

Fitbit Heart Study

Purpose: To test a novel software algorithm that uses frequent and overlapping pulse photoplethysmography (PPG) signals from smartwatches and fitness trackers to detect undiagnosed atrial fibrillation (AF) or flutter.

Trial Design: Large-scale single-arm remote clinical trial among eligible Fitbit device users in the U.S. without a history of AF. Participants with an irregular heart rhythm detection (IHRD) notification were invited to a telehealth visit and mailed a one-week ECG-patch monitor.

Primary Endpoint: IHRD positive predictive value (PPV) for concurrent AF.

Additional Endpoints: Frequency of IHRD notifications, fraction of individuals with AF on subsequent ECG patch monitor, AF burden and duration.

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	Overall		Age ≥ 65 years	
	N events / N eligible	% or measure	N events / N eligible	%
Primary Endpoint				
IHRD PPV for concurrent AF	221 / 225	98.2%	96 / 99	97.0%
Additional Endpoints				
Frequency of IHRD notifications	4,728 / 455,699	1.0%	2,070 / 56,870	3.6%
Fraction with AF on subsequent ECG patch monitor	340 / 1,057	32.2%	141 / 422	33.4%
Median AF burden on ECG patch	340 / 1,057	7%	–	–
Median longest AF episode on ECG patch	340 / 1,057	7 hours	–	–

Results:

- A novel PPG software algorithm for Fitbit wearables may enable large-scale identification of undiagnosed AF.
- Individuals with an IHRD device who wear an ECG patch monitor have a substantial likelihood of AF detection with considerable AF burden.

Results reflect the data available at the time of presentation.