Original Paper

Feasibility and Adherence of a Multicomponent Digital Health Monitoring Platform in Ambulatory Heart Failure: Multicenter Observational Study

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Abstract

Background: Digital health platforms combining wearable biosensors with smartphone apps offer scalable approaches to heart failure (HF) management, yet sustained patient engagement and initial technology adoption, particularly among older adults, remain uncertain.

Objective: We conducted a prospective, multicenter observational study to explore the feasibility and adherence of using a digital health monitoring platform for 8 weeks in a population of ambulatory patients with HF.

Methods: In this prospective multicenter observational study, patients with New York Heart Association (NYHA) class I to III HF were prescreened across 6 institutions in the United States and Singapore. Participants wore an Everion multisensor armband and an Apple Watch continuously and completed daily electrocardiograms (ECGs), daily symptom questionnaires, weekly voice recordings, and biweekly KCCQ-12 (Kansas City Cardiomyopathy Questionnaire-12) assessments. Prespecified end points included recruitment yield, device wear-time, task-specific compliance, dropout rate, and adverse events.

Results: Of 3386 prescreened individuals, 520 (15.4%) were clinically eligible; 66 consented (1.9% of prescreened; 12.7% of eligible), with technology-related concerns driving most declinations. Among 65 enrolled patients (mean age 56.5, SD 12.3 years; n=53, 81.5% male), 52 (80%) completed 8 weeks. Mean daily wear-time was 11.7 (SD 5.7) hours, significantly exceeding the 8-hour benchmark (P<.001). Task completion rates were 76.6% (2788/3640, daily ECG), 68.5% (2493/3640, daily symptoms), 86.5% (450/520, weekly voice), and 88.1% (229/260, biweekly KCCQ-12). Adherence did not differ significantly by age group (P=.81). No serious device-related adverse events occurred.

Conclusions: Enrolled patients with HF, including older adults, sustained robust engagement with a multicomponent digital platform over 8 weeks. However, technology-related concerns prevented most eligible patients from enrolling, identifying adoption, not adherence, as the primary barrier to scalable remote monitoring.

Trial Registration: ClinicalTrials.gov NCT04191356; https://clinicaltrials.gov/study/NCT04191356

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KEYWORDS

heart failure; digital health; wearable sensors; patient adherence; feasibility; mobile health; mHealth; remote monitoring; patient-reported outcomes

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Introduction

Heart failure (HF) affects more than 6 million adults in the United States and imposes an enormous burden of recurrent hospitalization, functional impairment, and diminished quality of life [1,2]. Functional capacity, symptom burden, and patient-reported health status are central to clinical management and represent increasingly important regulatory end points for HF therapeutics [3,4]. However, assessment of these domains traditionally requires in-clinic visits—for supervised 6-minute walk tests (6MWT), laboratory biomarkers, or structured questionnaires—imposing a logistical burden on patients and health care systems alike.

Digital health platforms combining wearable biosensors with smartphone apps have emerged as promising tools for continuous, remote physiological monitoring and electronic patient-reported outcome (ePRO) capture [5-7]. Such platforms may enable a paradigm shift from episodic in-clinic assessment to longitudinal real-world surveillance, with the potential to detect clinical deterioration earlier, personalize treatment, and support decentralized clinical trial designs [8,9]. Indeed, the US Food and Drug Administration has increasingly recognized the importance of developing patient-centric end points amenable to remote capture [10].

Despite this promise, the operational viability of multicomponent digital health platforms in HF populations remains incompletely characterized. Patients with HF are often older, manage multiple comorbidities, and may face technology anxiety—all potential barriers to sustained engagement [11,12]. Prior telemonitoring studies have reported suboptimal adherence to relatively simple tasks such as daily weight measurement or blood pressure logging [13,14]. Fewer studies have evaluated compliance with more complex protocols requiring continuous wearable device use, multiple active daily tasks, and longitudinal ePRO completion over extended periods.

Moreover, the magnitude of the recruitment challenge itself remains underappreciated. Large-scale prescreening often reveals that most clinically eligible patients with HF decline participation in wearable monitoring studies—not because of medical contraindications, but because of technology-related anxiety, discomfort with device management (charging, pairing, or troubleshooting), and reluctance to engage with app-based symptom reporting [11,12]. Patients with HF are already managing complex medication regimens, dietary restrictions, and frequent clinic visits; the addition of a multicomponent digital platform may feel overwhelming. Quantifying these adoption barriers is essential for designing scalable monitoring programs that do not inadvertently exclude the patients who stand to benefit most.

