HHS Public Access

Author manuscript

Int J Cardiol. Author manuscript; available in PMC 2026 March 10.

Published in final edited form as:

Int J Cardiol. 2025 November 01; 438: 133575. doi:10.1016/j.ijcard.2025.133575.

The mobile health intervention for rural patients with atrial fibrillation a randomized controlled trial

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Abstract

Background: Rural individuals with atrial fibrillation (AF) experience challenges to anticoagulation adherence and self-management of the condition. We tested an intervention to improve anticoagulation adherence, quality of life, and health care utilization in rural individuals with AF.

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[1]This author takes responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation

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Trial registration

https://clinicaltrials.gov/study/NCT04076020

Declaration of competing interest

None.

Methods: We randomized rural patients with AF receiving anticoagulation to receive a smartphone-based relational agent (for disease education and adherence guidance) and a heart rate and rhythm monitor for 4 months or a smartphone-based health education app. Adherence was determined with 12-month proportion of days covered (PDC), and secondary outcomes of quality of life and health care utilization from interviews and health records.

Results: The trial randomized 270 individuals 1:1 (median [IQR] age 73.1 [67.5–78.6]; 163 [60.4 %] female sex). Over the 4-month intervention, intervention participants used the relational agent a median of 101 (IQR: 72, 110) days. In an intention-to-treat analysis there was no significant difference in 12-month PDC between the intervention and control groups (median [IQR]: intervention 0.97 [0.89–1.00] versus control 0.97 [0.92–1.00]) or in PDC ≥0.80. Intervention participants were more likely to self-report anticoagulation adherence than control at 4 and 8 months (95.7 % vs 88.4 % and 93.0 % vs 78.8 %, respectively) but not at 12 months. There were no significant differences by assigned intervention for the other secondary outcomes.

Conclusions: Randomization to the relational agent intervention was not associated with improved PDC at 12-months but with greater interim self-reported adherence compared to a control. This study demonstrates the successful use of a smartphone-based agent to address adherence among rural individuals with AF.

Keywords

Atrial fibrillation; Digital health; Rurality; Self-management; Health literacy

1. Introduction

Atrial fibrillation (AF) is associated with clinical adversity, poor quality of life, and health care utilization. [1] Patients experience AF as a challenging disease: it has an uncertain prognosis; requires daily adherence to anticoagulation for thromboembolic stroke prevention; monitoring for symptoms; and adequate health literacy for self-care and partnership with clinical providers. [2] Social and structural factors contribute to patients' experience of AF, as individual- and neighborhood-level factors are associated with clinical adversity and access to specialized care. [3] Health literacy is particularly relevant because of the specialized terminology and importance of adherence. [4–6] Rural individuals may experience additional health-related disparities due to geographic distance to care, decreased health-related resources, and other social determinants. [7]

We developed a mobile health application, termed a relational agent, for individuals with AF in rural, Western Pennsylvania. [8] The relational agent is an interactive health coach accessible to individuals with limited literacy to provide education, reinforce and guide self-care, and address barriers to medication adherence.

Guided by pilot data that demonstrated acceptability and utility of the relational agent, [9] we coupled the agent with a smartphone-based heart rate and rhythm monitor and conducted a randomized controlled trial (RCT) of a 4-month intervention. The trial's primary outcome was the effect of the smartphone-based relational agent and heart monitor intervention on anticoagulation adherence, measured by pharmacy records and self-report. Secondary

outcomes were the effect of the intervention on disease-specific and general health-related quality of life and hospitalization events.

2. Methods

2.1. Study design

We conducted the Mobile Health Intervention for Rural AF as a parallel-arm RCT for adults living in Western Pennsylvania enrolled in a regional health care system (NCT04076020). All study participants provided written informed consent and the study protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki with approval by the University of Pittsburgh Institutional Review Board. The study additionally adhered to the Consolidated Standards of Reporting Trials (CONSORT) reporting guideline. The data that support the findings of this study are available from the corresponding author upon reasonable request.

2.2. Study participants

This trial enrolled individuals age ≥ 18 years who met the following inclusion criteria: (1) a diagnosis of AF documented in the electronic health record; (2) prescription of anticoagulation with the primary indication being thromboembolic stroke prevention; (3) residence in a rural municipality determined by the Rural Health Information Hub's "Am I Rural?" geolocation service using U.S. Census demographics; (4) English-speaking adequate for study participation; and (5) no plan to relocate within 12 months. We excluded individuals receiving anticoagulation for a reason other than AF, had undergone procedural treatment for AF (such as a pulmonary vein isolation), been hospitalized within 3 months of randomization for cardiovascular disease (acute coronary syndrome, heart failure, cardiothoracic surgery), had a comorbid condition with likelihood of mortality within 12-months, or had planned cardiac surgery, pacemaker, or defibrillator implantation.

