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Health behavior outcomes in stroke survivors prescribed wearables for atrial fibrillation detection stratified by age

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ABSTRACT

BACKGROUND Smartwatches have become readily accessible tools for detecting atrial fibrillation (AF). There remains limited data on how they affect psychosocial outcomes and engagement in older adults. We examine the health behavior outcomes of stroke survivors prescribed smartwatches for AF detection stratified by age.

METHODS We analyzed data from the Pulsewatch study, a randomized controlled trial that enrolled patients (≥ 50 years) with a history of stroke or transient ischemic attack and CHA2DS2-VASc ≥ 2. Intervention participants were equipped with a cardiac patch monitor and a smartwatch-app dyad, while control participants wore the cardiac patch monitor for up to 44 days. We evaluated health behavior parameters using standardized tools, including the Consumer Health Activation Index, the Generalized Anxiety Disorder questionnaire, the 12-Item Short Form Health Survey, and wear time of participants categorized into three age groups: Group 1 (ages 50-60), Group 2 (ages 61-69), and Group 3 (ages 70-87). We performed statistical analysis using a mixed-effects repeated measures linear regression model to examine differences amongst age groups.

RESULTS Comparative analysis between Groups 1, 2 and 3 revealed no significant differences in anxiety, patient activation, perception of physical health and wear time. The use of smartwatch technology was associated with a decrease in perception of mental health for Group 2 compared to Group 1 ($\beta = -3.29$, $P = 0.046$).

CONCLUSION Stroke survivors demonstrated a willingness to use smartwatches for AF monitoring. Importantly, among these study participants, the majority did not experience negative health behavior outcomes or decreased engagement as age increased.

Atrial Fibrillation (AF) is the most prevalent arrhythmia and is associated with heart failure, stroke, and systemic embolism.[1,2] The global burden of AF reached an estimated 59.7 million cases in 2019, with older adults accounting for a substantial portion due to aging being a major risk factor.[1,3–5] As the world's population continues to age, AF prevalence is expected to rise. The insidious nature of AF often leads to underdiagnosis.[6,7] Consequently, approximately 20% of those who suffer ischemic strokes related to AF are first diagnosed with the arrhythmia around the time of the stroke.[8] AF-associated strokes tend to have worse outcomes, being more fatal and carry higher recurrence rates with severe functional deficits.[9]

To detect AF, clinicians have traditionally relied on 12-lead electrocardiogram (ECG) recordings, serving as the gold standard. However, its utility is limited as it often only identifies those individuals who present with clinical symptoms.[10] Efforts have been made to explore alternative methods for early AF identification in the general population.[11] Utilizing ex-

isting technology that is widely available, researchers have developed smartwatches with ECG detection capabilities to enhance diagnostic yield.[12–14] However, skepticism remains regarding their clinical validity and applicability among older populations, known to be late adopters of new technologies.[15] Additionally, there are concerns about the potential impact of these technologies on health outcomes, such as anxiety, which may hinder their adoption. Unfortunately, scarce literature exists exploring these pertinent questions. In this manuscript, we analyze data from the Pulsewatch study, a randomized clinical trial (NCT03761394) that prescribed a smartwatch-app dyad for AF screening in stroke survivors, to investigate the effects of smartwatch prescription on health behavior outcomes and engagement in different age groups.

METHODS

The Pulsewatch study was designed as a multiphase randomized clinical trial aimed at determining if the Pulsewatch system could detect paroxysmal AF with similar accuracy compared to a gold standard cardiac monitoring device. Moreover, it also sought to determine the adherence to the Pulsewatch system amongst the study participants.[16] The Pulsewatch system consists of a smartwatch with ECG detecting capabilities, specifically the Samsung Gear S3 or Samsung Galaxy Watch 3, along with the Pulsewatch smartphone application designed and downloaded onto Samsung smartphones, which were provided to enrolled participants.

