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# A DIGITAL, END-TO-END, NATIONWIDE, PRAGMATIC TRIAL OF SCREENING FOR UNDIAGNOSED ATRIAL FIBRILLATION: PRIMARY RESULTS OF THE mSToPS TRIAL

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# Background – Atrial Fibrillation (AF)

- For adults >55, 37% lifetime risk of developing AF
- AF is associated with a 2-fold increased risk in mortality & 5-fold increase for stroke.
- Once recognized, therapeutic anticoagulation can decrease the risk of stroke by 2/3rds, mortality by 30%.

Weng L-C. Circulation 2017;CIRCULATIONAHA.117.031431

Lin HJ. Stroke 1995;26:1527-30

Aguilar MI. The Cochrane database of systematic reviews. 2005;3:Cd001927



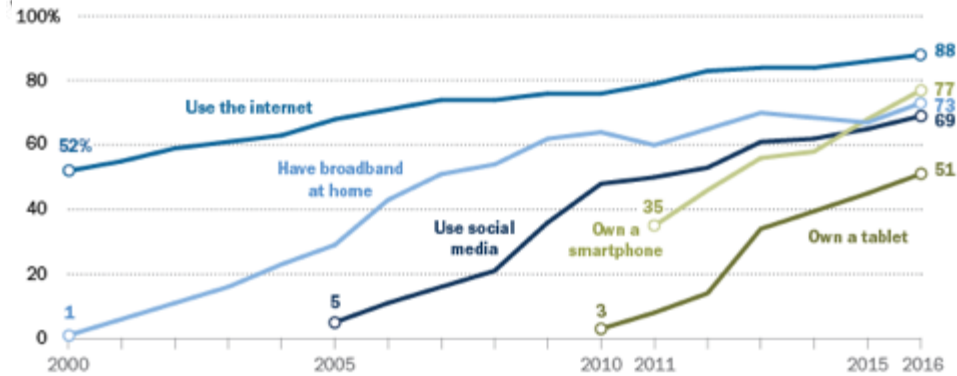
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# Background – Transforming Clinical Trials

- Only 1.7% of eligible patients are enrolled in clinical trials
- < 1/3 of RCTs meet their original recruitment targets.
- 88% of US adults use the internet and 77% own a smartphone

The evolution of technology adoption and usage

% of U.S. adults who ...



Source: Surveys conducted 2000–2016. Internet use figures based on pooled analysis of all surveys conducted during each calendar year.

PEW RESEARCH CENTER

McDonald AM. Trials 2006;7:9 <https://doi.org/10.1186/1745-6215-7-9>

Murthy VH. JAMA 2004;291:2720-2726

Steinhubl SR. Lancet 2017;390:2135



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# mHealth Screening To Prevent Strokes (mSToPS) Overview

aetna<sup>®</sup> Members



**aetna**  
Quality care. Every day. Every member.

You can help with an important heart health study.

You're invited to join an important research study on how to better detect irregular heart rhythm. And you can do it from the comfort of your own home.

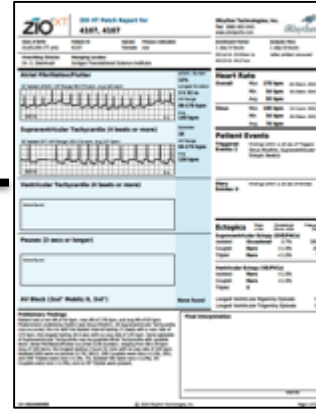
**About the study**  
Atrial fibrillation is a common heart rhythm problem. It's an irregular and often fast heart rate that can lead to stroke. It's an important health condition that needs more research.

We are searching out for tens of thousands of Aetna members like you. Please consider being a part of this study. We hope you'll help make a difference in improving heart care. Research like this can help enhance the lives of others by improving medical knowledge for future generations.

**What's involved in the study**  
The study is voluntary. No money will be paid. If you do, there aren't too any risks involved in your own health. No other studies are needed to participate in this study.

**mSToPS**  
Aetna  
A Clinical Research Study to Screen for Atrial Fibrillation - An Unusual Heart Rhythm

About Clinical Research Studies



**Study consent**

Answer the following questions to complete the enrollment process.

