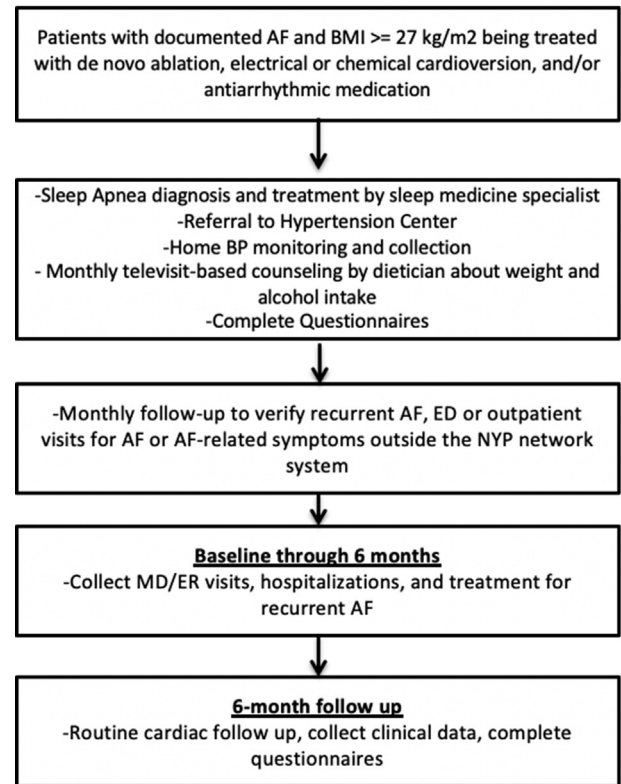


Figure 1 Study protocol for the AF-HEART (Atrial Fibrillation – Helping Address Care with Remote Technology) study. AF = atrial fibrillation; BMI = body mass index; BP = blood pressure; ED = emergency department; MD = doctor; NYP = New York-Presbyterian Hospital.

Enrollment criteria included men and women 18 years or older with documented nonvalvular AF and body mass index ≥ 27 kg/m² undergoing a rhythm control strategy for AF using catheter ablation, cardioversion, and/or membrane-active antiarrhythmic medication. AF was defined by the presence of symptomatic AF >30 seconds captured by standard 12-lead ECG, Holter monitor, or other cardiac rhythm monitoring device. Definitions of paroxysmal vs permanent AF were derived from the 2014 AHA/ACC/HRS guidelines.² Patients were excluded if they had complex congenital heart disease, left ventricular ejection fraction <40%, clinically significant pulmonary hypertension, or severe renal or hepatic disease. Baseline questionnaires were completed to assess perceptions of health, QOL, risk for sleep apnea, comfort with electronics, and alcohol use. Outcome assessments included the Berlin Questionnaire⁴¹; Short Form 12 (SF-12)^{42,43}; European Quality of Life Scale (EQ-5D)⁴⁴; Atrial Fibrillation Severity Scale (AFSS)^{45,46}; Atrial Fibrillation Effect on QualiTY-of-Life (AFEQT)⁴⁷; Alcohol Use Disorders Identification Test (AUDIT)^{48–51}; modified, multidimensional Health Locus of Control (HLC)^{52,53}; and a baseline comfort with electronics questionnaire developed for this trial (see [Supplemental Material](#) for details).

Table 1 Demographics of patients enrolled in AF-HEART pilot study at baseline

Age (years)	65.2 (SD: 8.2)		
Sex (male)	13 (65%)	Anticoagulants	19 (95%)
White	17 (89.5%)	Beta blockers	17 (89.5%)
African American	1 (5.3%)	Diuretics	8 (42.1%)
Hispanic	1 (5.3%)	CCB	7 (38.9%)
BMI (kg/m ²)	33.7 (SD: 6.3)	ACE/ARB	4 (25.0%)
CAD	2 (10.5%)	Aspirin	3 (16.7%)
TIA/stroke	1 (5.6%)	Baseline comfort with electronics	14 (73.7%)
CHADSVASC >1	16 (80%)	Ablation	11 (55%)
Diabetes	4 (21.1%)	Cardioversion	7 (35%)
Hypertension	17 (85%)	Antiarrhythmics	2 (10%)
Obesity (BMI ≥30 kg/m ²)	14 (70%)	Paroxysmal AF	7 (35%)
Smoking (previous)	3 (15.8%)	Persistent AF	13 (65%)
OSA (prior history)	4 (20%)	Berlin Questionnaire – high risk for sleep apnea	13 (68.4%)

ACE = angiotensin-converting enzyme; AF = atrial fibrillation; ARB = angiotensin receptor blocker; BMI = body mass index; CAD = coronary artery disease; CCB = calcium channel blocker; OSA = obstructive sleep apnea; TIA = transient ischemic attack.

