About the Heartline™ Study

Synopsis

Heartline: A Heart Health Study Using Digital Technology to Investigate if Early Atrial Fibrillation Diagnosis Reduces the Risk of Thromboembolic Events Like Stroke in the Real-World Environment.

Study Rationale

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.[1]

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.[2] Additionally, results from the Apple Heart Study demonstrated that the Apple Watch can detect irregular heart rhythms, such as AF.[3]

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."[4]

Heartline is a large, randomized study with the hypothesis that early identification, diagnosis, and treatment of AF will lead to better clinical outcomes.

Study Duration

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.

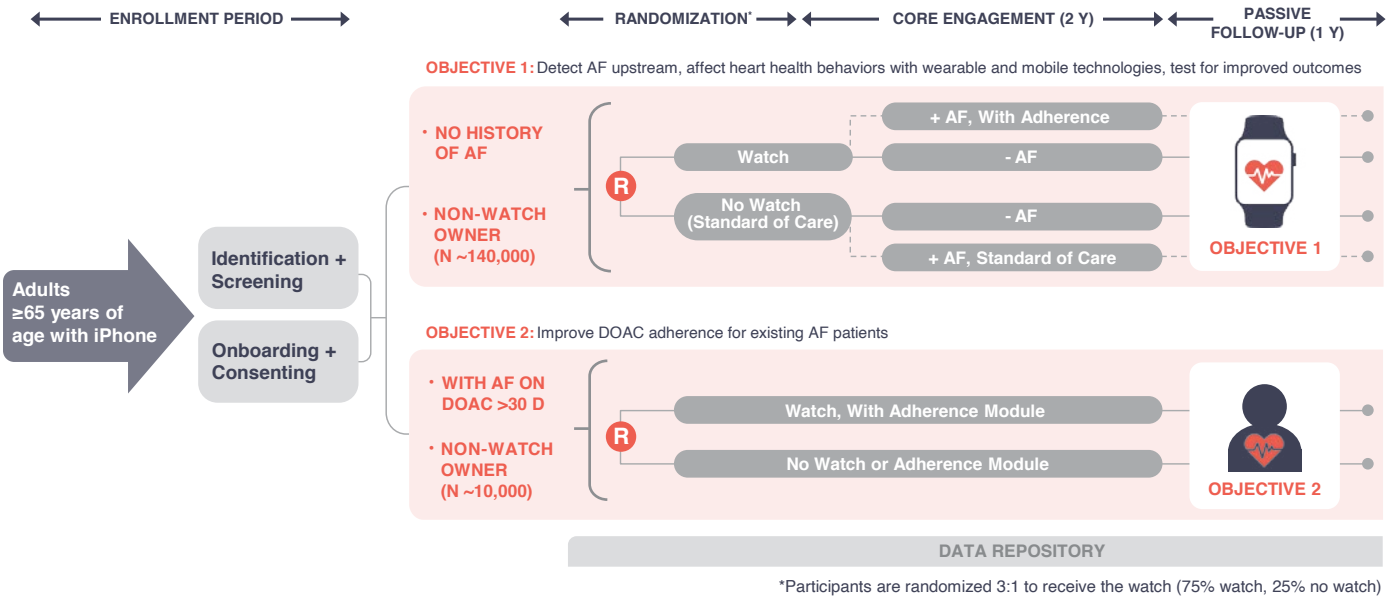
Study Population

This study has a target of 140,000 participants for randomized cohorts and 10,000 participants for observational cohorts. To be eligible, participants must be age 65 or older, be a US resident for the duration of the study, able to read/understand English, own an iPhone 6s or later (with iOS 12.2 or later), and have Original Medicare. They must also authorize data sharing.

Participants with limited life expectancy and/or current diagnosis of terminal cancer are not eligible for the study. Nor are participants with a confirmed AF diagnosis who have been taking a Direct Oral Anti-Coagulant (DOAC) for <30 days, are taking AF medication other than a DOAC, or currently not taking medication for AF.

Study Design

This is a pragmatic, randomized, controlled, app-based virtual research study sponsored by Janssen Scientific Affairs, LLC, an affiliate of Johnson & Johnson. 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.



*Participants are randomized 3:1 to receive the watch (75% watch, 25% no watch)

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Study Objectives and Endpoints

AF Detection (Non-AF cohort)

OBJECTIVE:

To measure the impact of a heart healthy Engagement Program delivered via the Heartline app on the iPhone, paired with the Irregular Rhythm Notification (IRN) and ECG app of the Apple Watch, on the identification and diagnosis of AF.

ENDPOINTS:

The primary endpoint is time from randomization to a clinically confirmed diagnosis of AF with validation obtained from a healthcare claims database. Secondary endpoints are time to a composite of cardiovascular events including stroke and all-cause death.

DOAC Medication Adherence (AF cohort)

OBJECTIVE:

To 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.

ENDPOINTS:

The endpoint is Percent Days Covered (PDC) of any prescription DOAC at 12 months.

All participants will also enter into a longitudinal health data repository

OBJECTIVE:

To build a longitudinal health data repository comprised of all study data including (but not limited to) sensor data from Apple Watch, iPhone Health data, clinical information and Heartline app data.

ENDPOINTS:

Endpoints include changes from baseline in participant characteristics over time due to disease, medications and healthcare utilization. (Specifically, incident disease burden, incident HCU, and incident clinical outcomes.)

Learn more online at www.heartline.com/providers

Additional Resources

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

[2] 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.

[3] 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.

[4] 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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