We therefore conducted a prospective multicenter feasibility study to quantify device wear-time, task-specific compliance rates, dropout rates, adverse events, and age-related differences in adherence among ambulatory patients with HF using a comprehensive digital health monitoring platform over 8 weeks. Critically, we also report the prescreening-to-enrollment attrition cascade, including the proportion of clinically eligible patients who declined due to technology-related concerns. This study serves as the operational foundation for 2 companion analyses from this cohort that validated a wearable-derived passive 6-minute walk distance (p6MWD) as a digitally-derived end point for functional capacity and developed a machine learning pipeline for continuous estimation of patient-reported health status [15].

Methods

Study Design and Population

This was a prospective, nonrandomized, multicenter observational study (ClinicalTrials.gov NCT04191356) designed to evaluate the feasibility of a novel mobile health monitoring platform for capturing patient-centered outcomes in HF. The study enrolled 65 patients across 6 institutions: Mayo Clinic (Jacksonville, Florida, United States) and 5 academic medical centers in Singapore. Enrollment occurred from late 2020 through mid-2023, with each participant followed for 8 weeks. All participating sites obtained institutional review board or ethics committee approval, and all participants provided written informed consent.

Eligible patients were adults aged 21 to 85 years with a diagnosis of HF (New York Heart Association [NYHA] functional class I-III), screened within 30 days of a clinic visit or hospitalization for HF, and with current or recent (within 6 months) diuretic therapy. Key exclusion criteria included recent major cardiovascular events (myocardial infarction, stroke, or cardiac surgery within 90 days), uncontrolled hypertension, severe arrhythmias, or inability to comply with the monitoring protocol. The study was originally powered for a target enrollment of 150 patients; recruitment challenges during the COVID-19 pandemic resulted in a final enrollment of 65 participants, which remained adequate for the primary feasibility objectives.

Patients who declined participation completed a survey asking them to provide one or more of the following reasons for declining: discomfort with wearing a continuous biosensor, anxiety about managing multiple electronic devices, unfamiliarity with smartphone apps, concerns about device charging and Bluetooth pairing, and data synchronization requirements. Patients who opted not to provide one of the specific reasons could select unspecified personal reasons.

Ethical Considerations

This study was reviewed and approved by the Mayo Clinic Institutional Review Board (Jacksonville, Florida, 19-011520), National University Hospital (Singapore, Singapore, 119074), National Heart Centre Singapore (Singapore, Singapore, 169609), Tan Tock Seng Hospital (Singapore, Singapore, 308433), Changi General Hospital (Singapore, Singapore, 529889), and Khoo Teck Puat Hospital (Singapore, Singapore, 768828). All participants provided written informed consent prior to any study procedures. Privacy and confidentiality of data were affirmed, and data were deidentified.

Digital Health Platform

Participants were provided with the BiovitalsHF platform (Biofourmis), a comprehensive digital health monitoring system comprising (1) an Everion multisensor armband (Biovotion

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AG) worn on the upper arm for continuous capture of heart rate, heart rate variability, respiratory rate, blood oxygen saturation, skin temperature, and triaxial accelerometry; (2) an Apple Watch Series 4 or later for step counting and episodic single-lead electrocardiogram (ECG) acquisition; and (3) a smartphone app (iOS) for ePRO delivery, data synchronization, and physiological trend visualization.

The monitoring protocol required participants to wear the Everion armband continuously (removing it only for charging and bathing), perform a daily single-lead ECG via Apple Watch, complete a daily symptom questionnaire via the smartphone app, complete a weekly voice recording task (counting from 1 to 30), and complete a biweekly Kansas City Cardiomyopathy Questionnaire-12 (KCCQ-12) assessment. All participants received standardized in-person training at enrollment, written instructions, and access to technical support throughout the study.

Feasibility End Points

Feasibility metrics were reported against explicitly defined denominators. The prespecified feasibility end points are described below.

Device Wear-Time Adherence

Mean daily hours of valid Everion data capture were assessed against a prespecified benchmark of ≥8 hours per day. This threshold reflected the minimum duration established in prior accelerometry research for reliable estimation of daily physical activity patterns [16]. Mean wear-time was compared with the 8-hour benchmark using a 1-sided *t* test (α=.05). Device wear-time was computed across all participants who initiated monitoring (N=65).