2.3. Recruitment and randomization

Study enrollment occurred from December 19, 2019, through March 9, 2022, at 16 rural clinic sites affiliated with a regional health care system. With the start of COVID in March 2020, the study adopted a remote recruitment strategy. Recruitment occurred by identification of potfential participants via review of patient rosters with providers either on-site prior to COVID or remotely. Potential participants were introduced to the study team by providers or sent a study brochure and letter signed by the provider followed by up to three telephone calls. Those amenable to participation underwent eligibility screening and a 6-item cognitive screen. [10] Individuals scoring ≤3 on the cognitive screen were deemed ineligible given the expectation that study procedures may be challenging. Eligible individuals underwent informed consent and the baseline visit. Participants received compensation up to $150 for participation.

Participants were randomized 1:1 to intervention or control using permuted block randomization. Randomization was stratified by type of oral anticoagulant (warfarin or direct-acting oral anticoagulant [DOAC]) given differences in monitoring and incidence of bleeding between these classes of agents. Investigators were blinded to study arm while research staff and study participants were not.

2.4. Interventions

Participants in both arms were provided a study smartphone with study applications pre-installed. The study team did not presume familiarity or experience with smartphones and provided individualized training on their use and a booklet for operation and trouble-shooting specific to the study arm. *Intervention participant* smartphones had the relational agent and application for the KardiaMobile heart rate and rhythm monitor (https://www.kardia.com) installed and received the monitoring device.

The relational agent, shown in Fig. 1, is a digital health application that simulates face-to-face health counseling, using synthetic speech and synchronized conversational behavior (gestures, head nods, gaze shifts), to deliver accessible, patient-facing content for health education and counseling. In this application, agent dialogue content and curriculum were informed by consultations with patients, pilot testing, and professional society guidelines. Content was further guided by our prior interventions using relational agents to address medication adherence, quality of life, and chronic disease self-management in cardiovascular disease. [9,11,12] We selected a relational agent for our intervention because of its capacity to address intentional and non-intentional barriers to adherence. Further the agent provided education about AF and counseling and problem-solving pertinent to symptom monitoring, communication with health care providers, preparation for a clinical encounter, and longitudinal use of heart rate and rhythm monitoring for AF self-care. [13–20]

The KardiaMobile is a validated device for single-lead electrocardiographic tracing to measure heart rate and rhythm widely used for AF detection. [21] Tracings were set to record for 30 s and uploaded to a secure server followed by study team interpretation and results placed on a web-based dashboard. Inter-reader interpretation of tracing results exceeded 95 %.

Control participants received a smartphone with a general health application (WebMD, https://www.webmd.com) to improve health-related knowledge and material developed by the American Heart Association about anticoagulation and AF.

Intervention participants were instructed to use the relational agent application daily for the 4-month intervention period and the KardiaMobile as frequently as they would like and particularly when they experienced symptoms of AF. Control participants were instructed to use the general health application as often as they would like. The study tracked use of the relational agent and KardiaMobile, while use of the control arm application (WebMD) was not tracked. To support older adults with limited smartphone experience, participants were contacted by phone at days 7, 14, 30, and 60 to inquire about problems they had with smartphone use. At 120 days, participants received a postage-paid container to return the study smartphone. Intervention participants were invited to keep the KardiaMobile but were informed that the study team would no longer track results.

2.5. Study outcomes

The primary outcome was adherence to anticoagulation as measured by proportion of days covered (PDC) [22] determined by pharmacy records of prescription fills for oral

anticoagulation over 12 months. PDC is an objective measure of adherence analyzed as a continuous variable ranging from 0 to 1 with higher values indicating superior adherence and as a categorical variable where high PDC was defined using a cut point of ≥0.80. [23] Non-adherence to oral anticoagulation was also measured using a 3-item, validated instrument with a score ranging 1 (“Strongly disagree”) to 5 (“Strongly agree”) asking participants if they took all medication doses, missed or skipped at least one dose, or were not able to take their medication. [24] Since anticoagulation requires uniform adherence, participants who scored <5 on the first item (anything but strong agreement) or > 1 on the other items were categorized as non-adherent.

