# Fully digital self-screening for atrial fibrillation with patch electrocardiogram

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Aims	Atrial fibrillation (AF) is the most common arrhythmia worldwide. The AF is associated with severe mortality, morbidity, and healthcare costs, and guidelines recommend screening people at risk. However, screening methods and organization still need to be clarified. The current study aimed to assess the feasibility of a fully digital self-screening procedure and to assess the prevalence of undetected AF using a continuous patch electrocardiogram (ECG) monitoring system.
Methods and results	Individuals $\geq$ 65 years old with at least one additional risk factor for stroke from the general population of Norway were invited to a fully digital continuous self-screening for AF using a patch ECG device (ECG247 Smart Heart Sensor). Participants self-reported clinical characteristics and usability online, and all participants received digital feedback of their results. A total of 2118 individuals with a mean CHA2DS2-VASc risk score of 2.6 (0.9) were enrolled in the study [74% women; mean age 70.1 years (4.2)]. Of these, 1849 (87.3%) participants completed the ECG self-screening test, while 215 (10.2%) did not try to start the test and 54 (2.5%) failed to start the test. The system usability score was 84.5. The mean ECG monitoring time was 153 h (87). Atrial fibrillation was detected in 41 (2.2%) individuals.
Conclusion	This fully digitalized self-screening procedure for AF demonstrated excellent feasibility. The number needed to screen was 45 to detect one unrecognized case of AF in subjects at risk for stroke. Randomized studies with long-term follow-up are needed to assess whether self-screening for AF can reduce the incidence of AF-related complications.
Clinical trials	NCT04700865

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#### **Graphical Abstract**

# Fully digital self-screening for atrial fibrillation with patch ECG



Keywords Atrial fibrillation • Digital • Self-screening

#### What's new?

- A fully digitalized self-screening for atrial fibrillation (AF) by a patch ECG electrocardiogram (device) was feasible at low personnel and financial cost.
- More than 87% of the participants performed the self-screening procedure, and nearly all ECG recordings were interpretable.
- The number needed to screen to find one case of AF among individuals ≥65 years old with at least one additional risk factor for stroke with the self-screening procedure was 45.

# Introduction

Atrial fibrillation (AF) is the most common sustained cardiac rhythm disorder, affecting ~6 million people in Europe, and the incidence is increasing.<sup>1–5</sup> Due to the paroxysmal and often asymptomatic nature of AF, up to one-third of cases are undiagnosed.<sup>6,7</sup> Atrial fibrillation increases the risk of mortality, stroke, heart failure, cognitive impairment, hospital admissions, depression, and reduced quality of life.<sup>7</sup> The most serious and common complication of AF is embolic stroke.<sup>7</sup> Oral anticoagulation therapy reduces the risk of stroke significantly in patients with AF and increased risk of stroke, and implementation of AF screening and evidence-based management can improve outcome.<sup>7,8</sup>

The European Society of Cardiology recommends screening for AF to be considered in people >75 years of age and in patients with an increased risk of stroke.<sup>7</sup> However, no clear recommendations are given for screening method and frequency. Systematic screening for AF by 14 days of

intermittent, hand-held electrocardiogram (ECG) in 65-year-olds with additional risk factors for stroke disclosed unrecognized AF in ~1%.<sup>9</sup> In the Swedish STROKESTOP trial, a similar strategy in 75- to 76-year-old individuals identified additional 1.2% AF cases in the invited to screening group compared to the control group.<sup>10</sup> In the recent Danish LOOP study, AF screening with implantable loop recorders (ILR) resulted in a three-times increase in the number of AF patients detected compared to usual care (31.8% vs. 12.2%).<sup>11</sup> The cost-effectiveness of AF screening is still not settled, and randomized controlled trial data to confirm the health benefits from screening for AF and inform the choice of optimal screening programmes and strategies for implementation are scarce.<sup>12–14</sup>

A patch ECG monitor system may address most of the challenges with other ECG recording systems and has, in smaller studies, shown to be well suited for AF screening.<sup>15–17</sup> The ECG247 Smart Heart Sensor is a self-applicable patch sensor for prolonged continuous ECG monitoring with automatic data transfer to a secure medical backend cloud service and real-time ECG analysis.

The aims of this cohort study were to assess the feasibility of a fully digital self-screening procedure for AF using the ECG247 Smart Heart Sensor for prolonged continuous ECG monitoring and to assess the prevalence of previously undetected AF in individuals  $\geq$ 65 years with at least one additional risk factor for stroke.

