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Mobile health assessments of geriatric elements in older patients with atrial fibrillation: The Mobile SAGE-AF Study (M-SAGE)



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BACKGROUND Geriatric conditions (eg, cognitive impairment, frailty) are increasingly recognized for their impact on clinical and quality-of-life outcomes in older patients with cardiovascular disease, but are not systematically assessed in the context of clinical visits owing to time constraints.

OBJECTIVE To examine feasibility of remote monitoring of the physical, cognitive, and psychosocial status of older adults with atrial fibrillation (AF) via a novel smartphone app over 6 months.

METHODS Forty participants with AF and eligible for anticoagulation therapy (CHA₂DS₂VASc ≥ 2) enrolled in an ongoing cohort study participated in a mobile health pilot study. A 6-component geriatric assessment, including validated measures of frailty, cognitive function, social support, depressive symptoms, vision, and hearing, was deployed via a smartphone app and 6-minute walk test was completed using a Fitbit. Adherence to mobile assessments was examined over 6 months.

RESULTS Participants were an average of 71 years old (range 65–86 years) and 38% were women. At 1 month, 75% (30/40) of

participants completed the app-based geriatric assessment and 63% (25/40) completed the 6-minute walk test. At 6 months, 52% (15/29) completed the geriatric assessment and 28% (8/29) completed the walk test. There were no differences in demographic, clinical, or psychosocial factors between participants who completed the surveys at 6 months and those who did not. Participants, on average, required less than 10 minutes of telephone support over the 6-month period.

CONCLUSION It is feasible, among smartphone users, to use a mobile health app and wearable activity monitor to conduct serial geriatric assessments in older patients with AF for up to 6 months.

KEYWORDS Atrial fibrillation; Geriatric assessment; Mobile health application; Older adults

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Introduction

Atrial fibrillation (AF) is the most prevalent heart rhythm disorder in the world, affecting an estimated 8 million Americans currently and over 30 million people globally.¹ The condition is associated with a 5-fold increased risk for stroke as well as an increase in risk for dementia, hospitalization, and mortality.² In the era of COVID-19, clinical and research visits with patients with AF and other cardiovascular diseases may, for some time, take the form of telemedicine and remote visits.³ Although this poses some challenges to clinical and research operations, there may also be opportunities associ-

ated with this new form of communication with patients. These telemedicine modalities provide the opportunity to assess factors that may not fit into the time constraints of a typical in-person clinical encounter and the additional benefit of enabling assessment of patient behavior and experiences in real time, in an at-home setting that may be more reflective of the patient's day-to-day state.

Geriatric assessments, including measures of cognitive function, frailty, social isolation and depression, are increasingly recognized for their impact on clinical outcomes in patients with AF. For example, cognitive impairment (CI), prevalent in up to half of patients with AF, is associated with less successful anticoagulation (AC) and poorer clinical outcomes.^{4–7} In addition, CI, lack of social support, fall risk, and frailty are associated with poor adherence to AC and to lower time in therapeutic range.^{8–10} The importance of

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SNAPSHOT SUMMARY

In this pilot study of older participants with atrial fibrillation, we show it is feasible to administer a full geriatric assessment remotely multiple times over a 6-month period in a range of patients, including the oldest old and those with cognitive and functional impairments.

KEY FINDINGS

- In this pilot study of older participants with atrial fibrillation (AF), we found it is feasible to administer a full geriatric assessment remotely multiple times over a 6-month period.
- These assessments are feasible with minimal support in a range of patients, including the oldest old and those with cognitive and functional impairments.
- These results lay the groundwork for larger-scale studies of how remote geriatric assessments could be incorporated into in-office and telemedicine management of patients with AF or into large-scale cohort studies or clinical trials.

these factors was recognized in the 2019 American College of Cardiology/American Heart Association (ACC/AHA) AF Treatment Guidelines, which emphasize the need to weigh geriatric conditions, including CI and physical frailty, in therapeutic decision-making.² Despite the recognized importance of these factors, geriatric conditions are not systematically assessed in all patients owing to time constraints or lack of availability of standardized measures with clear administration, scoring, and interpretation criteria.¹¹

In the context of a diverse cohort of older patients with AF, we tested the feasibility of a geriatric assessment captured via an app and Fitbit wrist-based wearable activity monitor (Fitbit, Inc, San Francisco, CA) over a 6-month period. Establishing the feasibility of serial assessments of a systematic geriatric assessment via an app would be useful in clinical and research contexts. Clinically, routine assessment of cognitive function, frailty, social support, and depression could help identify a subset of patients at high risk for poor outcomes who may need more surveillance and tailored education. Remote geriatric assessments would promote inclusion of these data in large cohort studies and clinical trials.