Study Population

Participants were recruited from inpatient or ambulatory cardiology and neurology services at a single tertiary care center, UMass Memorial Medical Center. Eligible participants were 50 years of age or older, proficient in English, had a history of an ischemic stroke/transient ischemic attack, were willing to participate in a focus group, intended to use the Pulsewatch system for at least 44 days, and possessed the capacity and ability to provide informed consent. Exclusion criteria included the inability to provide informed consent, contraindications for wearing an ECG monitor (e.g., allergy to medical-grade adhesives or hydrogel), previously diagnosed AF with contraindications for anticoagulant therapy, an implantable pacemaker, or an arrhythmia requiring emergency analysis and in-patient monitoring. The identification of eligible patients was based on their electronic medical records between September 2019 and May 2021. Invitation letters containing study details and contact information for further inquiries were sent to identified participants. During their routine clinic appointments, interested patients were approached, provided with study information, and asked to provide informed consent. Baseline study questionnaires were completed to assess sociodemographic and psychosocial information. The study protocol received approval from the Institutional Review Board at the University of Massachusetts Chan Medical School (H00016067).

Study Design

The development of the Pulsewatch system, consisting of a smartphone with the Pulsewatch application and a Samsung smartwatch, for AF monitoring was performed in Part one of the study. Patient and provider focus groups were conducted, and feedbacks was incorporated into the design of the Pulsewatch app. The implementation of smartwatch-app system for AF monitoring occurred during Part II of the study and consisted of two phases.

In Phase I, participants were randomized in a 3: 1 ratio into the intervention and control groups for a period of 14 days. Both groups received the gold standard ECG patch monitoring (a cardiac outpatient telemetry patch monitor, the Cardiac Insight™). Additionally, the intervention group was fitted with the Pulsewatch system. Phase I primarily assessed the accuracy of the Pulsewatch system. In Phase II, all participants were re-randomized for an additional 30 days in a 1: 1 ratio to primarily study adherence. Participants in the control group received no additional devices, while those in the intervention group received the Pulsewatch system along with the FDA-approved AliveCor™ device to confirm their smartwatch readings.

Participants completed questionnaires at enrollment, the 14-day (end of Phase I), and 44-day (end of Phase II) follow-up visits. Anxiety was assessed using the Generalized Anxiety Disorder (GAD)-7 questionnaire. Physical and Mental Health were ac-

cessed using the 12-Item Short Form Health Survey, including the Physical Component Summary (PCS-12) and Mental Component Summary (MCS-12). Patient activation was evaluated using the Consumer Health Activation Index (CHAI). Wear time was calculated as the number of hours the smartwatch was worn during the day and the number of days the watch was worn during study period. Our study focused on comparing differences in anxiety, quality of life measures, patient engagement, and wear time across three different age groups.

The Farmington Heart Study noted that the attributable risk of stroke from AF significantly increased with age, and utilized the age distributions, 50-59, 60-69, 70-79, and 80-89.[6] Additionally, statistics have shown that in older individuals greater than 50, there is a statically significant decline in smartphone and wearable device usage in the age groups of 60-69 and 70 and above, when compared to the age group 50-59.[17] Therefore, as we were aiming to study the difference in perception of mental and physical health along with differences in patient engagement with the use of technology in post-stroke survivors, we utilized similar age distributions with Group 1 (ages 50-59), Group 2 (ages 60-69), and Group 3 (ages 70-87), with the comparative group being participants in group 1.

Statistical Analysis

Mixed-effects repeated measures linear regression model was performed to compare the difference in GAD-7 questionnaire scores, CHAI questionnaire scores, SF-12 scores, and wear times between the various age groups. Utilizing the Mixed-effects repeated measures linear regression model allowed for baseline characteristics to be adjusted for, which included a past medical history of a myocardial infarction, previous history of a percutaneous coronary intervention and cognitive impairment (Table 1 & 2). The analysis was completed used SAS 9.3.