Task-Specific Compliance

The proportion of expected task instances completed over the monitoring period was calculated for each active task (daily ECG, daily symptoms, weekly voice recording, and biweekly KCCQ-12). Compliance was calculated as assessments completed divided by assessments expected. Task compliance was reported both among protocol completers (n=52) and across the full cohort initiating monitoring (N=65), the latter assigning 0 compliance for scheduled tasks occurring after a participant's withdrawal. Participants who withdrew were retained in the full-cohort denominator without imputation.

Dropout Rate

The proportion of enrolled participants who did not complete the 8-week monitoring period was calculated, with documentation of reasons for withdrawal. The prespecified feasibility threshold was a dropout rate ≤30%.

Adverse Events

All device-related adverse events documented during the study period were recorded. To distinguish administrative truncation from behavioral disengagement, we additionally computed exposure-adjusted adherence, defined as the proportion of active days during the interval each participant remained enrolled. For participants who withdrew from the study, their reason for withdrawal was verbally recorded by study personnel in 1 of 4 categories: personal or logistical reasons, unrelated medical event, device discomfort or lost to follow-up. Participants were classified as lost to follow-up if they stopped participating in the study, despite attempts to contact them.

Statistical Analyses

Analyses were conducted using population definitions appropriate to each objective: enrolled participants for dropout rate analysis, protocol completers for wear-time and task compliance analyses, and the full analytic cohort for adverse event reporting. Continuous variables are presented as mean (SD) or median (IQR) as appropriate; categorical variables were presented as counts and percentages. Wear-time differences across age groups were assessed using 1-way ANOVA. All analyses were performed using R (version ≥3.6.1; R Foundation for Statistical Computing) and Python (version ≥3.7; Python Software Foundation). Two-sided P<.05 defined statistical significance except where 1-sided testing was prespecified.

Results

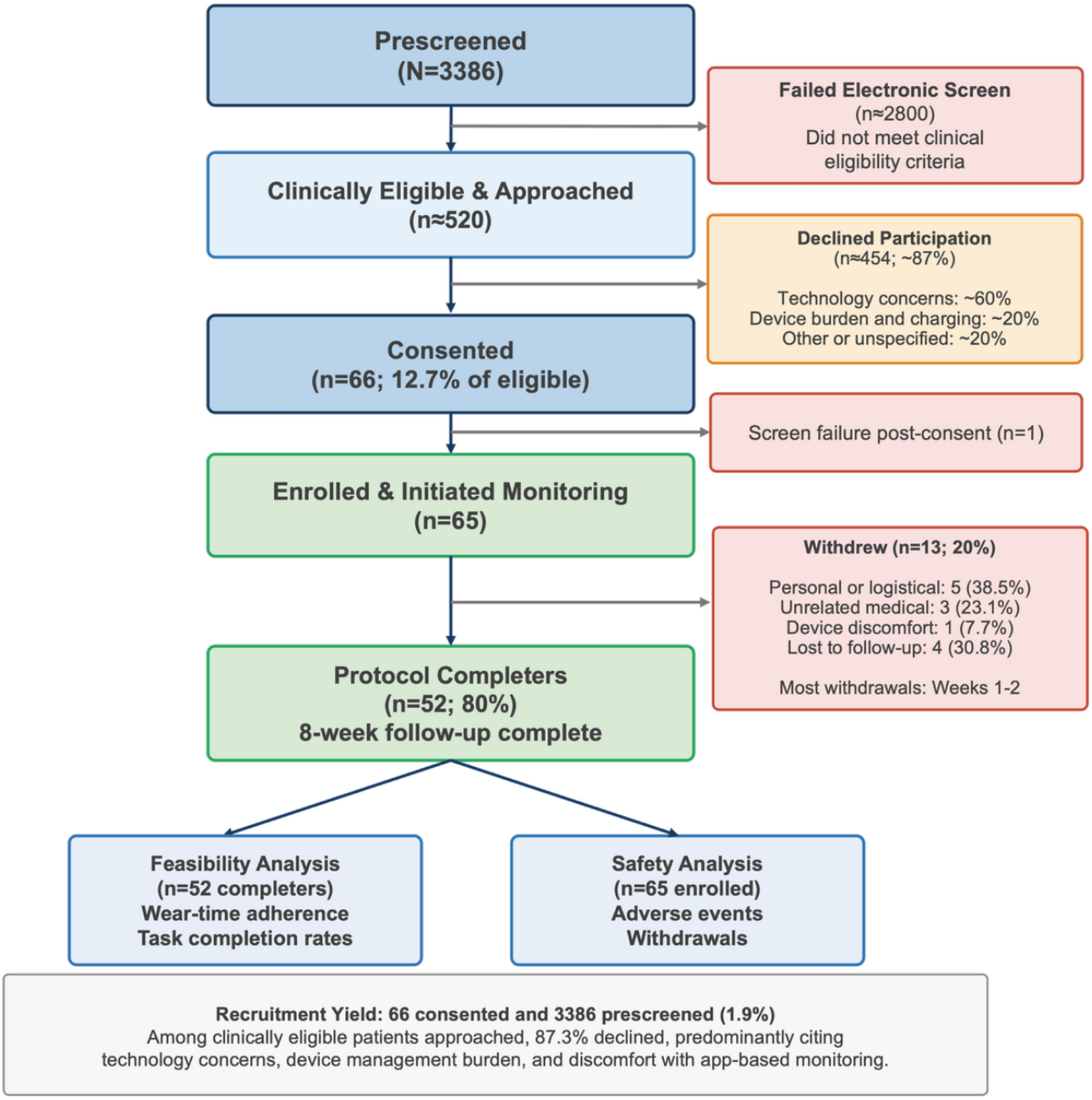
Participant Characteristics and Recruitment Yield