Methods

Population and setting

The present study is a mobile health (mHealth) pilot study nested within the ongoing Systematic Assessment of Geriatric Elements in Atrial Fibrillation (SAGE-AF) prospective

cohort study of 1244 older patients with AF. Details of the SAGE-AF study have been previously described.⁴ Briefly, to be eligible for SAGE-AF, participants must have AF (participants were considered to have AF if the arrhythmia was present on an electrocardiogram or Holter monitor or if AF was noted in any clinic note or hospital record), be aged 65 years or older, and have a CHA₂DS₂-VASC risk score ≥ 2 . Participants are not eligible for enrollment if they have documentation of an absolute contraindication to AC, if they have an indication for AC other than AF (ie, mechanical heart valve, deep venous thrombosis, or pulmonary embolism), if they do not demonstrate capacity to provide informed consent as assessed by a capacity instrument that combines direct questions about their understanding of study participation with interviewer observations of the patient,¹² if they do not speak English, or if they have a planned invasive procedure with high risk for uncontrollable bleeding. Participants in this mHealth pilot study had the additional inclusion criteria of ownership of an Apple iOS or Android smartphone. This study has been approved by the University of Massachusetts Medical School institutional review board. The research reported in this paper adhered to the guidelines established by the Declaration of Helsinki as revised in 2013.

Study procedures

Participants were recruited into the pilot mHealth study over 8 months during a cardiology/internal medicine clinic visit. All SAGE-AF participants who indicated owning a smartphone at enrollment were eligible for the pilot study. Of those, 104 were approached and 40 consented. Study staff helped download the MyDataHelps™ and Fitbit apps onto participants' smartphones. Fitbit Charge 2 heart rate devices (Fitbit Inc) were also given to participants at the time of enrollment and training was conducted on the Fitbit device and surveys. Training took an average of 15 minutes per participant.

Mobile health survey components

Validated assessments of depression,¹³ vision, hearing, and social isolation¹⁴ were adapted for mobile use by entering each question and all answer options into the MyDataHelps online survey designer (Figure 1) and were completed at baseline and at 30, 60, 90, 120, 150, and 180 days. Social support was measured by the 5-item modified version of the Social Support Scale and the 6-item Social Network Scale (range 0–30) to assess breadth and depth of social support available to participants,¹⁴ with a score of 12 used to indicate social isolation. The Patient Health Questionnaire (PHQ-9, range 0–27) was used to assess depressive symptoms,¹³ with 5 used as a cut point for high depressive symptoms. Patients' self-reported vision and hearing status are based on standardized questionnaires. Participants interacted with the questionnaires by clicking their phone screen and were only presented with 1 question at a time within each questionnaire. The cognitive assessments (modified versions of the Stroop test and Trail Making test, Part B) were completed

