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Mobile health adherence for the detection of recurrent recent-onset atrial fibrillation

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ABSTRACT

Objective The Rate Control versus Electrical Cardioversion Trial 7–Acute Cardioversion versus Wait and See trial compared early to delayed cardioversion for patients with recent-onset symptomatic atrial fibrillation (AF). This study aims to evaluate the adherence to a 4-week mobile health (mHealth) prescription to detect AF recurrences after an emergency department visit.

Methods After the emergency department visit, the 437 included patients, irrespective of randomisation arm (early or delayed cardioversion), were asked to record heart rate and rhythm for 1 min three times daily and in case of symptoms by an electrocardiography-based handheld device for 4 weeks (if available). Adherence was appraised as number of performed measurements per number of recordings asked from the patient and was evaluated for longitudinal adherence consistency. All patients who used the handheld device were included in this subanalysis.

Results 335 patients (58% males; median age 67 (IQR 11) years) were included. The median overall adherence of all patients was 83.3% (IQR 29.9%). The median number of monitoring days was 27 out of 27 (IQR 5), whereas the median number of full monitoring days was 16 out of 27 (IQR 14). Higher age and a previous paroxysm of AF were identified as multivariable adjusted factors associated with adherence.

Conclusions In this randomised trial, a 4-week mHealth prescription to monitor for AF recurrences after an emergency department visit for recent-onset AF was feasible with 85.7% of patients consistently using the device with at least one measurement per day. Older patients were more adherent.

Trial registration number NCT02248753.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Although mobile health devices are increasingly used to monitor patients with atrial fibrillation in various clinical scenarios, little is known about adherence levels to mobile health prescriptions.

WHAT THIS STUDY ADDS

⇒ Patients who had an emergency department visit for recent-onset atrial fibrillation had a median adherence of 83.3% to a 4-week mobile health prescription to monitor for recurrences.
⇒ In addition, 85.7% of these patients used the device consistently with at least one measurement per day.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Based on the results of this study, it seems feasible to use mobile health in this specific clinical scenario.

INTRODUCTION

Cardioversion is a frequently used treatment strategy for symptomatic patients with recent-onset atrial fibrillation (AF) in order to achieve acute symptom relief.[1] In the randomised Rate Control versus Electrical Cardioversion Trial 7–Acute Cardioversion versus Wait and See (RACE

7 ACWAS) trial, an early cardioversion approach was compared with a delayed cardioversion approach in patients with recent-onset symptomatic AF.[2] In the European Society of Cardiology AF guidelines, follow-up is recommended to, among other reasons, early recognise AF recurrence.[3] This is usually done using an ECG recording, such as a standard 10 s 12-lead ECG or 24-hour ambulatory ECG monitoring. Additionally, several mobile health (mHealth) devices and smartphone applications have been developed to perform repeated rhythm recordings.[4] Despite the fact that these mHealth devices and applications have good accuracy to detect AF,[4] the efficacy of long-term intermittent monitoring using mHealth devices or applications to detect AF recurrences is mainly determined by the adherence and the consistency of adherence of patients to collect measurements.[5] Data on patient adherence to and consistency of long-term intermittent mHealth
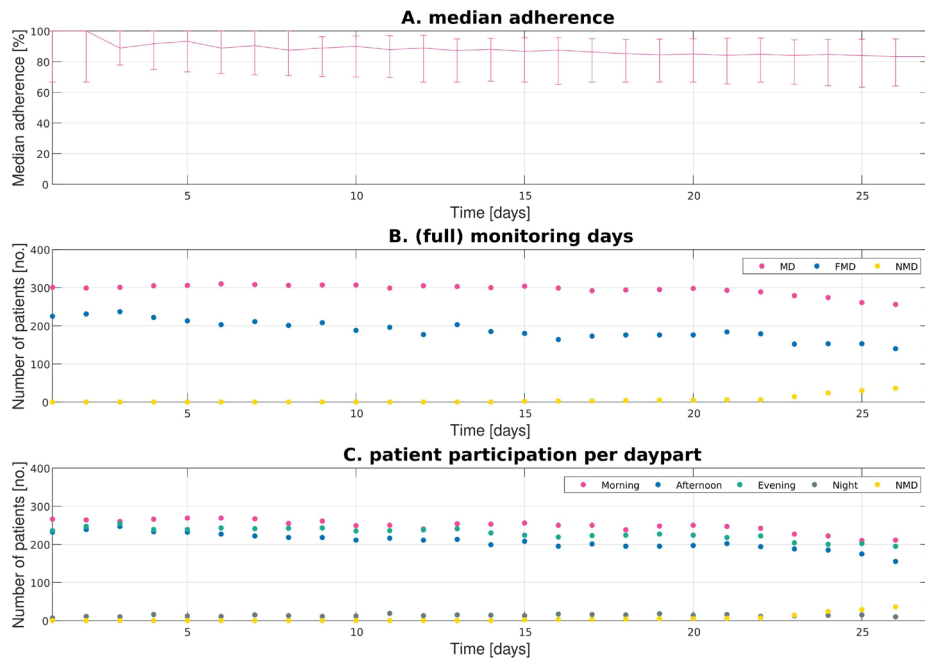
Figure 1 Longitudinal overviews. (A) Median adherence (IQR) over time for all patients. (B) Longitudinal overview of number of patients with (full) monitoring days. (C) Number of patients who performed at least one measurement during a specific daypart. FMD, full monitoring day, defined as at least three recordings per day; MD, monitoring day, defined as at least one recording on a certain day; NMD, non-monitoring day, defined as a day on which patients could not measure because the device was returned early.

prescriptions for rhythm monitoring in this specific clinical scenario are scarce.

