Mobile Electrocardiogram Monitoring and Health-Related Quality of Life in Patients With Atrial Fibrillation

Findings From the iPhone Helping Evaluate Atrial Fibrillation Rhythm through Technology (iHEART) Study

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Background: Atrial fibrillation (AF) is associated with high recurrence rates and poor health-related quality of life (HRQOL) but few effective interventions to improve HRQOL exist.

Objective: The aim of this study was to examine the impact of the “iPhone Helping Evaluate Atrial Fibrillation Rhythm through Technology” (iHEART) intervention on HRQOL in patients with AF.

Methods: We randomized English- and Spanish-speaking adult patients with AF to receive either the iHEART intervention or usual care for 6 months. The iHEART intervention used smartphone-based electrocardiogram monitoring and motivational text messages. Three instruments were used to measure HRQOL: the Atrial Fibrillation Effect on Quality of Life (AFEQT), the 36-item Short-Form Health survey, and the EuroQol-5D. We used linear mixed models to compare the effect of the iHEART intervention on HRQOL, quality-adjusted life-years, and AF symptom severity.

Results: A total of 238 participants were randomized to the iHEART intervention (n = 115) or usual care (n = 123). Of the participants, 77% were men and 76% were white. More than half (55%) had an AF recurrence. Both arms had improved scores from baseline to follow-up for AFEQT and AF symptom severity scores. The global AFEQT score improved 18.5 and 11.2 points in the intervention and control arms, respectively (P < .05). There were no statistically significant differences in HRQOL, quality-adjusted life-years, or AF symptom severity between groups.

Conclusions: We found clinically meaningful improvements in AF-specific HRQOL and AF symptom severity for both groups. Additional research with longer follow-up should examine the influence of smartphone-based interventions for AF management on HRQOL and address the unique needs of patients diagnosed with different subtypes of AF.

KEY WORDS: cardiac arrhythmias, mobile health, quality of life, self-management

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trial fibrillation (AF) is the most common cardiac arrhythmia, affecting approximately 33.5 million people globally.\textsuperscript{1,2} In the United States, the estimated prevalence of AF is 2.7 million to 5.3 million.\textsuperscript{3,4} By 2030, the prevalence of AF is expected to increase to 12.1 million and the incidence is expected to rise to 2.6 million.\textsuperscript{5} Because AF is often asymptomatic or associated with vague symptoms that could be attributed to other chronic conditions, approximately 13.1\% of all AF cases are undiagnosed.\textsuperscript{6}

Although stroke is the most recognized complication of AF,\textsuperscript{7} AF can increase risk for other conditions, including heart failure,\textsuperscript{8} myocardial infarction,\textsuperscript{9,10} and sudden cardiac death.\textsuperscript{11} Stroke accounts for 7\% of deaths related to AF, but more deaths are attributed to noncardiovascular death (35.8\%), sudden cardiac death (22.3\%), and worsening heart failure (15.1\%).\textsuperscript{12} Recurrence of AF is high, with an estimated rate of 41\% to 54\% after procedures to restore normal sinus rhythm.\textsuperscript{13,14} Treatment of AF and AF recurrence, which often requires repeated hospitalizations and ambulatory care visits,\textsuperscript{4,11} is also associated with significant costs to the healthcare system.\textsuperscript{16,17}

Higher symptom burden has been associated with worse health-related quality of life (HRQOL) in patients with AF,\textsuperscript{18} and symptom management to improve HRQOL has been recommended as part of AF treatment.\textsuperscript{19} Some studies suggest that reduced HRQOL\textsuperscript{20–22} is related to new-onset AF and AF recurrence in part because of greater symptom severity (eg, palpitations, fatigue, and shortness of breath).\textsuperscript{23} Other studies have found no direct relationship between persistent AF and HRQOL.\textsuperscript{24–26} Among individuals with paroxysmal AF, there is evidence that duration of AF is associated with worse HRQOL.\textsuperscript{21,27} Overall, undergoing treatment that targets rate and rhythm control is associated with improvements in HRQOL among adults with AF.\textsuperscript{20,27–32} but HRQOL is significantly lower in patients with AF recurrence after treatment.\textsuperscript{27,33,34} Factors that explain the improved HRQOL after undergoing treatment for AF (eg, decreased AF burden, conversion from symptomatic to asymptomatic AF, and improved rate control) remain poorly understood.