AF-HEART intervention

The overarching premise of the AF-HEART intervention was to target multiple AF risk factors including weight and alcohol intake reduction, together with sleep apnea and hypertension management, facilitated by mHealth and telehealth, as shown in Figure 1. Regarding weight loss and alcohol intake, patients met individually with a dietician biweekly for 6 months for 30-minute sessions. The first 3 visits were conducted in person, and the remainder of the visits alternated between in-person and telehealth (American Well, Boston, MA). The dietician provided a personalized plan to each patient for weight loss and reduction of alcohol intake that included verbal and written nutrition education, motivational interviewing, and American Heart Association–approved information sheets explaining the relationship of AF to weight and alcohol. Energy requirements for weight loss were calculated using the Mifflin–St. Jeor equation to create a 500–700 kcal/day energy deficit. Patients recorded daily weights with the BodyTrace scale (BodyTrace, Inc, Palo Alto, CA). Regarding sleep apnea, if the screening Berlin Questionnaire was positive, patients received referrals to see a sleep specialist, with treatment options including continuous positive airway pressure (CPAP), dental appliances, and repositioning device (at the discretion of the consulting sleep specialist). Patients with blood pressure ≥130/90 mm Hg were offered a referral to the Columbia University Irving Medical Center Hypertension Center, specializing in accurate blood pressure management. Patients were provided a home monitor, Omron Evolve 7000 (Omron Healthcare, Inc, Lake Forest, IL), to record blood pressure on a daily basis. Both the BodyTrace and Omron Evolve 7000 synced with the Kardia application. Altogether, the platforms used were Kardia platform for rhythm monitoring, American Well for telehealth, Omron Evolve 7000 for blood pressure, and BodyTrace for weight. At the end of 6 months, patients completed SF-12, EQ-5D, AFEQT, AFSS, AUDIT, and HLC questionnaires. The staff included up to a ½ full-time

equivalent total, including a research assistant, dietician, and nurse practitioner.

mHealth monitoring

Patients monitored their AF with the KardiaBand wristband connected to the Apple Watch (Apple, Cupertino, CA) or KardiaMobile device (AliveCor, Mountain View, CA). The KardiaBand device functions by using 1 electrode on the back of the watch face and tapping the opposite thumb on another electrode on the wristband, thereby recording a cardiac rhythm, while the KardiaMobile device requires placement of fingers from both hands on 2 electrodes that can wirelessly sync to a smartphone. Both devices had the capacity to record symptoms in addition to rhythm. Patients were asked to record an ECG once per day and when experiencing symptoms. All participants received training on how to use the KardiaBand or KardiaMobile at enrollment. All ECG recordings and symptoms were sent via a HIPAA-compliant network to the patients' providers via the KardiaPro platform. The patients' clinical care team logged onto the password-protected database to access, review, and interpret ECGs and incorporate ECG records into their treatment plans, as deemed clinically necessary.

Statistical analysis

All demographic data and clinical outcomes were reported as frequencies and percentages or as mean and standard deviation (SD). Paired *t* tests and Bowker's tests were used to compare difference in clinical outcomes and surveys from baseline to 6 months for continuous and categorical data, respectively. The Kolmogorov-Smirnov test was used to assess normality. When data were not normally distributed, a Wilcoxon signed rank test was used to assess the difference between the 2 time points. If a patient did not have a 6-month data point, the last observation was used. Analyses were performed using SAS 9.4 (SAS Institute, Cary, NC). A 2-tailed *P* value of ≤.05 was used to determine significance for all analyses.

Table 2 Clinical outcomes of patients who completed AF-HEART intervention at 6 months including weight loss, blood pressure, alcohol use, clinical outcomes, and arrhythmias

		<i>P</i> value
Weight loss (kg)		
Weight - baseline	102.2 (SD: 21.2)	<i>P</i> = .005
Weight - 6 months	98.7 (SD: 19.8)	
Percent weight loss (%)	3.3 (SD: 4.4)	
Blood pressure (mm Hg)		
Systolic BP - baseline	124.6 (SD: 12.5)	<i>P</i> = .31
Systolic BP - 6 months	126.1 (SD: 12.2)	
Diastolic BP - baseline	76.1 (SD: 9.0)	<i>P</i> = .58
Diastolic BP - 6 months	77.5 (SD: 8.6)	
Alcohol use (AUDIT scale)		
Risky drinking - baseline	6 (31.6%)	<i>P</i> = .32
Risky drinking - 6 months	4 (22.2%)	
OSA (total)	6 (30%)	
Treatment with CPAP	4 (20%)	
New diagnoses OSA	2 (10%)	
Cardioversions	5 (31.3%)	
Ablations	1 (5.9%)	
Hospitalizations	2 (15.4%)	
AF related visits	1 (5%)	
Stroke / TIA	0 (0%)	
New antiarrhythmic	1 (5.9%)	
New beta blocker or calcium channel blocker	1 (5.3%)	
Total ECG recordings (median)	181	
Total time recorded from first recording to last recording (median days)	174	
Percent readings in atrial fibrillation	16.6% (SD: 27.8)	
Time to atrial fibrillation (median days)	9	

AF = atrial fibrillation; BP = blood pressure; CPAP = continuous positive airway pressure; ECG = electrocardiogram; OSA = obstructive sleep apnea; TIA = transient ischemic attack.