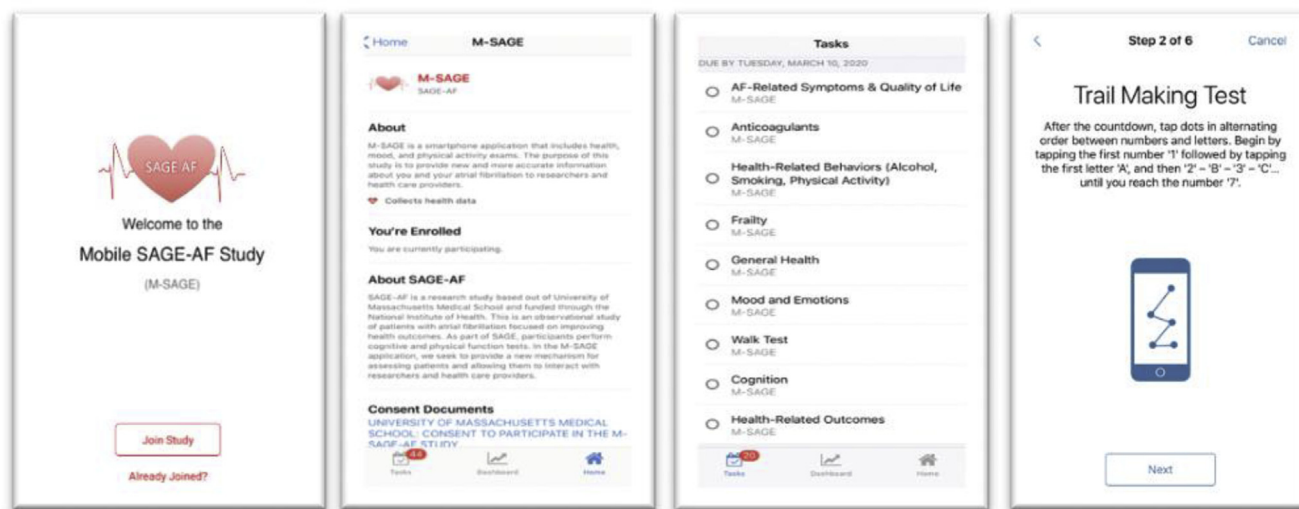


Figure 1 Application screenshots.

and timed. In the Stroop test, the participant is shown a series of words that are displayed in color and must select the first letter of the color's name.¹⁵ The number of errors and the time to complete the test is recorded. In the Trail Making test, the participant connects a series of labeled circles, in order.¹⁶ The number of errors and the time to complete the test is recorded. The frailty measure was adapted from the FRAIL questionnaire, a 5-item self-reported frailty index that has been validated against a myriad of well-established indicators of frailty, such as activities of daily living, physical performance, and blood tests.¹⁷ The measures were deployed to participants via the MyDataHelps app, along with automated personalized messages prompting completion of measures at baseline and every 30 days for the study duration.

Six-minute walk test

Participants in the mHealth pilot completed an in-clinic 6-minute walk test (6MWT) at the time of enrollment and were asked to complete an at-home 6MWT every 30 days by wearing their Fitbit device and using an automated text message service that communicated the start and end times of the walk test to study staff. The automated text message service prompted participants to complete a walk test each month with the message, "It's time to complete your 6-minute walk test! When you are ready for your walk, please find a flat surface and reply 'walktest.' Text 'help' if you need assistance." Participants responded to the automated message when they were ready to start their walk. They received start and stop prompts at the beginning and end of 6 minutes. These automated prompts did not require time from staff to send to participants. Participants were initially followed through the mobile technologies for 30 days; however, after 11 participants had been enrolled and completed the 30-day follow-up, we modified the study protocol to assess feasibility of serial mobile assessments over a longer follow-up period of 180 days. An additional 29 participants were

enrolled after this change to the study design. Participants were provided with study staff contact info if they needed support with using the app or devices.

The study staff recorded the reason for each call received in order to garner additional insights regarding the potential challenges and facilitators of implementing these remote assessments within our study cohort.

Other study variables

All SAGE-AF participants complete a guided interview that includes demographics, disease-specific health-related quality of life,¹⁸ a 6-component geriatric assessment using validated measures of frailty,¹⁹ cognitive function,²⁰ social support,¹⁴ depressive symptoms,¹³ vision, and hearing. History of heart failure, bleeding, and stroke were abstracted from the medical record by trained abstractors.

Results

Between August 2018 and March 2019, a total of 40 participants were enrolled into the m-SAGE pilot in the context of a SAGE-AF study visit and completed an in-person geriatric assessment per SAGE-AF protocol. Average age of participants was 70.9 (standard deviation [SD] = 4.8, range 65–86) years, 38% were female, and 95% were white (Table 1). Geriatric impairments were common among m-SAGE participants, with half (53%) falling into the pre-frail category and 5% categorized as frail. More than 1 in 6 participants (18%) were cognitively impaired, and approximately one-quarter (25%) reported high depressive symptoms. Twenty-nine of the 40 participants were offered participation in an extended, 6-month follow-up assessment. Compared to those enrolled in the extended follow-up, those enrolled in only the 1-month follow-up had higher levels of depression, anxiety, and frailty (all $P \leq .05$).