The aim of this substudy of the RACE 7 ACWAS trial is to evaluate adherence to a 4-week mHealth prescription to monitor for recurrences after an emergency department (ED) visit for recent-onset symptomatic AF and to study factors associated with adherence.

METHODS
Study design
This study is a post hoc subanalysis of the RACE 7 ACWAS trial (NCT02248753). A detailed overview of the design of this study has been published previously.[2 6]

In short, the RACE 7 ACWAS trial was a randomised, multicentre, non-inferiority trial comparing early to delayed cardioversion in patients with recent-onset AF at the ED followed by 4 weeks follow-up. Within this time period, patients in both groups were asked to use an ECG-based handheld device (MyDiagnostick, Applied Biomedical Systems) to record 1 min heart rate and rhythm recordings. On discharge from the ED, patients were given instructions on how to use the device and were instructed to use the device three times daily and in case of symptoms.[4 7] All recordings were collected at once after the follow-up period. Meanwhile, data were only stored in the handheld device, the study team did not contact patients regarding the telemonitoring device and the device did not send reminders to the patients. However, after each recording patients received visual feedback from the device regarding whether AF was present (red light appearing after completion of the recording) or not (green light).

Inclusion criteria of RACE 7 ACWAS trial
The study population consisted of adult (>18 years old) patients who presented to the ED with recent-onset (<36 hours) symptomatic AF. Exclusion criteria were haemodynamic instability, signs of myocardial infarction or heart failure and a history of either sick sinus syndrome, Wolff-Parkinson-White syndrome, persistent AF or unexplained syncope.

Patient involvement
A patient representative was involved in setting the research question and design for the main study.

Overall adherence and adherence consistency
Patients were asked to perform three measurements a day for a period of 4 weeks, without further rhythm monitoring afterwards. However, since the last day of the follow-up period (the 28th day) may not be a complete follow-up day for all patients, 27 days were used for the calculation of overall adherence and adherence consistency. For the first day of the monitoring period, the first full follow-up day was taken, either the date of baseline visit, or the day after baseline visit. Only completed measurements were taken into account.

Adherence is defined as the number of measurements performed by a certain patient per number of measurements that were asked from the patient over the entire follow-up period. For the calculation of adherence, a maximum of three recordings resulted in 100% compliance during a certain day; an excess of recordings on a certain day above three recordings did not further impact overall compliance (online supplemental figure 1). Some patients could not perform measurements for 27 days because their outpatient clinic visit was scheduled earlier or they returned the device earlier for other reasons. A correction was applied for the calculation of the adherence of these patients, that is, the duration of their actual monitoring period was used. For patients that recorded longer than the required time period, measurements were censored after 27 days. Adherence was calculated in percentages. Consistency of adherence was defined as (a) the number of days on which the number of measurements that were asked were performed, that is, at least three (number of 'full monitoring days') and (b) as

Table 1 Characteristics of patients with adherence <83.3% vs patients with adherence ≥83.3%

	Total (n=335)	Adherence <83.3% (n=166)	Adherence ≥83.3% (n=169)	P value
Age in years—median (IQR)	67 (15)	65 (17)	69 (14)	**0.001**
Male—no. (%)	195 (58.2)	101 (60.8)	94 (55.6)	0.333
BMI in kg/m^2—median (IQR)	26.6 (6.0)	26.4 (7.0)	26.8 (5.7)	0.198
Hypertension—no. (%)	189 (56.4)	81 (48.8)	108 (63.9)	**0.005**
Diabetes mellitus—no. (%)	33 (9.9)	16 (9.6)	17 (10.1)	0.897
Coronary artery disease—no. (%)	60 (17.9)	27 (16.3)	33 (19.5)	0.436
Heart failure—no. (%)	7 (2.1) *n=334*	5 (3.0)	2 (1.2) *n=168*	0.245
Chronic obstructive pulmonary disease—no. (%)	19 (5.7)	5 (3.0)	14 (8.3)	**0.037**
Stroke/TIA—no. (%)	18 (5.4)	7 (4.2)	11 (6.5)	0.352
Smoking—no. (%)	Current—30 (9.0)	Current—16 (9.6)	Current—14 (8.3)	0.400
	Past—136 (40.6)	Past—63 (38.0)	Past—73 (43.2)	
	Unknown—27 (8.1)	Unknown—10 (6.0)	Unknown—17 (10.1)	
CHA$_2$DS$_2$-VASc score—median (IQR)	2 (2)	2 (2)	2 (2)	**0.006**
AF characteristics				
First detected AF—no. (%)	148 (44.2)	88 (53.0)	60 (35.5)	**0.001**
Medication—no. (%)	BB—114 (34.0)	BB—53 (31.9)	BB—61 (36.1)	0.421
	NDCCB—15 (4.5)	NDCCB—9 (5.4)	NDCCB—6 (3.6)	0.408
	Digoxin—8 (2.4)	Digoxin—4 (2.4)	Digoxin—4 (2.4)	0.980
	AAD*—75 (22.4)	AAD—27 (16.3)	AAD—48 (28.4)	**0.008**
Previous electrical cardioversion—no. (%)	80 (23.9)	38 (22.9)	42 (24.9)	0.604
	Unknown—23 (6.8)	Unknown—10 (6.0)	Unknown—13 (7.7)	
Previous pharmacological cardioversion—no. (%)	95 (28.3)	41 (24.7)	54 (32.0)	0.141
Previous ablation—no. (%)	35 (10.4) *n=334*	17 (10.2)	18 (10.7) *n=168*	0.888
Patients in delayed cardioversion group—no. (%)	164 (49.0)	84 (50.6)	80 (47.3)	0.550
Patients with spontaneous conversion—no. (%)	136 (40.6)	72 (43.3)	64 (37.9)	0.305
Recurrence of AF—no. (%)	99 (29.6)	41 (24.7)	58 (34.3)	0.054
ED visit due to recurrence of AF—no. (%)	17 (5.1)	9 (5.4)	8 (4.7)	0.774
Cardiovascular complications during index visit and 4 weeks of follow-up—no. (%)†	17 (5.1)	10 (6.0)	7 (4.1)	0.433
AFEQT questionnaire overall score—median (IQR)	76.4 (22.9) *n=212*	76.9 (25.5) *n=109*	76.0 (22.2) *n=103*	0.569