Before 2012, mobile health technology for capturing and sending cardiac rhythms to healthcare providers from a smartphone for rapid real-time evaluation of arrhythmias did not exist.\textsuperscript{35} Given the intermittent nature of AF and the challenge of identifying it in healthcare settings, mobile health which involves mobile devices and wireless technologies to support medical care and self-management, offers a promising approach for monitoring and management of arrhythmias in the community. Based upon findings of a pilot study that supported the utility of mobile health electrocardiogram monitoring via smartphone technology for the detection and management of recurrent AF in adults who had undergone treatment to restore normal sinus rhythm,\textsuperscript{36} we conducted the “iPhone Helping Evaluate Atrial Fibrillation Rhythm Through Technology” (iHEART; R01NR014853) study.

The iHEART study was a 2-arm randomized controlled trial that used mobile health electrocardiogram technology to allow participants to rapidly communicate detection of AF recurrence and related symptoms to their providers. The primary hypothesis of this study was that participants randomized to receive the iHEART intervention (composed of mobile health electrocardiogram monitoring and text messages related to AF knowledge and AF-associated lifestyle risk factors), in addition to usual care, would be more likely to detect AF episodes and receive more timely treatment for recurrence compared with the usual care group.\textsuperscript{37} Subsequently, this would result in improved HRQOL and decreased symptom severity. Moreover, the text messages related to improving lifestyle risk factors (eg, level of physical activity) may also directly influence HRQOL. The purpose of the present article was to compare the iHEART intervention and controls groups on (1) HRQOL scores and symptom severity from baseline to 6 months and (2) quality-adjusted life-years from baseline to 6 months.

\section*{METHODS}

\subsection*{Study Design}

The iHEART study was a single-center randomized controlled trial that included 238 patients with AF or atrial flutter. Patients with AF seen at the Columbia University Irving Medical Center’s ambulatory cardiac electrophysiology clinic were approached for enrollment after their provider agreed to the iHEART study protocol, including receiving and reviewing electrocardiogram transmissions. The institutional review board at Columbia University Irving Medical Center approved all study procedures. Below, we provide an overview of study procedures; however, more detailed information can be found elsewhere.\textsuperscript{38}

\subsection*{Inclusion/Exclusion Criteria}

We recruited English- and Spanish-speaking patients older than 18 years with documented AF who were undergoing treatment for their AF with either direct current cardioversion or radiofrequency ablation to restore normal sinus rhythm. Inclusion criteria were having AF seen at the Columbia University Irving Medical Center’s ambulatory cardiac electrophysiology clinic. Exclusion criteria included receiving and reviewing electrocardiogram transmissions. The institutional review board at Columbia University Irving Medical Center approved all study procedures. Below, we provide an overview of study procedures; however, more detailed information can be found elsewhere.\textsuperscript{38}
the intervention arm and 8 in the control arm; see Figure for reasons). The final sample included 238 participants (115 in the intervention arm; 123 in the control arm).

**Randomization**

We used a random computer number generator to randomize participants in a one-to-one block allocation ratio to either receive usual care or usual care plus the iHEART intervention for 6 months. Participants were stratified based on age and gender to achieve a balance of participant characteristics.

**Intervention Group**

In addition to usual care, participants randomized to receive the iHEART intervention received an iPhone that was equipped with the AliveCor Kardia mobile ECG system and unlimited data/text messaging. The AliveCor mobile ECG monitor is a Food and Drug Administration–approved smartphone technology that is compatible with most iPhone, iPad, and Android devices and works through a free application called Kardia. AliveCor has been shown to capture highly sensitive (98%), specific (97%), and accurate (98%) single-lead 30-second electrocardiogram recordings through 2 electrodes on the mobile device.35 Electrocardiogram recordings were automatically transmitted to the study portal using the AliveCor cloud. All participants randomized to the iHEART intervention received in-person training on the use of AliveCor at baseline, followed by a return demonstration from the participant. The training provided information on how to capture a daily electrocardiogram and when symptoms occurred, including how to record associated symptoms in the application.

Study staff conducted daily review and interpretation of electrocardiogram strips transmitted to the AliveCor cloud during the previous day. Clinically significant arrhythmias were immediately referred to the provider caring for the participant.

