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Advantages of mobile health in the management of adult patients with congenital heart disease

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ABSTRACT

Background: Adults with congenital heart disease (ACHD) often suffer from deterioration related to cardiac arrhythmias, hypertension (HT) or heart failure (HF), frequently occurring between planned visits. Mobile health (mHealth) could improve management through remote monitoring by enabling swift therapeutic response and detecting new diagnoses.

Methods: We performed a prospective study employing mHealth in ACHD patients, weekly monitoring heart rhythm, weight and blood pressure. In case of consecutive threshold exceeding measurements or in case of new diagnosis, patients were contacted and if needed the treating physician was consulted. Inclusion criteria were: palpitations within the last three years (with or without arrhythmia diagnosis) or HF NYHA class ≥ II. We evaluated the detection of recurrences and new diagnosis of arrhythmias, HT and HF, adherence and patient experience (Net Promotor Score (NPS)).

Results: In total, 109 of the 268 invited ACHD patients were enrolled, 80 with palpitations, 13 with HF, 16 experienced both, mean age 45 (± 13) years, 33% male. Median follow-up was 12 (Q1-Q3;9–14) months, 91 patients initiated all measurements (heart rhythm, weight and blood pressure). In 25% of the patients with diagnosed arrhythmias (14/56) recurrences of arrhythmias were detected; 13% of the patients with undiagnosed palpitations (4/32) were diagnosed with novel arrhythmias. In 38% of the patients with HT at baseline (6/16), treatment adjustment was necessary, 4% of the patients without HT (4/76) received novel HT diagnosis. Diuretics were adjusted in 7% of the patients with HF (2/29). Adherence was > 70% in 77% of the patients that started weekly measurements (70/91). Patients that were female, older of age and experienced palpitations at inclusion were more likely to acquire an adherence of > 70%. NPS was completed by 68 patients, 57 patients (84%) were promotors or neutral, and 11 patients (16%) were critics.

Conclusions: mHealth offers advantages in the management of selected ACHD patients; it enabled early detection of recurrences and new diagnosis of arrhythmias, hypertension and heart failure, which lead to swift therapeutic response or remote reassurance. Furthermore, mHealth was well accepted with high adherence and positive patient experience.

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1. Introduction

Adult patients with congenital heart disease (ACHD) form a growing patient group, as survival has increased in the last decades [1]. However, these patients remain in lifelong follow-up as they often experience complications at a relatively young age such as arrhythmias, hypertension (HT) and heart failure (HF), often resulting in clinical deterioration [2]. As measurements of vital parameters are usually limited to outpatient clinic and hospital visits, asymptomatic cardiac deterioration can remain unnoticed for a long time and in case of symptoms patients have to plan an additional appointment or have to contact or visit the emergency room (ER) in the hospital. This can delay adequate diagnosis and swift initiation of treatment.

Mobile health telemonitoring (mHealth) is rapidly evolving as wearables, mobile health applications (apps) and smartphone possibilities are improving, and increasing in number [3]. mHealth enables frequent monitoring of vital parameters at home and can provide early intervention or reassurance, possibly preventing ER visits and hospital admissions [4]. Previous studies on telemonitoring of heart rhythm, blood pressure and weight in patients with acquired heart disease showed promising results. In patients with atrial fibrillation mHealth provided rapid recognition of atrial fibrillation and subsequently rapid management of the episode, patients with hypertension were treated more effectively and in selected patients with heart failure mHealth significantly reduced mortality [5–7].

ACHD patients seem particularly eligible to benefit from mHealth, as they often experience complications such as arrhythmias, HT and HF, frequently resulting in deterioration and hospital admissions [2]. Furthermore, previous studies showed that the majority of these patients are willing to start using mHealth and that symptomatic patients are most likely to benefit [8,9]. However, data on mHealth in ACHD patients are scarce [10].

Therefore, we performed a prospective study employing an mHealth program in ACHD patients. The aim of this study was to investigate what advantages mHealth offers in the management of these patients and to evaluate the acceptance of mHealth through adherence and patient experience.

