Supermarket/hypermarket opportunistic screening for atrial fibrillation (SHOPS-AF) using sensors embedded in the handles of supermarket trolleys: A feasibility study

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ABSTRACT

Background Atrial fibrillation (AF) increases the risk of death, stroke, heart failure, cognitive decline, and healthcare costs but is often asymptomatic and undiagnosed. There is currently no national screening program for AF. The advent of validated hand-held devices allows AF to be detected in non-healthcare settings, enabling screening to be undertaken within the community.

Method and results In this novel observational study, we embedded a MyDiagnostick single lead ECG sensor into the handles of shopping trolleys in four supermarkets in the Northwest of England: 2155 participants were recruited. Of these, 231 participants either activated the sensor or had an irregular pulse, suggesting AF. Some participants agreed to use the sensor but refused to provide their contact details, or consent to pulse assessment. In addition, some data were missing, resulting in 203 participants being included in the final analyses. Fifty-nine participants (mean age 73.6 years, 43% female) were confirmed or suspected of having AF; 20 were known to have AF and 39 were previously undiagnosed. There was no evidence of AF in 115 participants and the remaining 46 recordings were non-diagnostic, mainly due to artefact. Men and older participants were significantly more likely to have newly diagnosed AF. Due to the number of non-diagnostic ECGs (n = 46), we completed three levels of analyses, excluding all non-diagnostic ECGs, assuming all non-diagnostic ECGs were masking AF, and assuming all non-diagnostic ECGs were not AF. Based on the results of the three analyses, the sensor's sensitivity (95% CI) ranged from 0.70 to 0.93; specificity from 0.15 to 0.97; positive predictive values (PPV) and negative predictive values (NPV) ranged from 0.24 to 0.56 and 0.55 to 1.00, respectively. These values should be interpreted with caution, as the ideal reference standard on 1934 participants was imperfect.

Conclusion The study demonstrates that the public will engage with AF screening undertaken as part of their daily routines using hand-held devices. Sensors can play a key role in identifying asymptomatic patients in this way, but the technology must be further developed to reduce the quantity of non-diagnostic ECGs. (Am Heart J 2024;271:164–177.)

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Background

Atrial fibrillation (AF) is the most common heart rhythm disorder with increasing prevalence and is associated with a high risk of death,[1] stroke,[2] heart failure,[3] dementia,[4,5] cognitive decline,[4-6,] reduced health related quality of life,[7] and rising healthcare costs.[8]

Given these multiple risks and the improved clinical outcomes associated with holistic or integrated management of AF,[9-13] current guidelines[14,15] advocate a multidimensional management approach incorporating the following, the **A**voidance of stroke with oral anticoagulation; **B**etter symptom management with patient centered, symptom directed decisions on rate or rhythm control; and consideration of **C**ardiovascular and other comorbidities and lifestyle factors. However, data from the EORP-AF registry suggests that up to 40% of AF patients are asymptomatic, despite prognosis being similar or worse than symptomatic AF.[16] Consequently, screening incorporating ECG analysis is proposed.[17]

Screening can be systematic (also known as selective or targeted) where a population who fulfil a predefined criterion are targeted; opportunistic, where patients who present to clinical practice for some other health conditions are screened; or mass screening, which adopts a population-based approach.[17] The Screening for AF in the Elderly (SAFE) study[18] in the U.K. reported that systematic and opportunistic screening in primary care settings were equally effective (1.62% v 1.64%) in identifying AF, but opportunistic screening was more cost-effective. Using a systematic approach to recruit 75-76-year-olds from two Swedish regions the authors of the STROKESTOP study[19] found 37 people (0.5% of screened population) with AF on their first ECG but AF detection increased to 218 (3%) when patients recorded their ECGs over a two-week period using a handheld ECG recorder. After a median follow up of 6.9 years the STROKESTOP study[20] reported significantly fewer primary endpoint events (composite of ischemic or hemorrhagic stroke, systemic embolism, bleeding requiring hospitalization, and all-cause death) in the intervention group (4456 [31·9%] of 13 979; 5·45 events per 100 years [95% CI 5·52-5·61]) compared to the control group (4616 [33·0%] of 13 996; 5·68 events per 100 years [5·52-5·85]; hazard ratio 0·96 [95% CI 0·92-1·00]; $P = ·045$). In a cost effectiveness analysis[21] of the same study the authors reported incremental lower costs of £1.77M per 1000 individuals in the screening group compared to control group based on 77 gained life years and 65 gained quality-adjusted life years. Nevertheless, the LOOP study[22] that randomly assigned (1:3) 6004 participants to implantable loop recording or routine care reported no statistical difference in primary endpoint of stroke and arterial embolism between groups. The primary outcome was reported in 318 participants. 67 (4·5%) in the intervention group compared to 251 (5·6%) in the control group (HR 0·80 [95% CI 0·61-1·05]; $P = ·11$). While the STROKESTOP study was a population-based study with no exclusion criteria, the LOOP study recruited people already known to have at least one stroke risk factor.

However, participation in systematic and opportunistic AF screening in traditional healthcare settings may be restricted to those from higher socioeconomic groups and the "worried-well." Mass screening could increase access to those at greatest risk and with the advent of new non-invasive technology may now be practical.

Handheld devices record and analyze a single lead ECG and can be used independently. A systematic review and meta-analysis by Wong et al.[23] analyzed the results of 14 studies incorporating seven single-lead handheld devices: AliveCor (Kardia), MyDiagnostick, Omron HCG-801, Beurer, ECG Check, Bodyguard 2 and Polar-H7. Whilst the review considered both hospital and community settings the pooled sensitivity and specificity of all devices used in community settings ($n = 6064$) was 89% (95% CI 81%-94%) and 99% (95% CI 98%-99%).