# **Methods**

#### Study design

This prospective nationwide cohort study was conducted and reported according to the STROBE recommendations.  $^{\rm 18}$ 

#### **Study population**

People from the general population in Norway, fulfilling the inclusion/no exclusion criteria, were recruited via social media and newspapers to participate in the study between 1 January 2021 and 6 June 2022.

#### **Inclusion criteria**

The study had the following inclusion criteria: informed digital consent for participation, age  $\geq$ 65 years, and minimum one other risk factor for stroke according to the CHA<sub>2</sub>DS<sub>2</sub>-VASc risk score, <sup>7</sup> age  $\geq$ 75 years, female gender, diabetes, heart failure, hypertension, previous stroke/TIA, and/or vascular disease (myocardial infarction/percutaneous coronary intervention/coronary artery bypass surgery/angina pectoris, intermittent claudication/previous surgery or percutaneous intervention on the abdominal aorta or the lower extremity vessels, and/or arterial/venous thrombosis).

#### **Exclusion criteria**

Individuals who self-reported a prior diagnosis of AF or without access to a smartphone were excluded from participation in the study.

#### **Screening device**

The self-screening procedures were performed with the ECG247 Smart Heart Sensor system (Appsens AS, Lillesand, Norway, www.ecg247.com). The system consists of a disposable ECG electrode patch, a re-usable sensor, a medical grade smartphone app, and a secure medical back-end cloud service with real-time ECG analysis by a dedicated artificial intelligence algorithm (*Figure 1*).<sup>19</sup> The system is designed according to the General Data Protection Regulation requirements and is CE certified according to the EU Medical Device Directive (93/42/EEC). The system has improved diagnostic accuracy and usability compared to conventional Holter technology and allows for high ECG quality even during physical activity.<sup>20,21</sup> Equipment cost per test was ~35 euros.

#### Atrial fibrillation self-screening procedure

Invitation to participate in the study was published on the hospital's Facebook pages and was further shared on several of the study sponsors' (pharmaceutical companies) Facebook pages (*Figure 2*). The study also received some mention in regional newspapers and radio. Potential study participants were openly invited to a web-based screening procedure at a study-specific web page. All individuals fulfilling the inclusion/no exclusion criteria were included after signing digital consent for participation (Services for Sensitive Data, University of Oslo, Norway).

All participants self-reported their medical history regarding stroke, transient ischemic attack, systemic embolism, heart failure, hypertension, diabetes mellitus, myocardial infarction, coronary revascularization, other vascular diseases, and smoking in a study-specific questionnaire. 'Yes', 'No' or 'Unknown' were possible options to report.

Self-reported data on height, weight, and medication were also collected. A web-based solution from Services for Sensitive Data, University of Oslo, was used.

The AF screening device was sent by post from the study centre at Sorlandet hospital Arendal, Norway, to all participants (*Figure 3*) free of charge. User guides (paper, digital, and video) were available from the manufacturer (Norwegian and English), and a 'help desk' was available for phone assistance. A minimum 3-day test period was recommended, but everyone was encouraged to continue the test until the electrode patch loosened, ran out of power (max 14 days battery capacity), or until they wanted to terminate it for other reasons. Participants who failed to perform the ECG self-screening test were defined as participants who create an account in the ECG system, but without any ECG recordings. The ECG sensor was returned to the study centre for reuse in an already addressed and prepaid letter.

All participants were invited by mail to answer a digital questionnaire focusing on usability after completing the ECG monitoring period. Usability in different daily life situations was scored on a 10-level Likert-type scale (1: excellent to 10: very poor). A system usability score (SUS) >68 was defined as 'acceptable'.<sup>22</sup>



Figure 1 The ECG247 Smart Heart Sensor self-screening device.

Sorlandet Hospital invites everyone over the age of 65 to check whether they can participate in the Atrial Fibrillation study. Participation is free and everything happens from home. A small heart sensor must be attached to the chest and connected with your own smartphone. Everyone will receive feedback from a physician.





All ECG recordings were reviewed by a trained and experienced cardiology fellow. The following variables were registered: duration of the heart rhythm recording, heart rhythm [sinus rhythm, AF/flutter >30 s, supraventricular tachycardia (SVT) >15 s, ventricular tachycardia (VT) (>4 beats), and pause ( $\geq$ 4 s)], timing, duration, and heart rate of arrhythmias. A cardiologist confirmed all abnormal ECGs and all arrhythmias.

All participants received a digital report of the study results in the ECG247 application on their smartphones. Participants were also contacted by phone in case of significant arrhythmias and were recommended to contact their general practitioner (GP) for further treatment assessment.

