Undetected AF can have potentially life-threatening consequences

Atrial fibrillation (AF) is a type of an irregular heart rhythm, or arrhythmia, that occurs when the upper chambers of the heart beat out of sync with the lower chambers. It's a leading cause of stroke and can be difficult to detect because it is often not associated with any symptoms. Early diagnosis and treatment can help prevent complications.

More than 33 million people worldwide and between 3 to 6 million in the US have AF.[1,2]

70%

AF affects more people as they age – approximately 70% of individuals with AF are between the ages of 65 and 85.[3]

AF results in 130,000 deaths and 750,000 hospitalizations each year in the US.[1]

30%

Up to 30% of people living with AF aren't diagnosed because AF is often not associated with any symptoms.[4]

15-20%

AF is the most common sustained cardiac arrhythmia and accounts for up to 15-20% of strokes per year in the US.[1]

Learn more about the Heartline Study

To be eligible, individuals must be age 65 or older, be a US resident for the duration of the study, able to read/understand English, and own an iPhone 6s or later (with iOS 12.2 or later), and have Original Medicare. They must also authorize data sharing.

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Learn more online at www.heartline.com/providers

Additional Resources

[1] Centers for Disease Control and Prevention. Atrial Fibrillation Fact Sheet. Available at: https://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_atrial_fibrillation.htm. Accessed November 2019.

[2] Chugh SS, Havmoeller R, Narayanan K, et al. Worldwide epidemiology of atrial fibrillation: a Global Burden of Disease 2010 Study. Circulation. 2014;129(8):837-847.

[3] Kistler P, Sanders P, Fynn S, et al. Electrophysiologic and electroanatomic changes in the human atrium associated with age. J Am Coll Cardiol. 2004;44:109–116.

[4] Svennberg E, Engdahl J, Al-Khalili F, et al. Mass Screening for Untreated Atrial Fibrillation: The STROKESTOP Study. Circulation. 2015;131(25):2176-84.

[5] Kaufman BG, Kim S, Pieper K, et al. Disease understanding in patients newly diagnosed with atrial fibrillation. Heart. 2018;104:494-501.

[6] Steinhubl SR, Waalen J, Edwards AM, et al. Effect of a Home-Based Wearable Continuous ECG Monitoring Patch on Detection of Undiagnosed Atrial Fibrillation: The mSToPS Randomized Clinical Trial. JAMA. 2018;320(2):146–155.

[7] Turakhia MP, Desai M, Hedlin H, et al. Large-Scale Assessment of a Smartwatch to Identify Atrial Fibrillation: The Apple Heart Study. N Engl J Med. 2019;381:1909-1917.

[8] Freedman B, Camm, J, Calkins H, et al. Screening for Atrial Fibrillation. A Report of the AF-SCREEN International Collaboration. Circulation. 2017;135:1851-1867.

• The Heartline Study is not a Government-funded or endorsed clinical trial. Please carefully review all materials and disclosures.

• Information is intended for healthcare providers only. All patients should refer to Heartline.com for study information.

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Welcome to the Heartline Study

Learn how wearable technology may help individuals 65+ understand and directly engage in their heart health.

Patients may have limited understanding of the risks and therapeutic benefits associated with a diagnosis of AF, and evidence suggests lack of knowledge of their condition and treatment options presents a key barrier to the use of medications and adherence to recommendations.[5]

The Heartline™ Study is a virtual randomized controlled study. The primary objective is to assess if everyday technology such as iPhone and Apple Watch features, with a heart health engagement program, can help with early detection of AF and ultimately reduce the likelihood of stroke. Through the Heartline app developed for the study, individuals will also learn more about and make lifestyle changes to improve their heart health.

Advancing heart health research

An earlier mHealth Screening to Prevent Strokes (mSToPs) study found that a wearable continuous ECG monitoring patch can identify people with asymptomatic AF earlier and more efficiently than routine care.[6] Additionally, results from the Apple Heart Study demonstrated that the Apple Watch can detect irregular heart rhythms, such as AF, with a low notification rate in a population with a low burden of AF.[7] These findings indicate the Apple Watch can be used to increase detection of AF without causing over notification.

Heartline™

A white paper from the AF-SCREEN International Collaboration stated that "Based on current knowledge, this white paper provides a strong case for AF screening now while recognizing that large randomized outcomes studies would be helpful to strengthen the evidence base."[8]

Heartline is designed to measure the impact of a heart healthy Engagement Program – delivered via the Heartline app developed for the study and available on the iPhone 6s or later (with iOS 12.2 or later) – paired with the Irregular Rhythm Notification (IRN) and ECG app of Apple Watch Series 4 or later, on the identification and diagnosis of AF, and whether this leads to improved hard clinical outcomes such as stroke and all-cause death.

Study design and objectives

Once enrolled in the study, participants will be assigned to one of the following cohorts, and within each cohort be randomized in a 3:1 fashion to either an iPhone and Apple Watch Group, or an iPhone Only Group:

- Participants without a diagnosis of AF (non-AF cohort)
- Participants with a confirmed diagnosis of AF and on a DOAC for >30 days (AF cohort)

Heartline is designed to:

- Measure the impact of a heart healthy Engagement Program delivered via the Heartline app on the iPhone and Apple Watch on the identification and diagnosis of AF (non-AF cohort), as well as the impact of earlier diagnosis on hard clinical outcomes including stroke and all-cause death.

Direct-to-participant virtual research study

Heartline is a pragmatic, randomized, controlled, app-based virtual research study sponsored by Janssen Scientific Affairs, LLC, an affiliate of Johnson & Johnson, in collaboration with Apple. It will span a total of three years: two years of active engagement, followed by one year of additional data collection. During active engagement, participants will receive a variety of activities related to heart health education, wellness tips, electronic Patient-Reported Outcomes (ePRO) assessments, and topic-related modules directly in the Heartline app that has been developed for the study.

Unlike site-based clinical studies that require multiple participant visits, innovative technology allows individuals to participate remotely, with enrollment and data collection completed via the Heartline app. A virtual investigative site will be used to manage participation, data collection, and data analysis.

- Determine the impact of a heart healthy Engagement Program delivered via the Heartline app on the iPhone and Apple Watch, paired with an Anti-Coagulation Adherence Module intervention, on improving adherence to physician-directed DOAC therapy (AF cohort).

- Build a longitudinal health data repository comprised of all study data including (but not limited to) sensor data from Apple Watch, iPhone Health data, health-care claims data and Heartline app data, which includes responses to ePRO's, surveys, etc. collected throughout the two-year Active Engagement Phase of the study (All cohorts).