Patient-reported outcomes in symptom-driven remote arrhythmia monitoring: evaluation of the Dutch HartWacht-telemonitoring programme

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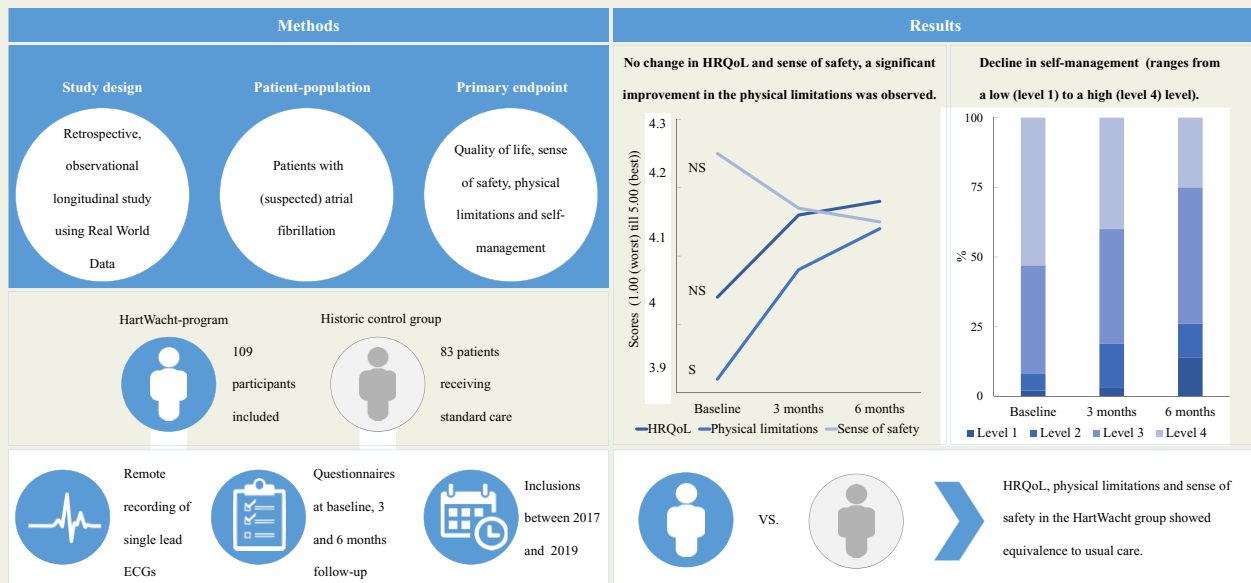|	
Aims	There is limited quantitative evidence on the effect of symptom-driven telemonitoring for cardiac arrhythmias on patient-reported outcomes. We evaluated the effect of a symptom-driven remote arrhythmia monitoring programme on the patient-reported health-related quality of life (HRQoL), sense of safety, physical limitations, and self-management.
Methods and results	This was an observational retrospective longitudinal study of the symptom-driven HartWacht-telemonitoring programme using a remote single-lead electrocardiogram monitoring system. Real-world patient data from participants who were enrolled in the telemonitoring programme for (suspected) symptomatic atrial fibrillation (AF) between July 2017 and September 2019 were evaluated. Primary outcomes were the patient-reported generic HRQoL, disease-specific HRQoL, sense of safety, physical limitations, and self-management at date of enrolment, 3 months and 6 months of follow-up. Outcomes were compared to a historical control group consisting of AF patients receiving standard care. A total of 109 participants in the HartWacht programme [59 men (54%); mean age 61 ± 11 years; 72% diagnosed AF] were included in complete case analysis. There was no significant change in HRQoL and sense of safety during follow-up. A significant improvement in the perceived physical limitations was observed. The level of self-management declined significantly during follow-up. Comparisons to the historic control group ($n = 83$) showed no difference between the patient-reported disease-specific HRQoL, sense of safety and physical limitations at 6 months of follow-up.
Conclusion	Symptom-driven remote arrhythmia monitoring for AF does not seem to affect HRQoL and sense of safety, whereas the perceived physical limitations tend to improve. Patient-reported self-management declined during the first 6 months of participation.