**What is The Purpose of This Study?**

The purpose of this study is to identify people with asymptomatic heart rhythm - atrial fibrillation. Your health is not guaranteed to improve because of this, but your participation will help others.



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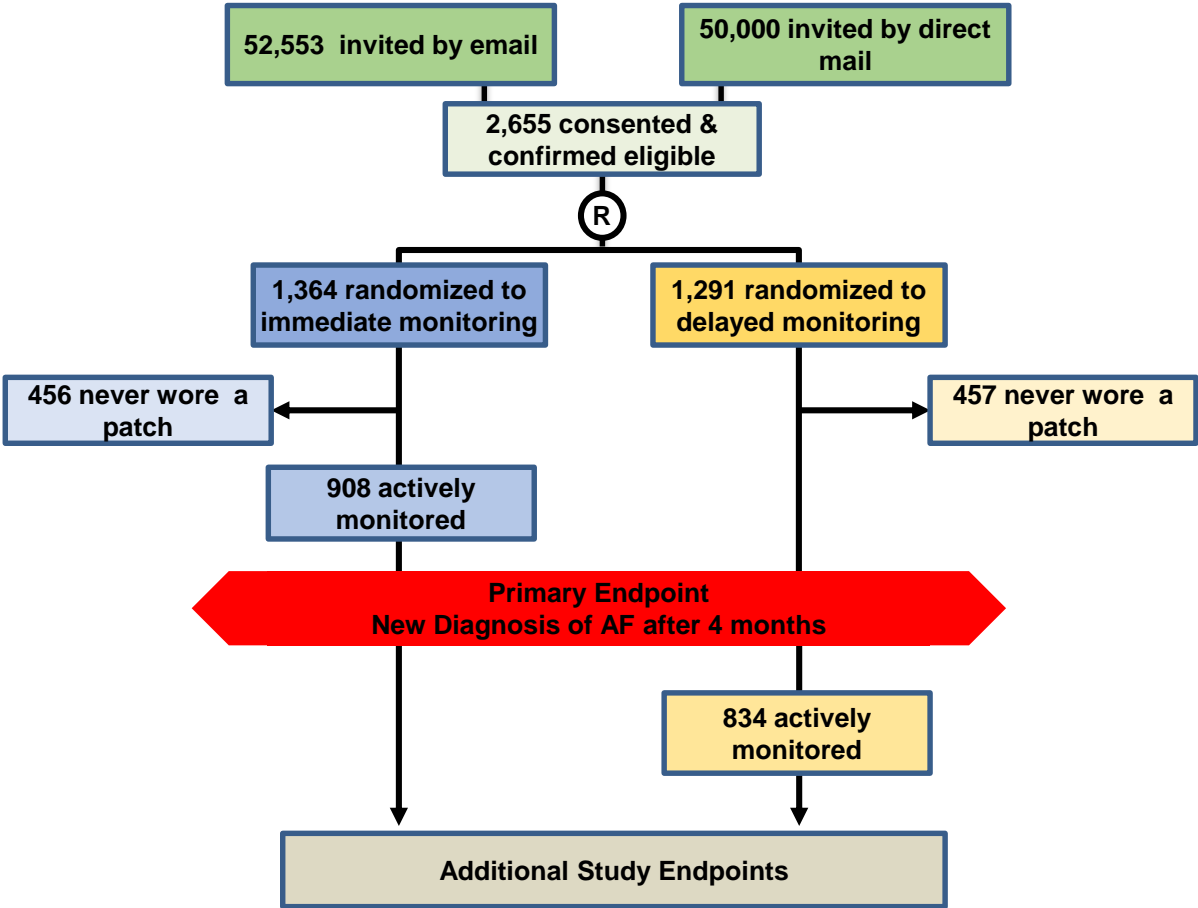
# Primary Objective

In the context of a digital clinical trial, determine if participant-generated data available through a wearable ECG patch can improve the identification of AF relative to routine care.