Whilst the independent use of single-lead ECG and photoplethysmography have some merit, self-monitoring deprives participants of access to professional support to provide reassurance or onward referral. A hybrid approach that blends the benefits of technology with access to a qualified professional could provide a way forward. The SEARCH-AF study has shown that pharmacists can successfully screen and identify those with AF[24] and that their intervention is acceptable to patients.[25] Nevertheless, given the evidence of poor uptake from lower socioeconomic groups associated with traditional screening, pharmacy intervention alone may not be sufficient to attract those at greatest risk.

Nonetheless, despite these advancements the benefits and harms of routine AF screening over and above diagnosis of AF through routine clinical practice is currently insufficient to justify the introduction of national screening programs. The UK National Screening committee[26] who completed a rapid review of the evidence in 2019 reported a limited number of Randomized Controlled Trials that compared formal screening with routine clinical diagnosis and a failure to consider relevant outcomes. In 2020 Jones and colleagues reinforced this observation noting that many AF screening trials used trial designs that made comparisons impossible.[27] A further systematic review was undertaken by the US Preventive Services Task Force in 2021 on the benefits and harms of screening for AF.[28] This review included studies that had incorporated contemporary screening methods such as blood pressure machines, pulse oximeters, smartwatches, and mobile applications. However, despite these technical advancements the authors did not find sufficient evidence for or against screening for AF and the merit of routine AF screening remain unclear.

Therefore, we assessed the feasibility of screening for AF in the community while people undertook their shopping, in supermarkets with resident pharmacists.

Methods

This observational study was undertaken to establish whether shoppers would undertake their shopping using a trolley with an ECG sensor embedded into the trol-

Figure 1. MyDiagnostick single lead ECG sensor embedded into the handles of a supermarket trolley to detect AF.

ley handle, and second to assess the positive and negative predictive value, sensitivity, and specificity of the embedded sensor in detecting AF in this environment.

Research teams were located in four supermarkets with resident pharmacists in the Northwest of England between April and July 2021. Shoppers were asked to undertake their shopping using a test trolley which included a MyDiagnostick sensor embedded into the trolley handle (Figure 1). Except for the sensor, the trolleys were standard issue, purchased from the supermarket's supplier.

MyDiagnostick is a cylindrical shaped MDD Class IIa medical device, intended to discriminate AF from normal rhythm. The device is activated when contact is made, and a single Lead I ECG is recorded over one minute. The device flashes while recording and illuminates a red or green light to indicate AF or non-AF when complete. The ECG is then downloaded to a laptop via a USB connection. The ECG tracing is presented as a PDF for interpretation.

Ethical considerations

Ethical approval and sponsorship were granted by Liverpool John Moores University's University Research Ethics Committee (21/NAH/001). The study was undertaken in compliance with the published research protocol.[29] Verbal consent was obtained upon recruitment, with written consent secured for those with an abnormal sensor recording or irregular pulse, whose personal data were required for onward referral for 12-lead ECG analysis.

Study design

A cross-sectional observational study with a convenience sample was used to address the research objectives.

Patient population: Inclusion and exclusion criteria

Members of the public aged ≥18 years, able to grip a shopping trolley handle and provide written consent who were visiting one of four large supermarkets in the Northwest of England were eligible for inclusion. Participants were excluded if they had participated previously or had a physical tremor that could cause ECG artefact. Those with known AF were included to assess the sensitivity of the sensor and minimise selection bias.

Data collection

In previous studies, the index test, MyDiagnostick has been shown to be highly sensitive in detecting AF, with sensitivity levels ranging between 94% (95% CI 87%-98%)[30] to 100% (95% CI 93%-100%).[31] In addition, high specificity values of 93% (95% CI 85%-97%)[30] to 95.9% (95% CI 91.3%-98.1%)[31] were also reported in the same datasets, using the same detection threshold. The detection threshold is already embedded in MyDiagnostick and was not modified for this study. A review of a single lead ECG by a consultant cardiologist was used as the reference standard.

Researchers approached shoppers as they entered the store and invited them to participate in the study. Verbal consent was gained prior to recruitment with written consent obtained for all participants with an abnormal sensor reading or irregular pulse to enable onward referral for a 12-lead ECG and review by a consultant cardiologist.

Each participant was advised to use a research supermarket trolley to undertake their shopping and, by doing so, would inevitably grip the trolley handle at differing points and for differing time periods. It was made clear to each participant that only one person should push the trolley during their visit to the store. During each contact with the trolley handle, the sensor stored a recording of the rhythm strip in the sensor's file storage system. The handles of all trolleys were sanitised between participants to minimise the risk of infection.

If AF was detected by the sensor, a store pharmacist was alerted who met the participant to repeat the sensor check (static) and undertake a manual pulse check. If the pulse sensor did not detect AF whilst the person was shopping, the researcher met with the participant when leaving the store and completed a manual pulse check (Figure 2). At the outset of the study, we were unsure whether the MyDiagnostick sensor would be able to detect AF when embedded into a trolley handle. We therefore undertook additional pulse checks when the participants left the supermarket. This aspect of the process was undertaken solely to ensure AF was not missed in any participants engaged in the study and would not be included if adopted into routine practice.