Secondary outcomes were: (1) Atrial Fibrillation Effect on Quality of Life (AFEQT) a health-related quality of life measure specific to AF and the Patient-Reported Outcomes Measurement Information System (PROMIS)-29 [25,26] a general quality of life measure; (2) Health care utilization, ascertained by both self-report and review of the regional health care system’s longitudinal electronic health record. The study team sought records for events reported by participants as occurring outside of our health care system. Health care utilization was summarized as counts of number of hospitalizations, emergency room visits, and treatments for AF (summarized as cardiac device implantation, electrical or pharmacologic cardioversion, and any electrophysiologic procedure for AF).

2.6. Study assessments

Baseline assessments entailed: (1) demographics (age, sex, race, ethnicity); (2) social factors (annual household income, educational attainment, cohabitation with partner); (3) habits (tobacco and alcohol use); (4) AF treatment with pharmacologic or electrical cardioversion; (5) health literacy, measured by the Newest Vital Sign [27]; (6) quality of life assessment with the AFEQT [25] and PROMIS-29 [26]; and (7) 3-item self-reported adherence to oral anticoagulation. [24]

Participants had assessments at 4-, 8-, and 12-months that included: (1) PROMIS Self-Efficacy, (2) AFEQT and PROMIS-29; (3) self-reported adherence; and (4) health care utilization. The 14 participants enrolled prior to COVID underwent the baseline assessment in-person. Thereafter materials were mailed to participants to assist with their completion and measures were assessed by telephone.

2.7. Statistical analysis

Analyses were based on the intention-to-treat principle. Differences in 12-month PDC between the trial arms were assessed with linear regression for the continuous PDC outcome and with logistic regression for the dichotomous PDC variable. Follow-up measures of self-reported adherence and secondary outcomes were analyzed longitudinally using generalized estimating equation or linear mixed effect models. Outcomes were assessed at each timepoint by assigned intervention, and the interaction between assigned intervention and study visit was tested to assess sustainability of the intervention effect. All models were adjusted for the stratification factor in the trial (anticoagulation therapy at baseline). Education, partnership status, and smoking were not balanced by arm and included as covariates for multivariable adjustment.

Accounting for 10 % attrition over 12 months, we determined that a sample size of 119 per study arm would enable detection of a minimum difference in PDC of 11.7 % with 85 % power assuming a standard deviation of 30 % and use of a 2-sided test with 0.05 significance level. We aimed to enroll 264 participants (132 per arm). We pre-specified secondary analyses stratified by type of anticoagulant (warfarin or DOAC) since routine monitoring in those using warfarin could reinforce medication adherence. Study data were collected and managed using REDCap electronic data capture tools. [28,29] Analyses were completed using SAS 9.4 (SAS Institute, Inc.).

3. Results

3.1. Patient characteristics

Supplementary Fig. 1 presents the CONSORT diagram for the trial. The study staff reviewed electronic health records for 2106 individuals and 416 had additional screening. Of those, 276 were eligible and consented to participate from January 2020 through March 2022 with 14 participants enrolled prior to March 2020. In total, 270 participants (median age, 73.1; 60.4 % female and 95.2 % white race) were randomized and included in the intention-to-treat analysis with 135 in each study arm. In this rural cohort, 47.4 % had a high school education, and health literacy was limited in 46.3 % participants and adequate in 53.7 %. The baseline characteristics by assigned intervention are provided in Table 1.

Following randomization, 14 intervention participants and 13 control participants withdrew, died, or were lost to follow-up by the 4-month study visit. An additional 4 intervention participants and 1 control participant withdrew, missed the visit, or died by the 8-month visit, and 2 control participants were lost by the 12-month visit as described by the CONSORT diagram. Individuals randomized to the relational agent intervention used it a median 101 (IQR: 72, 110) days during the 120-day intervention phase.

3.2. Anticoagulation adherence outcomes

Prescription Days Covered: The median (IQR) PDC over 12 months was 0.97 (0.89–1.00) in the intervention and 0.97 (0.92–1.00) in the control group, and 105 (84.7 %) intervention participants had high (≥0.80) PDC compared to 115 (91.3 %) control participants. These differences were not statistically significant.

Adjusting for stratification and other baseline covariates, PDC ≥80 % did not differ significantly between the intervention and control groups (OR: 0.59 [95 % CI 0.25, 1.35]).

