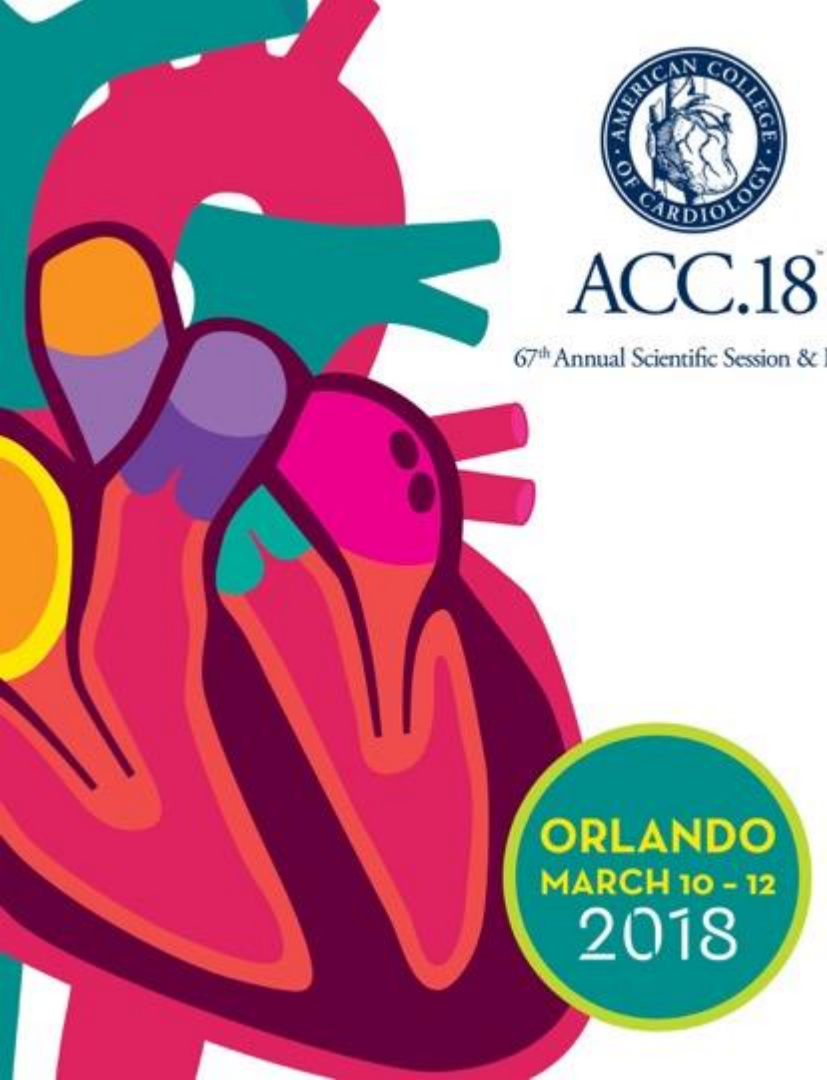

A DIGITAL, END-TO-END, NATIONWIDE, PRAGMATIC TRIAL OF SCREENING FOR UNDIAGNOSED ATRIAL FIBRILLATION: PRIMARY RESULTS OF THE mSToPS TRIAL