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Graphical Abstract

Methods

Study design
Retrospective, observational longitudinal study using Real World Data

Patient-population
Patients with (suspected) atrial fibrillation

Primary endpoint
Quality of life, sense of safety, physical limitations and self-management

HartWacht-program
109 participants included

Historic control group
83 patients receiving standard care

Remote recording of single lead ECGs

Questionnaires at baseline, 3 and 6 months follow-up

Inclusions between 2017 and 2019

Results

No change in HRQoL and sense of safety, a significant improvement in the physical limitations was observed.

Scores (1.00 (worst) till 5.00 (best))

HRQoL — Physical limitations — Sense of safety

Decline in self-management (ranges from a low (level 1) to a high (level 4) level).

Level 1 Level 2 Level 3 Level 4

VS.

HRQoL, physical limitations and sense of safety in the HartWacht group showed equivalence to usual care.

Keywords   Digital health • Innovation • Remote monitoring • Telemedicine • Atrial fibrillation • Patient-reported outcome measures

Introduction

Atrial fibrillation (AF) is the most common cardiac arrhythmia with an estimated prevalence of 260 000 patients in the Netherlands alone (prevalence of 1–4%).[1] Since AF predominantly manifests in older adults, its incidence has increased with advancing ages over the past decades and will continue to rise in the future.[2–5] Prior research has demonstrated an adverse effect of AF on health-related quality of life (HRQoL).[6] Especially, the presence of arrhythmia-related symptoms, symptom-related anxiety, symptom frequency, and symptom severity have been associated with a decline in HRQoL.[7] Furthermore, patients with AF generally report low levels of self-management and reluctance towards physical activity.[8,9] Over the past decade, there has been an increase in the implementation of eHealth strategies such as telemonitoring, which aim to improve safety and quality of care, enhance efficiency and support communication between healthcare providers and patients.[9–11] Nevertheless, eHealth can only live up to its promise if HRQoL is preserved and remains equivalent to usual care. Evidence on the effect of symptom-driven remote arrhythmia monitoring on patient-reported outcomes such as HRQoL, physical limitations, self-management, and sense of safety is however limited. A feasibility study evaluating symptom-driven telemonitoring for patients ($n = 12$) with arrhythmia-related symptoms demonstrated an improvement in the HRQoL during 6 months of participation, but this lacked statistical significance.[12] Therefore, we performed an observational retrospective longitudinal study using real-world data to evaluate the effect of symptom-driven remote arrhythmia monitoring for AF on patient-reported HRQoL, sense of safety, physical limitations and self-management.

Methods

Study design and setting

This was a retrospective observational longitudinal study design evaluating the Dutch HartWacht-telemonitoring programme for (suspected) AF using real-world data. Eligible patients were referred to one of in total 12 outpatient cardiology clinics of Cardiology Centers of the Netherlands (CCN). Cardiologists consulted the patients about enrolment in the HartWacht programme, which was reimbursed by most Dutch insurance companies.

Study population and patient selection

The study population consisted of patients who were enrolled in the HartWacht-telemonitoring programme between July 2017 and September 2019. Participants needed to be older than 18 years and either diagnosed with (i) symptomatic AF or (ii) having complaints of palpitations of unknown origin suspected of AF. Exclusion criteria for the HartWacht-telemonitoring programme were unwillingness to participate or to follow the online training programme, having tremors or an impaired cognition as assessed by the cardiologist. Out of pocket payment was allowed for patients without the appropriate health insurance. Participants who did not own a smart device were not able to participate. Enrolment in the HartWacht-telemonitoring programme was at the cardiologists' discretion based on individual patient circumstance and the patient's willingness to participate. All patients enrolled in the

HartWacht-telemonitoring programme who were diagnosed with AF were evaluated and treated according to the European Society of Cardiology (ESC) Guidelines on the Management of Atrial Fibrillation.[13] For explorative reasons, outcomes were compared to a historic control group consisting of patients who were diagnosed with AF and received standard care instead of HartWacht-telemonitoring at CCN. Patients in the control group visited the CCN in the same period as the HartWacht participants.