Participants in the intervention group also received text messages, in their preferred language, 3 times per week for 6 months. Only 1 participant opted to receive messages in Spanish. Text messages were sent automatically from a bank of text messages developed through collaboration by the study team and an expert interdisciplinary panel from the American Heart Association. Participants received text messages about AF management every Wednesday and about lifestyle factors associated with AF risk on Mondays and Fridays. Examples of AF management messages are as follows: “Keeping a log of activity and events may help isolate what triggered the onset of an AF episode”; “Keeping your medications filled and taking them at the same time every day will give you better and more consistent results with AFib management”; “Take a proactive approach to learn more about AFib”; and “Become an informed advocate for yourself or a loved one is the best approach for managing AFib.” Lifestyle-related messages included the following: “Schedule exercise time on your calendar and treat it like an important appointment”; “Try a grilled chicken sandwich over a fast-food burger when you are on the run”; “Stressed? Break down big problems into smaller parts”; and “Do not deal with everything at once”.

FIGURE. Consolidated Standards of Reporting Trials (CONSORT) flow diagram.
Control Group
Participants in the usual care group received guideline-directed medical care defined by the treating cardiologist and evidence-based clinical guidelines for the management of AF. Three control group participants completed data collection in Spanish.

Measures
Validated English- or Spanish-language versions of all instruments were used based on participants’ language preferences.

Baseline Characteristics
Demographic and clinical characteristics were assessed at baseline, including age, sex, race, ethnicity, electrocardiogram rhythm at baseline, and procedure to restore normal sinus rhythm.

Atrial Fibrillation Recurrence
The presence of AF recurrence between baseline and follow-up was defined as the presence of AF captured by the AliveCor Mobile system, a 12-lead electrocardiogram, Holter monitor, or other type of external recording mechanism for detection of AF. During the 6-month follow-up period, participants with 7 days or less of AF were considered paroxysmal and those with more than 7 days were defined as having persistent AF based on AF treatment and management guidelines.

Health-Related Quality of Life
We examined 3 HRQOL measures. The Atrial Fibrillation Effect on Quality of Life is a 20-item questionnaire used to assess AF disease-specific HRQOL across 4 domains (symptoms, daily activities, satisfaction with treatment, and satisfaction with care). The Atrial Fibrillation Effect on Quality of Life questionnaire has good internal consistency and test-retest reliability. Individual domain and global scores can be calculated, with higher scores indicating better health status. The Cronbach’s α for the global Atrial Fibrillation Effect on Quality of Life score was .94 and .95 at baseline and follow-up, respectively. The 36-item Short-Form Health Survey is a generic measure of HRQOL that yields a health component summary, with higher scores representing better health. The EuroQol-5D questionnaire is a generic measure of HRQOL, which evaluates different aspects of health status (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression). Health status is represented as an aggregated index (EuroQol-5D index), which is commonly used to calculate quality-adjusted life-years. The EuroQol-5D also includes a visual analog scale (range, 0–100).

Symptom Severity
The University of Toronto AF Severity Scale is a widely used instrument to assess the severity of 7 AF symptoms: palpitations, shortness of breath at rest, shortness of breath during physical activity, exercise intolerance, fatigue at rest, lightheadedness/dizziness, and chest pain/pressure. The AF Severity Scale has shown adequate internal consistency and test-retest reliability. Scores on the AF Severity Scale range from 3 to 30, with higher scores indicating higher AF symptom severity. The Cronbach’s α was .86 and .90 at baseline and 6-month follow-up, respectively.

Statistical Analyses
Before conducting the study, we calculated a power analysis that estimated that a sample size of 300 participants would be adequate for at least 80% power to detect a 19% difference in quality-adjusted life-years between the intervention and control groups. The original study was not powered to detect differences in HRQOL or AF symptom severity. Using pairwise deletion (available-case analysis), we calculated mean scores and standard deviation for measures to assess HRQOL, quality-adjusted life-years, and AF-related symptoms at baseline and follow-up for each arm of the trial. Changes in score were calculated. Student t tests were used to compare the difference between the 2 study arms. A Bonferroni correction was applied to Student t tests to account for multiple comparisons (P < .01). The standardized response mean, which is commonly used to measure the effect size of an intervention, was calculated by dividing the mean change in the score by the standard deviation of individual changes in the score.