Values in bold are statistically significant.

*Either flecainide, propafenone, sotalol or amiodarone.

†Composed of: admission for heart failure, ischaemic stroke or TIA, unstable angina or acute coronary syndrome, bradycardia or hypotension and tachycardia.

AAD, antiarrhythmic drugs; AF, atrial fibrillation; AFEQT, Atrial Fibrillation Effect on QualiTy of life; BB, beta-blocker; BMI, Body Mass Index; BMI, body mass index; ED, emergency department; NDCCB, non-dihydropyridine calcium channel blocker; TIA, transient ischaemic attack.

the number of days on which at least one measurement was performed (number of '*monitoring days*'), and expressed as absolute number. The former is used to provide information on the number of days patients were fully adherent to the given instructions, whereas the latter is used to visualise the consistency of performing measurements over time.

Statistical analysis

Since all continuous variables were non-normally distributed, they are presented as median (IQR) and compared using the Mann-Whitney U test. Categorical variables are presented as numbers (no.) with percentages (%) and compared using a χ^2 test. To determine factors associated with adherence, variables were tested in an univariable logistic regression model (α-level of <0.05). All significant variables were then entered in a multivariable logistic regression model, using the stepwise backward procedure (with α-level of <0.05). A backward procedure was used to arrive at a more parsimonious model including only significant factors. A two-sided p value <0.05 was considered statistically significant. All analyses were conducted using IBM SPSS Statistics, V.25 and MATLAB r2019b (The MathWorks).

RESULTS

Of the 437 patients included in the trial, 335 patients (58% males; median age 67 (11) years) were included in this analysis. The remaining 102 patients did not use the MyDiagnostick device due to unavailability at the time of inclusion and were therefore excluded. Baseline characteristics of the included patients are presented in online supplemental table 1.

Overall adherence

The median overall adherence of all patients was 100% (IQR 33.3%) at day 1 and 83.3% (IQR 29.9%) over the entire monitoring period (day 27). With an average of 0.5% per day, the decrease in adherence over time was small (figure 1A).

One hundred sixty-nine patients (50.4%, median age 69 years, 55.6% male) had an adherence rate of ≥83.3% (≥ median). These patients were older (69 vs 65 years, p=0.001), had more often hypertension (63.9% vs 48.8%, p=0.005) and chronic obstructive pulmonary disease (8.3% vs 3.0%, p=0.037), had higher CHA$_2$DS$_2$-VASc scores (p=0.006), had less frequently first detected AF (35.5% vs 53.0%, p=0.001) and were more often treated with antiarrhythmic drugs (AADs) (28.4% vs 16.3%, p=0.008). Remarkably, ED visits, the occurrence of cardiovascular complications and

Table 2 Characteristics of patients with <median adherence consistency versus patients with ≥median adherence consistency