HartWacht-telemonitoring for atrial fibrillation

Participants in the HartWacht-telemonitoring programme received the KardiaMobile (KM, AliveCor, Inc. Mountain View, CA, USA) remote electrocardiogram (ECG) monitoring device which had to be connected to the KM Application on a participant-owned smart device such as a smartphone or tablet. Participants were instructed to record a 30-second single-lead ECG when they experienced palpitations or other arrhythmia-related symptoms (e.g. dizziness, shortness of breath, fainting, syncope etc.) in an ambulant setting. ECG recordings were instantly assessed by the KM ECG analysis algorithm which classified the ECG as either sinus rhythm or potentially abnormal. The outcome of the classification was directly available on the participant's smart device. All ECGs were subsequently interpreted by a dedicated remote healthcare team consisting of a supervising cardiologist and specialized nurses (*HartWacht-team*). According to the HartWacht protocol, personalized feedback to the participants was provided if there were implications for the patient based on the recording (e.g. to arrange a consultation at the outpatient clinic, referral to the emergency department or reassurance). If the ECG recordings were not eligible for assessment due to artefacts, participants were asked to make a new recording. There were no restrictions on the number of ECGs participants could record. To ensure the quality of the ECG recordings, participants were provided with an online instruction video, complemented with a personal onboarding consultation if needed. Participants were allowed to stop their participation at any time during the programme.

Measurements

The primary outcomes in this study were the HRQoL, sense of safety, physical limitations, and self-management measured using self-administered questionnaires at time of enrolment in the HartWacht programme, 3 months and 6 months of follow-up. Participants received these questionnaires via email and were able to fill out the questionnaires in a secure online environment until four weeks after they had received it. A reminder was sent to participants who did not fill out the questionnaires after 2 weeks. The patient-reported outcomes were routinely sent, collected and documented in the electronic health record (EHR). The three questionnaires were the Care-Related Quality of Life for Chronic Heart Failure (CaReQoL CHF), the EuroQoL 5-Dimensions 5-Levels (EQ5D-5L), and the Patient Activation Measure (PAM)-13-NL.[14–16] The historic control group only received the CaReQoL CHF questionnaire. The CaReQoL CHF questionnaire consists of 20 items scored on a five-point Likert-scale, categorized into three domains: sense of safety, physical limitations and social-emotional problems [scores ranging from 1.00 (worst score) till 5.00 (best score)]. Secondly, the EQ5D-5L questionnaire is a generic, preference-based questionnaire as a measure for the HRQoL. The EQ5D-5L questionnaire consists of a descriptive system which comprises five domains (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression). The EQ5D-5L utility index for HRQoL ranges between -0.590 (worst score) and 1.000 (best score). Each of the five domains is scored between 1.00 (no problems) and 5.00 (severe

Table I Sociodemographic and clinical characteristics of patients participating in the HartWacht-telemonitoring programme (*n* = 109)

	HartWacht-telemonitoring (*n* = 109) Mean (SD) or *n* (%)
Sociodemographic variables	
Age, years	61.3 (10.9)
Age ≥70 years old, yes, *n* (%)	20 (18)
Gender, male, *n* (%)	59 (54)
Clinical variables	
Number of medications	3.8 (3.0)
Body mass index	25.3 (4.0)
General morbidity, yes, *n* (%)	
Atrial fibrillation	78 (72)
Psychiatric disorder(s)	10 (9)
Cerebral vascular accident(s)	1 (1)
Chronic heart failure	3 (3)
Cardiovascular risk factors, *n* (%)	
Hypertension	45 (41)
Hypercholesterolaemia	23 (21)
Diabetes mellitus	8 (7)

Data are presented as mean (SD) unless otherwise indicated.
SD, standard deviation.