The baseline surveys were completed using the m-SAGE app by 93% (37/40) of participants, while 75% (30/40)

Table 1 Cohort Characteristics (N=40)

Demographics	
Age (years), mean (SD)	70.9 (4.8)
Female	15 (37.5)
College graduate	28 (70.0)
Clinical characteristics	
AF type	
Paroxysmal	27 (67.5)
CHA ₂ DS ₂ VASc score, mean (SD)	3.3 (0.9)
Bothered by ≥1 AF symptom in the past 4 weeks	7 (17.5)
On anticoagulant	34 (85.0)
Medical history	
Heart failure	7 (17.5)
Bleeding	4 (10.0)
Stroke	3 (7.5)
Psychosocial characteristics and geriatric elements	
Frailty category	
Frail	2 (5.0)
Pre-frail	21 (52.5)
Not frail	17 (42.5)
Fall in past 6 months	4 (10.0)
Cognitive impairment (MOCA ≤ 23)	7 (17.5)
Social isolation (MOS < 12)	3 (7.5)
Visual impairment	8 (20.0)
Hearing impairment	11 (27.5)
Depression (PHQ-9 ≥ 5)	10 (25.0)
Anxiety (GAD-7 ≥ 5)	8 (20.0)
Living alone	8 (20.0)

All values are n (%) unless otherwise noted.

AF = atrial fibrillation; GAD = generalized anxiety disorder; MOCA = Montreal Cognitive Assessment; MOS = Medical Outcomes Study; PHQ = Patient Health Questionnaire.

completed the day 30 surveys, 72% (21/29) the day 60 surveys, 66% (19/29) the day 90 surveys, 55% (16/29) the day 120 surveys, 52% (15/29) the day 150 surveys, and 52% (15/29) the day 180 surveys (Figure 2). We also examined completeness of surveys, to determine whether the mHealth battery was too long, and patterns of missing on specific tests, to determine whether 1 measure was problematic for participants and thus often skipped. We found that with the exception of 2 participants, the full battery of surveys was completed once started, suggesting that the mHealth battery was not too long. In the 2 participants who did not complete the full survey, different measures were skipped, indicating that there was not 1 “problematic” measure. In general, once participants began the mHealth surveys, they completed all study assessments. Partial completion was uncommon (n = 2) and skipped assessments were not restricted to a single survey measure. It took participants an average of 23 minutes to complete the surveys (range = 9–81 minutes). All participants completed an in-clinic 6MWT at baseline, while 63% (25/40) completed the at-home day 30 6MWT. More than half of participants completed the at-home day 60 (59%; 17/29) and day 90 (55%; 16/29) 6MWT, just under half were adherent at day 120 (48%; 14/29) and day 150 (45%; 13/29), and 28% (8/29) completed the day 180 6MWT. At 6 months, 40% (6/15) of those who completed surveys also completed a 6MWT, and 14% (2/14) of those who did not complete surveys completed a 6MWT ($P = .12$). There were no significant

sociodemographic (age, sex, race, marital status, education) or clinical (AF type, CHA₂DS₂VASc score, bothered by ≥1 AF symptom in past 4 weeks, anticoagulant status, past medical history [heart failure, hypertension, type II diabetes, bleeding, dyslipidemia, stroke]) differences between those who completed the surveys and walk test at 6 months and those who did not (all $P > .05$).

Because there were baseline differences in several geriatric elements between participants enrolled in the 1-month follow-up (n = 11) and those enrolled in the 6-month follow-up (n = 29), we also examined adherence only among those in the extended follow-up. When we restricted the sample to only those enrolled in the 6-month follow-up, adherence rates were similar, with 90% (26/29) of participants completing all baseline surveys (compared to 93%; 37/40; $P = .65$), 76% (22/29) completing all day 30 surveys (compared to 75%; 30/40; $P = .92$), and 62% (18/29) completing the day 30 6MWT (compared to 63%; 25/40; $P = .93$).