An additional sensor check was undertaken if the pulse was irregular. An irregular pulse was defined as any irregularity between pulse waveforms in the radial artery within a period of sixty seconds. Guidance recommends pulse palpation as the first step for AF screening.[14] Two randomised controlled trials have found that pulse palpa-

Figure 2. Study procedure.
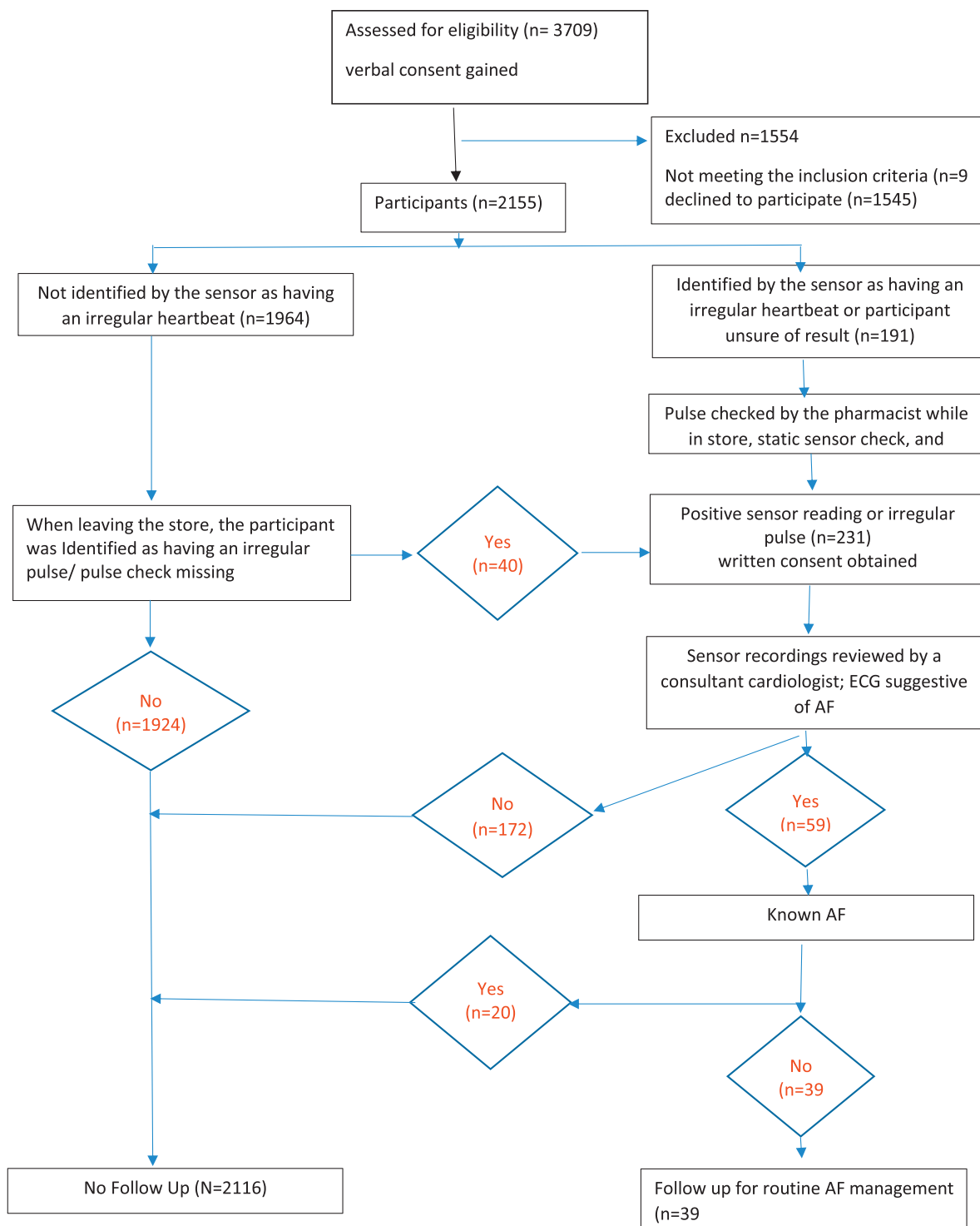
tion is an effective and cost-effective approach for screening for AF.[18,32] However, Gudmundsdottir et al.[33] report that pulse palpation is inferior to single lead ECG when screening for AF. Therefore, both approaches have their place. All nursing and research staff undertaking manual pulse checks undertook additional training using simulation manikins to ensure that they were practising in line with the procedures outlined in the Royal Marsden Manual of Clinical Nursing Procedures.[34]

With consent, the personal details and ECG recordings of all those with a positive sensor reading or irregular pulse were stored on a research database. A consultant cardiologist (GL) reviewed the sensor recordings to eliminate those that were non-diagnostic. Participants with an irregular pulse or positive sensor reading were contacted within one week and provided with the results of their ECG review. Some participants were advised that the readings were normal, some that the sensor had been activated by artefact, and others that the ECG was suspicious of, or confirmed AF. Participants with artefact on their ECG were invited to return to the supermarket for a repeat check. Those with an ECG with suspected or confirmed AF were offered an appointment with a consultant cardiologist at the local cardiac centre.

Primary outcomes

The primary outcome was to determine the accuracy (sensitivity, specificity, PPV, and NPV) of a MyDiagnostick sensor embedded in the handle of a supermarket trolley in detecting AF.

Secondary outcomes

The secondary outcome was to establish the feasibility and acceptability of screening for AF using shopping using a trolley with a pulse sensor embedded in the handle.