2. Material and methods

2.1. Study design and participants

We performed a prospective study in two medical centers in the Netherlands. The local medical ethical committees of both institutions issued a waiver for this study. ACHD patients were eligible for inclusion if they met the inclusion criteria: Palpitations within the last three years (with or without arrhythmia diagnosis) or HF NYHA class ≥ II, and possession of a mobile device. Patients with impaired cognition, as assessed by their treating physician, tremors or patients with an insurance not covering costs of the mHealth program, were excluded. Patients were recruited from the outpatient clinic and clinical wards. After informed consent for the use of their clinical data was acquired, patients were enrolled in the mHealth program.

2.2. mHealth program

The mHealth program required routinely evaluation of heart rhythm, blood pressure and body weight [11]. Measurements were performed at home using a wireless pocket-sized single lead EKG recording device that could record a 30 s single lead EKG (Kardia, AliveCor), wireless digital blood pressure monitor (Omron) and a wireless and digital weight scale (i-Health), connected to their smartphone. Two mobile applications (apps) were used, for heart rhythm recordings (Kardia [12]) and blood pressure and weight (CVitals). Results were integrated in the EMR of the patient and also available for the patients in the apps. At the start of the program, patients received instructions by telephone for the medical devices and corresponding apps and were asked to perform daily measurements for seven days to establish reference values. After the first week, a single lead EKG was recorded once every month and blood pressure and weight were measured twice every week. Patients could perform extra measurements in case of symptoms. However, at the start of the study it was emphasized that the program was not intended for emergency care.

2.3. Protocol mHealth program

Blood pressure and weight measurements were only analyzed in case of consecutive threshold exceeding measurements. All EKGs and measurements exceeding a threshold were analyzed daily on weekdays by trained nurses, Analysis of all measurements for each patient takes approximately a single minute per EKG and similar for weight and blood pressure measurements. Sinus bradycardia was defined as a heart rate of < 50 beats per minute and sinus tachycardia was defined as a heart rate of > 100 beats per minute; the thresholds for blood pressure were 140 mmHg for systolic blood pressure (SBP) and 90 mmHg for diastolic blood pressure (DBP). The threshold for body weight was personalized for every patient. After the first week the mean weight was calculated and the threshold was set two kilograms above the mean. These thresholds were only modified in consultation with the treating physician. If an arrhythmia was recorded, recurrent or novel, the patient would be contacted for additional information and the frequency of measurements would be intensified and if needed the treating physician would be consulted. The app for weight and blood pressure would generate an alarm if a threshold was exceeded. In case of two consecutive alarms, the patient would also be contacted for additional information. Furthermore, they received life style advice, measurement instructions and were asked to perform daily measurements for seven days. When HF signs and symptoms were present in case of two consecutive weight alarms, the treating physician or specialist nurse would be consulted for treatment adjustments. If hypertension persisted after life style advice and measurement instructions, the treating physician would be consulted for treatment adjustments. Participation in the current mHealth program was reimbursed by the majority of health insurance companies in the Netherlands. Patients without reimbursement did not participate in the study.

2.4. Adherence and patients experience

Adherence was evaluated using the weekly measurements of weight and blood pressure. Adherence rates of > 70% were assessed as sufficient for monitoring [7]. Patients experience was evaluated through the Net Promotor Score (NPS), which lets patients rate from 0 to 10 to which extent they would recommend the use of the mHealth program to a friend or colleague [13]. After 6 months of follow-up patients were asked fill in the NPS questionnaire. Patients with a score of 9–10 were promotors, 7–8 were neutrals and 0–6 were critics. The NPS was calculated by subtracting the percentage of critics from the percentage of promotors.

2.5. Outcomes

The primary outcome measures of this study were interventions made based on mHealth data in case of recurrences of arrhythmias, HT or HF and the detection of new diagnoses of arrhythmias and HT. This program was not set-up for establishing new diagnoses of HF. A cardiac arrhythmia was considered a new diagnosis if the arrhythmia had not been previously recorded. Recurrences of arrhythmias were defined as an mHealth recording of previously identified arrhythmias. An episode of HT in our study was defined as three or more consecutive measurements of a SBP of ≥ 140 mmHg or DBP of ≥ 90 mmHg. HT was considered a new diagnosis if this had not been previously detected during outpatient clinic visits and no previous treatment was initiated

for HT. Secondary outcome measures were adherence and patients experience measured by the NPS score.