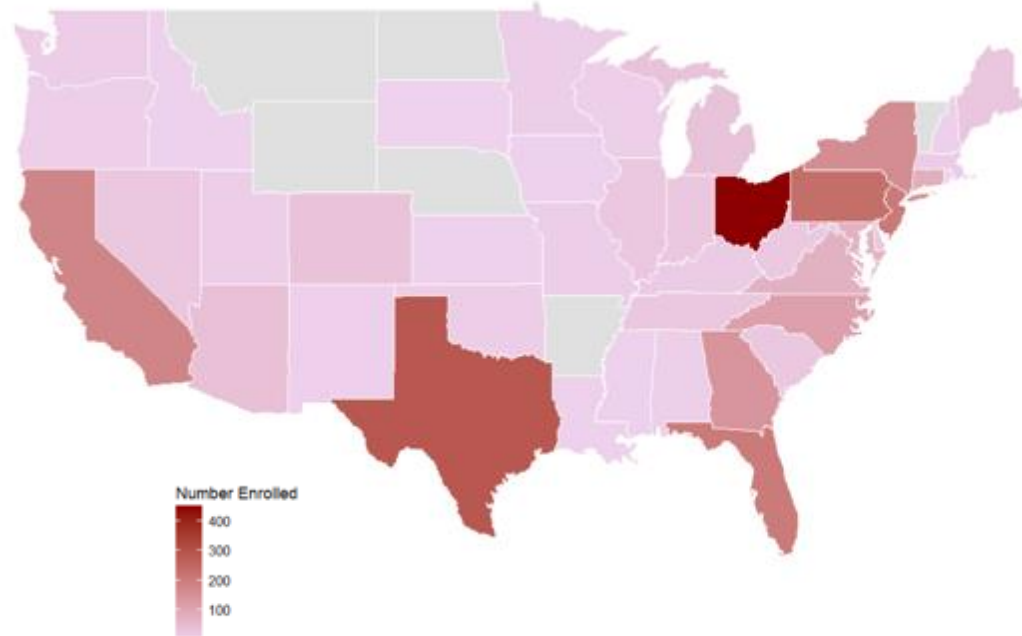
**359,161 Aetna members meeting eligibility criteria**

Main Inclusion Criteria	Main Exclusion Criteria
Age ≥ 75 years old, OR	History of atrial fibrillation or flutter, or atrial tachycardia
Males age >55, females >65 AND	Chronic Anticoagulation
Prior CVA, OR	Implantable Pacemaker or ICD
Heart Failure Diagnosis, OR	
Diagnosis of Diabetes and HTN, OR	
Obstructive Sleep Apnea, OR	



# Baseline Demographics

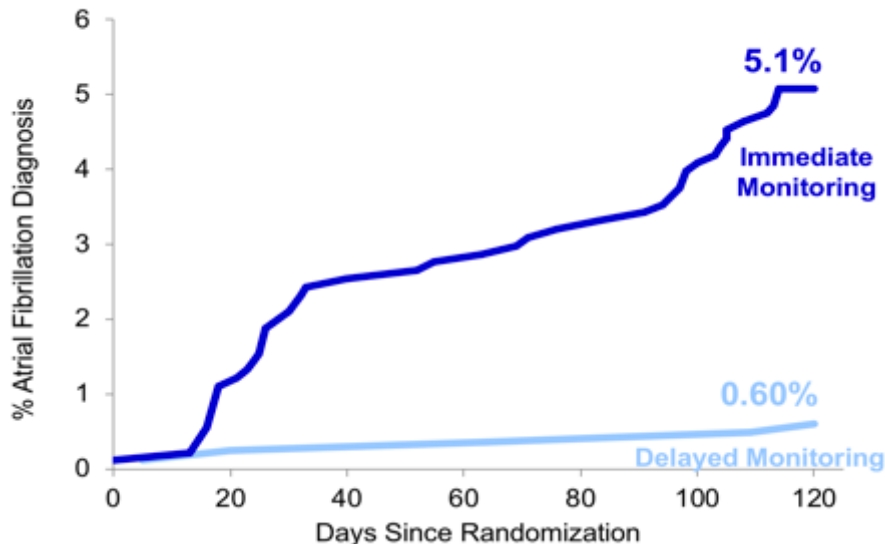
	Immediate n=1364	Delayed n=1291	p-value
Age (mean, SD)	73.5 (7.3)	73.1 (7.1)	0.12
% Female	38.2	39.0	0.66
CHA <sub>2</sub> DS <sub>2</sub> -VAsc (median, Q1-Q3))	3 (2-4)	3 (2-4)	0.82
Prior Stroke (%)	13.7	14.0	0.82
Heart Failure (%)	5.1	4.6	0.56
Hypertension (%)	77.1	76.8	0.86
Diabetes (%)	38.7	36.5	0.24
Sleep Apnea (%)	24.9	29.0	0.02
Hx of MI (%)	5.5	5.6	0.93
Obesity (%)	17.3	18.4	0.45
Chronic Renal Failure (%)	10.9	9.6	0.29