Results

Demographics

Twenty patients were enrolled in the AF-HEART pilot study; demographic and clinical data are listed in Table 1. The average age was 65.2 years (SD: 8.2); 13 patients (65%) were men. Overall, the average body mass index was 33.7 kg/m² (SD: 6.3). A total of 17 patients (85%) had a history of hypertension, and 4 patients (20%) had a history of obstructive sleep apnea (OSA). Patients recorded and downloaded a median of 181 heart rhythm recordings, for an average of 1 recording per day, median of 1.1 recording, and standard deviation of 0.6 recordings, for the requested 1 recording, with an additional recording if symptomatic. An average of 16.6% (SD: 27.8%) recordings were in AF. Baseline comfort with electronics was 73.7%. Of interventions to maintain sinus rhythm, 11 patients (55%) underwent catheter ablation, 7 patients (35%) underwent electrical cardioversion, and 2 (10%) were managed with antiarrhythmic medications.

AF risk factor outcomes

Clinical outcomes after the AF-HEART intervention are listed in Table 2. Over the 6-month follow-up period, patients lost an average of 3.5 kg (*P* = .005). The average percentage of body weight lost was 3.3% (SD: 4.4%), with 8 patients

(40%) losing more than 5% total body weight. There was an average of 9.7 (SD: 4.1) total dietician visits, with 4.6 (SD: 2.4) in-person visits and 5.1 (SD: 2.8) televisits per patient. There was no significant correlation between in-person dietician visits and weight loss (*P* = .82). Of note, 2 patients who gained 5.1 kg and 3.3 kg were lost to follow-up by the dietician after no visits and 1 visit, though they completed other components of the AF-HEART intervention.

Systolic and diastolic blood pressure averaged 125/76 mm Hg, without any significant changes from baseline to 6 months for either systolic (*P* = .31) or diastolic (*P* = .58) blood pressure. Two of 6 patients (33%) whose alcohol use was classified as risky at baseline, as measured by the AUDIT score, improved to low-risk use at 6 months. There were 2 additional patients (10%) diagnosed with OSA, and 4 of the 6 total patients (67%) with OSA adhered to CPAP. During the follow-up period, 5 patients (31.3%) required a cardioversion and 1 patient (5.9%) required an ablation. Patients recorded a median of 181 recordings, with 16.6% of readings (SD 27.8%) in AF.

AF symptoms

Baseline and 6-month follow-up questionnaires are available in Table 3. The physical component of the SF-12 showed improvement from baseline to 6 months (*P* = .01), while the mental component did not show significant difference

Table 3 Symptom and quality-of-life questionnaires comparing baseline to 6 months for patients who completed the AF-HEART intervention

Survey	Baseline	6 months	P value
SF-12 Physical	45.7 (SD: 9.1)	50.1 (SD: 7.9)	.01
SF-12 Mental	51.9 (SD: 7.5)	54.3 (SD: 5.0)	.19
EQ-5D Health state (Scale 0 - 100)	77.3 (SD: 14.2)	82.1 (SD: 9.2)	<.01
AFSS total severity score	15.3 (SD: 6.6)	11.1 (SD: 6.5)	.01
AFEQT global score	66.3 (SD: 21.9)	84.5 (SD: 13.3)	<.01
HLC - external	21.8 (SD: 3.8)	20.7 (SD: 5.3)	.45
HLC - chance	15.4 (SD: 4.0)	15.3 (SD: 4.5)	.91
HLC - internal	26.1 (SD: 4.5)	23.3 (SD: 6.6)	.13
AUDIT (risky drinking)	6 (31.6%)	4 (22.2%)	.16

($P = .19$). The decrease in AFSS total symptom severity score demonstrated significant improvement ($P = .01$), with specific improvements in shortness of breath during exercise ($P = .003$), exercise intolerance ($P = .006$), and fatigue at rest ($P = .04$). There were significant correlations between maximum weight loss and decrease in symptom severity score ($r = -0.45$, $P = .05$), as well as between % weight loss and decrease in symptom severity score ($r = -0.49$, $P = .03$). There was no significant correlation between total AF burden and AFSS total severity score ($P = .55$).

Quality of life

Patients demonstrated improved overall health state on the EQ-5D from baseline to 6 months ($P = .006$). Meanwhile, the increase in AFEQT global score showed better QOL ($P = .003$), with specific improvements for symptoms ($P = .04$), daily activities ($P = .002$), and treatment concerns ($P = .03$). There was no significant difference in modified HLC.