Sample size considerations

Large supermarkets attract 25,000 people per week,[35] providing a weekly population of 100,000 people across four stores. We aimed to recruit 2% of the total population, resulting in a sample size of 2000. Sample size was justified in a power calculation, as follows. The prevalence of AF in the study region was estimated to be 2.1%,[36] resulting in 42/2000 positive results, including some with known AF. However, those at greatest at risk of AF are ≥65 years. Whilst no UK data are available, one American study estimated those >60 years constitute 24% of supermarket consumers.[37] Recognising that the prevalence of AF in 65 to 79 years old ranges from 4% to 11%, we estimated a total of 480/2000 people would be screened in this age group with between 19/480 and 53/480 in AF. The remaining 1520 customers <65 years present a 0.1% to 1.5% risk of AF suggesting between 2/1520 and 23/1520 additional presentations. It was estimated that 21-76 participants would be in AF.[38]

Sample size calculations based on sensitivity of 95% and specificity of 90% is sufficiently accurate for an AF screening device to be incorporated into clinical practice. Such high sensitivity and specificity values are indicated by two published papers, with 95% CI of 93% to 100% and 91.3% to 98.1%[31] and 87% to 98% and 85% to 97% Vaes et al.,[30] for sensitivity and specificity, respectively. At the planning stage of our study, sample size calculations showed that with 21 to 76 AF cases, we would estimate the 95% CI of sensitivity and specificity with precision of at least 19.0% and 9.8%, respectively (as the total interval width). Sample size was calculated according to Burder's statistical methodology[39] for Incorporating the prevalence of disease into sample size calculation for sensitivity and specificity.

Statistical analysis

The Standards for Reporting of Diagnostic Accuracy Studies (STARD) guidelines were followed.[40] Descriptive statistics are provided to demonstrate uptake and rates of detection. Conditional percentages are used to describe the sensitivity and specificity of the sensor. The index test (MyDiagnostic result) was recorded as: positive, negative, or unsure. Unsure was reported when it was unclear if the sensor had flashed red and reflects a case of indeterminate index test. The reference test (result of ECG Review) was recorded as AF, not AF, or non-diagnostic. The non-diagnostic category was used where the recorded trace was such poor quality that the rhythm was uninterpretable. This category is a type of missing data. To investigate if the missingness of data was random, we undertook an association test between missingness and gender and age. Association between age and the reference test was analysed using the independent t-test, if age was normally distributed in all groups, otherwise the non-parametric Mann-Whitney test was used. The association between categorical demographics and the reference test was undertaken using the Chi-squared test of association (with exact P-value reported).

All analyses were completed using SPSS software version 28. For all association analyses we used a level of significance of $P < .05$. We did not adjust for multiple comparisons, because such analyses are secondary analyses.

Results

Uptake of screening

Three thousand seven hundred and nine shoppers were invited to participate, of whom 2155 (58.1%) were recruited: 231 people (10.8%) were identified as having either an irregular pulse and/or a positive sensor reading. We have subsequently defined this cohort as "Positive screening test."

Population characteristics

Age was recorded in 193 (83.5%) participants with a positive screening test (Table 1). The mean (SD) age was

Table 1. Demographics, index test and reference test in 231 participants with a positive screening test. For some participants some information is missing

Participant characteristics	n (%)
Sex (n = 209)	
Female	141 (67.5%)
Male	68 (32.5%)
Age, years (n = 193)	
0-54	34 (17.6%)
55-64	37 (19.2%)
65-74	61 (31.6%)
75-84	50 (25.9%)
85+	11 (5.7%)
Irregular pulse (n = 220)	
Yes	126 (57.3%)
No	94 (42.7%)
Positive sensor result (index test), n = 222	
Yes	182 (82%)
No	40 (18%)
Results of review (reference test), n = 220	
AF	59 (26.8%)
Not AF	115 (52.3%)
Non-diagnostic	46 (20.9%)

65.2 (15.4). Sex was recorded in 209 (90.5%) people with a positive screening test (Table 1);141 (67.5%) were female.

Reason for referral for ECG check

Of the 231 participants with a positive screening test, 126 (57.3%) had an irregular pulse, and 182 (82.0%) recorded a positive sensor reading. Of these participants, 79 had a positive sensor result and an irregular pulse, while 93 with a positive sensor result were found to have a regular pulse (Table 2).

Outcome of single lead ECG analysis

Single lead ECG analysis (reference test) was available for 220 (95.2%) participants (Table 1): 59 (25.5%) participants had evidence of AF on their ECG sensor recording. Twenty of these (33.9%) were known to have AF and 39 (66.1%) were previously undiagnosed. There was no evidence of AF in 115 (49.8%) participants and the remaining 46 (20.0%) recordings were non-diagnostic, mainly due to artefact.

Sex and the outcome of single lead ECG analysis (reference test) were recorded in 205 participants, 66 males and 139 females (Table 3). In those with diagnostic ECG tracings, significantly more men than women were found to be in AF 26/54 (48%) versus 20/106 (19%), respectively; ($\chi^2 = 14.9729, P < .001$) (Table 3). Gender was unknown in 13 participants noted to have AF. There was no association between sex and the finding of a non-diagnostic ECG trace ($\chi^2 = 8072, P = .602$) (Table 3).

Age and the outcome of single lead ECG analysis (reference test) were recorded in 191 participants. Those in

AF were statistically significantly older than those not in AF 73.6 (11.4) versus 61.4 (15.6), respectively; $P < .001$).

Non-diagnostic ECG in those referred for single lead ECG trace analysis

Forty-six participants referred for single lead ECG analysis had a non-diagnostic ECG (20.9% out of 220 with an available ECG) (Table 3). There was no significant difference in sex, or age category for those with a non-diagnostic ECG (Table 3).

Prevalence of undiagnosed AF in our sample

The single lead ECGs (sensor recordings) of those participants that did not have an irregular pulse or who did not trigger the sensor were not reviewed. Consequently, we cannot be certain if they did not have AF or atrial flutter; to determine the prevalence of AF we assumed that they did not have AF (Figure 3). Our screening identified 59 (2.7%) people with AF; 20 (0.9%) had previously diagnosed AF.

Accuracy of index test: MyDiagnostick sensor

The single lead ECG analysis of sensor recordings, pulse and outcome, were available on 203 (203/231 = 88%) of referred participants (Figure 3).