	<Median monitoring days (<27) (n=161)	≥Median monitoring days (=27) (n=174)	P value	<Median full monitoring days (<16) (n=158)	≥Median full monitoring days (≥16) (n=177)	P value
Age in years—median (IQR)	66 (16)	68 (12)	0.103	65 (17)	69 (14)	**0.003**
Male—no. (%)	96 (59.6)	99 (56.9)	0.613	96 (60.8)	99 (55.9)	0.371
BMI in kg/m^2—median (IQR)	26.3 (6.5)	27.1 (5.7)	0.134	26.6 (6.7)	26.7 (5.9)	0.704
Hypertension—no.(%)	87 (54.0)	102 (58.6)	0.398	84 (53.2)	105 (59.3)	0.257
Diabetes mellitus—no. (%)	14 (8.7)	19 (10.9)	0.495	17 (10.8)	16 (9.0)	0.598
Coronary artery disease—no. (%)	28 (17.4)	32 (18.4)	0.812	27 (17.1)	33 (18.6)	0.711
Heart failure—no. (%)	4 (2.5) n=160	3 (1.7)	0.621	5 (3.2)	2 (1.1) n=176	0.196
Chronic obstructive pulmonary disease—no. (%)	6 (3.7)	13 (7.5)	0.139	5 (3.2)	14 (7.9)	0.061
Stroke/TIA—no. (%)	9 (5.6)	9 (5.2)	0.865	8 (5.1)	10 (5.6)	0.812
Smoking—no. (%)	Current—15 (9.3)	Current—15 (8.6)	0.412	Current—19 (12.0)	Current—11 (6.2)	0.107
	Past—61 (37.9)	Past—75 (43.1)		Past—58 (36.7)	Past—78 (44.1)	
	Unknown—10 (6.2)	Unknown—17 (9.8)		Unknown—11 (7.0)	Unknown—16 (9.0)	
CHA$_2$DS$_2$-VASc score—median (IQR)	2 (2)	2 (2)	0.324	2 (2)	2 (2)	0.217
AF characteristics						
First detected AF—no. (%)	75 (46.6)	73 (42.0)	0.394	78 (49.4)	70 (39.5)	0.071
Medication—no. (%)	BB—49 (30.4)	BB—65 (37.4)	0.182	BB—54 (34.2)	BB—60 (33.9)	0.957
	NDCCB—6 (3.7)	NDCCB—9 (5.2)	0.523	NDCCB—9 (5.7)	NDCCB—6 (3.4)	0.308
	Digoxin—4 (2.5)	Digoxin—4 (2.3)	0.911	Digoxin—4 (2.5)	Digoxin—4 (2.3)	0.871
	AAD*—31 (19.3)	AAD—44 (25.3)	0.186	AAD—26 (16.5)	AAD—49 (27.7)	**0.014**
Previous electrical cardioversion—no. (%)	42 (26.1)	38 (21.8)	0.358	38 (24.1)	42 (23.7)	0.989
	Unknown—11 (6.8)	Unknown—12 (6.9)		Unknown—10 (6.3)	Unknown—13 (7.3)	
Previous pharmacological cardioversion—no. (%)	49 (30.4)	46 (26.4)	0.417	40 (25.3)	55 (31.1)	0.243
Previous ablation—no. (%)	20 (12.4)	15 (8.6) n=173	0.263	17 (10.8)	18 (10.2) n=176	0.874
Patients in delayed cardioversion group—no. (%)	84 (52.2)	80 (46.0)	0.257	80 (50.6)	84 (47.5)	0.562
Patients with spontaneous conversion—no. (%)	72 (44.7)	64 (36.8)	0.139	69 (43.7)	67 (37.9)	0.279
Recurrence of AF—no. (%)	40 (24.8)	59 (33.9)	0.069	39 (24.7)	60 (33.9)	0.065
ED visit due to recurrence of AF—no. (%)	7 (4.3)	10 (5.7)	0.560	6 (3.8)	11 (6.2)	0.314
Cardiovascular complications during index visit and 4 weeks of follow-up—no. (%)†	12 (7.5)	5 (2.9)	0.056	9 (5.7)	8 (4.5)	0.624
AFEQT questionnaire overall score—median (IQR)	79.6 (25.0) n=103	74.1 (20.8) n=109	0.119	76.4 (21.3) n=100	76.4 (23.2) n=112	0.859

*Either flecainide, propafenone, sotalol or amiodarone.
†Composed of: admission for heart failure, ischaemic stroke or TIA, unstable angina or acute coronary syndrome, bradycardia or hypotension and tachycardia.
AAD, antiarrhythmic drugs; AF, atrial fibrillation; AFEQT, Atrial Fibrillation Effect on QualiTy of life; BB, beta-blocker; BMI, body mass index; ED, emergency department; NDCCB, non-dihydropyridine calcium channel blocker; TIA, transient ischaemic attack.

the overall score on the Atrial Fibrillation Effect on QualiTy of life (AFEQT) questionnaire were not determinants of higher adherence (table 1). A sensitivity analysis applying other thresholds provided very similar results.

Consistency of adherence

Overall, the median number of monitoring days was 27 (IQR 5), whereas the median number of full monitoring days was 16 (IQR 14). The medians on a weekly basis are presented in online supplemental table 2. The 42 patients (12.5%) without full follow-up had a median of 23 (IQR 3) monitoring days. Figure 1B presents a longitudinal overview of the number of patients with (full) monitoring days. With an average decline of 1.9% per day, the percentage of patients with full monitoring days declines more over time (67.2% at day 1 vs 48.1% at day 27) compared with the percentage of patients with monitoring days (89.9% at day 1 vs 85.7% at day 27) which declined on average 0.7% per day.

Table 2 shows patient characteristics based on adherence consistency. One hundred seventy-four patients (51.9%, median age 68 (12) years, 56.9% male) had 27 monitoring days ((above) median). There were no differences between patients with 27 monitoring days (above median) or patients below the median

of 27 monitoring days. One hundred seventy-seven (52.8%, median age 69 (14) years, 55.9% male) patients had ≥16 full monitoring days (≥median). These patients were older (69 years vs 65 years, p=0.003) and were more often treated with AADs (27.7% vs 16.5%, p=0.014). Adherence and consistency of adherence of the patients are shown in figure 2.

Diurnal patterns in adherence and motivation

Patients were most likely to measure in the mornings, with a mean of 247 (SD 18) patients performing at least one recording in the morning and a decrease over time of −1.9 patients per day. Excluding nightly recordings, patients were least likely to perform measurements during the afternoon, with a mean of 206 (SD 23) patients performing at least one recording in the afternoon and a decrease of −2.7 patients per day. An overview of the diurnal patterns of the patients is given in figure 1C.