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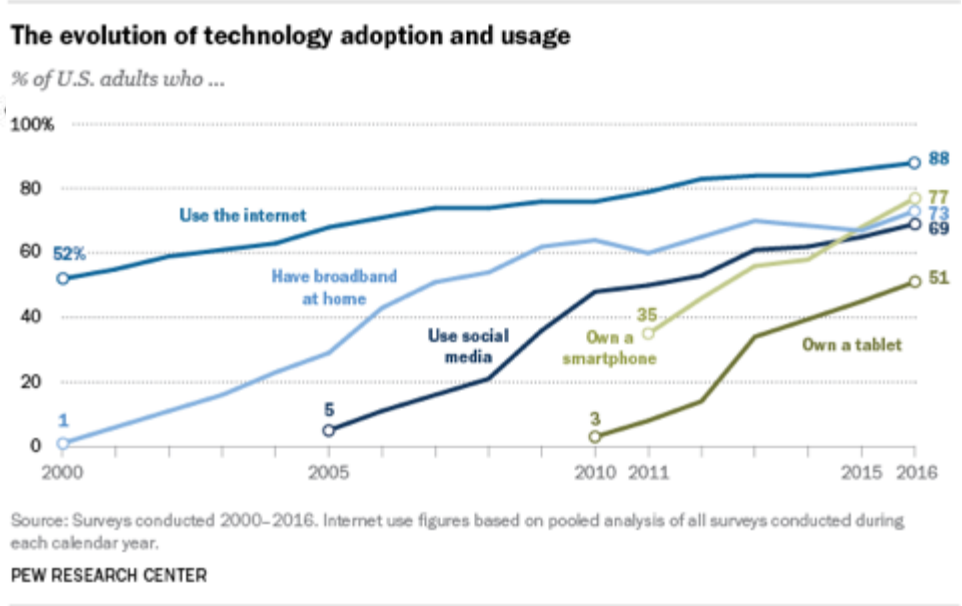
Background – Atrial Fibrillation (AF)

- 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

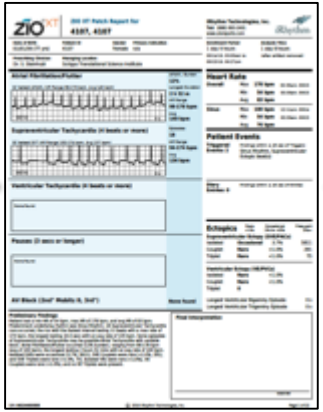
Background – Transforming Clinical Trials

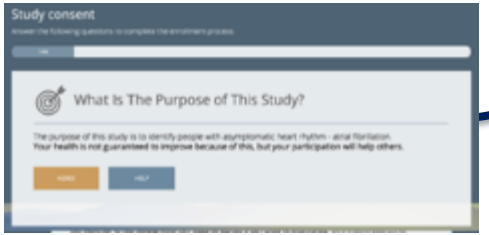
- Only 1.7% of eligible patients are enrolled in clinical trials
- < 1/3 of RCTs meet their original recruitment targets.
- 88% of US adults use the internet and 77% own a smartphone