2.6. Data and statistical analysis

All data were extracted from the EMR of each patient and pseudonymized. Data were managed and stored respecting the FAIR (Findable–Accessible–Interoperable–Reusable) principles [14]. Analyses were performed using SPSS version 25 (IBM, Armonk, New York). Chi-square test or independent *t*-test were used to assess differences between patients with an adherence of higher or lower than 70%.

3. Results

3.1. Participants

We screened patients for eligibility from June 2017 until December 2018 and 268 patients with ACHD from two medical centers in the Netherlands were invited to participate in this study. In total, 109 patients were enrolled, of whom 98 started with monthly heart rhythm recordings and 91 with weekly blood pressure and weight measurements (Fig. 1). Mean age was 44.8 (± 13.1) years and 33% were male (Table 1). The primary diagnoses of the patients are summarized in Supplementary Table 1. Follow-up started in June 2017 and ended in May 2019 with a median follow-up of 12 (Q1-Q3; 9–14) months. Reasons for patients to decline consent (n = 159) were 1) Lack of time or interest to participate in research (72, 48%) and 2) Fear of experiencing stress due to frequently performing measurements (47, 32%).

3.2. Heart rhythm

A total of 5547 single-lead EKGs were recorded by 98 patients, 56 patients with documented arrhythmias, 31 patients with palpitations without a documented arrhythmia and 11 patients with no previous complaints of palpitations. Of these EKGs, 2925 were recorded by 90 patients during episodes of palpitations with a median of 16 (Q1-Q3; 8–37) recordings per patient. These recordings predominantly showed sinus rhythm (1616/2925, 55%). In 25% of the patients (14/56) with previous arrhythmia diagnosis, recurrences of arrhythmias could be confirmed during palpitations and treatment initiated. In 13% of the patients (4/32) with previous palpitations but without diagnosis that performed EKG measurements, a new arrhythmia was found. In patients without prior palpitations no significant arrhythmias were found. Atrial fibrillation (AF) was the most frequently recorded clinically significant arrhythmia in both groups (Fig. 2A and B). Noise was recorded in 3% (174/5547) of all EKGs. All patients that experienced sinus rhythm or benign PACs and PVCs during complaints were remotely reassured. An example of the implications of mHealth on the management of a patient is displayed in Supplementary Fig. 1A.

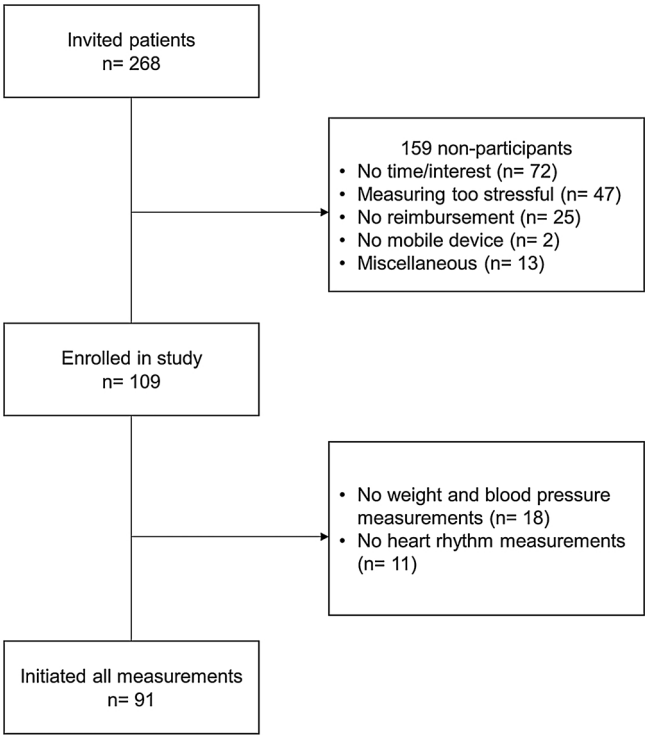

Fig. 1. Flowchart for the study population.

Table 1
Baseline characteristics.

Characteristics		Total patients (n = 109)*	
Age (years)		44.8	± 13.1
Male		36	33%
Severity of CHD			
	Mild	25	23%
	Moderate	50	46%
	Severe	34	31%
History of cardiac surgery		93	85%
Pacemaker		17	16%
Cardiac arrhythmias		61	56%
Palpitations without diagnosis		35	32%
Hypertension at baseline		16	15%
NYHA class			
	I	80	73%
	II	24	22%
	III	5	5%
	IV	0	0%
Medication			
	Anti-arrhythmics	63	58%
	Diuretics	17	16%
	Anticoagulation	49	45%

*Data are number (percentage) or mean (± standard deviation).
CHD; Congenital Heart Disease.
NYHA; New York Heart Association.