We used linear mixed models with an individual-level random effect to compare the effect of the iHEART intervention on each outcome with participants who completed both baseline and follow-up outcome measures. To account for reduced HRQOL and increased symptom severity related to AF recurrence, all models were adjusted for AF recurrence.

RESULTS
Table 1 presents baseline sample characteristics for the intervention and control groups. There were no differences in baseline characteristics between participants who completed the study and those who dropped out.

Of the total sample, 77% were men, 76% were white, and 9% were Hispanic. In terms of procedures performed at baseline, 43% had a radiofrequency ablation and 57% had direct current cardioversion. With the exception of more participants in the control group having had a cardioversion (65%, P < .05), there were no significant differences at baseline. At follow-up, AF recurrence was detected in 55% (61% intervention, 49% control) of participants.
Table 2 shows HRQOL and symptom severity at baseline, follow-up, and change in scores from baseline to 6-month follow-up for both arms. A considerable number of participants in the intervention and control groups had missing data at follow-up. The global Atrial Fibrillation Effect on Quality of Life score significantly increased at the 6-month follow-up, 18.5 points and 11.2 points for the intervention and control groups, respectively. Whereas intervention group participants had higher scores for all Atrial Fibrillation Effect on Quality of Life subscales (including symptoms, daily activities, treatment concern, and satisfaction), control group participants demonstrated changes only in the symptoms and daily activities subscales. Intervention group participants had improved scores on the physical component summary of the Short-Form Health Survey (mean change, 3.0; \(P < .05\)). However, the EuroQol-5D score was unchanged. Scores on the Atrial Fibrillation Severity Scale significantly decreased, 5.4 and 4.5 points for the intervention and control groups, respectively. There was no difference in the EuroQol-5D scores between the intervention and control group participants.

Table 3 shows differences between the intervention and control groups over time. Although the global Atrial Fibrillation Effect on Quality of Life score and all subscales had greater improvement in the intervention group than in the control group, these differences did not reach statistical significance. Furthermore, in the sample of 110 participants with complete data to compute quality-adjusted life-years (55 in each group), no difference from baseline to 6 months between intervention and control group participants was identified (\(P = .24\)). Although the Atrial Fibrillation Severity Scale score decreased more in the intervention group than in

### Table 1: Baseline Characteristics for Each Group (N = 238)

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n = 115)</th>
<th>Control (n = 123)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD), y</td>
<td>61.4 (11.9)</td>
<td>61.2 (11.8)</td>
</tr>
<tr>
<td>Age categories</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;50</td>
<td>19 (16%)</td>
<td>20 (16%)</td>
</tr>
<tr>
<td>50–60</td>
<td>26 (22%)</td>
<td>30 (24%)</td>
</tr>
<tr>
<td>60–70</td>
<td>34 (29%)</td>
<td>33 (27%)</td>
</tr>
<tr>
<td>&gt;70</td>
<td>28 (25%)</td>
<td>27 (22%)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>88 (77%)</td>
<td>96 (78%)</td>
</tr>
<tr>
<td>Female</td>
<td>27 (23%)</td>
<td>27 (22%)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>88 (77%)</td>
<td>93 (76%)</td>
</tr>
<tr>
<td>Black</td>
<td>3 (3%)</td>
<td>8 (7%)</td>
</tr>
<tr>
<td>Asian</td>
<td>1 (1%)</td>
<td>5 (4%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>23 (20%)</td>
<td>17 (14%)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>10 (9%)</td>
<td>11 (9%)</td>
</tr>
<tr>
<td>None Hispanics</td>
<td>61 (53%)</td>
<td>67 (54%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>44 (38%)</td>
<td>45 (37%)</td>
</tr>
<tr>
<td>Electrocardiogram at baseline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AF</td>
<td>75 (65%)</td>
<td>79 (64%)</td>
</tr>
<tr>
<td>Atrial flutter</td>
<td>18 (17%)</td>
<td>26 (21%)</td>
</tr>
<tr>
<td>AF/atrial flutter</td>
<td>20 (16%)</td>
<td>17 (14%)</td>
</tr>
<tr>
<td>Other</td>
<td>2 (2%)</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Procedure at baseline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiofrequency ablation</td>
<td>60 (52%)</td>
<td>43 (35%)</td>
</tr>
<tr>
<td>Direct current cardioversion</td>
<td>55 (48%)</td>
<td>80 (35%)</td>
</tr>
<tr>
<td>AF recurrence(^a)</td>
<td>70 (61%)</td>
<td>60 (49%)</td>
</tr>
</tbody>
</table>

\(^a\)P < .05.