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

mHealth Screening To Prevent Strokes (mSToPS) Overview



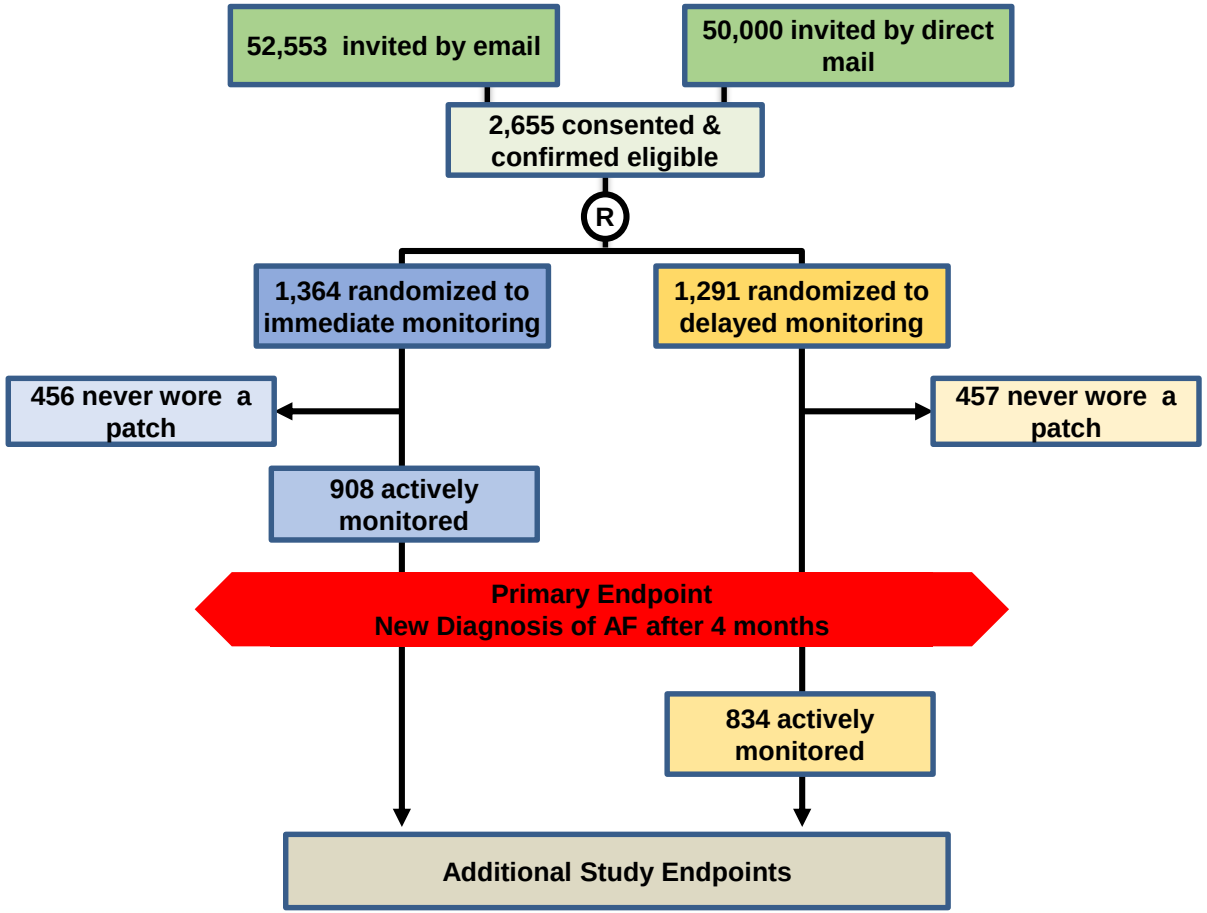


Primary Objective

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.

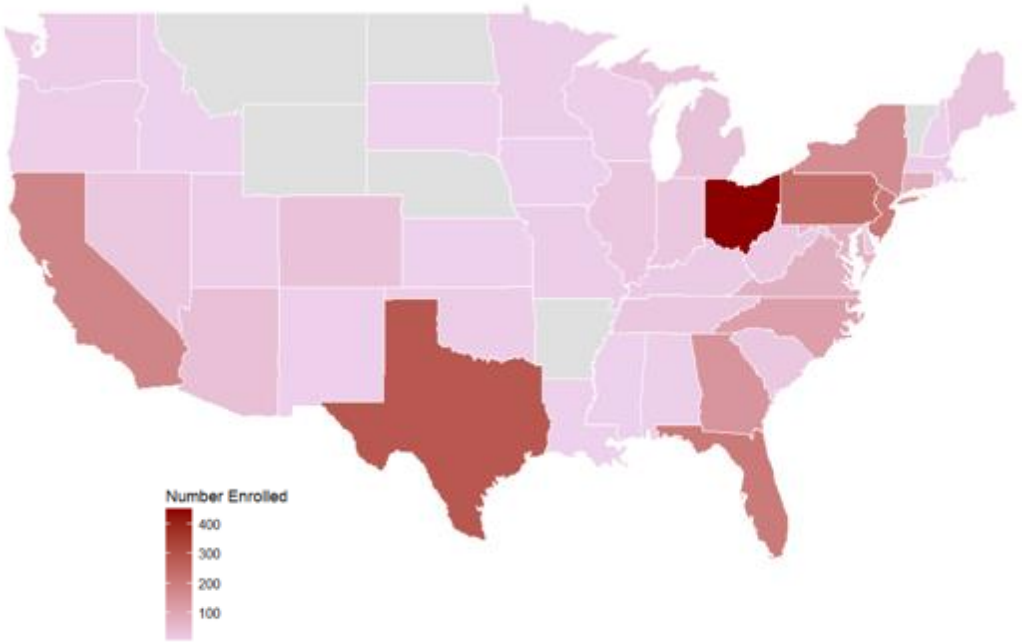
359,161 Aetna members meeting eligibility criteria