An external independent data monitoring committee (DMC) performed a new manual review of randomly selected tests. The DMC also verified all arrhythmias.

#### Outcomes

The primary outcome was to assess the feasibility of a fully digitalized self-screening procedure for AF, i.e. the proportion of the included participants who managed to perform an interpretable ECG self-screening test. The secondary outcome was the prevalence of AF ( $\geq$ 30 s) in those who performed the ECG tests. Finally, we report usability data for the self-screening ECG test procedure.

The study involved no follow-up after the completion of the screening test, and no participants were clinically assessed or treated at a physical doctor-patient consultation by the study researchers.

#### Statistics

Continuous variables are presented as mean  $\pm$  standard deviation or median (25th and 75th percentile), and differences between groups were analysed using independent samples *t*-tests or Mann–Whitney non-parametric tests, as appropriate. Categorical variables are presented as numbers and percentages, and differences between groups were analysed by the chisquare test. Proportions are given by non-missing values. A *P*-value of <0.05 was regarded statistically significant. The analyses were performed using STATA, version 17 (StataCorp, College Station, TX, USA).

#### Patient and public involvement

A user representative was consulted in the preparation of the study protocol, and feedback from participants was used to adjust the study procedure within the protocol frames.

#### Ethics

The study was approved by the Regional Committee for Medical and Health Research Ethics (REK 147963). All participants signed informed consent for study participation.

#### Results

#### Study population

A total of 2118 participants from all over Norway signed the digital consent and were included in the study from 1 January 2021 to 6 June 2022 (*Figure 4*). An interpretable ECG self-screening test was performed in 1848 (87.3%) participants. A total of 215 (10.2%) did not try to start the ECG self-screening test and 54 (2.5%) failed to start the test due to technical issues. Only one of the 1849 completed self-screening, ECG tests were non-interpretable.

Self-reported clinical characteristics of the study population are described in *Table 1* and Supplementary material online, *Table S1*. More women than men (74.1% vs. 25.9%) signed up for the study. Mean age was 70.1 years (4.2), 1118 (52.3%) participants were 65–69 years old, 677 (32.0%) participants were 70–74 years old, and 333 (15.7%) participants were  $\geq$ 75 years old. The participants who signed the digital consent but did not perform the ECG test were older and more likely to be women than those who performed the test.

#### Atrial fibrillation detection

The mean ECG monitoring time of participants performing the ECG self-screening test was 153 h ( $\pm$ 87), and 677 (36.6%) tests had a duration of >7 days.

Atrial fibrillation was detected in 41 (2.2%) of the 1849 participants who performed the ECG tests. The number needed to screen to detect one case of AF was 45 among those who performed the test.

More men than women were diagnosed with AF [21 of 494 men (4.3%) vs. 20 of 1335 women (1.5%), P = 0.001] (*Table 2*). The mean age of individuals with detected AF was higher compared to participants without AF (72 vs. 70 years, P < 0.01). More participants with AF reported palpitations and tachycardia compared to patients without AF. However, we found no differences between the groups for self-reported dyspnoea, chest pain, and syncope.

Paroxysmal AF was present in 36 (88%) of the 41 AF cases. Participants with paroxysmal AF had an average of 2.8 ( $\pm$ 2.6) AF episodes with a mean total AF duration of 19.4 h ( $\pm$ 25.2), corresponding to 9.4% of the total test period [mean 206 h ( $\pm$ 112)]. The median ECG self-screening test duration before the first episode of AF was 47 h (interquartile range 16–83) (*Figure 5*). Atrial fibrillation was present at the beginning of the ECG self-screening test period in two (1%) participants with paroxysmal AF and occurred during the first 24 h in 11 (31%) participants with paroxysmal AF, within 48 h in 18 (50%) participants with paroxysmal AF, and within 72 h in 26 (72%) participants with



paroxysmal AF. Nocturnal (23:00–06:00) episodes of AF were registered in 29 (81%) of the 36 participants with paroxysmal AF.

In five (12%) study participants, AF persisted throughout the ECG self-screening test. The median test duration in these cases was 102 h (min 6, max 299).

#### Other arrhythmias

Other arrhythmias than AF were detected in 42 (2.3%) participants, including 23 (1.2%) cases of short episodes of non-sustained VT (<30 s), 18 (1.0%) cases of SVT, and 1 (0.1%) pause  $\geq$ 4 s (sinus arrest). No

immediately life-threatening arrhythmias were detected, and all participants with other arrhythmias were advised to contact their GP to assess the need for further investigation and treatment.