Self-reported adherence: In unadjusted analyses, self-reported adherence was significantly higher in the intervention group at 4- and 8-months, (intervention vs. control: at 4-month:112 [95.7 %] vs, 107 [88.4 %], and at 8 months:106 [93.0 %] vs. 93 [78.8 %]), but not at 12 months as shown in Fig. 2. Analyzing self-reported adherence over time, the odds of self-reported adherence to anti-coagulants was 1.9-fold greater in the intervention compared with the control group (OR 95 % CI: 1.89 [1.16, 3.08]) adjusting for study visit, stratification factors, and education, partnership status, and smoking. In the multivariable-adjusted model, differences between the two groups were statistically significant at 4 and 8

months but not at 12 months; the interaction between study visit and assigned intervention was not statistically significant ($p = 0.11$). (Table 2).

3.3. Secondary outcomes

There were no statistically significant differences between intervention and control arms in the disease-specific quality of life (AFEQT) overall and specific domains across study visits (Supplementary Table 1). Results were similar using longitudinal linear mixed effect models. The interaction between study visit and intervention group was not significant in these models. PROMIS-29 scores were not different by assigned intervention across visits (Supplementary Table 2) or using adjusted linear mixed models (Supplementary Table 3).

Supplementary Table 4 summarizes health care utilization over the 12-month trial. Trial participants had an equivalent number of ambulatory visits (133, intervention, versus 127, control) but intervention participants had a higher number of telemedicine visits (43) compared to control (27) arm participants. Over the course of the 12-month follow-up, 43 (31.9 %) intervention and 43 (31.9 %) control arm participants had ≥1 emergency room visits with 9 (6.7 %) of intervention visits being for AF compared to 5 (3.7 %) of control arm participant emergency room visits. Regarding all-cause hospitalization, there were 36 (26.7 %) intervention and 32 (23.7 %) control arm hospitalization events. In total, 20 (14.8 %) intervention arm participants underwent a procedure relevant to AF with 9 (6.7 %) ablations compared to 10 (7.4 %) control arm participants with 5 (3.7 %) ablations.

4. Discussion

We report here on the recruitment, enrollment, and engagement of individuals with a diagnosis of AF residing in rural Pennsylvania who were prescribed long-term oral anticoagulation for stroke prevention. The trial did not demonstrate a significant difference in PDC between a 4-month mobile health intervention with a relational agent combined with a heart rate and rhythm measurement compared to a control arm that used a general mobile health application. However, the trial did identify differences in self-reported adherence to anticoagulation between the intervention and control arms at the 4 and 8-month visits, such that intervention participants were more likely to report adherence at both time points. There were no differences between the two study arms regarding the secondary outcomes of AF-specific and general quality of life or health care utilization.

PDC is determined using pharmacy claims; it is an objective measure of medication possession and indirectly reflects adherence. Its precision may be more accurate with larger, administrative data sets. While the study was readily able to obtain such data, we determined that both intervention and control participants had fairly high levels of PDC. In contrast, significant differences in self-reported adherence were identified, such that those randomized to the intervention reported significantly higher likelihood of oral anticoagulation adherence than the control. The higher level of adherence was sustained at 8 months and then negligible at 12, potentially suggesting that the effect of the 4-month intervention waned.

We identified a difference between the number of procedures for AF performed in the intervention and control arms (n = 20 versus 10, respectively). It is possible that the additional clinical attention received by intervention participants may have influenced subsequent self-reported adherence to oral anticoagulation during the course of the trial. Likewise, it is also possible that results of heart rate and rhythm monitoring during the 4-month intervention phase prompted more procedural treatments during the 12-month trial. We are not able to infer causality and would consider these findings hypothesis-raising regarding the secondary outcomes of the intervention. The trial design precludes our determination of the temporal association between the 4 months of monitoring and subsequent treatments.

Furthermore, our trial did not distinguish type of AF (e.g., paroxysmal, persistent, or permanent), which may have potential to influence self-monitoring and likelihood of receiving a procedure for AF. We would expect that randomization would likely result in equivalent distribution by type in both intervention and control arms. Further, such classification schemes may have limited reliability and in turn limited relation to the outcomes evaluated by this trial. [30,31] Larger trials with more robust capacity may consider whether classification modifies the effects of a mobile health intervention.