From a prescreening pool of 3386 individuals, 2866 failed the initial electronic eligibility screen based on clinical criteria. Of the 520 clinically eligible patients approached for participation, approximately 454 (87.3%) declined—yielding an overall recruitment rate of 1.9% (66 consented of 3386 prescreened) and a consent rate among eligible patients of 12.7%.

Among patients who declined, technology-related concerns were the predominant barrier: approximately 60% cited discomfort with wearing a continuous biosensor, anxiety about managing multiple electronic devices, or unfamiliarity with smartphone apps. An additional 20% (91/454) expressed specific concerns about device charging, Bluetooth pairing, and daily data synchronization requirements. The remaining 20% (91/454) declined for unspecified personal reasons. These recruitment data underscore that technology adoption—not clinical eligibility—represented the primary barrier to study participation (Figure 1).

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Figure 1. Study flow diagram. eGFR: estimated glomerular filtration rate; EHR: electronic health record; KCCQ-12: Kansas City Cardiomyopathy Questionnaire-12; p6MWD: passive 6-minute walk distance; TIA: transient ischemic attack.



Of 66 consented patients, 65 met all eligibility criteria and were enrolled. The analytic cohort comprised predominantly middle-aged adults (mean age 56.5, SD 12.3 years; range 25-80), with 81.5% (n=53) male and 69.2% (n=45) classified as NYHA functional class I to II. Mean left ventricular ejection fraction was 28.3% (SD 13.7%), and the baseline KCCQ-12 overall summary score was 63.0 (SD 24.4), consistent with moderate symptomatic HF. Complete baseline characteristics are presented in the companion validation manuscript [15].

Study Retention

Of 65 enrolled participants, 52 (80%) completed the full 8-week protocol. The dropout rate of 20% (n=13) met the prespecified feasibility threshold of ≤30%. Withdrawals occurred predominantly in the first 2 weeks and were attributable to personal or logistical reasons (relocation, n=2; family obligations, n=3), unrelated medical events (n=3), persistent device discomfort (contact dermatitis, n=1), and loss to follow-up (n=4). Notably, no withdrawals were attributed to dissatisfaction with the monitoring concept itself or to perceived invasiveness of data collection (Table 1).

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Table 1. Study withdrawals: timing, reasons, and characteristics (n=13)[a].

Reason for withdrawal	Participants, n (% of total participants)	Timing	Wear-time (h/day) mean (SD)	NYHA[b] class
Personal or logistical	5 (38.5)	Week 1-2	3.2 (3.5)	I-II
Unrelated medical event	3 (23.1)	Week 1-4	4.8 (4.2)	II-III
Device discomfort	1 (7.7)	Week 3	6.1	II
Lost to follow-up	4 (30.8)	Week 2-6	2.9 (3.1)	I-III
Total	13 (20)[c]	—[d]	3.7 (3.8)	—

[a]No withdrawals were attributed to dissatisfaction with the monitoring concept.

[b]NYHA: New York Heart Association.