# Usability of the electrocardiogram self-screening test system

A total of 1709 (92.4%) study participants who performed the ECG self-screening test reported usability data. The usability of the ECG self-screening test system was generally high, with a SUS<sup>22</sup> in the high

 Table 1
 Baseline self-reported clinical characteristics of the study population

	Participants performed the ECG self-screening test n = 1849 (87%)	Participants did not perform the ECG self-screening test n = 269 (13%)	Р
	n	n	
Women (%)	1355 (73)	214 (80)	0.03
Mean age (years) (SD)	70 (4)	71 (5)	0.02
Mean body mass index (kg/m2) (SD)	26 (4)	27 (4)	0.06
Smoking (%)	120 (6)	20 (7)	0.20
Hypertension (%)	806 (47)	104 (47)	0.91
Diabetes (%)	142 (8)	14 (6)	0.39
Previous coronary heart disease			
Myocardial infarction (%)	104 (6)	15 (7)	0.57
Percutaneous coronary intervention (%)	130 (7)	24 (11)	0.06
Coronary artery bypass grafting (%)	28 (2)	3 (1)	0.81
Previous stroke (%)	56 (3)	8 (4)	0.73
Peripheral artery disease (%)	17 (1)	2 (1)	0.94
Heart failure (%)	27 (2)	9 (4)	0.01
Hypothyroidism (%)	239 (13)	37 (17)	0.21
Hyperthyroidism (%)	25 (1)	3 (1)	0.95
Chronic obstructive pulmonary disease (%)	76 (4)	20 (9)	0.00
Sleep apnoea (%)	181 (11)	21 (11)	0.83
Mean CHA <sub>2</sub> DS <sub>2</sub> -VASc risk score (SD)	2.6 (0.8)	2.7 (1.0)	0.02
Median CHA <sub>2</sub> DS <sub>2</sub> -VASc risk score (IQR)	2 (2–3)	2 (2–3)	0.09
Medication use			
Acetylsalicylic acid (%)	433 (24)	60 (27)	0.37
Anticoagulation therapy (%)	23 (1)	2 (1)	0.63
Lipid lowering therapy (%)	644 (36)	82 (37)	0.75
Beta blocker (%)	234 (13)	39 (18)	0.06
Angiotensin-converting enzyme (ACE) inhibitors (%)	87 (5)	16 (7)	0.14
Angiotensin II receptor blockers (%)	377 (21)	43 (19)	0.53

 $CHA_2DS_2$ -VASc: congestive heart failure, hypertension, age  $\geq$ 75 years (doubled), diabetes, stroke (doubled), vascular disease, age 65–74 years and sex category (female). Not calculated for participants with missing/unknown information of the individual risk factors (see Supplementary material online, *Table S1*).

IQR, interquartile range; SD, standard deviation.

Proportions are given by non-missing values.

acceptable range (*Table 3*). Itching and erythema were reported as minor problems.

### Discussion

This cohort study including 2118 participants (74.1% women)  $\geq$ 65 years old with at least one additional risk factor for stroke [mean CHA<sub>2</sub>DS<sub>2</sub>-VASc risk score 2.6 (±0.9)] demonstrated high feasibility of a fully digital prolonged continuous self-screening procedure for AF by the ECG247 Smart Heart Sensor. A total of 1849 (87%) participants performed the self-screening procedure, and nearly all ECG recordings were interpretable. The mean heart rhythm monitoring time was >6 days. The incidence of previously undetected AF was 2.2%, and the number needed to screen was 45 to find one AF case.

Both traditional clinical arrhythmia work-up and the conduction of traditional clinical studies demand human resources and are timeand cost-consuming. A fully digital approach with self-performing diagnostic procedures out-of-hospital may streamline the assessment of patients with suspected heart rhythm disorders and the recommended screening of individuals at risk. Similarly, a digital solution may increase the inclusion rate and protocol adherence and reduce costs in a clinical study. A digital study can also be carried out with a larger geographical sampling, avoiding selection biases.<sup>23</sup> However, the digital approach may partly explain that more women than men participated in the study. The gender distribution may represent gender differences in the use of social media. Further, one could speculate that women might be more interested in health issues and therefore more willing to take part in such screening procedures. Finally, female gender was included as a risk factor in the inclusion criteria, and this may also have contributed to the gender skewness in the study. Stratification by gender and use of more traditional media for invitation may be considered for inclusion in future digital studies.