# Primary 4-Month Endpoint – New Diagnosis AF

## Definition of Atrial Fibrillation

- > 30 consecutive seconds of AF by ECG. (CEC adjudicated), or
- A new diagnosis of AF through claims data. (A single new ICD9 or ICD10 code)



**OR 8.8**  
**95%CI 3.5-22.4**  
**P<0.0001**

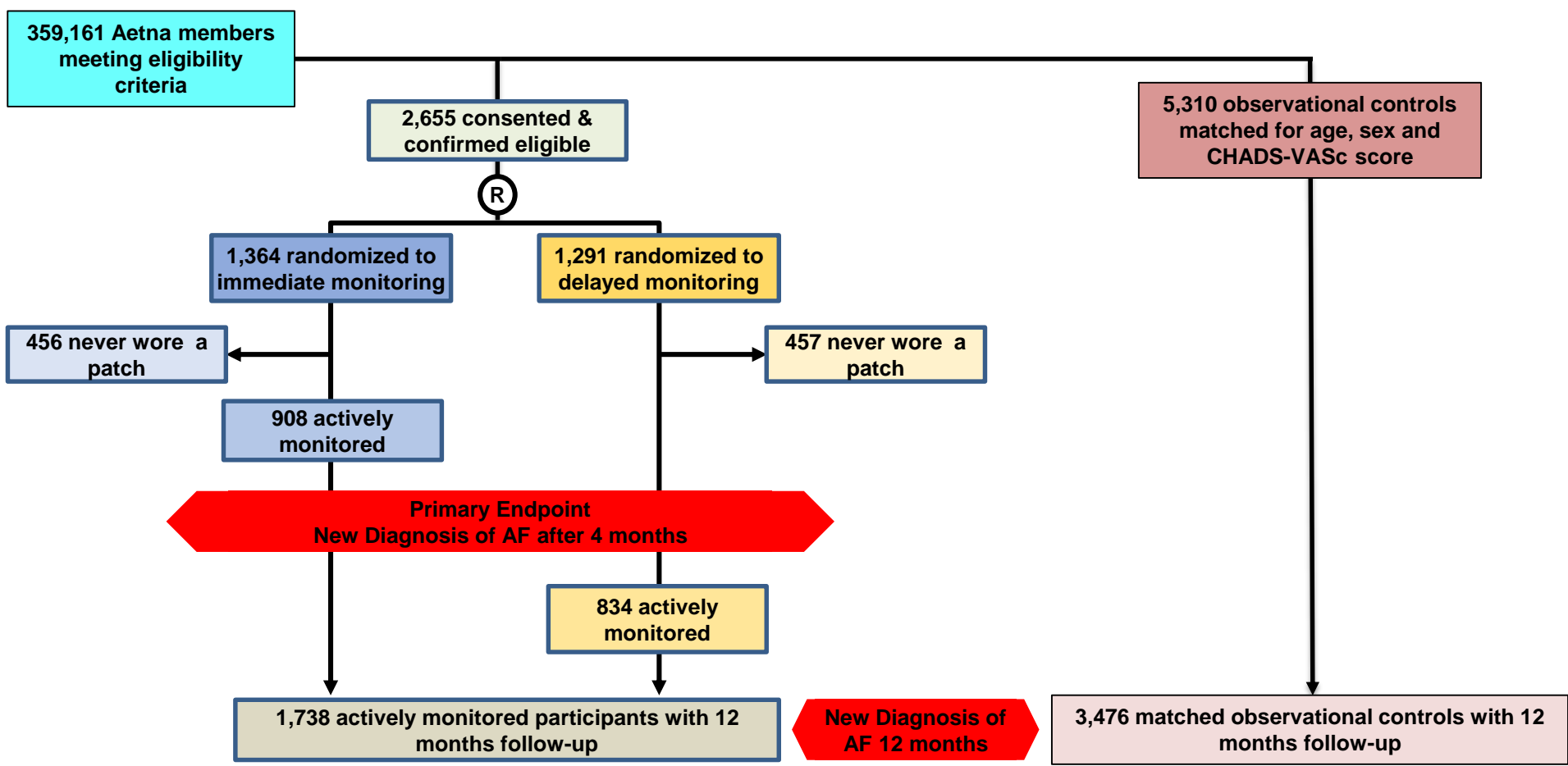