problems). Third, the PAM-13-NL questionnaire was used to assess the patients' knowledge of and confidence in their self-management. The PAM-13-NL consists of 13 items scored on a four-point Likert-scale. Raw PAM-13 scores were subdivided into different levels of self-management (level 1–4): start of role taking (level 1); gaining knowledge and confidence (level 2); taking action (level 3); and sustaining behaviour change (level 4). All data used for this HartWacht study, including the abovementioned questionnaires, were routinely documented in the EHR system. All data were analysed at CCN in accordance with its privacy statement.[17]

Statistical analysis

All primary outcomes were continuous variables and presented by its median, mean, interquartile range (IQR) and standard deviation. Categorical sociodemographic and clinical variables were presented as frequencies (percentages). The Kolmogorov–Smirnov test was used to assess whether there was a normal distribution. The nonparametric Friedman two-way analysis of variances was used to compare the patient-reported outcomes at baseline and during follow-up assuming there was a non-normal distribution. Categorical sociodemographic and clinical variables were compared between participants in the HartWacht-telemonitoring programme and patients receiving standard outpatient care using the χ^2 test when appropriate, otherwise using Fisher's exact test. Means were compared using independent *T*-tests and tested for equality of variances using Levene's Test, or using the nonparametric Mann–Whitney *U* test. A *P*-value of <0.05 was considered statistically significant. Non-responders were defined as the participants who did not respond to one or more questionnaires at 3 months and/or 6 months of follow-up. Separate analysis regarding the non-responders was performed to gain insight in the characteristics of participants from whom

Table 2 Patient-reported outcomes in the HartWacht-telemonitoring programme at baseline and during follow-up (n = 109)

	Baseline		3 months		6 months		P-value[a] for trend
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	
CaReQoL HRQoL	4.04 (0.63)	4.16 (3.57–4.57)	4.16 (0.60)	4.28 (3.67–4.66)	4.18 (0.65)	4.35 (3.75–4.76)	0.06
Social-emotional problems	4.06 (0.72)	4.19 (3.44–4.67)	4.38 (0.66)	4.67 (3.89–5.00)	4.39 (0.68)	4.67 (4.00–4.89)	<0.001
Physical limitations	3.92 (0.81)	4.14 (3.43–4.57)	4.08 (0.72)	4.29 (3.57–4.57)	4.14 (0.74)	4.29 (3.71–4.71)	0.002
Sense of safety	4.25 (0.71)	4.50 (3.75–4.75)	4.17 (0.88)	4.25 (3.75–5.00)	4.15 (0.91)	4.25 (3.67–5.00)	0.55
EQ5D-5L utility index	0.852 (0.13)	0.845 (0.765–1.000)	0.866 (0.13)	0.874 (0.765–1.000)	0.867 (0.14)	0.874 (0.765–1.000)	0.43
Mobility	1.25 (0.61)	1.00 (1.00–1.00)	1.29 (0.61)	1.00 (1.00–1.00)	1.33 (0.68)	1.00 (1.00–1.00)	0.36
Self-care	1.02 (0.13)	1.00 (1.00–1.00)	1.06 (0.23)	1.00 (1.00–1.00)	1.07 (0.30)	1.00 (1.00–1.00)	0.07
Usual activity	1.51 (0.81)	1.00 (1.00–2.00)	1.38 (0.66)	1.00 (1.00–2.00)	1.40 (0.67)	1.00 (1.00–2.00)	0.01
Pain/discomfort	1.68 (0.69)	2.00 (1.00–2.00)	1.61 (0.73)	1.00 (1.00–2.00)	1.55 (0.71)	1.00 (1.00–2.00)	0.10
Anxiety/depression	1.47 (0.68)	1.00 (1.00–2.00)	1.46 (0.67)	1.00 (1.00–2.00)	1.45 (0.63)	1.00 (1.00–2.00)	0.92

Data are presented as mean (SD) and median (IQR).
CaReQoL, Care-Related Quality of Life for Chronic Heart Failure; EQ5D-5L, EuroQoL 5-dimension 5-level; HRQoL, Health-Related Quality of Life; IQR, interquartile range; SD, standard error.
[a]Friedman test for multiple related samples.

follow-up was lost. All statistical analyses were performed using SPSS Statistics IBM version 24, Chicago.[18]