There were 165 participants who had a single lead device alert and who also had complete data. Of them, 129 participants had a conclusive diagnosis (Figure 3).

There were 113 participants with an irregular pulse, who also had complete data. Of them, 92 participants had a conclusive diagnosis (Figure 3). 52 participants of these had AF confirmed (56.5%).

Among those participants with complete and conclusive data (162), there were 3 who were alerted by the single lead device but had a regular pulse, 1.9%.

There were 41 participants (of 203) with a non-diagnostic ECG, this however was not associated with gender ($P = .602$, Table 3) or age ($P = .299$, Table 3). Given the 41 (41/203 = 20.2%) non-diagnostic ECGs we completed a series of analyses which provides a range of values depending on the percentage number of those with non-diagnostic ECGs presenting with AF (Tables 4 and 5)

Some participants refused to have their pulse taken and/or refused consent to allow us to use their sensor recordings, hence much of the missing data. Additionally, for 46 participants, the ECGs were not diagnostic; hence, the reference standard is inconclusive.

The main accuracy result of the index test is presented in Table 4. Note that in Table 4 the number of participants with available data is 212 (48 + 10 + 85 + 24 + 40 + 5) which is higher than 203 reported in Figure 3. The 203 excludes 9 participants with missing pulse information but non-missing sensor index and reference test results. Table 4 and

Table 2. Reasons for referral for ECG check

		Irregular pulse			
		Yes	No	Pulse missing	Total
Positive sensor result*	Yes	79	93	10	182
	No	39	0	1	40
	Participant is unsure of result)	8	1	0	9
Total		126	94	11	231

* Sensor is the index test.

Table 3. Relationship of demographics to the outcome of single lead ECG analysis in the 231 referred participants

n (%)	Reference standard (Outcome of the follow-up determinate)			Reference standard (Outcome of the follow-up overall)		
	AF	Not AF	P-value	Diagnostic	Non-diagnostic	P-value
Sex			$P < .001$			$P = .602$
Female	20 (18.9%)	86 (81.1%)	$\chi2 = 14.9729.$	106 (76.3%)	33 (23.7%)	$\chi2 = 0.807$
Male	26 (48.1%)	28 (51.9%)		54 (81.8%)	12 (18.2%)	Group 172
Age						
Mean (SD) age, years	**73.6** (11.4) $n = 45$ 2 (7.4%)	**61.4** (15.6) $n = 107$	$P < .001$ Mann-Whitney test	**65.02** (15.54, $n = 152$)	**66.1** (SD = 15.8, $n = 39$)	$P = .299$ Mann-Whitney test
Below 55	4 (11.8%)	25 (92.6%)	$U = 15,368.0$	27 (79.4%)	7 (20.6%)	$U = 49.2$ where
55-64	14 (33.3%)	30 (88.2%)	where Age was	34 (91.9%)	3 (8.1%)	Age was not
65-74	20 (47.6%)	28 (66.7%)	not categorized	42 (71.2%)	17 (28.8%)	categorized
75-84	5 (71.4 %)	22 (52.4%)		42 (84.0%)	8 (16.0%)	
85+		2 (28.6%)		7 (63.6%)	4 (36.4%)	

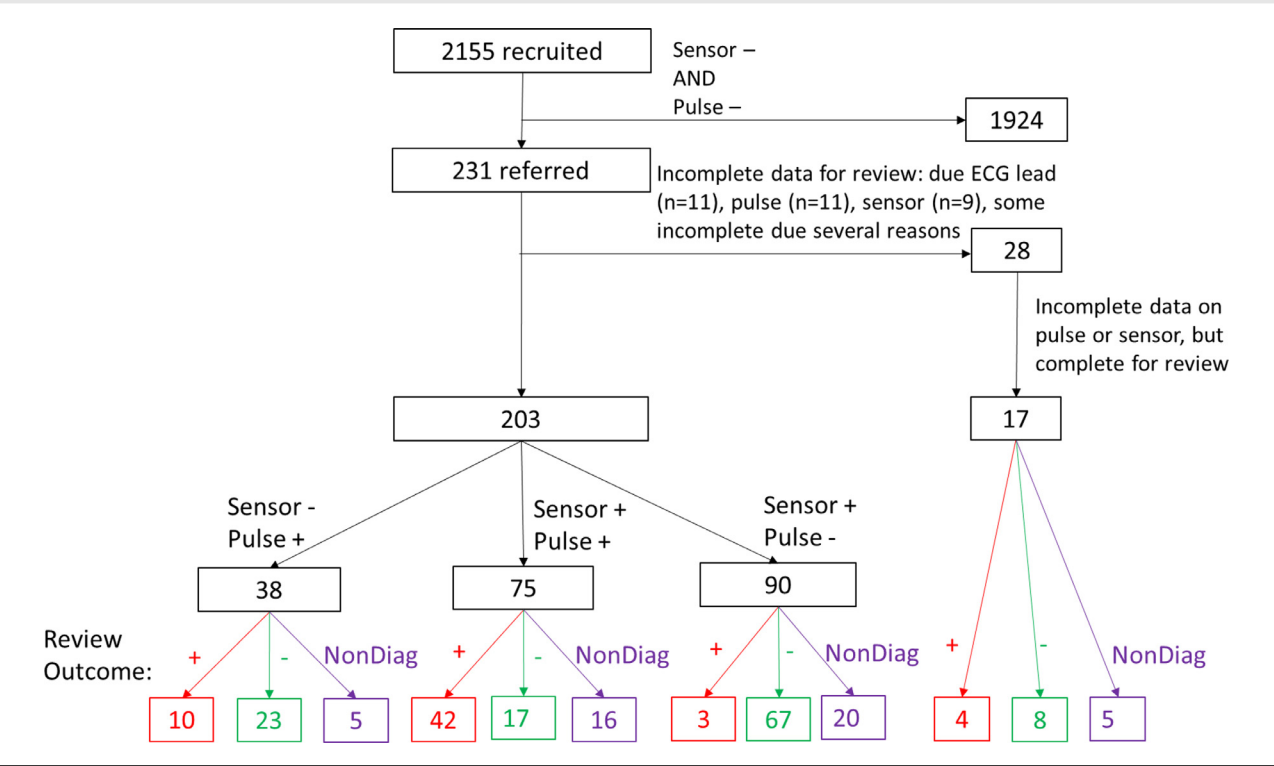**Figure 3.** Flow chart of the participants and of the outcome of MyDiagnostic and ECG review.