We also note the discrepancy between claims-based and self-reported assessments of adherence observed in our trial. We appreciate the contrast as reinforcing the complex and multiple components that comprise adherence to pharmacotherapies. [32] Prior literature on adherence to cardiovascular therapies has demonstrated that even patients who have access to medications may have barriers to their routine use. [3] Neither PDC nor self-report reflects ingestion of medication and as such neither provides a perfect measure of medication adherence. A similar trial to promote adherence to anticoagulation with a mobile health application used pill counts, likely a more reliable estimate of adherence than applied here. [33] In our cohort, many individuals with access to anticoagulants, confirmed by a uniformly high PDC, indicated lapses in their medication adherence.

AF is a complex and challenging disease that has variable symptoms and requires patient education and engagement. We elected to use a relational agent (a software interface that displays an interactive character who speaks and uses nonverbal behaviors to support the user) as our intervention to provide disease-specific education and address longitudinal self-care. We have used relational agents in a variety of health contexts to promote adherence to pharmacologic and non-pharmacologic therapies and provide disease-specific education and thereby demonstrated their accessibility to older adults and those with limited health literacy. [14,16,34–36] Individuals randomized to the intervention showed excellent fidelity to the agent, as they used it a median 84 % of the 120-day intervention phase. Prior to our activities, relational agents have not been used in AF to our knowledge. We note that the dialogue content for the agent was designed and validated in advance and did not make use of generative artificial intelligence which has safety concerns. [37–39] Our program further combined the relational agent – a vehicle for education – with the KardiaMobile – a vehicle for self-monitoring. However, our analysis did not account for the interrelated effects of both of these components on the trial outcomes. A more sophisticated design may

measure the association of episodes of AF as detected by the KardiaMobile might relate to anticoagulation adherence.

The rural health divide, particularly for cardiovascular disease, is well-established. [7] Western Pennsylvania differs from other rural regions in the U.S. in terms of geographic distance to metropolitan centers and demographic composition. Mobile health technologies have potential to alleviate the burden of geographic distance and to increase patient capacity to address a chronic disease such as AF. Further study of rurality and AF is a priority, as this literature remains limited. [40] Our remote design provided rural individuals with an opportunity to participate in clinical research. [41] Providing technology to participants for the intervention facilitated participation of those without mobile health devices used here.

4.1. Strengths and limitations

Our study enrolled rural individuals, provided access to contemporary technologies with an accessible mobile health tool for patient education, and had maintained satisfactory retention to 12 months. This trial has several important limitations. Trial participants were racially homogenous, reflective of the demographics of rural Pennsylvania being only 5 % non-white or Hispanic ethnicity. [42] Analyses of administrative and registry-based data have ascertained consistently that individuals of Black race and Hispanic ethnicity are less likely to receive anticoagulation than referents of white race. [43,44] This inequity may limit participation in trials such as ours that use receipt of anticoagulation as an inclusion criterion. This study was not designed to address equitable provision of anticoagulation, and the study team made efforts throughout the trial, albeit with limited success, to enhance the diversity of participants. Second, participants in this trial were identified by their receipt of care in a regional health care system, such that may not generalize to other rural settings given the diversity of rural individuals' experience with health care access, distance to care, and social resources. [45] Third, we recognize the complexity of patient experience with AF and additional, unaccounted for factors that may influence engagement with the relational agent intervention, application of heart rate and rhythm monitoring, use of WebMD by the control, and anticoagulation adherence. It is possible that application usage, burden of AF, and the results of heart rate and rhythm monitoring may influence adherence to oral anticoagulation. As we did not collect data on use of WebMD by control participants, we are not able to compare the effect of smartphone application engagement on adherence by study arm. We further did not include data on the results of heart rate and rhythm monitoring in our analyses. A future direction of our rural health program will account for application usage and results of heart monitoring, essential for assessing how mobile health applications may mediate adherence to oral anticoagulation. Fourth, medication adherence is challenging to measure. Pill counts, for example, were not feasible given the study's conduct in a rural region and the intent to facilitate an opportunity to participate in clinical research without the burden of additional travel. We recognize that PDC reflects prescriptions filled rather than medications taken and that self-reported adherence may result in misclassification. Nonetheless, these measures reflect important and complementary attributes of adherence.