RESULTS

Of 120 participants recruited in the study, a total of 104 participants used the Pulsewatch system and therefore have been included in this analysis.

Smartwatch users in Group 2 (ages 61–69 years) and Group 3 (ages 70–87 years) did not have increased odds of having anxiety as compared to Group 1 (ages 50–60 years; $\beta = 0.84 \pm 0.8$, $P = 0.29$ and $\beta = -0.89 \pm 0.8$, $P = 0.28$; respectively). There was no significant difference in patient activation in Group 2 and Group 3 as compared to Group 1 ($\beta = -2.76 \pm 3.2$, $P = 0.39$ and $\beta = -0.58 \pm 3.39$, $P = 0.86$, respectively). There was no significant difference in perceived physical health in Group 2 and Group 3 as compared to Group 1 ($\beta = 0.87 \pm 2.1$, $P = 0.68$ and $\beta = -1.96 \pm 2.2$, $P = 0.38$; respectively). There was no significant difference found in perceived mental health in Group 3 compared to Group 1 ($\beta = 2.08 \pm 1.73$, $P = 0.23$). However, Group 2 had a decrease in perception of mental health compared to Group 1 ($\beta = -3.29 \pm 1.63$, $P = 0.046$, Table 3). There was no difference found in mean wear time or number of days the device was worn in Group 2 and Group 3 as compared to Group 1 (Table 4).

DISCUSSION

Patient engagement is a vital component of high-quality healthcare, correlating with improved health outcomes, increased compliance with medical therapies, and lower healthcare costs. The emergence and rapid development of digital technology, particularly mobile health technologies, have provided new avenues to foster patient engagement. However, challenges persist in encouraging and sustaining the adoption of these tools. This can be particularly challenging in older adults, with studies reporting a reluctance to utilize these innovations due to a perception of low reliability of the results, difficult to understand health information and a perception of low utility.[18,19] Interestingly, our study indicated that older study participants, ages 60-69 and ages 70-87, engaged with smartwatch technology just as much as younger participants, ages 50-59, with similar wear time for the smartwatches capable of AF detection.

Sustaining interest in the use of these technologies can be challenging and some studies have emphasized the importance of usability of these newer devices to increase adoption and sustained use, referring to aspects such as user interface. Due to age-related changes in vision, cognition and motor control, these studies have noted that it may be beneficial to design these technologies keeping the limita-

Table 1 Demographics and medical characteristics of participants.