**For ITT population**

**OR 9.0**  
**95%CI 3.6-22.7**  
**P<0.0001**

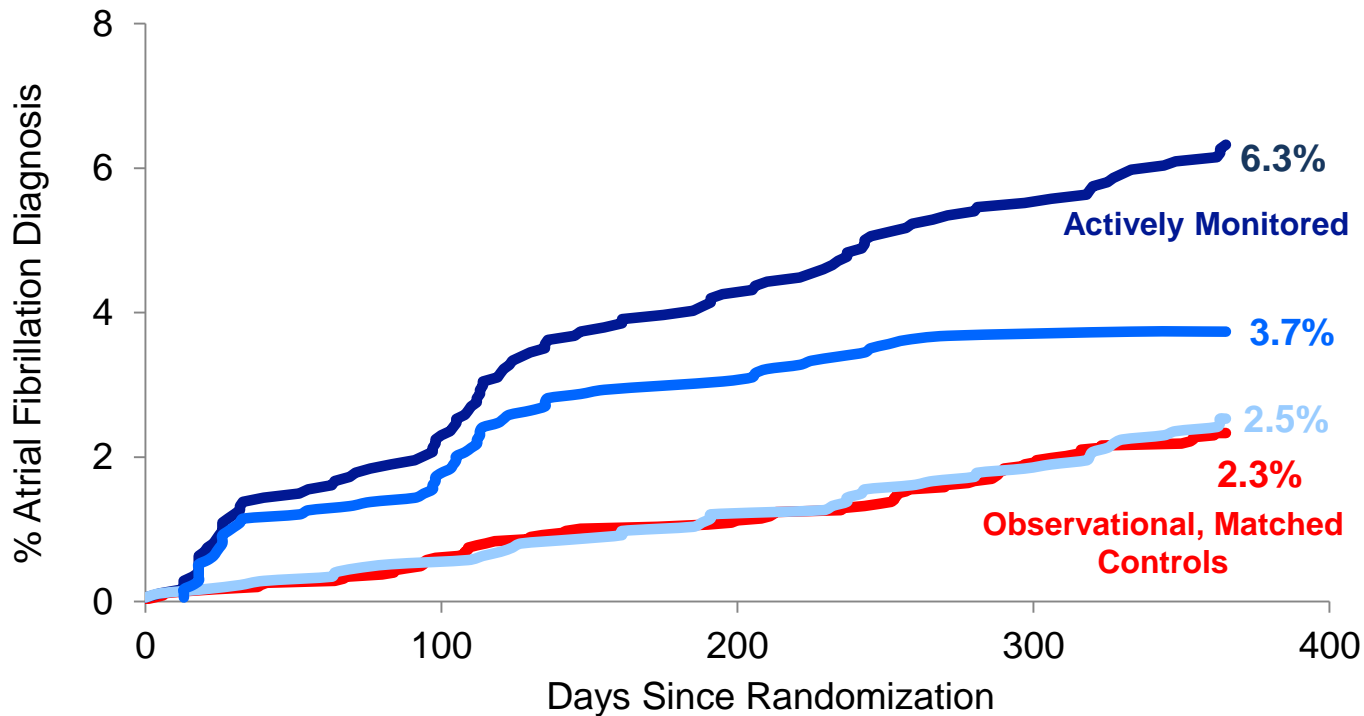


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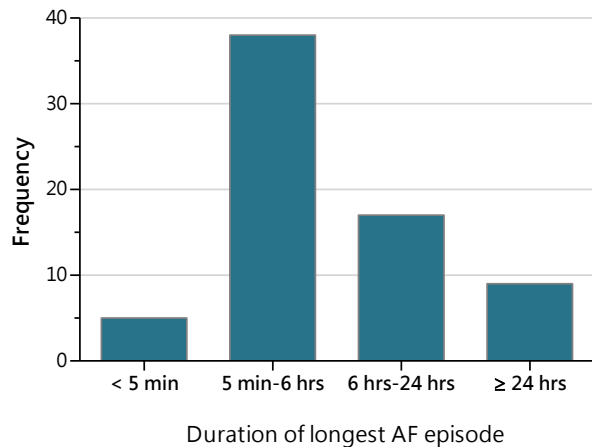
# 1-Year New Diagnosis of AF