Few participants (2.5%) reported technical problems with the performance of the AF self-screening test at home. We did not systematically record the reason for non-performance, but some possible

	New atrial fibrillation $n = 41$ (2.2%)	No atrial fibrillation n = 1808 (97.8%)	Р
	<i>n</i>		
Women	20	1335	
Mean age (years) (SD)	72 (5)	70 (4)	0.01
Mean body mass index (kg/m2) (SD)	26 (5)	26 (4)	0.95
Smoking (%)	4 (10)	116 (7)	0.42
Hypertension (%)	19 (51)	787 (47)	0.56
Diabetes (%)	3 (7)	139 (8)	0.88
Previous coronary heart disease			
Myocardial infarction (%)	1 (2)	103 (6)	0.36
Percutaneous coronary intervention (%)	1 (2)	129 (7)	0.23
Coronary artery bypass grafting (%)	0 (0)	28 (2)	0.42
Previous stroke (%)	1 (2)	55 (3)	0.81
Peripheral artery disease (%)	2 (5)	15 (1)	0.01
Heart failure (%)	0 (0)	27 (2)	0.43
Hypothyroidism (%)	4 (10)	235 (14)	0.52
Hyperthyroidism (%)	0 (0)	25 (1)	0.45
Chronic obstructive pulmonary disease (%)	3 (7)	73 (4)	0.34
Sleep apnoea (%)	2 (6)	179 (12)	0.35
Mean CHA <sub>2</sub> DS <sub>2</sub> -VASc risk score (SD)	2.5 (0.8)	2.6 (0.8)	0.39
Median CHA <sub>2</sub> DS <sub>2</sub> -VASc risk score (IQR)	2 (2–3)	2 (2–3)	0.31
Medication use			
Acetylsalicylic acid (%)	8 (20)	425 (24)	0.49
Anticoagulation therapy (%)	1 (2)	20 (1)	0.43
Lipid lowering therapy (%)	16 (39)	628 (36)	0.67
Beta blocker (%)	9 (22)	225 (13)	0.09
Angiotensin-converting enzyme (ACE) inhibitors (%)	3 (8)	84 (5)	0.43
Angiotensin II receptor blockers (%)	7 (18)	370 (21)	0.63
Symptoms			
Irregular heartbeats (%)	29 (74)	680 (46)	<0.001
Tachycardia (%)	22 (63)	602 (40)	0.01
Dyspnoea (%)	9 (24)	390 (25)	0.86
Chest pain (%)	0 (0)	117 (7)	0.08
Syncope (%)	2 (5)	110 (7)	0.76

Table 2 Baseline self-reported clinical characteristics of participants with and without atrial fibrillation

 $CHA_2DS_2$ -VASc: congestive heart failure, hypertension, age  $\geq$ 75 years (doubled), diabetes, stroke (doubled), vascular disease, age 65–74 years and Sex category (female). Not calculated for participants with missing/unknown information of the individual risk factors (see Supplementary material online, *Table S1*).

Proportions are given by non-missing values.

IQR, interquartile range; SD, standard deviation.

explanations were non-compatible mobile phones and incorrect handling of electrode patches. Some patients reported premature termination of the test due to rash and/or skin itching under the electrode patch, while others experienced loosening of the patch after a few days. Nonetheless, the mean test duration time was much higher than what is usually achievable with traditional Holter systems. Nearly all tests were interpretable, the SUS was in the acceptable range, and the self-reported usability was high in most daily life situations, including showering and training.

The prevalence of previously undetected AF was higher in this study compared to studies with comparable mean age groups, as the Akershus Cardiac Examination 1950 study and The Belgian Heart Rhythm Week screening programme study<sup>9,24</sup> The Swedish STROKESTOP study reported 3.0% previously undetected AF, but the participants in that study were older and had a higher CHA<sub>2</sub>DS<sub>2</sub>-VASc risk score.<sup>25</sup> The prevalence of previously undetected AF depends on the prevalence of diagnosed AF in the population. Norway has a universal public healthcare system available for all citizens, and a Norwegian registry study has shown a high prevalence of diagnosed AF.<sup>26</sup> Atrial fibrillation is more frequent in men compared to women, and the gender skewness in this study may have had impact on the overall prevalence of previously undetected AF.<sup>26</sup>

In patients with paroxysmal (intermittent) AF, AF will often be missed by single or repeated ECG recordings, while long-term continuous ECG-monitoring improves the detection rate.<sup>27,28</sup> Conventional





Та	ble 3	Usability	of the ECC	G self-screening	g test s	ystem
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Mean usability score in different situations (SD) <sup>a</sup>		
Eating	1.1	(0.8)
Lavatory (WC) use	1.1	(0.6)
Showering	2.5	(2.3)
Social relations	1.1	(0.6)
At work	1.2	(0.8)
Physical activity	1.3	(1.1)
Training	1.6	(1.7)
Sleeping	2.0	(1.8)
Adverse events <sup>b</sup>		
Itching	2.8	(2.4)
Erythema	2.8	(2.5)
System usability score <sup>c</sup>	84.5	(15.7)

ECG, electrocardiogram; SD, standard deviation; WC, water closet.