3.3. Blood pressure

A total of 8350 blood pressure measurements were performed by 91 patients with a median of 88 (Q1-Q3; 58–119) measurements per patient. Of the 16 patients with HT at baseline, 15 regularly performed measurements, 1 patients experienced difficulties using the devices. Of the 93 patients without HT, 76 regularly performed blood pressure measurements. Eight patients dropped out before starting measurements, 4 never initiated measurements and 5 were just enrolled and were still setting up the devices. In 38% of the patients with HT at baseline (6/16) treatment was adjusted and in 2 patients, blood pressure restored to normal after lifestyle advice. In Supplementary Fig. 1B mHealth interventions are displayed in a patient with HT who had multiple episodes of HT.

3.4. Heart failure

During follow-up, a total of 7984 body weight measurements were performed by 91 patients with a median of 82 (Q1-Q3; 56–117). Seventeen patients did not start weight pressure measurements, 8 patients dropped out before starting measurements, 4 patients never started using the measurement devices and 5 patients were still setting up the measurement devices. In 2 of the 29 patients (7%) with HF NYHA class ≥ II at baseline the diuretics were adjusted as a weight gain of ≥ 2 kg and additional signs and symptoms of HF were detected through mHealth and telephone contact.

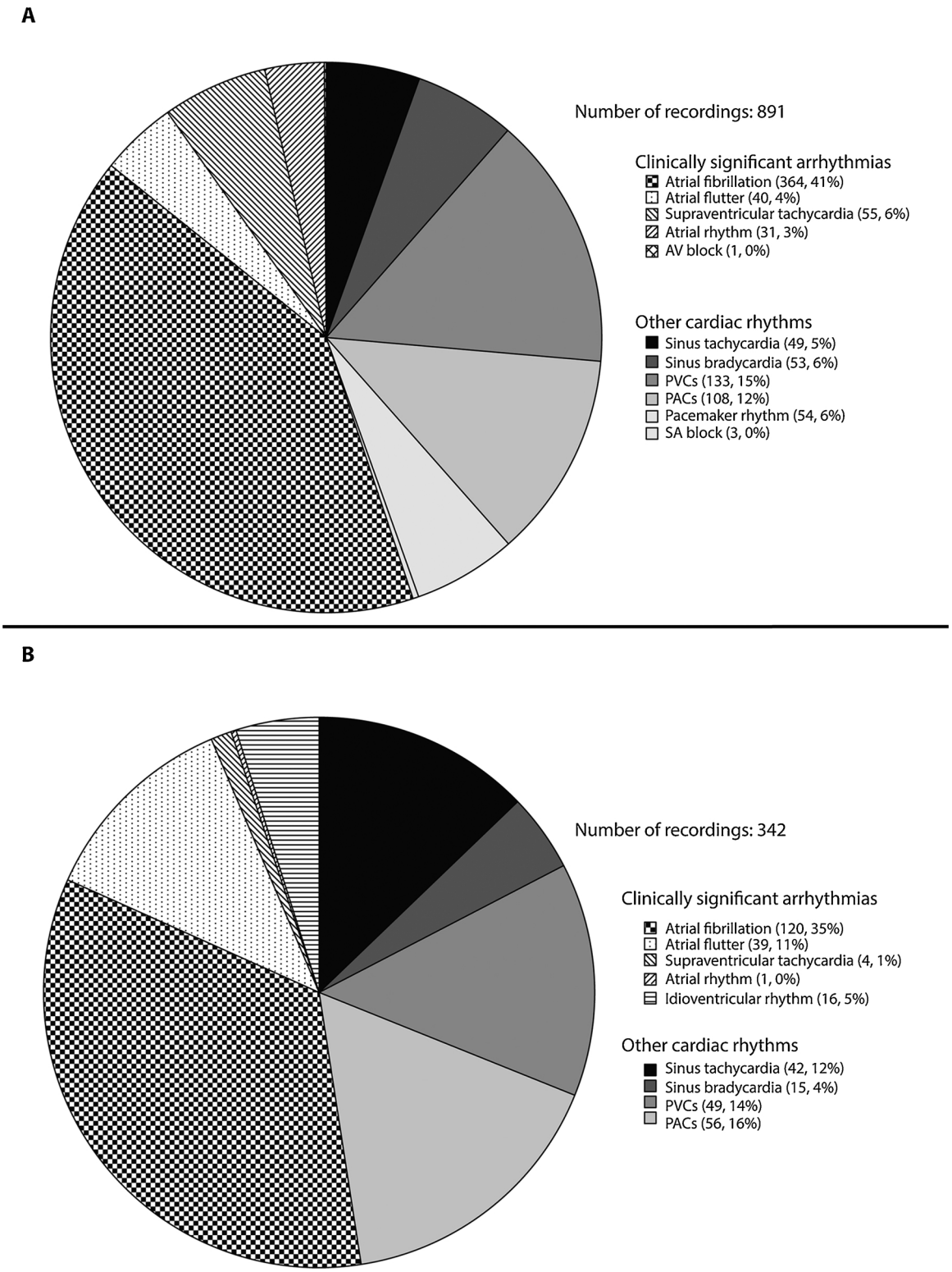

Fig. 2. Recordings during palpitations.
A: Recordings of patients with previous arrhythmia diagnosis.
Sinus rhythm n = 1027, 52%, only noise n = 41, 2%.
B: Recordings of patients without previous arrhythmia diagnosis.
Sinus rhythm n = 388, 53%, only noise n = 11, 1,5%.
Recordings with sinus rhythm and only noise were excluded from these figures.
PVC: Premature ventricular contraction.
PAC: Premature atrial contraction.
AV: atrioventricular.
SA: Sinoatrial.

3.5. New diagnoses

In 8 patients new diagnoses were established through mHealth; 4 patients received novel arrhythmia diagnosis, 4 patients received novel HT diagnosis (Supplementary Table 2), all patients previously underwent regular diagnostic methods with no resulting diagnosis. Of the 109 enrolled patients, 48 patients did not have prior arrhythmia diagnosis, 35 of whom experienced palpitations in the past three years and 32 regularly performed single lead EKGs. In 13% (4/32) of the patients that experienced palpitations without prior arrhythmia diagnosis and performed EKGs, new diagnoses were established during follow-up through mHealth. In 3 patients AF was registered and in 1 patient sinus node dysfunction was identified. Of the 94 patients without HT, 76 patients regularly performed blood pressure measurements, of whom 4 patients (4%) received new HT diagnosis. No false-positive diagnoses were found during follow-up.