Table 4. Accuracy of the MyDiagnostick test compared to the outcome of ECG review

		Reference test (ECG Review)				
		AF	No AF	Non diagnostic*	Unavailable	Total
Index test (MyDiagnostick test)	Test +ve	48	85	40	9*	182
	Test -ve	10	24	5	1925	1964
	Unavailable	1	6	1	1†	9‡
	Total	59	115	46	1935	2155

* Nine participants reported that the sensor was triggered, but their ECG lead was unavailable for the review.
† One participant could not remember if the sensor was triggered, and his/her ECG trace was also unavailable for the review.
‡ Nine participants could not remember if the sensor was triggered.

Table 5. Sensitivity analysis of the accuracy of the index test.

Analysis	% of Non-diagnostic ECGs assumed to be AF	Sensitivity	Specificity	Positive predictive value	Negative predictive value
1	Accuracy analysis of those with complete data on index test as well as reference test. We excluded those with non-diagnostic ECG, and those who did not trigger the sensor or have an irregular pulse, thus assumed missingness at random.	48/58 = 0.83 0.70-0.93	24/109 = 0.22 0.15-0.31	48/133 = 0.36 0.33-0.40	24/34 = 0.71 0.55-0.82
2	Accuracy analysis on all 2155 participants, while assuming those with nondiagnostic ECG had AF, and assuming those who did not trigger the sensor or have an irregular pulse did not have AF.	88/103 = 0.85 0.78-0.92	1949/2034 = 0.96 0.95-0.97	88/173 = 0.51 0.45-0.56	1949/1964 = 0.99 0.99-1.00
3	Accuracy analysis on all 2155 participants, while assuming those with nondiagnostic ECG did not have AF, and assuming those who did not trigger the sensor or have an irregular pulse did not have AF	48/58 = 0.83 0.71-0.91	1954/2079 = 0.94 0.92-0.95	48/173 = 0.28 0.24-0.32	1954/1964 = 0.99 0.99-1.00

Figure 3 have different goals and hence provide different insights into the data. Figure 3 shows the flow of participants with respect to index test, pulse, and reference test. Table 4 provides a comparison of index versus reference test; hence it does not consider if the pulse was missing or available. Consequently, there is the difference of 9 participants. There was no association between missing data on sensor or pulse versus review outcome ($n = 17$) ($P = .47$, Fisher exact test). Note: Sensor = Index test, MyDiagnostick.

As a consequence of the missing values highlighted above, we performed a further sensitivity analysis of the index test accuracy. We assumed three types of missing data and non-diagnostic data scenarios (Table 5). The first accuracy analysis (Table 5, analysis 1) excluded all non-diagnostic ECGs and assumed that all participants who did not trigger the sensors or have an irregular pulse did not have AF. Based on these analyses the findings suggest a test sensitivity of 0.83 (95% CI 0.70-0.93), a specificity of 0.22 (95% CI 0.15-0.31), a positive predictive value (PPV) of 0.36 (95% CI 0.33-0.40) and a negative predictive value (NPV) of 0.71 (95% CI 0.55-0.82).

The second sensitivity analysis of index test accuracy assumes that 100% of those with non-diagnostic ECGs were experiencing AF (Table 5, analysis 2). Based on these assumptions the data suggests sensitivity of 0.85 (95% CI 0.78-0.92), specificity of 0.96 (95% CI 0.95-0.97), PPV of 0.51 (95% CI 0.45-0.56) and NPV of 0.99 (95% CI 0.99-1.00).

The third sensitivity analysis of index test accuracy assumed (Table 5, analysis 3) that 0% of those with non-diagnostic ECGs had AF. Based on these assumptions the data suggests sensitivity of 0.83 (95% CI 0.71-0.91), specificity of 0.94 (95% CI 0.92-0.95), PPV of 0.28 (95% CI 0.24-0.32) and NPV of 0.99 (95% CI 0.99-1.00).

From the results of these three sensitivity analyses, if the assumptions are satisfied, we are able to demonstrate that the sensor's sensitivity (95% CI) ranges from 0.70 to 0.93, specificity ranges from 0.93 to 0.97, with PPV and NPV ranging from 0.21 to 0.58 and 0.992 to 0.998, respectively (Table 6).

These values are a summary of Table 5. The values should be interpreted with caution, as we did not have an ideal reference standard on 1934 participants, hence

Table 6. Range of index test accuracy as a summary from the sensitivity analysis

	Range of values
Sensitivity (%)	0.70-0.93
Specificity (%)	0.15-0.97
Positive predictive value (%)	0.24-0.56
Negative predictive value (%)	0.55-1.00

we made assumptions, and hence specificity and negative predictive values are likely to be overestimated.

Discussion

In this innovative mass AF screening study, we have demonstrated that the public are prepared to engage with sensor-based screening when the process is integrated into their daily routine. Single lead ECG sensors can detect AF when embedded into the handles of supermarket trolleys, but adopting this approach results in a high proportion of non-diagnostic ECGs as a consequence of movement artefact.