### Table 2: Mean Scores for Heart-Related Quality of Life and Atrial Fibrillation Symptom Severity at Baseline and Follow-up (N = 238)

<table>
<thead>
<tr>
<th>Scale</th>
<th>Intervention (n = 115)</th>
<th>Control (n = 123)</th>
<th>SRM</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>Follow-up</td>
<td>Response</td>
</tr>
<tr>
<td>Atrial Fibrillation Effect on Quality of Life</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Global</td>
<td>87 (21.0)</td>
<td>56 (20.3)</td>
<td>53 (25.9)</td>
</tr>
<tr>
<td>Symptom</td>
<td>87 (24.0)</td>
<td>56 (24.6)</td>
<td>53 (17.1)</td>
</tr>
<tr>
<td>Daily activities</td>
<td>87 (27.0)</td>
<td>56 (26.4)</td>
<td>53 (21.9)</td>
</tr>
<tr>
<td>Treatment concern</td>
<td>86 (27.5)</td>
<td>55 (21.2)</td>
<td>51 (29.5)</td>
</tr>
<tr>
<td>Satisfaction</td>
<td>83 (23.9)</td>
<td>54 (20.2)</td>
<td>29 (27.2)</td>
</tr>
<tr>
<td>Short-Form Health Survey</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical component summary</td>
<td>88 (8.6)</td>
<td>57 (9.1)</td>
<td>54 (5.8)</td>
</tr>
<tr>
<td>Mental component summary</td>
<td>88 (8.5)</td>
<td>57 (8.6)</td>
<td>54 (6.9)</td>
</tr>
<tr>
<td>EuroQol-5D</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Index</td>
<td>90 (0.16)</td>
<td>58 (0.14)</td>
<td>55 (0.5)</td>
</tr>
<tr>
<td>Visual Analog Scale</td>
<td>93 (15.8)</td>
<td>60 (14.6)</td>
<td>59 (15.7)</td>
</tr>
<tr>
<td>University of Toronto Atrial Fibrillation Severity Scale</td>
<td>90 (7.0)</td>
<td>57 (7.1)</td>
<td>55 (7.2)</td>
</tr>
</tbody>
</table>

Response = score at follow-up minus score at baseline.

Abbreviations: SRM, standardized response mean.

\(^a\)P < .01 for testing response mean score equal to 0 (t-test, P values were adjusted for multiple tests with Bonferroni correction).
the control group, this difference was not statistically significant. Overall, no significant differences between the intervention and control groups were found at the 6-month follow-up for any of the measures assessed.

**DISCUSSION**

The iHEART study is one of the first randomized clinical trials to leverage mobile health technologies to examine the effect of smartphone-based electrocardiogram monitoring and text messaging on HRQOL in patients with AF. We did not identify significant differences in AF-specific or generic HRQOL between participants in the intervention and control arms. However, it is important to note that participants in both groups had clinically meaningful improvements in global AF-specific HRQOL (≥5 points)⁴⁸ and AF symptom severity (≥3 points).⁴⁴ Based on previous evidence indicating that patients with AF who underwent treatments for rate or rhythm control had improved HRQOL,³⁰,²⁷–³² it is likely that the improvements in AF-specific HRQOL and AF symptom severity observed in the present study are a result of all participants in the study having undergone treatment for AF.

Although not statistically significant, our data show trends toward greater improvement in global AF-specific HRQOL and its subscales among those that received the iHEART intervention compared with usual care. It is likely that participating in both components of the iHEART intervention (mobile electrocardiogram monitoring and text messaging) had an effect on different components of AF-specific HRQOL. Indeed, intervention group participants, not control group participants, had improvements in the treatment concern and satisfaction with current treatment subscales of the Atrial Fibrillation Effect on Quality of Life scale. Thus, participating in the iHEART intervention was associated with lower treatment concerns and greater satisfaction with their current AF treatment. These data suggest that future work should further explore the potential influence of the iHEART intervention on individual components AF-specific HRQOL.