Factors associated with adherence

The results of univariable and multivariable logistic regression analysis are demonstrated in table 3 and online supplemental table 3. Age and the index visit being a recurrent paroxysm of AF rather than a first presentation were identified as multivariable
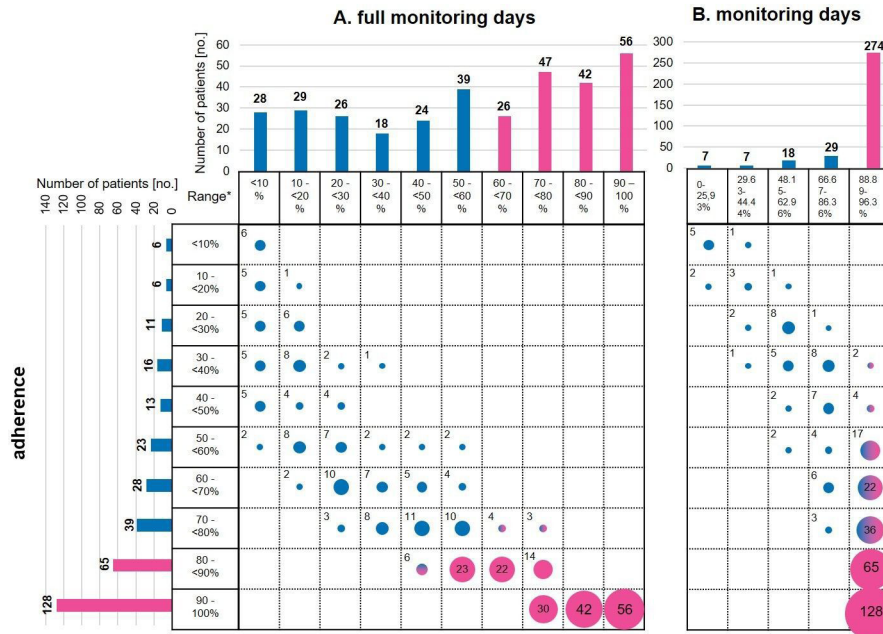
Figure 2 Adherence and adherence consistency overview. Left: the number of patients in a certain range of adherence, that is, six patients had adherence levels <10%. Top: the number of patients in a certain range of (full) monitoring days, that is, 28 patients had <10% full monitoring days. *Range=adherence and adherence consistency based on full monitoring days (A) and monitoring days (B) are divided into categories of approximately 10%. Numbers in the table indicate the number of patients that fall into that adherence and adherence consistency category, for example, top left of (A) both <10% adherence and <10% full monitoring days, bottom right of (A) both 90%–100% adherence and 90%–100% full monitoring days. Pink bars=the median falls into this category or the category is above median.

adjusted factors associated with above median adherence with OR 1.438 (95% CI 1.161 to 1.791) for every 10 years of increased age (p=0.001) and OR 1.863 (95% CI 1.190 to 2.916) for recurrent versus first paroxysm (p=0.007), respectively. There is a moderately positive relationship (correlation coefficient 0.453) between the adherence in the first 3 days and the adherence in the rest of the monitoring period.

Adherence and adherence consistency based on recurrence pattern
In table 4, adherence and adherence consistency for patients with AF recurrences are compared with those without recurrences. Median adherence was significantly higher for patients with recurrences (87.7% vs 81.5%, p=0.028), irrespective of the occurrence or timing of the recurrence. Although there was no difference in monitoring days between patients with recurrences compared with patients without recurrences, patients

with recurrences had significantly more full monitoring days (18 (14) days vs 15 (13) days, p=0.024) and were more likely to perform additional recordings (78.8% vs 49.2%, p≤0.001) (figure 3).

Of all 99 patients with AF recurrences, 78 patients performed additional recordings. Together, these patients performed additional recordings on 349 days. Patients appeared to perform additional recordings mainly because of the occurrence of a recurrence and during the recurrences, potentially due to symptoms and thus they were compliant with the given instructions.

Sixty-one patients had more than one recurrence. There was no difference in median adherence or number of patients with adherence ≥83.3% between patients with only one, and patients with multiple recurrences. For patients with AF recurrences, adherence was better on days with AF recurrence compared with days without AF recurrence (93.3% (33.3) vs 86.1% (32.3), p=0.004). There were no differences in adherence and

Table 3 Multivariable adjusted factors associated with above median adherence

	Adherence ≥83.3%			
	Univariable		Multivariable	
	OR (95% CI)	P value	OR (95% CI)	P value
Age	1.495 (1.207 to 1.842)	<0.001	1.438 (1.161 to 1.791)*	0.001
Use of AAD	2.042 (1.201 to 3.472)	0.008	1.566 (0.856 to 2.863)†	n.s.
Hypertension	1.858 (1.200 to 2.877)	0.005	1.510 (0.945 to 2.413)†	n.s.
COPD	2.908 (1.023 to 8.267)	0.045	2.490 (0.856 to 7.243)†	n.s.
Recurrent paroxysm of AF‡	2.050 (1.322 to 3.177)	0.001	1.863 (1.190 to 2.916)	0.007

Additional adjustment for randomisation did not affect results to a substantial extent.
*Odds per every 10 years increase in age.
†Last OR before removal from model.
‡The index visit being a recurrent paroxysm of AF rather than a first presentation.
AAD, antiarrhythmic drugs; AF, atrial fibrillation; COPD, chronic obstructive pulmonary disease; n.s., not significant.

Table 4 Adherence and adherence consistency based on recurrence versus no recurrence

	No recurrence (n=236)	Recurrence (n=99)	P value
Adherence—median% (IQR)	81.5 (30.9)	87.7 (27.2)	**0.028**
Adherence ≥83.3%—no. (%)	111 (47.0)	58 (58.6)	0.054
Monitoring days—median (IQR)	26 (5)	27 (4)	0.113
Full monitoring days—median (IQR)	15 (13)	18 (14)	**0.024**
Patients with additional recordings—no. (%)	116 (49.2)	78 (78.8)	**<0.001**

adherence consistency between patients who had a first recurrence within the first 2 weeks, and patients that had a first recurrence later than 2 weeks (online supplemental table 4).