Discussion

The AF-HEART intervention pilot study demonstrated the feasibility of multimodal mHealth and telehealth risk reduction intervention facilitated by remote technology in a captive group of patients with AF undergoing a rhythm-control strategy. Patients sustained engagement with recording their heart rhythm (median of 181 days), daily weight and BP measurements, televisit-based dietitian meetings, and hypertension and sleep center referrals. Over the course of 6 months, patients lost an average 3.5 kg (3.3% total body weight), and patients reported significant improvement in both symptoms and QOL. Compared to previous studies, this pilot study incorporated multiple risk factor reduction facilitated by mHealth and telehealth technology, including heart rhythm, weight, and blood pressure monitoring and virtual dietitian visits, to facilitate care and assess outcomes in patients with AF.

Previous trials have focused on risk factor reduction and improved outcomes in AF patients. For example, weight loss with meal replacements in patients with AF (with or without ablation) has been shown to improve AF symptoms and cardiac remodeling in a randomized clinical trial by Abed and colleagues.²⁴ When targeting multiple risk factors in addition to weight loss, including blood pressure, lipid

management, glycemic control, sleep-disordered breathing, smoking, and alcohol, Pathak and colleagues²² were able to demonstrate improvement across a wide variety of cardiac risk factors, AF recurrence, frequency, and symptoms in the ARREST-AF Cohort Study. Pathak and colleagues²³ continued this work in the LEGACY cohort study, showing that weight fluctuation and loss can affect AF recurrence. A randomized trial regarding alcohol consumption in New Zealand showed decreased recurrence of AF when abstaining from alcohol for patients who drank greater than 10 standardized drinks per week.⁵⁴ A meta-analysis examining AF outcomes after antihypertensive agents concluded a modest decrease in AF that was most pronounced in heart failure patients.³⁸ Additionally, studies have shown that treating OSA with CPAP ameliorates any effect OSA has on AF recurrence.²⁰

Mobile health is increasingly used in clinical practice and is ideal for patients with AF to monitor their risk factors and rhythm actively. Mobile health can promote more efficient and timely detection and treatment of AF and risk factors through improved self-management and lifestyle-based interventions. Specifically, our previous study, the iHEART trial, analyzed the use of daily ECG recordings and showed increased detection of recurrence in patients who used daily records in patients after ablation or cardioversion.⁵⁵ iHEART used a strategy of once-daily recordings for detection of AF as feedback to catalyze patient empowerment with risk factor management. The potential application of mHealth-based strategies such as the AF-HEART pilot trial extends to using this intervention across geographic distances that traditionally serve as barriers to care, thereby modifying and improving traditional AF risk factors including weight loss, while also improving AF-related symptoms and QOL parameters. Another review demonstrated improved patient knowledge of AF, adherence to medications, and QOL for patients who used mHealth in AF.⁵⁶ Therefore, addressing AF risk factors, symptoms, and QOL via mHealth and telehealth utilization, in conjunction with a rhythm-control strategy, promises to help improve the overall morbidity of AF disease, including symptoms as well as even mortality.⁵⁷

Limitations

While this study was designed for feasibility, its limitations include its relatively small sample size, single-center design,

follow-up time period of 6 months, and lack of randomized control population. Moreover, although the questionnaires are designed to detect differences in symptoms and QOL related to AF, it is possible that ameliorating risk factors improves symptoms and QOL independent of AF. A larger randomized trial is required to assess the significance of the AF-HEART intervention on outcomes in AF patients.

Conclusion

The AF-HEART intervention proved feasible in integrating risk factor management and mHealth in patient care after interventions to maintain sinus rhythm in AF patients in a pilot study of 20 patients. Additionally, preliminary results from this pilot have demonstrated weight loss, amelioration of symptoms, and improvement in QOL. We believe that this study serves to support the need for a larger randomized study that will provide further evidence for integration of risk reduction facilitated by mHealth into both AF patients' lives and clinic workflow, thereby improving outcomes for a common disease with significant morbidity.

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Disclosures

EW has received teaching fees from Medtronic and Boston Scientific. JK has served as a scientific advisory board member for GI Dynamics, and as a consultant for Digma Medical and Found Health. AB is a medical advisory board member for Boston Scientific.

Authorship

All authors attest they meet the current ICMJE criteria for authorship.

Patient Consent

All participants provided written consent for the study.

Ethics Statement

The Columbia University Medical Center Institutional Review Board approved the study (IRB-AAAR3990). All data collection was carried out in accordance with the Health Information Portability and Accountability Act regulations.

Appendix

Supplementary data

Supplementary data associated with this article can be found in the online version at <https://doi.org/10.1016/j.cvdhj.2021.11.003>.

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