<sup>a</sup>Usability score: 1 (excellent) to 10 (very poor).

<sup>b</sup>Score: 1 (no problem) to 10 (not acceptable).

<sup>c</sup>System usability score: 0–100, >68 acceptable.

hospital-based Holter monitoring systems are cumbersome to use, usually have short test periods (24–72 h), and are sensitive to disturbances.<sup>29</sup> High operational costs often lead to lower use than recommended.<sup>30</sup> Several previous AF screening studies have used single point time screening procedures (thumb ECG), which run the risk of missing cases of paroxysmal AF.<sup>27</sup> Our findings highlight the value of continuous ECG monitoring to detect intermittent episodes of AF. Detection of nocturnal episodes of AF may also indicate increased diagnostic accuracy of continuous ECG recording systems compared to user-initiated recording systems. Furthermore, prolonged ECG-monitoring improves the detection rate of AF.<sup>11,27,31</sup> The ILR allow for continuous rhythm monitoring over several years but are expensive and require invasive procedures. Some large trials using wearable devices with photoplethysmography sensors have indicated a high positive predictive value for AF.<sup>32–34</sup> However, ECG documentation is necessary for the diagnosis of AF.<sup>7</sup> The relatively low proportions who performed a subsequent ECG monitoring in these trials may indicate potentially advantages of a primary long-term ECG screening.

The yield of AF screening depends on the underlying risk of AF and AF-related complications. The prevalence of the risk factors diabetes mellitus, heart failure, hypertension, previous stroke/TIA, and vascular disease was relatively low in our study population compared to other comparable AF screening studies.<sup>9–11</sup> Men, people  $\geq$ 80 years old and multi-morbid patients appeared to be difficult to enrol in this study. Atrial fibrillation screening in these groups probably requires more active outreach. We found no differences in risk factors between the groups with and without AF, but the study was not powered to identify risk factors for AF detected by self-screening.

Atrial fibrillation fulfils most criteria for population screening, being a severe and prevalent health problem that can be asymptomatic and with highly effective treatment for preventing stroke and other AF-related complications.<sup>35</sup> International guidelines recommend opportunistic screening for AF in people with an increased risk of stroke.<sup>7</sup> However, randomized controlled trial data to confirm the health benefits of screening for AF and inform the choice of optimal screening programs and strategies for implementation are scarce. In the recently published STROKESTOP trial, a strategy with AF screening by thumb-ECG twice daily for two weeks was found to reduce the composite primary endpoint (stroke, systemic embolism, bleeding leading to hospitalization, and all-cause death) by 4%.<sup>10</sup> In the Danish LOOP study, AF screening with ILR resulted in a 20% reduction in the risk of stroke or systemic arterial embolism during follow-up, which however did not reach statistical significance (HR 0.80; 95% Cl 0.61–1.05; P = 0.11).<sup>11</sup>

Incidental findings of other arrhythmias represent a potential challenge in performing AF screening. The prevalence of other arrhythmias is difficult to compare with other studies due to different study population and partly different definitions of the arrhythmias. In this study, we chose to refer participants with arrhythmias to local GPs. We do not have information on whether participants with arrhythmias contacted a GP, nor on any further investigation and treatment.

This study has several important limitations. Invitation to study participation was mainly via social media, and 'the number needed to invite to screening' was not possible to estimate. People who did not use digital media had limited opportunities to participate. Furthermore, the study required access to a Norwegian BankID for digital signing and access to a smartphone to perform the AF self-screening test. This may have created a selection bias in relation to gender, age, socioeconomic status, symptoms, and digital competence. However, the fully digital design enabled a nationwide inclusion during a short time interval and at low personnel and financial cost. We did not collect data on time spent for administration, packaging, and postage of the ECG devices, nor for the manual review of the ECG recordings, and total cost for the screening procedure cannot be estimated. Furthermore, we had no opportunity to validate the self-reported health information. Only one physician assessed most of the ECG recordings. Misinterpretation of arrhythmias may occur. To reduce this risk, an external DMC verified the accuracy of the study data. The diagnostic accuracy of the diagnostic device is described previously, but some arrhythmia episodes might be undetected by the system.