DISCUSSION

Among patients presenting with recent-onset AF at the ED, the use of a mHealth device for the detection of AF recurrences within 4 weeks was feasible, with a median adherence at 4 weeks of 83.3%, and a median number of monitoring days and full monitoring days of 27 and 16, respectively.

Whenever using mHealth approaches, physicians rely on their patients to provide the necessary information on heart rate and rhythm, and are therefore dependent on the adherence and willingness of patients to perform measurements.[5] Placing patients at the centre of their AF management process may increase patient empowerment, self-management and involvement. The adherence levels in this study were in line with the findings of other mHealth studies, which reported similar adherence levels to long-term intermittent or continuous mHealth monitoring.[8–12] For instance, Guo et al reported that 70.8% of patients had an adherence of ≥70%.[8] Importantly, this study by Guo et al also evaluated the effect of mHealth monitoring for the optimisation of treatment on clinical outcomes, which was found to be positive.

Naturally, the highest possible adherence levels should be pursued to provide the best information. On analysis of adherence patterns, we observed that patients were least likely to perform measurements during the afternoon, possibly because of patient inconvenience. To increase adherence, improvement of patient convenience and optimal usability is important, for example, by using wearables or smartphone-based applications integrated into the patient's own smartphone, and implementation of notifications to remind patients to make a registration.[13] Education on the importance of adherence to mHealth is crucial to achieve maximal results. Also, since we observed lower long-term adherence in patients with lower adherence in the first three monitoring days, surveillance of the initial days may be used to identify and positively reinforce initial low-adherent patients later during follow-up.

In this study, there was little indication of device fatigue. Although the percentage of patients performing full monitoring days declined over time, the percentage of patients with monitoring days only slightly declined, indicating that most patients kept on performing at least one measurement per day. Additionally, older age is usually seen as a limiting factor in mHealth use. However, in this study age was associated with higher adherence, suggesting that this may not be an issue at all. Furthermore, patients using AADs showed more full monitoring days. This could be explained by the fact that patients on AADs may be more symptomatic and therefore more focused on their heart rhythm and more actively monitoring the effect of their AAD therapy.

In addition, the occurrence of AF recurrences during follow-up seems to influence adherence and adherence consistency. Interestingly, adherence and consistency of adherence did not particularly increase after recurrences, but were higher the entire period. One potential explanation for this could be that recurrences are more likely to be caught when adherence is higher.
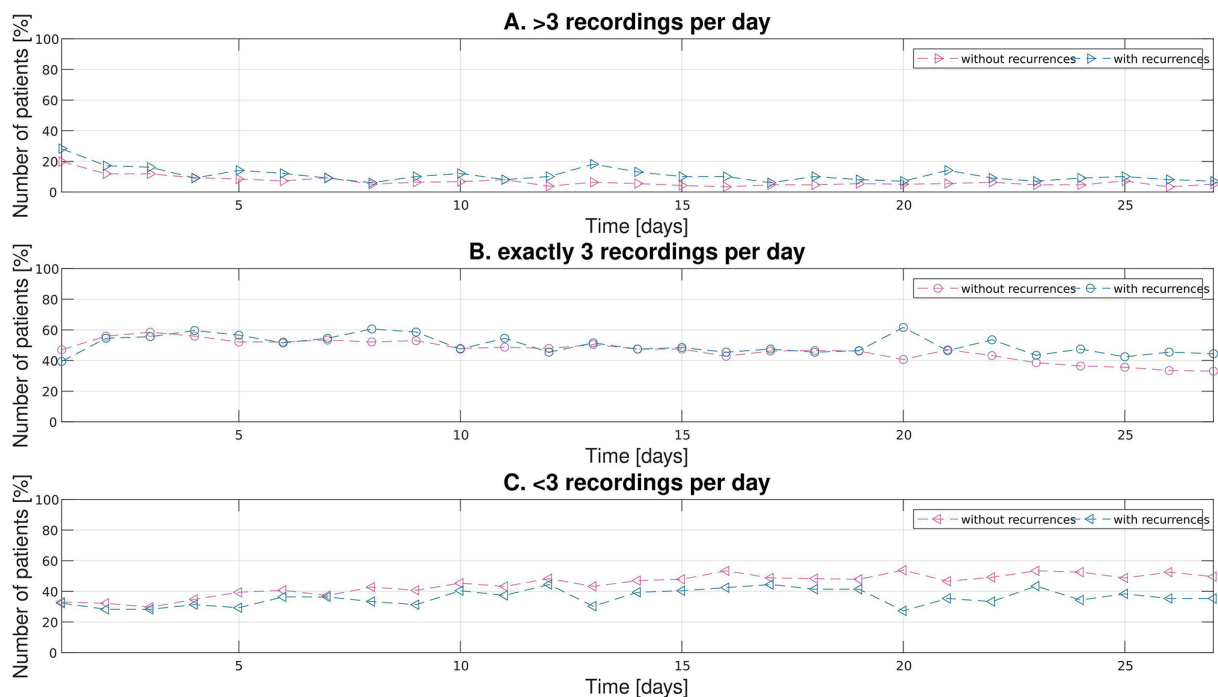

Figure 3 (A, B, C) Percentages of patients with and without recurrences with a certain number of recordings per day.

However, the occurrence of recurrences may contribute to the fact that adherence in these patients stays stable at ±90% over time, whereas the adherence of patients without recurrences declines to ±85%. Patients with recurrences were more likely to perform additional recordings, especially around recurrences. This possibly reflects that additional recordings were performed in the case of symptoms, in line with the given instructions. Other potential reasons for additional recordings may be the occurrence of symptomatic extrasystoles and the presence of noise or extrasystoles leading to a false positive AF result from the handheld device.