Results

In total, 256 participants in the HartWacht-telemonitoring programme were eligible for the study. Of these 256 participants, 147 participants (57%) did not respond to the questionnaires at 3 months and/or 6 months of follow-up. A total of 109 participants (59 men (54%); mean age 61 ± 11 years) were included in complete case analysis and described in Table 1. There were no significant differences in sociodemographic and clinical characteristics between the non-responders and the responders, whereas sense of safety and self-management at baseline were significantly lower among non-responders compared to responders (Supplementary material online, Table S1). The median monthly number of recordings was 2.4 (IQR 0.85–5.94) among responders to the questionnaires, compared to 1.8 (0.40–4.90) recordings among non-responders (P = 0.153). In total, 79 (72%) of responders were diagnosed with AF at time of enrolment in the HartWacht programme, which was lower among non-responders 75 (51%). Paroxysmal AF was the most common diagnosis in both the HartWacht group (44%) and control group (42%) (Supplementary material online, Table S2).

Patient-reported outcomes
The primary outcomes of the EQ5D-5L and CaReQoL CHF questionnaires at baseline and during follow-up are displayed in Table 2. Longitudinal analysis showed no significant change in the EQ5D-5L utility index for HRQoL (P = 0.43). A positive trend in the overall HRQoL as measured with the disease-specific CaReQoL CHF questionnaire was observed, but this lacked statistical significance (P = 0.06). There was no significant change in the sense of safety from baseline until 6 months of follow-up (P = 0.55). The patient-reported

physical limitations (P = 0.002) and EQ5D-5L domain usual activities (P = 0.01) both showed a significant improvement during follow-up. No significant change was seen in the EQ5D-5L domains mobility, self-care, pain/discomfort, and anxiety/depression during follow-up. The level of patient-reported self-management significantly declined during follow-up (P < 0.001), where 92.6% of participants were at level 3 (taking action) or 4 (sustaining behaviour change) at baseline, 74.3% of participants reported these levels of self-management after 6 months of follow-up (Figure 1).

Comparisons of the CaReQoL CHF outcomes HRQoL, physical limitations and sense of safety between the historical control group (57 men (69%), mean age 69.3 ± 7.9 years) and the HartWacht group showed equivalence at 6 months of follow-up (Table 3). No significant changes in the HRQoL (P = 0.14), physical limitations (P = 0.45), and sense of safety (P = 0.60) were seen in the historic control group during follow-up (Table 4). The domain social-emotional problems improved during 6 months of follow-up both in the historic control group (P < 0.001) and the HartWacht group (P < 0.001).

Discussion

The aim of this retrospective observational longitudinal study using real-world data was to evaluate the effect of participation in the symptom-driven HartWacht-telemonitoring programme for AF on the self-reported HRQoL and the perceived sense of safety, physical limitations, and self-management. Our results demonstrated (i) no significant change over time in the patient-reported HRQoL and perceived sense of safety, (ii) a significant improvement in the patient-reported physical limitations, and (iii) a decline in the patient-reported self-management during 6 months of follow-up. HRQoL, physical limitations and sense of safety in the HartWacht group showed equivalence to usual care.

Effect on health-related quality of life, sense of safety, and physical limitations

The findings from our study demonstrated no significant change in HRQoL during follow-up in the HartWacht group and the historical control group, which is in line with the results from a randomized controlled trial (iHEART) that compared smartphone-based ECG monitoring using a KM device and behavioural text messaging to usual care. Similar to our study, the iHEART trial found equivalence between the intervention and usual care group on the EQ5D-5L utility index at 6 months of follow-up.[19] In contrast to the iHEART trial which has evaluated a dual telemonitoring programme using both ECG recordings and motivational text messaging, this HartWacht

Figure 1 Percentage of participants in the HartWacht-telemonitoring programme (*n* = 109) per level of self-management measured using the Patient Activation Measure (PAM)-13-NL questionnaire at baseline and during follow-up. The four levels of self-management, ranging from a low (level 1) to a high (level 4) level of self-management.