5. Conclusion

We conducted a parallel-arm, RCT among individuals in rural western Pennsylvania with chronic AF. We assessed the effectiveness of a relational agent and heart rate and rhythm measurement device to improve anticoagulation adherence, our primary outcome, and quality of life and health care utilization, our secondary outcomes. The effectiveness of the intervention was limited to significantly higher self-reported adherence. We anticipate further engagement of rural individuals to guide technological and mobile health strategies to improve patients' experience of chronic cardiovascular disease.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Funding sources

This research was supported by NIH/NHLBI award R01HL143010.

Appendix A.: Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcard.2025.133575.

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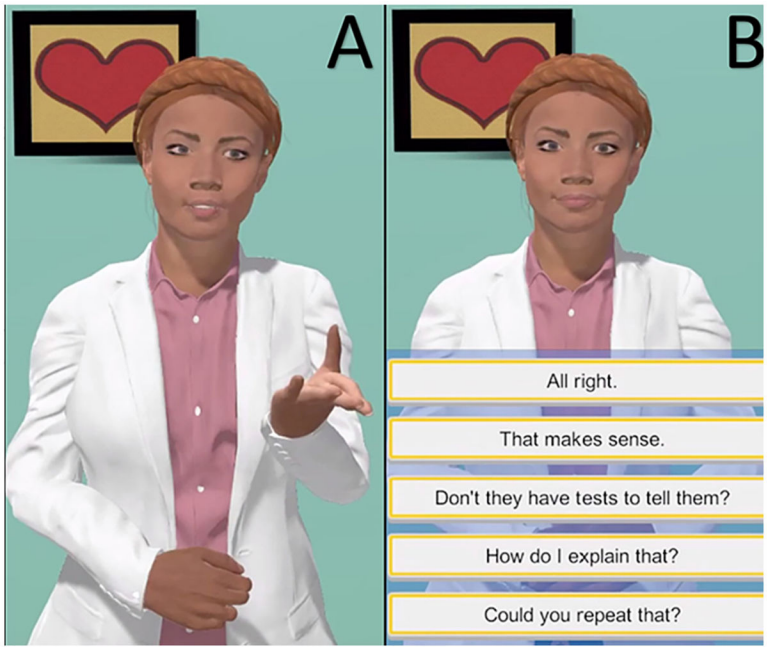

Fig. 1.

The relational agent provided by smartphone to trial participants randomized to the intervention, (A) gesturing for emphasis when providing education and (B) eliciting input from the user.

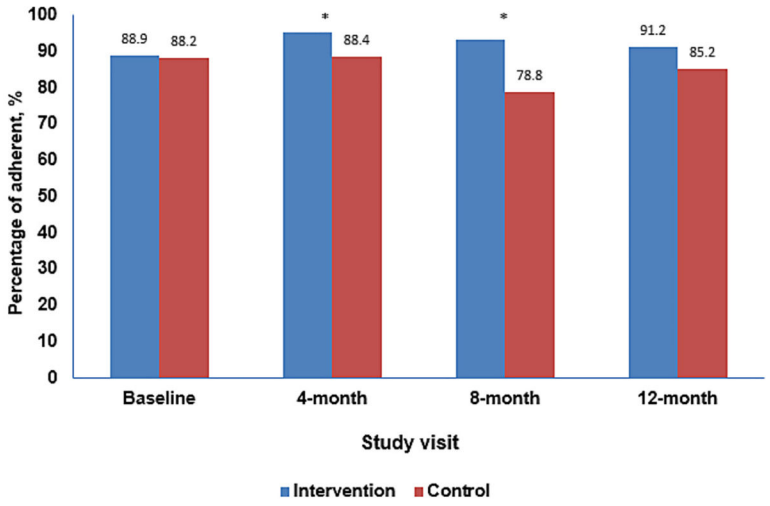

Fig. 2.

Percentage of study participants at each visit self-reporting adherence to oral anticoagulation. *Indicates statistical difference ($P < 0.05$) at the 4- and 8-month study visits.

Table 1

Baseline characteristics of the cohort, total and by study arm (n = 270).