Monitoring for AF recurrences after cardioversion helps to evaluate the effectiveness of the intervention. AF recurrence after cardioversion is common and associated with several risk factors. Therefore, an early AF recurrence within 4 weeks after cardioversion should trigger an intensified and structured search for potentially modifiable risk factors to optimise the success rate of the rhythm control strategy.[14–16] Additionally, mHealth devices may also play a role for rate and rhythm monitoring after AF catheter ablation. A study by Hermans *et al* showed that the use of 4-week intermittent mHealth for the monitoring of recurrences after catheter ablation is feasible and identified more AF recurrences than short continuous ECG monitoring.[9] In addition, mHealth monitoring may be of additional value in many other clinical scenarios, such as heart rate and rhythm assessment around (tele)consultation, assessment of symptom-rhythm correlation, detection and understanding of AF patterns or guidance of remote adaptation of rate and rhythm control therapies.[17 18]

Limitations

One of the main drivers of adherence, consistency of adherence and incidental measurements may be the occurrence of symptoms. However, real-time symptoms could not be assessed by the MyDiagnostick directly, which is one of the main limitations. In addition, in this study all recordings were collected simultaneously at the end of the monitoring period, which did not allow real-time integration of possible actionable data into the decision-making process of the treating physician. Most importantly, this study is performed in the setting of a randomised controlled trial and results may therefore be more positive compared with a real-world scenario. Obviously, willingness to monitor may be lower in a screening scenario but screening was not the focus of the present study. Lastly, since the monitoring is intermittent and dependent on the adherence and motivation of the patients, not all AF recurrences will have been captured. Although implantable loop recorders are the gold standard for detection of AF recurrences, they are invasive and relatively expensive, which does not apply to mHealth solutions. However, certain monitoring approaches, that is, smartphones or smartwatches, may be less suitable for (older) patients with a low digital literacy. Therefore, according to the current European Heart Rhythm Associaton (EHRA) practical guide, a structured pathway assessing patient digital health literacy, identifying individual needs and improving both knowledge and skills is beneficial when engaging patients and to ensure future adherence to mHealth technologies.[19]

Future perspectives

In this study, we demonstrate a median adherence to a mHealth device of 83.3% and consistency of use in 85.7% of patients, indicating the feasibility to use mHealth devices in the herein described clinical scenario according to specific instructions.

However, the integration of mHealth derived data requires further infrastructure and was not scope of this study. Identification of actionable data by implemented alert systems and the connection to a secured cloud would allow the early detection of a specific situation and may trigger a prespecified action and initiate a timely patients contact to adapt treatment strategies. The impact of such an approach should be investigated in future studies. To achieve high adherence in future mHealth studies, it is recommended to appreciate patient convenience and education and to implement surveillance by either the study team or by automatic notifications.

CONCLUSION

In this study, a 4-week mHealth prescription to monitor for AF recurrences after an early or delayed cardioversion approach was feasible. Older patients were more adherent. In addition, the occurrence of AF recurrences, both at baseline and during follow-up, increased adherence and adherence consistency. Whether comparable mHealth adherence and adherence consistency can be achieved in real-world clinical scenarios outside a randomised study warrants further observational studies.

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Supplementary Table 1: Baseline characteristics of patients based on randomization group

	Early cardioversion (N=171)	Delayed cardioversion (N=164)
Age in years - median [IQR]	67 [14]	67 [13]
Male – no. (%)	98 (57.3)	97 (59.1)
BMI in kg/m² - median [IQR]	26.8 [5.7]	26.6 [6.6]
Hypertension – no. (%)	102 (59.6)	87 (53.0)
Diabetes mellitus – no. (%)	18 (10.5)	15 (9.1)
Coronary artery disease – no. (%)	29 (17.0)	31 (18.9)
Heart failure – no. (%)	2 (1.2) *n=170*	5 (3.0)
Chronic obstructive pulmonary disease – no. (%)	9 (5.3)	10 (6.1)
Stroke/TIA – no. (%)	9 (5.3)	9 (5.5)
Smoking – no. (%)	Current - 14 (8.2)	Current - 16 (9.8)
	Past - 73 (42.7)	Past - 63 (38.4)
	Unknown - 11 (6.4)	Unknown - 16 (9.8)
CHA_2DS_2-VASc score – median [IQR]	2.0 [2.0]	2.0 [2.0]
AF characteristics		
First detected AF – no. (%)	75 (43.9)	73 (44.5)
Medication – no. (%)	BB - 59 (34.5)	BB - 55 (33.5)
	NDCCB - 8 (4.7)	NDCCB - 7 (4.3)
	Digoxin - 3 (1.8)	Digoxin - 5 (3.0)
	AAD - 39 (22.8)	AAD - 36 (22.0)
Previous electrical cardioversion – no. (%)	40 (23.4)	40 (24.4)
	Unknown - 14 (8.2)	Unknown - 9 (5.5)
Previous pharmacological cardioversion – no. (%)	57 (33.3)	38 (23.2)
Previous ablation – no. (%)	23 (13.5)	12 (7.3) *n=163*

Abbreviations: AAD= antiarrhythmic drugs, AF= Atrial fibrillation, BB= Beta blocker, NDCCB = Non-dihydropyridine calcium channel blocker, TIA = transient ischemic attack

Supplementary Table 2: Weekly medians for monitoring days and full monitoring days