study was primarily focused on remote ECG monitoring. This has granted us the opportunity to solely reflect on the effect of an ECG remote monitoring programme on HRQoL in everyday practice. Second, our hypothesis that the sense of safety of patients participating in the HartWacht-telemonitoring programme is equivalent to those receiving usual care, was confirmed.[20,21] We expect the experienced sense of safety to potentially be higher than usual care if the direct and personalized feedback loop to participants following a recording would be consistently executed without exception, which has not been the case in the HartWacht-telemonitoring programme. There were in fact situations possible in which recordings were categorized as possible AF by the algorithm but were not followed by a consultation with the HartWacht team. There may be two explanations for this discrepancy. First, considering that the algorithm has a specificity of 0.95 for AF, there may have been situations where the HartWacht team has overruled false positive assessments of the algorithm.[22] Second, recordings interpreted as AF were only followed by a consultation if the recording would have direct implications for the patient, for instance when it led to a new diagnosis or changes in medication. This occasional absence of an immediate and personalized feedback loop to the participants following the recording of an ECG could have affected the perceived sense of safety.[23,24] Further, a prerequisite for participants to gain confidence in using a telemonitoring device is the practicality and simplicity of the device, the participant's experience with new technology, and the presence of training or assistance.[25,26] Despite the fact that new participants were instructed either by a video or a personal intake consultation by telephone, participants were presumably following a learning curve in mastering the device and familiarizing themselves with the HartWacht-programme. However, due to potential advantages of eHealth regarding its cost-effectiveness and scalability compared to usual care, the absence of an adverse effect of the HartWacht-
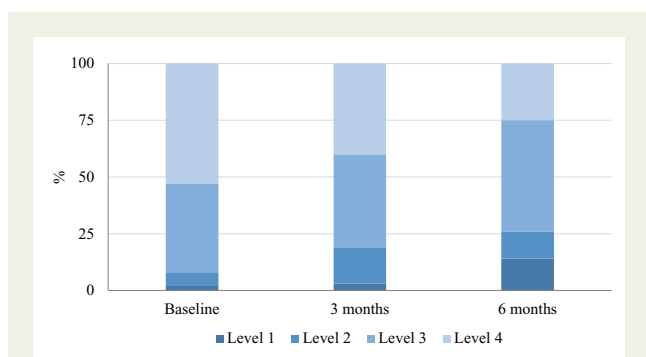
Table 3 Comparison of a historical control group receiving standard care (*n* = 83) and HartWacht-telemonitoring (*n* = 109)

	Standard care (*n* = 83)	HartWacht-telemonitoring (*n* = 109)	*P*-value[a]
CaReQoL HRQoL			
Baseline	4.15 (0.56)	4.04 (0.63)	0.28
3 months	4.24 (0.59)	4.16 (0.60)	0.35
6 months	4.19 (0.55)	4.18 (0.65)	0.73
Social-emotional problems			
Baseline	4.29 (0.68)	4.06 (0.72)	0.02
3 months	4.53 (0.59)	4.38 (0.66)	0.05
6 months	4.47 (0.60)	4.39 (0.68)	0.34
Physical limitations			
Baseline	3.94 (0.86)	3.92 (0.81)	0.81
3 months	3.99 (0.84)	4.08 (0.72)	0.70
6 months	4.01 (0.83)	4.14 (0.74)	0.34
Sense of safety			
Baseline	4.22 (0.74)	4.25 (0.71)	0.82
3 months	4.18 (0.86)	4.17 (0.88)	0.99
6 months	4.10 (0.90)	4.15 (0.91)	0.65

[a]Independent samples Mann–Whitney *U* test.