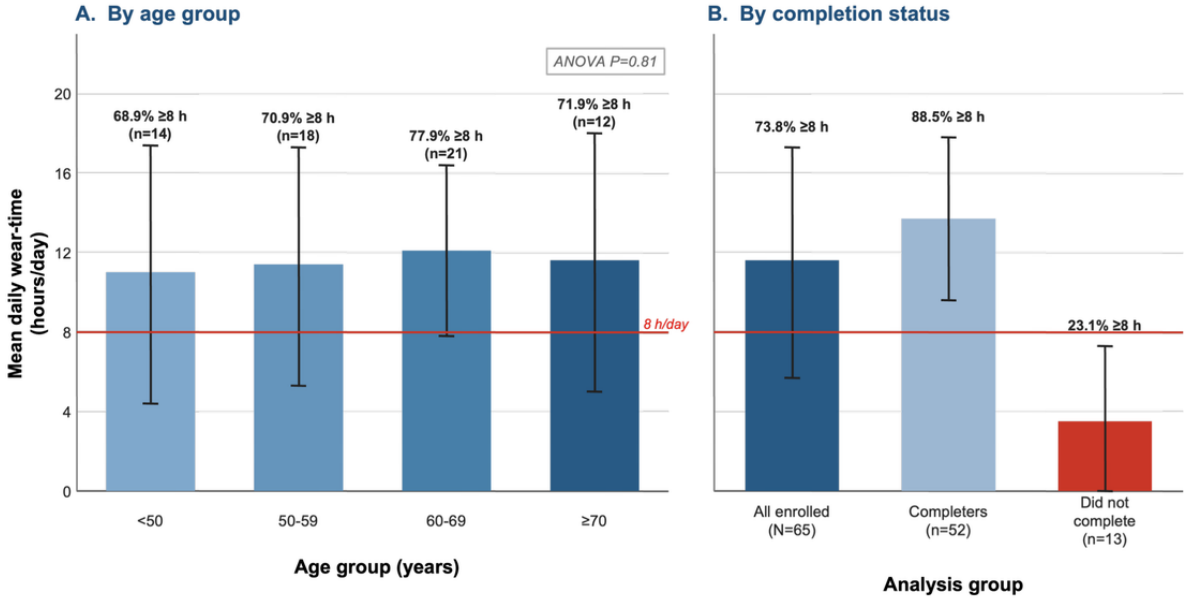
[c]The percentage in the total row (13/65, 20%) is calculated using all enrolled participants (N=65).

[d]Not applicable.

Device Wear-Time Adherence

Mean daily wear-time across the 65 participants who initiated monitoring was 11.7 (SD 5.7) h/day. The proportion of participants achieving the prespecified ≥8 h/day threshold was 73% (2657/3640). One-way ANOVA revealed no significant difference among the age groups (68.9%, 70.9%, 77.9%, and 71.9% for ages <50, 50-59, 60-69, and ≥70 years, respectively (Figure 2); ANOVA: $F_{3,61}$=0.32; P=.81 for mean wear-time). Approximately one-quarter of participants did not reach the 8-hour threshold, and this subgroup was distributed evenly across age strata.

Figure 2. Mean daily Everion wear-time.