Almost two thirds of those invited to participate were recruited. A Cochrane review of AF screening effectiveness[41] reported uptake rates of 53% for systematic screening and 46% for opportunistic screening. Our results suggest that people are prepared to engage in technology-supported screening when delivered as part of their daily routine.

Two thirds of the sample were female which is in keeping with the results of a previous Polish pharmacy-based study.[42] Some would argue that these results are related to the study settings, which are more likely to be visited by women.[43] However, a Belgian study[44] that recruited participants via a media campaign, and the Fitbit Heart study[45] that analyzed the wearable devices of 455,699 people in the USA both recruited predominantly females demonstrating that women are more likely to participate in health screening even though in this, and other studies,[24,44] AF was more likely to be detected in males, an outcome which is unsurprising given that AF is more common in men.[46,47] To recruit a higher proportion of males, screening in male dominated environments should be undertaken and additional research that focusses on male decision making should be considered.

Increasing age is a prominent risk factor for AF, thought to occur because of progressive atriopathy.[48] Whilst recruitment was not limited by age, nearly two thirds of participants were over 65 years. In a population-based screening study of 75-year-olds in two towns in Sweden, uptake was recorded between, 47% to 61.2%.[19] Our findings demonstrate that older people can be recruited and are prepared to use technology despite previous evidence suggesting otherwise.[49-51] Yao and Murphy[51] reported that older people are concerned with the effort

required to use the technology but Venkatesh and Morris[52] found that facilitating conditions significantly impacts usage. Consequently, we acknowledge that providing access to an onsite research team may have increased participation in this group.

Fifty-nine (2.7%) participants were identified with AF, 39 of those were previously undiagnosed resulting in a newly detected AF yield of 1.8%. A meta-analysis[53] of 25 studies from 14 countries comparing the outcomes of opportunistic versus systematic screening reported incident rates for AF of 1.1% (95% CI 0.6%-1.6%) and 1.8% (95% CI 1.4%-2.3%) respectively. In a recent network meta-analysis[54] including nine randomized controlled trials with 85,209 patients aged >65 years, systematic and opportunistic screening detected 1.8% and 1.3% new AF (95% CI 1.2-3.65), respectively. The rate of newly detected AF in our screening study is preferable to many other systematic screening studies[55-62] and opportunistic screening studies.[24,63-69] A Cochrane review[41] reported that it was necessary to systematically screen 172 participants and opportunistically screen 167 participants to detect one AF case. Whereas a meta-analysis[70] of 141,220 single-time screened individuals reported varying numbers, dependent on age groups (83 for ≥ 65 years, 926 for 60-64 years, 1089 ≤ 60 years) highlighting greater yield of AF with older participants. In this study we screened 2155 participants and identified 39 new AF cases, indicating a yield of 55:1.

Improvements in technology has enabled AF to be detected without access to a 12 lead ECG or a cardiac specialist. These innovations have widened the scope of AF screening without significantly reducing the diagnostic accuracy of the testing. A systematic review and meta-analysis[71] of 10 studies including 4296 patients reported that the sensitivity of PPG and handheld devices was 0.93 (95% CI 0.87-0.96) and 0.87 (95% CI 0.74-0.94), respectively. Analogous figures for specificity were 0.91 (95% CI 0.88-0.94) and 0.96 (95% CI 0.90-0.98), respectively. Alivecor and Mydiagnostick were the most common devices used in these studies.

Unlike opportunistic and systematic screening, wearable technology offers greater access to patient's health status with limited resources required. The Fitbit Heart study[45] examined data from smart wrist-worn devices and reported an AF prevalence of 1%, but only 32% of those with suspected AF had AF detected using an ECG patch. The authors report a PPV of 98% for those with an irregular heart rate alert. The Huawei Heart study[72] that monitored >187,000 adults in China for suspected AF reported a PPV of 91.6% (95% CI 91.5%-91.8%). The Apple Heart study,[73] that recruited 419, 297 participants in the USA noted a PPV of 0.84 (95% CI 0.76-0.92) for observing AF on the ECG with a subsequent irregular pulse notification and 0.71 (97.5% CI 0.69-0.74) for observing AF on the ECG with a subsequent irregular tachogram. In this study we report a PPV and NPV from 0.24 to 0.56

and 0.55 to 1.00, respectively. Our PPV was lower than reported, likely due to low prevalence in our shopping cohort.

The sensitivity and specificity of the MyDiagnostick sensor used in this study ranged from 0.70 to 0.93 and 0.15 to 0.97. Two previous studies investigating the accuracy of the MyDiagnostick sensor[30,31] report sensitivity 0.93 to 1.00[31] and 0.87 to 0.98[30] and specificity 0.913 to 0.98[30] and 0.85 to 0.97.[30]

Our analyses highlighted 20% of the ECGs were non-diagnostic. Most of these non-diagnostic readings were complicated with movement artefact. This was anticipated considering the nature of the study. Participants were asked to carry out their shopping as per their usual routine while being monitored. This inevitably resulted in hand movement across the trolley handle and multiple disconnections and reconnections as they steered the trolley around the store. However, while 75 people were noted to have a positive sensor reading and an irregular pulse of which 16 of these ECG recordings were non diagnostic due to artefact, 17 were adjudged to be normal. Moreover, only 3 from the 90 people who recorded a positive sensor reading, and a regular pulse were found to have AF. These results suggest that while the perceived presence of an irregular adds little to the process, the presence of a regular pulse would reduce the number of ECGs needing to be reviewed and the level of false positives.