Participants (n = 104)	Group 1 50-60 (Q1) n = 36	Group 2 61-69 (Q2) n = 35	Group 3 70-87 (Q3) n = 33	P-value
Female	13 (36.1%)	16 (45.7%)	14 (42.4%)	0.705
Male	23 (63.9%)	19 (54.3%)	19 (57.6%)	
Race				
White	30 (83.3%)	30 (85.7%)	31 (93.9%)	0.505
Non-white	5 (13.9%)	3 (8.6%)	1 (3.1%)	
Unknown	1 (2.8%)	2 (5.7%)	1 (3.0%)	
Past medical history				
Congestive heart failure	1 (2.8%)	3 (2.9%)	3 (2.9%)	0.502
Cardiac arrhythmias	3 (8.3%)	5 (14.3%)	7 (21.2%)	0.314
Valvular disease	4 (11.1%)	2 (5.7%)	5 (15.2%)	0.446
Vascular disease	10 (27.8%)	5 (14.3%)	13 (39.4%)	0.065
Hypertension	25 (69.4%)	26 (74.3%)	28 (84.9%)	0.314
Diabetes	8 (22.2%)	7 (20.0%)	11 (33.3%)	0.399
Hyperlipidemia	31 (86.1%)	33 (94.3%)	26 (78.8%)	0.173
Chronic pulmonary disease	2 (5.6%)	6 (17.1%)	2 (6.1%)	0.179
Renal disease	2 (5.6%)	1 (2.9%)	2 (6.1%)	0.799
Major bleeding event or predisposition to bleeding	1 (2.8%)	4 (11.4%)	2 (6.1%)	0.341
Prior myocardial infarction	7 (19.4%)	2 (5.7%)	10 (30.3%)	0.031*
Sleep apnea	5 (13.9%)	13 (37.1%)	10 (30.3%)	0.076
Treatment history				
Percutaneous coronary intervention	3 (8.3%)	1 (2.9%)	8 (24.2%)	0.017*
Cardiac surgery	2 (5.6%)	4 (11.4%)	8 (24.2%)	0.069
Anti-arrhythmic medication	0 (0%)	2 (5.7%)	0 (0%)	0.134
Beta blocker	15 (41.7%)	12 (34.3%)	20 (60.6%)	0.081
Calcium channel blocker	5 (13.9%)	8 (22.9%)	8 (24.2%)	0.502
Hypertension medication	19 (52.8%)	17 (48.6%)	24 (72.7%)	0.100
Antiplatelet medication	30 (83.3%)	31 (88.6%)	29 (87.9%)	0.782
Anticoagulant	5 (13.9%)	4 (11.4%)	4 (12.1%)	0.949
Statin use	32 (88.9%)	33 (94.3%)	30 (90.9%)	0.717
Vitals				
BMI	28.1 ± 5.1	30.9 ± 12.3	36.1 ± 32.2	0.237
Diastolic BP	78.7 ±7.7	76.7 ± 9.7	72.3 ± 8.2	0.011*
Systolic BP	129.0 ± 16.9	130.6 ± 14.3	132.8 ± 18.7	0.643
Heart rate	78.0 ± 15.6	73.9 ± 13.1	68.3 ± 12.0	0.017*

Data are presented as mean ± SD or n (%). BMI: body mass index; BP: blood pressure.

tions of the elderly in mind.[20–23] Indeed, when designing a patient portal linked to an electronic health record to help improve medication safety, Schnipper *et al.*,[24] conducted usability tests with participants to help improve the interface. The study highlighted the importance of such testing and had implemented features such as easy-to-understand language, drop-down menus, examples for how to enter information and incorporated branching logic to enhance user experience.[24]

In the initial phase of our study, we facilitated focus groups that included participants and health-

Table 2 Psychosocial characteristics of participants.

Technology engagement, *n* = 104	50-60 (Q1), *n* = 36	61-69 (Q2), *n* = 35	70-87 (Q3), *n* = 33	*P*-value
Device ownership				
Smartphone (Y/N)	29 (80.6%)	33 (94.3%)	23 (71.8%)	0.051
Smartwatch (Y/N)	11 (30.6%)	7 (20.0%)	8 (25.0%)	0.592
App use frequency				
Daily	25 (80.7%)	22 (66.7%)	15 (53.6%)	0.531
A few days a week	3 (9.7%)	6(18.2%)	3 (10.7%)	
At least once a week	1 (3.2%)	2 (6.1%)	4 (14.3%)	
Less than once a week	0	1 (3.0%)	1 (3.6%)	
Once a month	1 (3.2%)	1 (3.0%)	2 (7.1%)	
Never	1 (3.2%)	1 (3.0%)	3 (10.7%)	
Psychosocial Characteristics				
> 8 alcohol drinks per week	1 (2.8%)	2 (5.7%)	5 (15.2%)	0.135
Social isolation at baseline (*n* = 103)	4 (11.1%)	5 (14.3%)	3 (9.4%)	0.816
Cognitive impairment (*n* = 101) (Y/N)	8 (23.5%)	7 (20.0%)	16 (50.0%)	0.016*
Depressive symptoms at baseline (*n* = 102)				
None (Score: 0-4)	21 (58.3%)	17 (48.6%)	19 (61.3%)	0.306
Mild (Score: 5-9)	13 (36.1%)	9 (25.7%)	10 (32.3%)	
Moderate (Score: 10-14)	1 (2.8%)	5 (14.3%)	2 (6.5%)	
Moderately severe (Score: 15-19)	1 (2.8%)	3 (8.6%)	0 (0%)	
Severe (Score: 20-27)	0 (0%)	1 (2.9%)	0 (0%)	
Anxiety symptoms (*n* = 101)				
None (Score: 0-4)	25 (69.4%)	20 (58.8%)	24 (77.4%)	0.551
Mild (Score: 5-9)	8 (22.2%)	8 (23.5%)	6 (19.4%)	
Moderate (Score: 10-14)	2 (5.6%)	5 (14.7%)	1 (3.2%)	
Severe (Score: 15 +)	1 (2.8%)	1 (2.9%)	0 (0%)	
Patient activation (*n* = 99)				
Low (0-79)	14 (38.9%)	11 (33.3%)	9 (30.0%)	0.479
Medium (80-94)	13 (36.1%)	17 (51.5%)	17 (56.7%)	
High (95-100)	9 (25.0%)	5 (15.2%)	4 (13.3%)	