**Unadjusted OR 2.8**  
**95%CI 2.1 – 3.7**  
**P<0.0001**

**Adjusted OR 3.0**  
**95%CI 2.2 – 4.0**  
**P<0.0001**

# Characteristics of Sensor-Detected AF

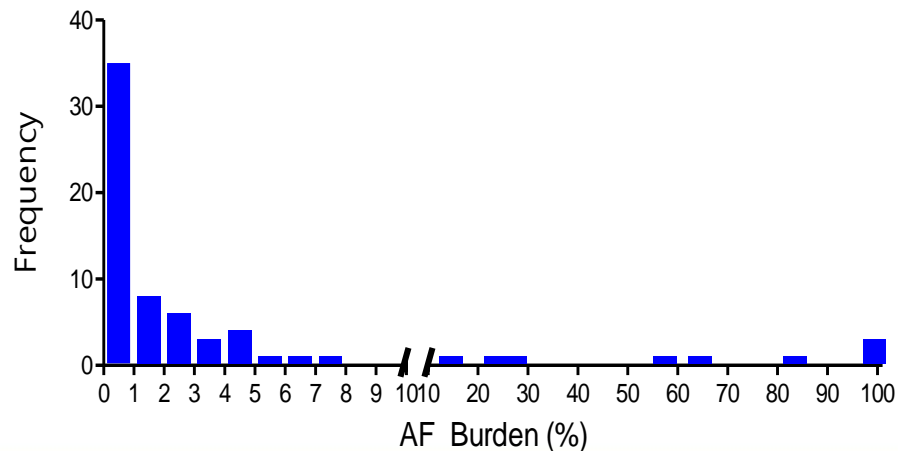


Median duration of longest AF episode 185.5 minutes

- 92.8% > 5 minutes
- 37.7% > 6 hours

Median total AF burden during monitoring was 0.9%

- Average patch wear time 11.7 days
- Median time until first AF detection 2 days (IQR 1-5)



# Clinical Outcomes & Resource Use of ECG Monitoring

	Actively Monitored (n=1,738)	Matched Controls (n=3,476)	p-value
Stroke	33 (1.9%)	71 (2.0%)	0.73
Myocardial Infarction	31 (1.78%)	64 (1.84%)	0.88
Systemic thromboembolism	0 (0.00%)	1 (0.03%)	1.00
All-cause Outpatient Office Visit to a PCP, n (%)	1,368 (78.7%)	2,606 (75.0%)	<b>0.003</b>
All-cause Outpatient Office Visit to a Cardiologist, n (%)	549 (31.6%)	819 (23.6%)	<b>&lt;0.0001</b>
All-cause ER or inpatient stays, median (Q1-Q3)	369 (21.2%)	748 (21.5%)	0.81
Placement of a pacemaker/defibrillator, n (%)	13 (0.7%)	0 (0.0%)	<b>&lt;0.0001</b>
Pharmacy fill for an anticoagulant, n (%)	94 (5.4%)	117 (3.4%)	<b>0.0004</b>



# Limitations

- The clinical significance of ‘short’ episodes of AF, especially in terms of stroke risk, requires greater clarity.
- Only 5.4% of individuals receiving an email invitation enrolled, although this is in a population with an average age of ~74.
- A substantial proportion (38%) of individuals who initially consented never wore a monitoring patch.



# Conclusions

- Through remote digital enrollment and use of participant-generated data, we observed a markedly improved rate of AF diagnosis (~9-fold short term, ~3-fold long-term) relative to routine care.
- Monitoring was associated with greater initiation of guideline-recommended therapies
- But also increased healthcare resource utilization at 1 year.



# THANK YOU

To all of the mSToPS participants

& co-investigators:

Jill Waalen, Alison M. Edwards, Lauren M. Ariniello, Rajesh R. Mehta, Gail S. Ebner, Chureen Carter, Katie Baca-Motes, Elsie Felicione, Troy Sarich, Eric J. Topol



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