We also captured information about the amount and type of telephone support provided to study participants by study staff over the 6-month study period. Two-thirds (n = 26; 65%) of participants called 2 times or less for support with the mHealth technologies over the 6-month study period (median = 2; range = 0–26; $Q_1 = 1$; $Q_3 = 5$). Three-quarters (n = 30; 75%) of participants called 3 times or less over the 6-month course of study. The primary reasons participants called were for assistance with Fitbit devices (26% of calls; 28/109), account login help for Fitbit and MyDataHelps (17% of calls; 18/109), and confusion with the text messaging system prompting the 6MWT (18% of calls; 20/109). The median duration of support calls was 4 minutes (interquartile range: $Q_1 = 3$; $Q_3 = 6$).

Discussion

In this pilot study of older patients with AF who are smartphone users, we demonstrate the feasibility of using an mHealth app and wearable activity monitor, such as a Fitbit Charge 2 heart rate device, to conduct a complete geriatric assessment, including cognitive, physical, and psychosocial function, for up to 6 months. Demographic, clinical, and psychosocial factors were not associated with adherence over 6 months, suggesting that remote monitoring for geriatric impairments is feasible in a wide range of older patients with AF.

Geriatric impairments such as CI, depression, and frailty are recognized for their potential impact on AF management success and clinical outcomes and are included in the 2019 ACC guidelines as important factors in therapeutic decision-making and because they may identify a subset of patients who need closer monitoring because they are high risk for poor medication adherence or falls.^{2,5–8,21} Despite this, these factors are not systematically assessed during routine clinical visits owing to time constraints. Our results suggest that it is possible to remotely monitor older patients with AF for changes in cognitive, physical, and psychosocial status. We found that nearly all participants (>90%)

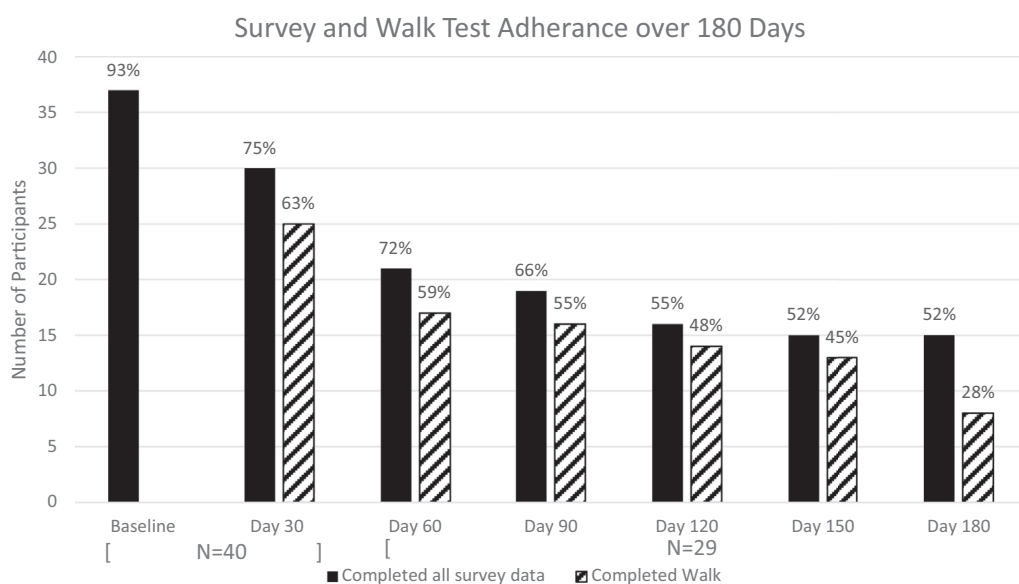


Figure 2 Survey and walk test adherence.

completed a single assessment, which would provide a clinician with information on prevalence of impairments, and that more than half of patients completed additional assessments over 6 months, which would allow providers to observe changes in cognitive or physical status over time. Importantly, these assessments were completed with minimal support from our staff (<10 minutes per participant).