Data are *n* (%).

Table 3 Measured outcomes among participants of different age groups.

	GAD7 scores			CHAI scores			PCS			MCS		
Unadjusted												
	Estimate	SE	*P*-value	Estimate	SE	*P*-value	Estimate	SE	*P*-value	Estimate	SE	*P*-value
61-69*	0.99	0.8	0.22	-3.4	3.15	0.28	1.39	2.2	0.52	-3.55	1.62	0.03
70-87*	-0.89	0.8	0.28	-0.65	3.21	0.84	-3.18	2.2	0.15	2.23	1.65	0.18
Adjusted												
61-69*	0.84	0.8	0.29	-2.76	3.2	0.39	0.87	2.1	0.68	-3.29	1.63	0.046
70-87*	-1.27	0.9	0.14	-0.58	3.39	0.86	-1.96	2.2	0.38	2.08	1.73	0.23

*Reference range 50-60. Adjusted for cognitively impaired, prior MI, and PCI

GAD7: Generalized Anxiety Disorder-7; CHAI: Consumer Health Activation Index; PCS: physical component score of SF-12; MCS: mental component score of SF-12.

Table 4 Mean daily hours and days smartwatches were worn.

Age Group (years old)	50-60		61-69		70-87		
	N	Hours/day	N	Hours/day	N	Hours/day	*P*-value
Mean time in hours/day	31	11.0 (6.0)	33	12.7 (5.1)	29	10.9 (6.2)	0.39
	N	#day	N	#day	N	#day	
Number of days worn	31	24.7 (12.3)	33	24.3 (12.1)	29	22.3 (11.4)	0.72

care providers to guide the development of the Pulsewatch system. We incorporated feedback stemming from discussions to enhance the usability of the Pulsewatch system in our post-stroke patient cohort. Participants in our study found the smartwatch-app dyad to be highly usable and preferred it over the traditional patch monitor.[25] Moreover, we observed no differences in the wear time of the smartwatch among the different age groups.

Interestingly, Steventon, *et al.*[26] designed a randomized control trial which sought to explore the impact of telemedicine on hospitalizations among older adults but noted challenges with recruitment. Indeed, in a follow-up qualitative study conducted among participants that had declined to participate or withdrew from the trial, individuals cited confusion regarding its utility, expressed doubts about their capacity to use this technology and some felt it threatened their independence in managing their conditions.[19] Unsurprisingly, those that expressed concerns also found other forms of technology to be complicated as well.[19] Similarly, a study conducted to assess willingness of older adults to utilize assisted living technologies found that prior experience with technology was a strong predictor for participant recruitment.[27] When examining the baseline characteristics of our study participants, a majority of the users in all age groups were found to have smartphones (80.6% in group 1, 94.3% in group 2 & 71.8% in group 3) with a significant subset reporting daily mobile phone application usage (80.7% in Group 1, 66.7% in Group 2 & 53.6% in Group 3). Perhaps, much like the study designed by Sanders et al.,[19] further research among those that did not consent to our study may unearth limitations in their prior knowledge and experience in using technology as a potential cause for unwillingness to participate. Further research could also ascertain additional ways in which these individuals can be supported when using these technologies.

