

# Psychosocial measures in relation to smartwatch alerts for atrial fibrillation detection



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Atrial fibrillation (AF) is the most common arrhythmia and is a common cause of mortality and cerebrovascular events.<sup>1</sup> Therefore, AF detection after a stroke is vital. Algorithms for analysis of pulse data from smartwatches have been approved by the Food and Drug Administration (FDA) for AF detection and are being increasingly recommended for AF screening.<sup>2</sup> At the same time, ownership of wearable devices has shown a steady annual increase among adults  $\geq 50$  years of age, with approximately 42% reporting almost daily use of the technology, thus highlighting the potential of wearable devices for AF monitoring.<sup>3</sup> The impact of AF screening on older adults with regard to key outcomes, including psychological well-being, has not been well explored.<sup>4</sup> Historically, AF has been associated with worse health-related quality of life,<sup>5</sup> especially among older adults. Additionally, anxiety among smartwatch users, possibly driven by receipt of alerts for possible rhythm abnormalities, has been reported.<sup>6</sup>

To examine the associations between smartwatch alerts for possible AF and psychological health, we analyzed data from the Pulsewatch study,<sup>7</sup> a multiphase, randomized controlled trial ([ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT03761394) Identifier: NCT03761394) of smartwatches for AF detection among survivors of stroke/transient ischemic attack (TIA). The study enrolled older adult (age

$\geq 50$  years) survivors of stroke/TIA with no contraindications to anticoagulation therapy. Phase I intended to assess the accuracy of the smartwatch system and phase II assessed the adherence to it. In phase I, participants were randomized 3:1 (intervention: control) to either receive a smartwatch/smartphone dyad capable of alerting the participant of possible AF and an FDA-approved mobile cardiac outpatient telemetry (MCOT) patch monitor (Cardiac Insight, Bellevue, WA) or receive only the MCOT patch (control) and monitor for AF for 14 days. In phase II, participants were re-randomized (1:1) following a permuted block randomization, to ensure adequate representation of phase I control group participants in the intervention group, who were offered continued use of the smartphone/smartwatch dyad for an additional 30 days. In this analysis, we included participants who received a smartwatch/smartphone dyad and grouped them into those receiving one or more alerts of possible AF detection vs those not receiving any alerts. The smartwatch would alert a participant to “hold still” to minimize motion artifact during the detection of a possible abnormal rhythm, followed by another alert of “abnormality detected” when AF was indeed captured (Figure 1). Trained research staff abstracted data from participants’ medical records, including demographic, clinical, and psychosocial characteristics. The study protocol was approved by the University of Massachusetts Medical School Institutional Review Board (H00016067).

The GAD (Generalized Anxiety Disorder)-7 Scale, a standardized 7-item questionnaire (range 0–21), was used to assess anxiety.<sup>8</sup> Presence of anxiety was defined as GAD-7 score  $\geq 5$ . The Consumer Health Activation Index (CHAI), a validated 10-item scale (range 0–100), was used to evaluate patient activation,<sup>9</sup> with CHAI score  $\geq 95$  indicative of high activation

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### KEY FINDINGS

- Receipt of atrial fibrillation (AF) alerts generated by smartwatches in older poststroke adults may be associated with a lower perception of physical health.
- AF smartwatch alerts in our poststroke cohort were not related to changes in self-reported anxiety, patient activation or mental health perception.

level. The Physical Component Summary and Mental Component Summary of the Short-Form Health Survey (SF-12), an established 12-item survey (range 0–100), were used to assess health-related quality of life, with higher scores indicative of higher-quality health status.<sup>10</sup> Questionnaires were delivered to all participants at baseline, 14 days, and 44 days.

Baseline participant characteristics were compared using Student *t* tests for continuous variables and  $\chi^2$  tests for categorical variables. Approximately one-third of participants demonstrated low anxiety levels at baseline in both groups (receiving alerts vs no alerts). Health status and patient activation were not different between the groups. Mixed-effects repeated measures linear regression models with anxiety, patient activation, and physical and mental health status as outcomes were used to examine their association with receiving alerts. Individual participants were included as the random effect to account for correlation among repeated measures from the same participant. Age, race, sex, baseline depression, cognitive impairment, as well as history of congestive heart failure, history of cardiac arrhythmias, and history of myocardial infarction were included as fixed effects.

A total of 94 participants (age  $64.6 \pm 9.1$  years; 44% female; 87% non-Hispanic white) were included in the analysis. Among participants who received alerts, 12 received 1–3 alerts, 3 received 11–18 alerts, and 1 received 226 alerts. Adjusting for confounders, receiving alerts was not

significantly associated with change in self-reported anxiety ( $\beta = -0.78$ ;  $P = .33$ ), patient activation ( $\beta = -1.70$ ;  $P = .60$ ), or mental health status ( $\beta = 2.85$ ;  $P = .09$ ), but receipt of an alert was associated with a statistically significant reduction in self-rated physical health status ( $\beta = -4.67$ ;  $P = .04$ ), over the study period.

Clinicians are increasingly recommending the use of wearable devices approved for AF detection to patients at risk for the arrhythmia, including older adults with stroke. Our study findings suggest that AF alerts generated by wearable devices are unlikely to lead to significant anxiety among older adults, but an alert may be associated with a lower perception of physical health. Our observation may be explained by the fact that an individual's perception of his or her well-being may be changed because of an alert for AF or, conversely, because of the symptoms from AF. Generalizability of our findings is limited by the small sample size, short observation time, and inclusion of only poststroke adults. Further studies are needed to examine any potential harms of AF screening using wearable devices to assist with their optimal clinical integration and to better inform clinicians and public health guidelines.

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### Disclosures

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Figure 1 Smartwatch interface with different alerts that participants received.

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### Authorship

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

### Patient Consent

All patients provided written informed consent.

### Ethics Statement

The authors designed the study, gathered, and analyzed the data according to the Helsinki Declaration guidelines on human research. The research protocol of the study was reviewed and approved by the institutional review board.

### Disclaimer

Given his role as Editor-in-Chief, Dr David McManus had no involvement in the peer review of this article and has no access to information regarding its peer review. Full responsibility for the editorial process for this article was delegated to Dr David Duncker. Given his role as Associate Editor, Dr Ki Chon had no involvement in the peer review of this article and had no access to information

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