To date, remote monitoring of older patients with cardiovascular disease has centered around activity monitoring with little focus on cognitive or functional phenotyping. With older adults increasingly engaging with technology and telehealth visits,²² opportunities for mHealth assessments are expanding.²³ Several studies have captured single components of a geriatric assessment, such as fall risk and depression, in the context of disease management interventions.^{24–26} However, remote administration of a more complete geriatric assessment remains an untapped resource for surveillance and identification of patients at high risk for poor medication adherence and disease management. Loh and colleagues²⁷ pilot tested a remote assessment of a geriatric assessment in older cancer patients and their caregivers over 1 month. They reported 80% adherence over 1 month, with high acceptability of the mobile technologies reported by patients and their caregivers. Our adherence rates at 30 days (75%) were similar to those reported by Loh and colleagues, and we extend their findings to include a complete geriatric assessment including measures of cognition, mood, and physical function over 6 months with over 50% adherence.

Previous studies have not reported on the frequency and duration of support calls with patients using the mHealth tools. We found that, on average, participants required 2 support calls or fewer for assistance with technology over the 6-month follow-up and that the median time of each call was 4 minutes. Although in our small pilot study this was manageable, in a large practice these calls could become

burdensome. Future studies should examine whether calls wane over time as patients become more familiar with the technology and the potential for outsourcing calls that are strictly technology, not clinical, in nature.

The COVID-19 pandemic has radically transformed existing infrastructures of medical practice as clinics and hospitals around the world have shifted to virtual means of patient care. Various professional societies including the AHA, ACC, and Heart Rhythm Society have released guidelines for triaging nonurgent patient care, and further emphasize the importance of converting to telemedicine whenever possible.²⁸ Furthermore, regulatory bodies in the United States have relaxed strict privacy regulations and now allow providers to use potentially non-HIPAA-compliant modalities to conduct virtual patient care,²⁹ and the Centers for Medicare & Medicaid Services have also drastically expanded the range of permissive contexts to conduct health care via telemedicine.³⁰ Increasing use of telemedicine and, eventually, improvements in reimbursement for telemedicine may also promote the implementation of mHealth monitoring systems like the one pilot tested in this study.

There is also consensus among some heart rhythm specialists that reverting to previous models of health care after the pandemic is unlikely for the foreseeable future.³¹ Advanced age and cardiac comorbidities are significant risk factors for COVID-19-related complications, making AF patients an especially vulnerable group, thus further highlighting the importance of a safe and effective means to conduct necessary clinical assessments for these patients.³² The pandemic response adaptations made by healthcare systems in embracing telemedicine have also lowered the infrastructural and implementation barriers traditionally faced by virtual patient care, and COVID-19-era remote monitoring strategies for AF patients are already being rapidly implemented in numerous hospitals around the world.³³ We show in the present study that it is also feasible to conduct

geriatric assessments remotely, which can provide invaluable data for clinical decision-making in the context of telemedicine and enrich the remote patient experience.

This study has a number of strengths. Our geriatric assessment was composed of validated measures adapted for our study mobile application. The study sample was diverse with respect to age and included participants over 85 years old, and with respect to cognitive and functional status. Our approach, after the initial visit when we assisted the participants in the app download, was completely automated, including preprogrammed text messages, and thus is scalable to large populations. However, the results should be interpreted with several limitations in mind. We did not collect data on acceptability of the app or measures, and future studies should examine this in addition to adherence. Our pilot sample was modest in size and exclusively non-Hispanic white and English-speaking; thus our pilot results should be examined in a larger and more diverse sample. In addition, our sample was composed of smartphone users, so the results cannot be extended to non-users. There were differences in the characteristics of patients who participated in 1 vs 6 months of our study and thus longer follow-up in a larger sample is necessary to confirm and expand findings. Finally, our pilot study sample was a subset of an ongoing prospective study.

Conclusion

In this pilot study of older participants with AF, we show it is feasible to administer a full geriatric assessment remotely multiple times over a 6-month period. Importantly, these assessments are feasible with minimal support in a range of patients, including the oldest-old and those with cognitive and functional impairments. Our pilot study was designed only to determine the feasibility of assessing geriatric elements remotely. The results lay the groundwork for larger-scale studies of how remote geriatric assessments could be incorporated into in-office and telemedicine management of patients with AF or into large-scale cohort studies or clinical trials.

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Conflicts of Interest

None.

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