Interestingly, we observe a decrease in perception of mental health in participants between ages 60-69 compared to those between ages 50-59 when prescribed the smartwatch-app dyad. This observation maybe be related to factors such as lack of familiarity or confidence in using the device or perhaps alerts from the devices cause an altered perception of well-being.[28] Indeed, when conducting a focus group study to ascertain older adults' perceptions of technology and barriers to interacting with tablet computers, Vaportzis, *et al.*[29] noted that some participants reported feelings of inadequacy and negatively compared themselves to younger generations that they felt were more technologically adept. Perhaps, participants in our study within the age group of 60-69 felt a similar sense of unfamiliarity with the technology which may have negatively contributed to their lower MCS scores. It remains unclear if this observation is due to our limited sample size and warrants further research.

Studies have noted provider endorsement as a significant factor influencing an individual's decision to adopt and continue to use newer technologies.[24,30–33] A study conducted to determine the willingness of individuals to utilize an mHealth app found that participants intentions to download the health app was greater if it was recommended by a doctor.[31] Despite the potential benefits and considerable interest in mHealth technologies among the elderly,[27,34] providers have been reluctant to recommend these innovations to their patients,[30,35–37] citing concerns such as the potential for increased anxiety.[36] We found that older participants, aged 60-69 years and aged 70-87 years, did not have increased anxiety or worsened perceived physical health and had similar patient engagement when compared to the younger participants, ages 50-59 years, when using our smartwatch-app dyad. Our results address apprehensions regarding potential adverse effects of smartwatch prescription among the older adults, suggesting overall safety and viability as an AF monitoring tool for this patient population.

Strengths & Limitations

The Pulsewatch study is a multi-phased randomized controlled trial investigating the accuracy, adherence and health behaviors impact of wearables deployed for AF detection in stroke survivors. Our study possesses well-defined sociodemographic, clinical, and psychosocial characteristics of participants. We incorporated standardized and validated instruments, namely the GAD-7, SF-12, and CHAI questionnaires, thereby augmenting the validity and generalizability of our findings. Our study has inherent limitations. Notably, the size of our participant cohort is modest, potentially lacking sufficient power to discern subtle differences among older adults participating in our study. Additionally, our cohort is predominantly comprised of individuals who are relatively homogeneous with respect to their race, ethnicity, and socioeconomic status. To broaden applicability of our conclusions, future research endeavors should include a larger and more diverse cohort.

Conclusions

Considering the increased prevalence of AF with age and the high risk of stroke among older adults with AF, older individuals may derive benefit from using wearables to detect undiagnosed AF. We did not observe significant differences across different age strata in anxiety or other key patient-reported outcomes. Future research is needed to validate our findings and explore whether screening for AF can reduce stroke and improve engagement among at-risk older adults.

DISCLOSURE

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Conflict of Interests

Dr. McManus reports receiving research support from Apple Computer, Bristol-Myers Squibb, Boehringer-Ingelheim, Fitbit, Pfizer, Samsung, Flexcon, Philips Healthcare, and Biotronik; consultancy fees from Bristol-Myers Squibb, Pfizer, Flexcon, Boston Biomedical Associates/Avania, Fitbit, and Heart Rhythm Society. Dr. Tran reports receiving research grants from Novartis.

Authorship

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

Patient Consent

All patients provided written informed consent.

Ethics Statement

The study protocol received approval from the Institutional Review Board at the University of Massachusetts Chan Medical School (H00016067).

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