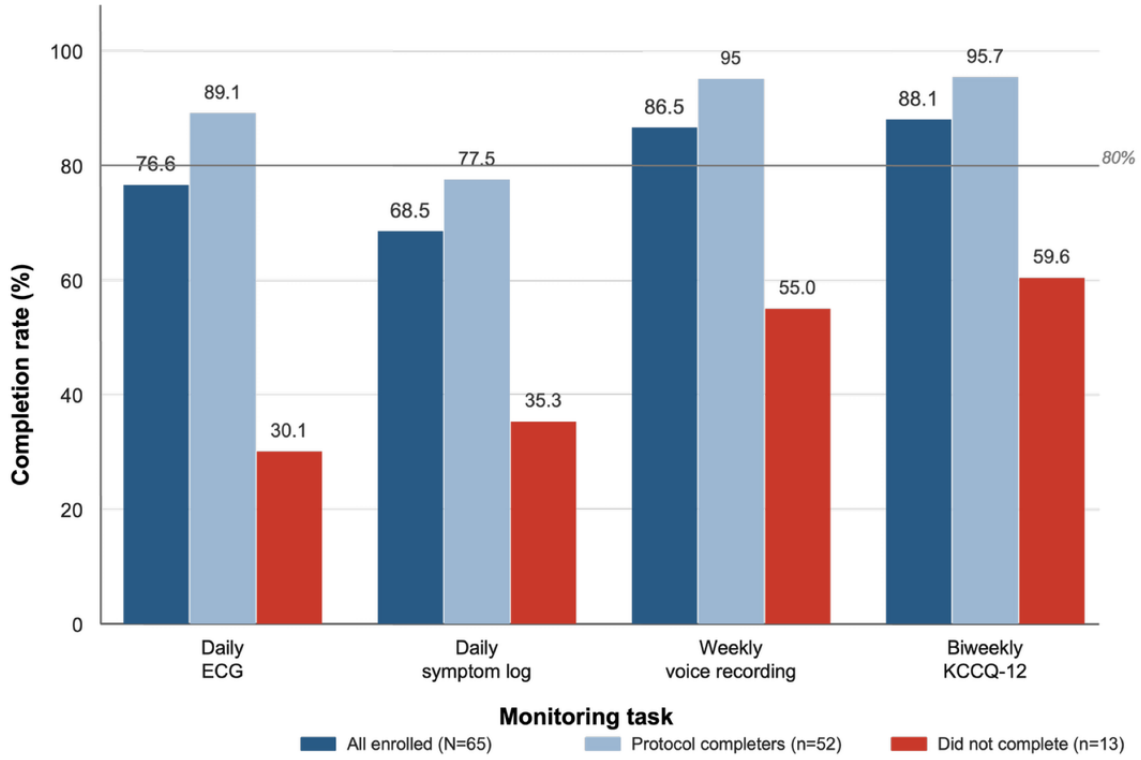
Task-Specific Compliance

For all enrolled participants (N=65), task completion rates were 76.6% (2788/3640, daily ECG), 68.5% (2493/3640, daily symptoms), 86.5% (450/520, weekly voice), and 88.1% (229/260, biweekly KCCQ-12).

Among protocol completers (n=52), task compliance was higher: 89.1% (2594/2912) for daily ECG, 77.5% (2256/2912) for daily symptom logs, 95% (395/416) for weekly voice recordings, and 95.7% (199/208) for biweekly KCCQ-12 (Figure 3). Compliance among participants who withdrew (n=13) was substantially lower during the period they remained enrolled (KCCQ-12, 59.6% (31/52) and 8 of 13 withdrawals occurred within the first 2 weeks. Adherence metrics restricted to completers therefore overstate feasibility.

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Figure 3. Completion rates for the 4 scheduled monitoring tasks, shown for all consented participants (N=66), protocol completers (n=52), and participants who did not complete the protocol (n=14). ECG: electrocardiogram; KCCQ-12: Kansas City Cardiomyopathy Questionnaire-12.



Adverse Events

No serious device-related adverse events occurred during the study. Three (4.6%) patients experienced transient, mild skin irritation beneath the Everion device strap, which resolved with adjustment of wear position. One additional participant withdrew due to persistent contact dermatitis (Table 2). No data privacy breaches, device malfunctions requiring medical intervention, or technical failures necessitating participant withdrawal were reported.

Table 2. Adverse events (AEs) and technical difficulties (N=65)[a].

Event	Participants, n (%)	Severity	Resolution	Withdrawal
Skin irritation (device strap)	3 (4.6)	Mild, transient	Repositioning	No
Contact dermatitis	1 (1.5)	Mild, persistent	Device removal	Yes
Device malfunction	0 (0)	—[b]	—	—
Data privacy breach	0 (0)	—	—	—
Serious device-related AE	0 (0)	—	—	—

[a]All events assessed by investigators.

[b]Not applicable.

Discussion

Principal Results

Overview

This multicenter study demonstrated that ambulatory patients with HF—including older adults—could sustain high-fidelity use of a comprehensive digital health monitoring platform requiring both continuous passive biosensing and multiple active daily tasks over an 8-week period. Mean device wear-time substantially exceeded the prespecified benchmarks, task compliance rates were consistently high across all modalities, and the safety profile was favorable. These findings directly address one of the most critical barriers to the clinical adoption of digital health technologies in HF: uncertainty about whether patients will engage with complex monitoring systems over clinically meaningful durations [17,18]. No statistically significant difference in adherence rates between patients aged ≥70 years and younger participants was observed, directly challenging prevailing assumptions that older patients with HF cannot sustain technology use [11,12]. This finding aligns with recent evidence that older adults are increasingly willing and able to adopt health-related technologies when provided with adequate training and support [19]. The clinical significance is substantial: most patients with HF requiring monitoring are aged 65 years and older, and age-based skepticism about digital

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health adoption should not preclude offering these tools to the populations most likely to benefit [20-23].