Despite greater improvements in AF-specific HRQOL in the intervention group, we found no difference compared with control group participants. There are several possible reasons for this. First, we had a lower than anticipated sample size of 238 participants (115 in the intervention group and 123 in the control group). Our original power calculation estimated that a sample size of 300 was needed to detect differences in quality-adjusted life-years. Therefore, the present study was not designed to examine change in AF-specific HRQOL or AF symptom severity scores, which may likely explain our findings. Second, it is likely that follow-up beyond 6 months (eg, 9 or 12 months) might be needed to observe improvements in HRQOL among patients with AF. Next, it is important to note that the text messages received by participants in the intervention group were focused on AF knowledge, management, and lifestyle risk factors, not directly HRQOL. This may further explain the lack of differences in HRQOL between the intervention and control groups. It may be that other outcomes (such as knowledge of AF management, AF management self-efficacy, or health behavior change) may be more appropriate to assess with 6-month follow-up. However, we did not measure these outcomes in the present study. We recommend that future research using similar interventions to the iHEART trial (smartphone-based electrocardiogram monitoring and motivational text messages) in patients with AF should examine treatment effects on knowledge of and self-efficacy for AF management as well as changes in health behaviors.

**TABLE 3 Differences in Health-Related Quality of Life, Quality-Adjusted Life-Years, Atrial Fibrillation Symptom Severity, and Mental Health Between Control and Treatment Groups**

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>β or Difference</th>
<th>SE</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atrial Fibrillation Effect on Quality of Life</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Global</td>
<td>7.3</td>
<td>4.3</td>
<td>0.09</td>
</tr>
<tr>
<td>Symptom</td>
<td>3.5</td>
<td>4.9</td>
<td>0.48</td>
</tr>
<tr>
<td>Daily activities</td>
<td>7.4</td>
<td>5.8</td>
<td>0.20</td>
</tr>
<tr>
<td>Treatment concern</td>
<td>9.6</td>
<td>5.3</td>
<td>0.07</td>
</tr>
<tr>
<td>Satisfaction</td>
<td>2.6</td>
<td>5.7</td>
<td>0.65</td>
</tr>
<tr>
<td>Short-Form Health Survey</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical Component Summary</td>
<td>1.2</td>
<td>1.3</td>
<td>0.37</td>
</tr>
<tr>
<td>Mental Component Summary</td>
<td>-0.5</td>
<td>1.4</td>
<td>0.74</td>
</tr>
<tr>
<td>EuroQol-5D</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Index</td>
<td>0.0</td>
<td>0.03</td>
<td>0.98</td>
</tr>
<tr>
<td>VAS</td>
<td>4.3</td>
<td>2.9</td>
<td>0.13</td>
</tr>
<tr>
<td>Quality-adjusted life-years</td>
<td>0.01</td>
<td>0.01</td>
<td>0.24</td>
</tr>
<tr>
<td>University of Toronto Atrial Fibrillation Severity Scale</td>
<td>-0.8</td>
<td>1.5</td>
<td>0.58</td>
</tr>
</tbody>
</table>

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β or difference = difference in mean score change from baseline to follow-up or difference in mean scores from baseline to 6 months between the 2 arms.$^\text{a}$

$^\text{a}$P < .05.
increased likelihood of recurrence detection, the lack of influence on HRQOL is consistent with the aforementioned scientific statement.\textsuperscript{37}

Based on previous evidence, it is likely that patients with paroxysmal AF may benefit the most from interventions designed to improve HRQOL.\textsuperscript{50} Approximately 55\% of participants in the iHEART trial had AF recurrence. Although the number of AF episodes before radiofrequency ablation and duration of AF in patients with paroxysmal AF have been identified as significant predictors of HRQOL,\textsuperscript{21,27,34} we did not measure these in the iHEART trial. Therefore, future research is needed that examines the influence of behavioral interventions, such as iHEART, on HRQOL, specifically in patients with paroxysmal AF. In addition, clinical factors that predict improvements in HRQOL among patients with AF should be examined further.

A recent mobile health intervention (n = 113) that incorporated electrocardiogram monitoring and patient education related to AF found significant improvements in HRQOL and reductions in mental health symptoms in adults with AF.\textsuperscript{51} Few participants in that study underwent treatment to restore normal sinus rhythm. The higher proportion of participants with persistent AF may explain the discrepancy between its findings and our own.