The use of the MyDiagnostick sensor was chosen due to its accuracy and its cylindrical shape, making it relatively easy to fit within a supermarket trolley handle. However, unlike other handheld devices that require only 30 seconds of connection, MyDiagnostick requires 60 seconds of constant connection before a decision is made. This additional time negatively impacted the quality of the ECG recording. Moreover, allowing participants to grip the trolley handle at any point inevitably resulted in movement across the sensor. Introducing a single hand grip position may reduce artefacts. We would therefore recommend adopting sensors that require only 30 seconds recordings and single contact points for screening for AF in naturalistic settings.

Systematic screening and opportunistic screening are considered beneficial with systematic screening providing greater uptake.[41,53] However, traditional screening programs are limited in their ability to attract some members of society. The STROKESTOP study[74] reported that people with lower educational levels, reduced income and who were geographically distant from the screening center were less likely to participate. Our study recruited from community supermarkets in areas of high deprivation, and in doing so recruited people from groups who might not typically engage in a traditional screening program or afford wearable technology. Consequently, we suggest that screening programs that can be delivered within the realms of daily life may increase the likelihood of participation, particularly in those who are traditionally harder-to-reach. This approach attempts to correct the inverse care law, bringing healthcare to the community.

This study demonstrates that technology-facilitated health screening can identify previously undiagnosed AF at rates comparable with a traditional screening program. However, the high levels of false positive readings suggests that the approach needs be developed further before being considered for adoption in routine practice. Nevertheless, with enhanced technology and improved accuracy this community-based approach may in the future increase access to people who might not traditionally engage with healthcare services and developing this concept further could provide a realistic means of remote screening, improving diagnostic rates and reducing the burden of AF induced stroke, heart failure and cognitive decline.

Limitations

Maximizing customer flow through a supermarket is an essential element of the customer experience and increases people's motivation to purchase goods. It was therefore essential that the researchers minimized any disruptions to this flow by only collecting the data of those who consented to participate in the study. However, by adopting this approach we have been unable to collect demographic data on those who refused to participate in the study, making it impossible to make comparisons across the two groups.

Finally, a large percentage of ECGs were not interpretable due to artefacts. We have attempted to overcome this limitation by undertaking three levels of analyses.

Conclusion

Members of the public are prepared to use health sensor technology when integrated into their daily lives. Older people were well represented in the study suggesting that technology need not be a barrier to this demographic. Supermarkets provide a convenient means of accessing large volumes of people from underserved groups, but alternative venues should be sought to increase male participation. ECG sensors embedded in supermarket trolleys can detect AF in ambulatory settings. However, sensor refinement and the introduction of specific contact points on the trolleys should be considered to minimize the number of non-diagnostic ECGs.

Recommendations

Further research should be undertaken to investigate the accuracy of a single lead ECG sensor specifically designed to be embedded into a supermarket trolley han-

dle. The sensor should incorporate algorithms that remove electrical interference and allow contact to be broken without negatively impacting the ECG tracing. Such algorithms that filter out artefacts and periods of inactivity will dramatically improve the ease with which ECGs can be recorded in this context.

Whilst we have reported the total number of people identified in AF, further studies should consider the thromboembolic risks of AF-positive participants to enable comparisons to be made with other screening modalities. This would enable researchers to compare the risks of those identified in mass screening events with participants already engaged with healthcare professionals.

Study organization

The study is coordinated by academic researchers and clinical collaborators at a Centre for Cardiovascular Science. The study steering committee provides overall governance for the project. The study has received approval and sponsorship from a University Research Ethics Committee (21/NAH/001).

Disclosures

The study is independently led by the academic team and is supported by educational grant funding from Bristol Myers Squibb. **Deirdre Lane** received investigator-initiated educational grants from Bristol-Myers Squibb (BMS) and Pfizer, has been a speaker for Bayer, Boehringer Ingelheim, and BMS/Pfizer and has consulted for BMS and Boehringer Ingelheim; all outside the submitted work. **Peter Penson** owns four shares in AstraZeneca PLC and has received honoraria and/or travel reimbursement for events sponsored by AKCEA, Amgen, AMRYT, Link Medical, Mylan, Napp, Sanofi. **Lis Neubeck** has received an investigator-initiated grant from Daiichi Sankyo, payment from Bristol Myers Squib for participation in a Global Medical Advisory Board and is the Former President of the Association for Cardiovascular Nursing and Allied Professionals of the ESC. **Gregory Lip** has been Consultant and speaker for BMS/Pfizer, Boehringer Ingelheim, Daiichi-Sankyo, Anthos. No fees are received personally. He is co-principal investigator of the AFFIRMO project on multimorbidity in AF, which has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No 899871. No further conflicts of interest declared.

CRediT authorship contribution statement

Ian D. Jones: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Supervision, Writing – original draft, Writing – review & editing. **Deirdre A. Lane:** Conceptualization, Formal analysis, Funding acquisition, Methodology, Supervision, Writing – original draft, Writing – review & editing. **Robyn R. Lotto:** Conceptualization, Methodology, Supervision, Writing – review & editing. **David Oxborough:** Conceptualization, Methodology, Writing – review & editing. **Lis Neubeck:** Methodology, Writing – review & editing. **Peter E. Penson:** Conceptualization, Methodology, Writing – review & editing. **Emma Johnston Smith:** Data curation, Investigation, Project administration, Resources, Supervision, Writing – review & editing. **Aimeris Santos:** Data curation, Investigation. **Emily E. McGinn:** Data curation, Investigation, Writing – original draft. **Aderonke Ajiboye:** Data curation, Investigation. **Nicola Town:** Data curation, Investigation. **Gabriela Czanner:** Formal analysis, Writing – review & editing. **Andy Shaw:** Conceptualization, Data curation, Investigation, Methodology, Resources, Writing – review & editing. **Hala El-Masri:** Formal analysis, Writing – review & editing. **Gregory Y.H. Lip:** Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Supervision, Writing – original draft, Writing – review & editing.

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