Table 4 CaReQoL HRQOL outcomes in the historical control group receiving standard care (*n* = 83) at baseline and during follow-up

	Baseline		3 months		6 months		*P*-value[a] for trend
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	
CaReQoL HRQoL	4.15 (0.56)	4.23 (3.78–4.58)	4.24 (0.59)	4.31 (3.91–4.70)	4.19 (0.55)	4.22 (3.90–4.65)	0.14
Social-emotional problems	4.29 (0.68)	4.56 (4.00–4.78)	4.53 (0.59)	4.78 (4.22–5.00)	4.47 (0.60)	4.67 (4.11–5.00)	<0.001
Physical limitations	3.94 (0.86)	4.14 (3.43–4.57)	3.99 (0.84)	4.14 (3.43–4.71)	4.01 (0.83)	4.14 (3.40–4.71)	0.45
Sense of safety	4.22 (0.74)	4.33 (3.75–5.00)	4.18 (0.86)	4.33 (3.75–5.00)	4.10 (0.90)	4.25 (3.50–5.00)	0.60

[a]Friedman test for multiple related samples.

programme on sense of safety further advocates the implementation of such programmes.[27] Lastly, paroxysmal and symptomatic AF are associated with reduced physical activity due to the fear of provoking symptoms.[8,28,29] In this HartWacht study, however, participants reported an improvement in perceived physical limitations and usual activities during follow-up. Similarly, in the iHEART randomized controlled trial a significant increase in the physical component summary of the Short-Form Health Survey (SF-36) was observed. Hence, from this we infer that symptom-driven remote arrhythmia monitoring could encourage patients to become more physically active.[19,30]

Effect on self-management

A decline in the level of self-management has been associated with more primary care consultations, visits to the emergency department and hospitalizations, whereas high levels of self-management are associated with a healthy lifestyle, undertaking preventive measures, pro-active behaviour in the patient–doctor interaction and health literacy.[31–34] This study has shown that while approximately 91% of the patients were at higher levels of self-management at baseline, only 75% of patients reported these levels of self-management after 6 months of follow-up. This is the first study to evaluate self-management levels using symptom-driven remote arrhythmia monitoring, hence it is uncertain whether the PAM-13-NL questionnaire is an appropriate measure for self-management in this population. Additionally, the use of telemonitoring tends to negatively affect self-management if patients have questions or concerns that remain unanswered.[35] A previous randomized controlled trial evaluating the effect of a mobile application for AF aimed to educate and increase patient-involvement illustrated a significant improvement in the patients' knowledge and drug adherence compared to standard care.[36] Hypothetically, the incorporation of patient education in a telemonitoring programme could aid in sustaining, or even improving patient-reported self-management.

Strengths and limitations

The use of real-world data has granted us the opportunity to reflect on the current, every-day, real-world setting of the reimbursed HartWacht-telemonitoring programme producing real-world evidence. Also, this is the first study to evaluate patient-reported self-management and sense of safety scores in patients participating in a symptom-driven remote arrhythmia monitoring programme. Besides these strengths, there are limitations to acknowledge in this study. First, missing values are a common in questionnaire-based

studies and could have led to selection bias. The differences in the number of patients diagnosed with AF and monthly number of recordings interpreted as AF between participants who responded to the questionnaire and non-responders indicate potential bias. Second, the validity and reliability of the CaReQoL CHF questionnaire and PAM-13-NL questionnaire have not been identified for patients with cardiac arrhythmias. The evaluation of remote monitoring platforms requires validated questionnaires designed for remote monitoring platforms specifically. Overall, the data presented could be used to inform the design of a future randomized controlled trial comparing the effect of symptom-driven telemonitoring for cardiac arrhythmias on patient-reported outcomes. Remote monitoring programmes for patients with cardiac arrhythmias could potentially mitigate a decline in self-management by intensifying contact with participants by using consistent feedback after self-measurements to avoid anxiety and improve patient education.

Conclusions

Symptom-driven remote arrhythmia monitoring, does not seem to affect the HRQoL and sense of safety, whereas the perceived physical limitations tend to improve. This equivalence in patient-reported outcomes to usual care advocates for a broader implementation of such eHealth programmes since this may improve accessibility and cost-effectiveness of healthcare. Patient-reported self-management declined during the first 6 months of participation showing the relevance of incorporating patient feedback and patient education.

Supplementary material

Supplementary material is available at *European Heart Journal – Digital Health* online.

Data availability

The data will be shared on reasonable request to the corresponding author.

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