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

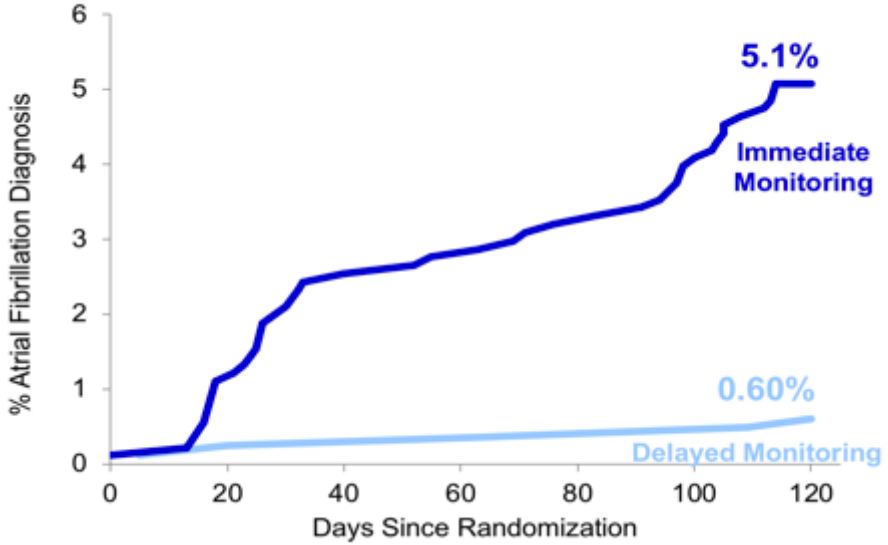
	Immediate n=1364	Delayed n=1291	p-value
Age (mean, SD)	73.5 (7.3)	73.1 (7.1)	0.12
% Female	38.2	39.0	0.66
CHA_2DS_2-VASc (median, Q1-Q3))	3 (2-4)	3 (2-4)	0.82
Prior Stroke (%)	13.7	14.0	0.82
Heart Failure (%)	5.1	4.6	0.56
Hypertension (%)	77.1	76.8	0.86
Diabetes (%)	38.7	36.5	0.24
Sleep Apnea (%)	24.9	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)