3.6. Adherence and patient experience

Adherence of more than 70% was registered in 77% of the patients (70/91). Patients with an adherence of 70% or higher were more likely to be female, older of age, have palpitations at baseline (with or without a previously identified arrhythmia), have a pacemaker in situ, use antiarrhythmic drugs and have experienced a clinical event during follow-up (Supplementary Table 3). The NPS questionnaire was completed by 72% (68/95) of the patients that received the NPS questionnaire, 57 patients (84%) were promotors (score 9–10) or neutral (score 7–8), and only 11 patients (16%) were critics (score 0–6), resulting in a total NPS of +18 for this mHealth program.

4. Discussion

This study is the first to show twelve months follow-up of mobile health in selected ACHD patients. mHealth in these patients offers multiple advantages by providing rapid detection of hypertension, recurrences of arrhythmias and heart failure, and enabling swift intervention. Furthermore, mobile health establishes new diagnoses of arrhythmias and hypertension. This mHealth program was well accepted with a high adherence rate and positive patient experience.

ACHD patients often experience cardiac arrhythmias and these arrhythmias are an important cause of unplanned hospital admissions and morbidity [15]. Previous studies showed that regular diagnostic methods in ACHD patients, such as Holter monitoring, often fail to establish diagnoses, as symptoms frequently do not occur during Holter monitoring [16]. In contrast, mHealth provided on demand recordings of heart rhythm during palpitations, enabling swift diagnosis and treatment or remote reassurance, possibly preventing unplanned visits to the hospital.

In our study, in 38% of the patients with HT at baseline (6/16), treatment adjustments were necessary during follow-up as episodes of HT were detected through mHealth. This emphasizes that the management of arterial HT through the outpatient clinic remains cumbersome and over- and undertreatment occurs as blood pressure is only measured during hospital visits. mHealth provides benefits in the treatment of HT by enabling more continuous monitoring of blood pressure at home [17].