In conclusion, this fully digital self-screening procedure for AF had excellent feasibility, with >87% of individuals successfully performing the ECG self-screening test. Prolonged continuous ECG monitoring (mean ECG monitoring time >6 days) increased the detection rate of previously unknown AF compared to previous studies with similar age groups using intermittent ECG recording. Of those who performed the ECG test, the number needed to screen was 45 to detect one case of AF in people  $\geq$ 65 years with at least one other risk factor for stroke. Larger, randomized studies with long-term follow-up are needed to assess whether prolonged continuous self-screening for AF to identify people needing anticoagulation therapy can reduce the incidence of AF-related complications.

# Supplementary material

Supplementary material is available at Europace online.

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# **Author contributions**

All authors contributed to the study design and conception. ELS was responsible for analyses and interpretation of the data. ELS, SH and JJ drafted, and TB, JG, DA, RF and BLG critically revised the manuscript. All authors gave final approval and agreed to be accountable for all aspects of this work, ensuring its integrity and accuracy.

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#### Data availability

The data underlying this article will be shared on reasonable request to the corresponding author (ELS).

#### References

- Bakhai A, Sandberg A, Mittendorf T, Greiner W, Oberdiek A, Berto P et al. Patient perspective on the management of atrial fibrillation in five European countries. BMC Cardiovasc Disord 2013;13:108.
- Lip GYH, Brechin CM, Lane DA. The global burden of atrial fibrillation and stroke: a systematic review of the epidemiology of atrial fibrillation in regions outside North America and Europe. Chest 2012;**142**:1489–98.
- Ball J, Carrington MJ, McMurray JJ, Stewart S. Atrial fibrillation: profile and burden of an evolving epidemic in the 21st century. *Int J Cardiol* 2013;**167**:1807–24.
- Chugh SS, Havmoeller R, Narayanan K, Singh D, Rienstra M, Benjamin EJ et al. Worldwide epidemiology of atrial fibrillation: a global burden of disease 2010 study. *Circulation* 2014;**129**:837–47.
- Di Carlo A, Bellino L, Consoli D, Mori F, Zaninelli A, Baldereschi M et al. Prevalence of atrial fibrillation in the Italian elderly population and projections from 2020 to 2060 for Italy and the European Union: the FAI Project. *Europace* 2019;**21**:1468–75.
- Davis RC, Hobbs FD, Kenkre JE, Roalfe A K, Iles R, Lip GYH et al. Prevalence of atrial fibrillation in the general population and in high-risk groups: the ECHOES study. *Europace* 2012;**14**:1553–9.
- 7. Hindricks G, Potpara T, Dagres N, Arbelo E, Bax JJ, Blomström-Lundqvist C et al. 2020 ESC guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association For Cardio-Thoracic Surgery (EACTS): the task force for the diagnosis and management of atrial fibrillation of the European Society of Cardiology (ESC) developed with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC. Eur Heart J 2020;42:373–498.
- Schnabel RB, Marinelli EA, Arbelo E, Boriani G, Boveda S, Buckley CM et al. Early diagnosis and better rhythm management to improve outcomes in patients with atrial fibrillation: the 8th AFNET/EHRA consensus conference. *Europace* 2022;25:6–27.
- Berge T, Brynildsen J, Larssen HKN, Onarheim S, Jenssen GR, Ihle-Hansen H et al. Systematic screening for atrial fibrillation in a 65-year-old population with risk factors for stroke: data from the Akershus Cardiac Examination 1950 Study. *Europace* 2017; 20:f299–f305.
- Svennberg E, Friberg L, Frykman V, Al-Khalili F, Engdahl J, Rosenqvist M et al. Clinical outcomes in systematic screening for atrial fibrillation (STROKESTOP): a multicentre, parallel group, unmasked, randomised controlled trial. Lancet 2021;398:1498–1506.
- Svendsen JH, Diederichsen SZ, Hojberg S, Krieger DW, Graff C, Kronborg C et al. Implantable loop recorder detection of atrial fibrillation to prevent stroke (the LOOP study): a randomised controlled trial. *Lancet* 2021;**398**:1507–16.
- Khurshid S, Healey JS, McIntyre WF, Lubitz SA. Population-based screening for atrial fibrillation. *Circ Res* 2020;**127**:143–54.
- Kalarus Z, Mairesse GH, Sokal A, Boriani G, Średniawa B, Casado-Arroyo R et al. Searching for atrial fibrillation: looking harder, looking longer, and in increasingly sophisticated ways. An EHRA position paper'. *Europace* 2022;25:185–98.
- Carrington M, Providencia R, Chahal CAA, Carrington M, Providência R, Chahal CAA et al. Clinical applications of heart rhythm monitoring tools in symptomatic patients and for screening in high-risk groups. *Europace* 2022;24:1721–29.
- Steinhubl SR, Waalen J, Edwards AM, Ariniello LM, Mehta RR, Ebner GS 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;320:146–55.
- Gladstone DJ, Wachter R, Schmalstieg-Bahr K, Quinn FR, Hummers E, Ivers N et al. Screening for atrial fibrillation in the older population: a randomized clinical trial. JAMA Cardiol 2021;6:558–67.
- Svennberg E, Tjong F, Goette A, Akoum N, Di Biase L, Bordachar P et al. How to use digital devices to detect and manage arrhythmias: an EHRA Practical Guide. Europace 2022;24:979–1005.
- von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. The strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies. *Int J Surg* 2014;**12**:1495–9.