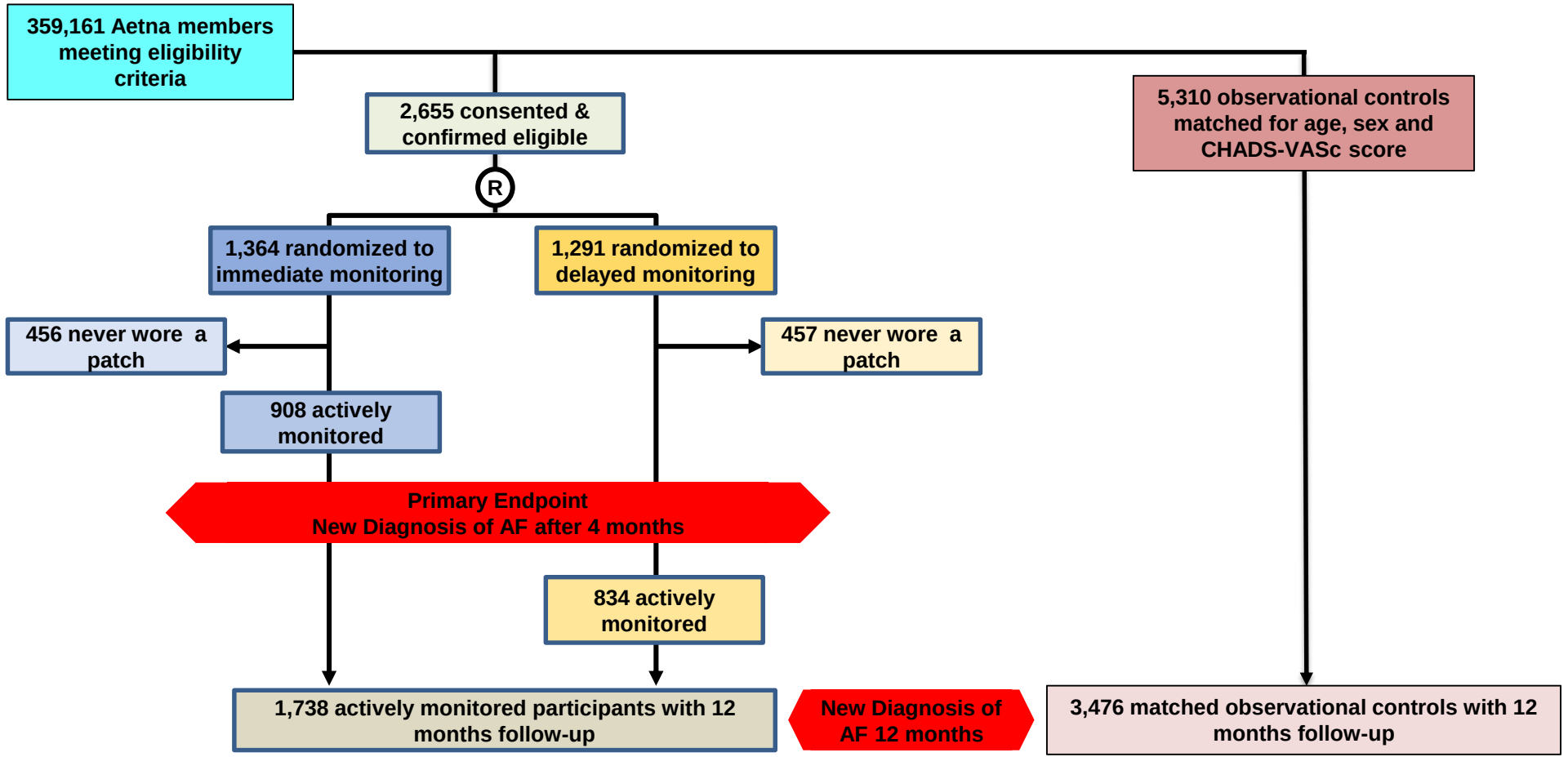


OR 8.8
95%CI 3.5-22.4
P<0.0001

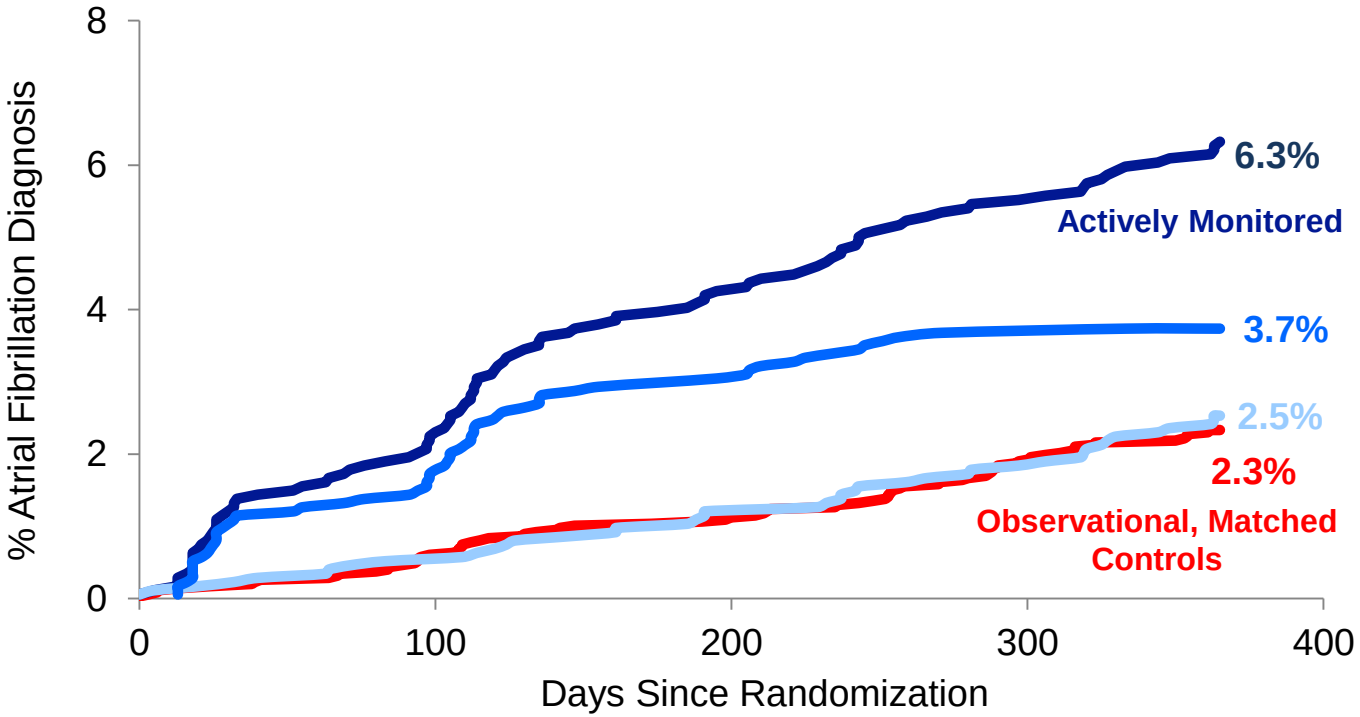
For ITT population

OR 9.0

95%CI 3.6-22.7
P<0.0001


359,161 Aetna members meeting eligibility criteria
2,655 consented & confirmed eligible
R
5,310 observational controls matched for age, sex and CHADS-VASc score
1,364 randomized to immediate monitoring
1,291 randomized to delayed monitoring
456 never wore a patch
457 never wore a patch
908 actively monitored
Primary Endpoint
New Diagnosis of AF after 4 months
834 actively monitored
1,738 actively monitored participants with 12 months follow-up
New Diagnosis of AF 12 months