The Technology Adoption Barrier: Implications of the Prescreening-to-Consent Cascade

While the adherence data among enrolled participants were encouraging, the recruitment cascade revealed a sobering counterpoint: among approximately 520 clinically eligible patients approached, 87.3% declined participation. Multiple technology-related concerns were barriers. Patients expressed anxiety about continuous device wear, discomfort with charging and syncing multiple devices, and unfamiliarity with app-based symptom reporting. This finding demands honest reckoning: the 52 patients who completed 8 weeks of monitoring represented a self-selected, technology-receptive minority of the eligible HF population.

This observation carries important implications for trial design and clinical deployment. First, current wearable monitoring studies likely overestimate real-world adherence by studying patients who have already overcome the adoption threshold. The true denominator for feasibility assessment should encompass not only enrolled participants but also the large fraction of eligible patients who never consent. Second, the nature of the barriers—technology anxiety, device management burden, and a sense of being overwhelmed—suggests that the problem is not one of patient capability but of system design. Patients with HF are already managing complex medication regimens, salt and fluid restrictions, daily weight monitoring, and frequent clinic visits. Adding continuous biosensor wear, daily ECG acquisition, symptom logging, voice recording, and questionnaire completion may exceed the cognitive and practical bandwidth of patients already struggling with disease management [24]. Third, and most critically, these barriers are not immutable. Several emerging strategies may substantially improve adoption. Simplified hardware—single-device platforms that eliminate the need to manage multiple sensors—would reduce the charging and pairing burden [24]. Adaptive task scheduling that modulates monitoring intensity based on clinical stability could reduce daily demands during stable periods. Passive-first architectures that maximize data capture without patient interaction and reserve active tasks for clinically necessary moments would align better with patients' limited bandwidth.

Implications for Data Quality and Digitally-Derived End Points

The volume and continuity of data generated in this study provided the substrate for companion analyses validating clinically meaningful digital biomarkers. Among completers, the mean of 13.7 hours of daily physiological data capture—encompassing waking, activity, and sleep periods—enabled derivation of a passive 6-minute walk distance (p6MWD) that correlated strongly with investigator-guided 6MWD (r=0.78, P<.001; strengthening to r=0.85 in high-adherence participants) [15]. Similarly, the regularity of KCCQ-12 completion (199/208, 95.7%) combined with continuous sensor data allowed the development of interpretable machine learning models estimating patient-reported health status from wearable features (area under the curve=0.77 for classification; R^2=0.58 for continuous prediction) [15].

This linkage between operational feasibility and analytic validity is important. Digitally-derived end points are only as robust as the underlying data, and the high signal-to-noise ratio achievable with sustained wear-time directly strengthens the precision of derived metrics. Our findings suggest that the data quality achievable under real-world monitoring conditions is sufficient to support regulatory-grade digitally-derived end point development [10].

Implications for Clinical Trials and Practice

From a trial design perspective, the demonstrated feasibility of comprehensive remote monitoring has direct implications for decentralized clinical trials in HF. Current trial designs typically require 6 to 12 in-person visits for 6MWT administration, biomarker collection, and questionnaire completion. Replacing a portion of these visits with continuous passive monitoring and remote ePRO capture could reduce site burden, lower trial costs, expand geographic reach, and improve participant diversity—all priorities for modernizing cardiovascular clinical research [25,26].

In clinical practice, the platform's feasibility profile supports integration into remote HF management programs [27-29]. The combination of continuous physiological surveillance (enabling early detection of decompensation) with regular patient-reported outcome capture (tracking symptom burden and quality of life) provides a multidimensional monitoring framework aligned with guideline-directed management principles [30].

Optimizing Daily Engagement

Among, protocol completers, the relatively lower compliance with daily symptom questionnaires (2821/3640, 77.5%) compared with other tasks (89.1%-95.7%) merits consideration. The pattern of skipped entries on asymptomatic days suggests that patients engage preferentially with tasks perceived as relevant, consistent with event-driven health behavior models. Adaptive questioning strategies—such as abbreviated assessments on stable days with expanded assessments triggered by symptom changes or physiological alerts—may improve daily engagement while reducing perceived burden. This design principle should inform future platform iterations.