- Jortveit J, Fensli R. Remote ECG monitoring by ECG247 smart heart sensor. Int J Telemed Appl 2022;2022:6812889.
- Sandberg EL, Grenne BL, Berge T, Grimsmo J, Atar D, Halvorsen S et al. Diagnostic accuracy and usability of the ECG247 smart heart sensor compared to conventional Holter technology. J Healthc Eng 2021;2021:5230947.
- Ausland Å, Sandberg EL, Jortveit J, Seiler S. Heart rhythm assessment in elite endurance athletes: a better method? Front Sports Act Living 2022;4:80–89.
- Brooke J. SUS: a 'quick and dirty' usability scale. In: McClelland P (ed.), Usability evaluation in industry. London: Taylor and Francis; 1986. p. 189–194.
- Schenck-Gustafsson K, Carnlof C, Jensen-Urstad M, Insulander P. Improving efficiency of clinical studies using a total digital approach: prospective observational study. JMIR Form Res 2021;5:e18385.
- Proietti M, Mairesse GH, Goethals P, Scavee C, Vijgen J, Blankoff I et al. A population screening programme for atrial fibrillation: a report from the Belgian heart rhythm week screening programme. Europace 2016;18:1779–86.
- Svennberg E, Engdahl J, Al-Khalili F, Friberg L, Frykman V and Rosenqvist M. Mass screening for untreated atrial fibrillation: the STROKESTOP study. *Circulation* 2015;**131**: 2176–84.
- Kjerpeseth LJ, Igland J, Selmer R, Ellekjær H, Tveit A, Berge T et al. Prevalence and incidence rates of atrial fibrillation in Norway 2004–2014. Heart 2021;107:201–7.
- 27. Fredriksson T, Kemp Gudmundsdottir K, Frykman V, Friberg L, Al-Khalili F, Engdahl J et al. Intermittent vs continuous electrocardiogram event recording for detection of

atrial fibrillation-compliance and ease of use in an ambulatory elderly population. *Clin Cardiol* 2020;**43**:355–62.

- Diederichsen SZ, Haugan KJ, Kronborg C, Graff C, Højberg S, Køber L et al. Comprehensive evaluation of rhythm monitoring strategies in screening for atrial fibrillation: insights from patients at risk monitored long term with an implantable loop recorder. *Circulation* 2020;**141**:1510–22.
- 29. Holter NJ. New method for heart studies. Science 1961;134:1214-20.
- Jortveit J, Lislevand TH, Rysstad L, Dahlslett T, Sjøli B. Long-term ECG recording: findings and implications. *Tidsskr Nor Laegeforen* 2020;**140**.
- Ratajczak-Tretel B, Tancin Lambert A, Hoie GA, Al-Ani R, Russell D, Atar D et al.. Detection of atrial fibrillation in patients with cryptogenic stroke: the nordic atrial fibrillation and stroke (NOR-FIB) study—topline results. *Europace* 2022;24.
- Lubitz SA, Faranesh AZ, Selvaggi C, Atlas SJ, McManus DD, Singer DE et al. Detection of atrial fibrillation in a large population using wearable devices: the Fitbit Heart Study. *Circulation* 2022;**146**:1415–24.
- Perez MV, Mahaffey KW, Hedlin H, Rumsfeld JS, Garcia A, Ferris T et al. Large-Scale assessment of a smartwatch to identify atrial fibrillation. N Engl J Med 2019;381:1909–17.
- Guo Y, Wang H, Zhang H, Liu T, Liang Z, Xia Y et al. Mobile photoplethysmographic technology to detect atrial fibrillation. J Am Coll Cardiol 2019;74:2365–75.
- Freedman B, Potpara TS, Lip GY. Stroke prevention in atrial fibrillation. *Lancet* 2016; 388:806–17.