3,476 matched observational controls with 12 months follow-up

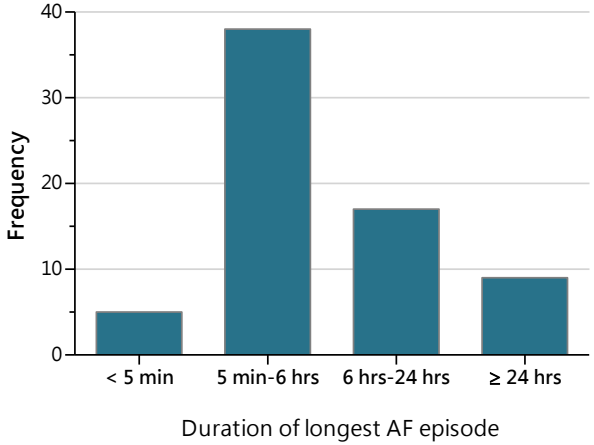
1-Year New Diagnosis of AF



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

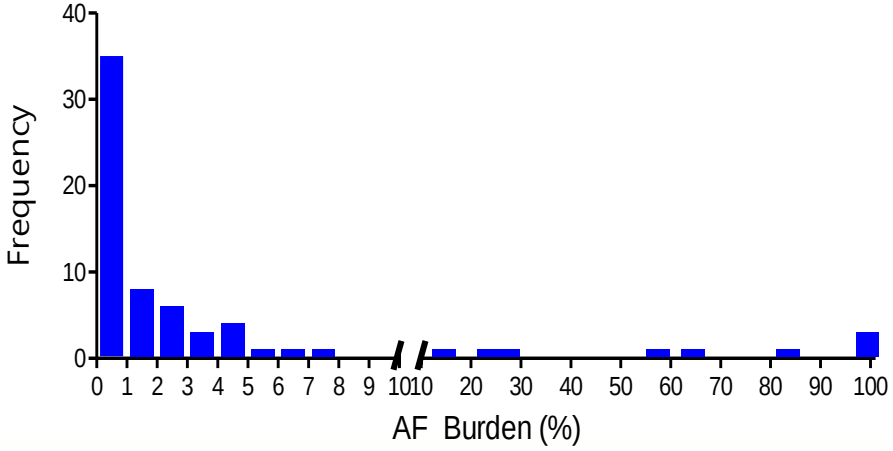


Median duration of longest AF episode 185.5 minutes

- 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%)	0.003
All-cause Outpatient Office Visit to a Cardiologist, n (%)	549 (31.6%)	819 (23.6%)	<0.0001
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%)	<0.0001
Pharmacy fill for an anticoagulant, n (%)	94 (5.4%)	117 (3.4%)	0.0004

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:

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