Although the iHEART intervention did not lead to improved HRQOL compared with participants who received usual care, this study has several strengths that add to the literature. The iHEART trial used a smartphone-based electrocardiogram monitoring intervention for the detection of AF recurrence. This approach is novel as previous studies have only used smartphone-based technology for screening for arrhythmias in participants.\textsuperscript{52–54} Furthermore, the iHEART trial had a follow-up period of 6 months, which is longer than comparable behavioral interventions designed to improve HRQOL in patients with AF.\textsuperscript{51,55} The 6-month period is also clinically important because it captures HRQOL beyond the 3-month “blanking period” during which the heart is remodeling and healing after an intervention to restore normal sinus rhythm and when recurrence and associated symptoms are still common. Measurements taken beyond the blanking period are generally considered to be a more reliable indication of the patient’s permanent postintervention state.\textsuperscript{56}

In addition, given the growing number of cellphone users in the United States who own smartphones,\textsuperscript{37} the use of mobile technologies for the detection and management of AF has the potential to reach vulnerable groups (eg, racial/ethnic minorities, low-income, and rural populations). More than 70\% of individuals in the aforementioned groups have access to smartphones.\textsuperscript{57} However, these groups may also have reduced access to specialized cardiovascular care.

Interventions to improve early detection of AF recurrence and promote symptom management are needed because few have focused on facilitating patient recognition of AF recurrence through improving AF knowledge and promoting lifestyle modifications.\textsuperscript{36} Behavioral interventions that incorporate smartphone-based technology and/or text messaging, such as the iHEART intervention, should be further tested to examine their influence on HRQOL and symptom severity among diverse patients with AF. For instance, the Apple Heart Study has already enrolled over 400 000 individuals to participate in Apple Watch–based remote monitoring of cardiac arrhythmia to better detect AF and connect individuals to appropriate care.\textsuperscript{58} Such work is critical to lay the foundation for future detailed analyses of AF subtypes, such as examining which subgroups of patients with AF may experience improved HRQOL after various interventions to restore normal sinus rhythm.

### Limitations

This study has several limitations. The iHEART trial was conducted at a single site in New York City with approximately 77\% male and 76\% white participants, which limits the generalizability of findings. Future work should examine the effectiveness of the iHEART intervention using a larger more diverse sample of participants at multiple sites across the United States. However, there is evidence that women and racial/ethnic minorities are less likely to have procedures to treat AF (including direct current cardioversion or radiofrequency ablation) than their male and white counterparts, respectively.\textsuperscript{59–61} The main eligibility criteria for the present study was having undergone direct current cardioversion or radiofrequency ablation to treat AF; therefore, these treatment disparities represent significant barriers for recruitment of diverse populations into future AF behavioral interventions. This indicates a clear need to reduce AF treatment disparities.

As described above, the sample size of 238 may have limited our ability to detect statistically significant differences between groups. Given the evidence of clinically significant improvements in AF-specific HRQOL and AF-related symptom severity, future studies should be conducted that are powered to examine the influence of electrocardiogram mobile technology on these outcomes. Furthermore, there was significant missing data for some study variables, further limiting statistical power. Participants in the iHEART trial completed only baseline and 6-month assessments. It is possible that more frequent assessment throughout the study may improve engagement among participants and reduce missing data. It is unknown whether differences in HRQOL or symptom severity would be observed with longer follow-up (eg, ≥12 months). Perhaps longer follow-up with shorter intervals (ie, every month or every 3 months) may detect crucial periods when mobile health interventions may be most effective at improving...
HRQOL and symptom severity in patients with AF. Future work can explore measuring HRQOL and symptoms with the same smartphone technology used in the iHEART study to capture more detailed data on these variables.

CONCLUSION

The present study sought to examine the impact of smartphone-based electrocardiogram monitoring and text messaging on HRQOL in patients with AF who had undergone treatment to restore normal sinus rhythm. Although we did not identify significant differences between intervention and control group participants, we found clinically meaningful improvements in AF-specific HRQOL and AF symptom severity. This is consistent with evidence that suggests receiving treatment for rate and rhythm control are associated with improved HRQOL in patients with AF. Additional research should examine the influence of smartphone-based interventions for AF management on HRQOL and focus on addressing the unique needs of patients diagnosed with different subtypes of AF.

REFERENCES