In this study the number of patients with HF was limited with 27% of the patients (29/109) experiencing HF NYHA class ≥ II at baseline. The majority of these patients were under follow-up of a specialized HF nurse, organized through frequent contact moments and consultations. Usual care by the nurse included daily weight measurements and the instruction to contact the nurse in case of weight gain or symptoms. The mHealth program only required two weight measurements per week, this might explain the small number of interventions made based on mHealth data in patients with HF in our study. However, in patients with less frequent follow-up and in more remote areas, mHealth could be a valuable tool as telemonitoring has shown to be effective in selected patients with HF [7].

Our study demonstrated an adherence rate that was similar to previous studies [18,19]. Interestingly, patients who experienced clinical events during follow-up were more adherent to the program. This emphasizes that adequate patient selection for telemonitoring seems essential as was also demonstrated by Koehler et al. in the TIM-HF2 trial. In patients, hospitalized for HF less than a year before inclusion, telemonitoring demonstrated a reduction of all-cause mortality and days lost due to unplanned cardiovascular hospital admissions [7].

This study is limited by the lack of a control group, this hampered evaluation of the effect of mHealth on clinical outcomes such as emergency hospital visits and admissions. Randomized controlled trials are therefore warranted to further evaluate the effects of mHealth in ACHD patients, other important outcomes including quality of life and costs of the mHealth intervention should be further evaluated. Only patients with a health insurance covering the costs of the mHealth program were included and the number of patients that declined participation was greater than the number of participants due to no interest or time, possibly introducing a systemic bias. Furthermore, this study population of ACHD patients was very heterogeneous as all complexities of CHD were included in this study and severity of disease differed greatly, possibly introducing a great heterogeneity in outcomes.

4.1. Conclusion

In this pilot study, we showed that the use of mHealth offers multiple advantages in selected ACHD patients; it enabled early detection of recurrences and new diagnoses of arrhythmias, hypertension and heart failure and enabled swift therapeutic response. As mHealth was also well accepted by these patients with high adherence and positive patient experience, mHealth could play a significant role in the management of this patient group.

Disclosures

The authors G.A. Somsen (founder) and I.I. Tulevski (founder and CEO) are major shareholders in the venture (Cardiology Centers of the Netherlands) that set up the mHealth program implemented in the methods of this study. The author D.A.J. Dohmen is CEO of the venture (FocusCura) supplying the hardware and software for the blood pressure and weight measurements in this mHealth program. D. Kauw, M.A.C. Koole, M.M. Winter, S. Blok, M.P. Schijven, J.W.J. Vriend, D. Robbers-Visser, B.J.M. Mulder, B.J. Bouma and M.J. Schuuring declare that they have no competing interests.

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Summary table

What was already known?

- Mobile health has shown promising results in patients with acquired disease
- Only little data is available on mobile health in adult patients with congenital heart disease

What this study added to our knowledge

- Mobile health provides more continuous care and remote reassurance for adult patients with congenital heart disease, a patient group with high mortality and morbidity

- Mobile health in adult patients with congenital heart disease provides clinical benefits such as establishing new diagnosis and quick detection of recurrences of arrhythmias enabling rapid treatment
- Mobile health in patients with hypertension can aid to optimize medical treatment
- Mobile health is well accepted in adult patients with congenital heart disease, especially in patients that experienced clinical events

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Declaration of Competing Interest

We wish to confirm that there are no known conflicts of interest associated with this publication and there has been no significant financial support for this work that could have influenced its outcome.

We confirm that the manuscript has been read and approved by all named authors and that there are no other persons who satisfied the criteria for authorship but are not listed. We further confirm that the order of authors listed in the manuscript has been approved by all of us.

We confirm that we have given due consideration to the protection of intellectual property associated with this work and that there are no impediments to publication, including the timing of publication, with respect to intellectual property. In so doing we confirm that we have followed the regulations of our institutions concerning intellectual property.

We further confirm that any aspect of the work covered in this manuscript that has involved either experimental animals or human patients has been conducted with the ethical approval of all relevant bodies and that such approvals are acknowledged within the manuscript.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.ijmedinf.2019.104011.

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