	Monitoring days	Full monitoring days
Week 1 – median [IQR]	7 [0]	5 [4]
Week 2 – median [IQR]	7 [0]	5 [4]
Week 3 – median [IQR]	7 [0]	4 [5]
Week 4* – median [IQR]	6 [2]	3 [5]

*week 4 only consisted of 6 days

Supplementary Table 3. Multivariable adjusted factors associated with above median full monitoring days (≥16)^

	≥Median full monitoring days			
	Univariable		Multivariable	
	OR (95% CI)	p-value	OR (95% CI)	p-value
Age	1.384 (1.127-1.708)	**0.002**	1.357 (1.094-1.676)+	**0.005**
Use of AAD	1.944 (1.139-3.315)	**0.015**	1.800 (1.047-3.093)	**0.033**

^monitoring days are not displayed, since there were no significant variables to enter into a multivariable logistic regression model. +Odds per every 10 years increase in age. Abbreviations: AAD = antiarrhythmic drugs. Additional adjustment for randomization did not affect results to a substantial extent.

Supplementary Table 4: adherence and adherence consistency based on recurrence ≤14 days versus recurrence >14 days

	Recurrence ≤ 14 days (n=64)	Recurrence > 14 days (n=35)	p-value
Adherence – median% [IQR]	91.8 [27.1]	87.7 [25.9]	0.333
Adherence ≥83.3% - no. (%)	37 (57.8)	21 (60.0)	0.833
Monitoring days – median [IQR]	27 [2]	27 [5]	0.243
Full monitoring days – median [IQR]	18 [14]	18 [10]	0.618
Patients with additional recordings – no. (%)	51 (79.7)	27 (77.1)	0.767

Supplementary Table 5: clinical characteristics of patients performing additional measurements.

	No additional measurements (N=141)	Additional measurements (N=194)	p-value
Age in years - median [IQR]	66 [16]	66 [13]	0.380
Male – no. (%)	83 (58.9)	112 (57.7)	0.836
BMI in kg/m^2 - median [IQR]	27.3 [6.9]	26.4 [5.6]	0.092
Hypertension – no. (%)	80 (56.7)	109 (56.2)	0.920
Diabetes mellitus – no. (%)	13 (9.2)	20 (10.3)	0.741
Coronary artery disease – no. (%)	28 (19.9)	32 (16.5)	0.428
Heart failure – no. (%)	2 (1.4)	5 (2.6) *n=193*	0.460
Chronic obstructive pulmonary disease – no. (%)	8 (5.7)	11 (5.7)	0.999
Stroke/TIA – no. (%)	10 (7.1)	8 (4.1)	0.234
Smoking – no. (%)	Current – 10 (7.1)	Current – 20 (10.3)	0.091
	Past – 48 (34.0)	Past – 88 (45.4)	
	Unknown – 16 (11.3)	Unknown – 11 (5.7)	
CHA$_2$DS$_2$-VASc score – median [IQR]	2.0 [2.0]	2.0 [2.0]	0.922
AF characteristics			
First detected AF – no. (%)	64 (45.4)	84 (43.3)	0.704
Medication – no. (%)	BB – 56 (39.7)	BB – 58 (29.9)	0.061
	NDCCB – 6 (4.3)	NDCCB – 9 (4.6)	0.867
	Digoxin – 1 (0.7)	Digoxin – 7 (3.6)	0.086
	AAD – 33 (23.4)	AAD – 42 (21.6)	0.704
Previous electrical cardioversion – no. (%)	36 (25.5)	44 (22.7)	0.667
Previous pharmacological cardioversion – no. (%)	37 (26.2)	58 (29.9)	0.464
Previous ablation – no. (%)	12 (8.5)	23 (11.9) *n=193*	0.315

Supplemental material

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Heart

Patients in delayed cardioversion group – no. (%)	64 (45.4)	100 (51.5)	0.266
Patients with spontaneous conversion – no. (%)	50 (35.5)	86 (44.3)	0.103
Recurrence of AF – no. (%)	21 (14.9)	78 (40.2)	**<0.001**
ED visit due to recurrence of AF – no. (%)	4 (2.8)	13 (6.7)	0.112
Cardiovascular complications during index visit and 4 weeks of follow-up* – no. (%)	6 (4.3)	11 (5.7)	0.560

Composed of: admission for heart failure, ischemic stroke or transient ischemic attack, unstable angina or acute coronary syndrome, bradycardia or hypotension and tachycardia. Abbreviations: AAD = antiarrhythmic drugs, AF= Atrial fibrillation, BB = beta blocker, ED = emergency department, NDCCB = Non-dihydropyridine calcium channel blocker, TIA = transient ischemic attack

Supplementary Figure 1: Definition of adherence and adherence consistency

Adherence:

The actual number or recordings performed divided by the maximum number of recordings that would have been possible

| 3 | 2 | 4* | 3 | 1 | 0 | 0 |

monitoring period of 7 days

Actual number of recordings: 3+2+3*+3+1+0+0 = 12

Number of recordings possible: 3 * 7 = 21

* 100% = 57.1%

*Since 100% is maximum, an excess above 3 recordings per day was not taken into account

Monitoring days:

A monitoring day is a day on which at least one recording was performed

| 3 | 2 | 4* | 3 | 1 | 0 | 0 |

= 5 monitoring days

monitoring period of 7 days

Full monitoring days:

A full monitoring day is a day on which at least three recordings were performed

| 3 | 2 | 4* | 3 | 1 | 0 | 0 |

= 3 full monitoring days

monitoring period of 7 days