	Full cohort (n = 270)	Intervention (n = 135)	Control (n = 135)
Age, years, median (IQR)	73.1 (67.5, 78.6)	73.6 (66.8, 78.8)	72.7 (67.9, 78.5)
Sex, n (%)			
Male	107 (39.6)	55 (40.7)	52 (38.5)
Female	163 (60.4)	80 (59.3)	83 (61.5)
Race, n (%)			
American Indian/Alaska native	1 (0.4)	0 (0)	1 (0.7)
Asian	1 (0.4 %)	0 (0)	1 (0.7)
Black	7 (2.6 %)	4 (3.0)	3 (2.2)
White	257 (95.2)	129 (95.6)	128 (94.8)
Unknown or preferred not to provide	4 (1.5 %)	2 (1.5)	2 (1.5)
Hispanic or Latino, n (%)			
Yes	5 (1.9 %)	3 (2.2)	2 (1.5)
No	261 (98.5 %)	131 (97.0)	130 (96.0)
Unknown	4 (1.5)	1 (0.7)	3 (2.2)
Income			
≤$19,999	33 (12.2 %)	18 (13.3 %)	15 (11.1 %)
$20,000 to $49,999	98 (36.3 %)	52 (38.5 %)	46 (34.1 %)
$50,000 to $99,999	69 (25.6 %)	34 (25.2 %)	35 (25.9 %)
≥$100,000	30 (11.1 %)	10 (7.4 %)	20 (14.8 %)
Unknow/prefer not to respond	40 (14.8 %)	21 (15.6 %)	19 (14.1 %)
Education, n (%)			
High school or vocational or trade school	128 (47.4)	70 (51.9)	58 (43.0)
Some college or associate degree	76 (28.2)	39 (28.9)	37 (27.4)
College graduate (bachelor or higher)	66 (24.4)	26 (19.3)	40 (29.6)
Employment status, n (%)			
Employed, full or part time	35 (13.0)	20 (14.8)	15 (11.1)
Not working	24 (8.9)	11 (8.2)	13 (9.6)
Retired	211 (78.2)	104 (77.0)	107 (79.3)
Partnership status, n (%)			
Cohabitating	181 (67.0)	86 (63.7)	95 (70.4)
Not cohabitating	89 (33.0)	49 (36.3)	40 (29.6)
Home ownership, n (%)			
Ownership	185 (68.5)	92 (68.2)	93 (68.9)
Other status	85 (31.5)	43 (31.9)	42 (31.1)
AF medication, n (%)			
Warfarin (coumadin)	44 (16.3)	22 (16.3)	22 (16.3)
Direct acting oral anticoagulant	226 (83.7)	113 (83.7)	113 (83.7)
Smoking			
Never smoked	136 (50.4)	62 (46.0)	74 (54.8)

	Full cohort (n = 270)	Intervention (*n* = 135)	Control (n = 135)
Currently smoked	17 (6.3)	12 (8.9)	5 (3.7)
Smoked in past	117 (43.3)	61 (45.2)	56 (41.5)
Alcohol consumption, heavy *			
Yes	10 (3.7)	5 (3.7)	5 (3.7)
No	260 (96.3)	130 (96.3)	130 (96.3)
Prior treatment with cardioversion †			
Yes	80 (29.6)	43 (15.9)	37 (13.7)
No	190 (70.4)	92 (34.1)	98 (36.3)
Health literacy (newest vital sign), n (%)			
Limited health literacy	125 (46.3)	63 (46.7)	62 (45.9)
Adequate health literacy	145 (53.7)	72 (53.3)	73 (54.1)

*Heavy weekly drinking defined as ≥8 drinks/week, women, and ≥ 15 drinks/week, men.

†Electrical or pharmacologic cardioversion.

Table 2

Unadjusted and adjusted Odds Ratio* (OR) and 95 % Confidence Interval (CI) for self-reported adherence to oral anticoagulation in the trial intervention arm compared to the control by study visit using longitudinal models.

	Unadjusted		**Adjusted for stratification factor**		**Additionally adjusted for Covariates***	
	Odds ratio (95 % CI)	***P*-value**	**Odds ratio (95 % CI)**	**P-value**	**Odds ratio (95 % CI)**	**P-value**
4 – Months	2.83 (1.00, 7.99)	0.049	2.82 (1.00, 7.97)	0.049	2.88 (1.03, 8.08)	0.04
8 – Months	3.34 (1.49, 7.52)	0.004	3.33 (1.48, 7.51)	0.004	3.39 (1.52, 7.56)	0.003
12 - months	1.75 (0.78, 3.93)	0.18	1.74 (0.77, 3.92)	0.18	1.75 (0.78, 3.92)	0.18
P-value for Interaction**	0.10		0.10		0.11	

*Odds Ratios determined with generalized estimating equations for the *intervention relative to control*; stratification factor (oral anticoagulant, warfarin or direct-acting oral anticoagulant), and covariates (education, cohabitation, and smoking status).

**interaction between assigned intervention group X study visit.