Limitations

Several limitations warrant acknowledgment. Most importantly, the high adherence reported here must be interpreted in the context of severe recruitment attrition: only approximately 13% of clinically eligible patients agreed to participate, with technology-related concerns driving most declinations. The enrolled cohort therefore represents a self-selected population with above-average technology receptivity, and adherence rates in unselected real-world HF populations would almost certainly be lower. This selection bias is inherent to all voluntary wearable monitoring studies but is rarely quantified; our reporting of the full prescreening-to-enrollment cascade provides a more honest assessment of operational feasibility than adherence metrics alone.

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The sample size was modest (N=65), reflecting recruitment challenges during the COVID-19 pandemic that prevented achievement of the original enrollment target of 150 participants; nevertheless, the sample was adequate for the primary feasibility end points. The cohort was predominantly male (81.5%) and relatively young for an HF population (mean age 56.5, 12.3 SD years), potentially limiting generalizability to older, frailer populations and to women—the very groups most likely to experience technology-related barriers. The 8-week monitoring period, while substantially longer than many prior wearable studies, does not capture long-term engagement patterns; adherence durability beyond 8 weeks requires dedicated assessment. The approximate nature of the prescreening attrition breakdown (technology concerns vs device burden vs other reasons) reflects the absence of structured declination questionnaires; future studies should systematically capture reasons for nonparticipation to better characterize and address adoption barriers. Finally, participant satisfaction was not formally assessed with validated instruments, and qualitative exploration of user experience would strengthen future feasibility evaluations.

Task compliance restricted to protocol completers overstates real-world feasibility, and we have reported full-cohort values alongside completer values to make the magnitude of this difference explicit. Because participants who withdrew were disengaged from the monitoring platform before withdrawal was recorded, missingness in this study is informative rather than random, and completer-restricted estimates should be interpreted as an upper bound. Withdrawal reasons were predominantly personal, logistical, or medical rather than device-related, so early attrition should not be attributed solely to technology intolerance; however, the concentration of attrition within the first 2 weeks, together with the absence of any age gradient in wear-time among those who remained, suggests that adoption and onboarding rather than sustained tolerability represent the principal barriers in this population.

Comparison With Prior Work

Prior investigations of remote monitoring in HF have yielded mixed results, in part because of heterogeneity in monitoring intensity and patient engagement requirements. Landmark telemonitoring trials such as Tele-HF and TIM-HF reported adherence challenges with relatively simple daily tasks (weight measurement and symptom reporting), contributing to neutral clinical outcomes [13,14]. In contrast, our participants simultaneously maintained continuous wearable device use, daily ECG acquisition, daily symptom logging, weekly voice capture, and biweekly validated health status questionnaires—a markedly more complex protocol—with wear-time adherence (13.7 h/day) well above the data quality threshold.

Several factors may explain this favorable engagement. First, the platform design minimized active burden: continuous physiological data collection occurred passively, requiring no patient interaction beyond wearing the device. Second, standardized in-person onboarding with written materials and 24/7 technical support reduced technology-related barriers. Third, the smartphone app provided push-notification reminders for active tasks, reducing reliance on patient-initiated behavior. Fourth, a perceived "care halo effect"—patients' awareness that clinicians could view their data—may have reinforced engagement, consistent with behavioral models of observed performance [31].

The low adoption rates for the wearable device and platform used in this study are consistent with the literature. Recent research suggests that less than 20% of adults with cardiovascular disease, including HF, use wearable devices [32]. In wearable studies with patients with HR, numerous factors contribute to this low adoption, including stress and anxiety about continuous monitoring, lack of guidance from providers on how to interpret and use the technology, comfort with using and charging batteries for these technologies, and skin irritation [33]. Thus, to facilitate ubiquitous adoption of wearable technologies and platforms in the near future, institution-wide efforts must be made to (1) facilitate co-development initiatives with technology companies to ensure the tools are easy to use, safe to wear, and easy to charge for HF populations, (2) provide real-time monitoring and interpretation of vital signals from patients with HF in real-world settings, and (3) support patients who have troubleshooting and support requests in their daily lives. In this study, no official help desk was launched to support patients and staff. Instead, research study staff were available for support when requested; however, it is foreseeable that future implementations of this work may require 24/7 help desk support to ensure patient safety as well as data quality.

Conclusions

This study reveals a dual reality in the feasibility of digital health monitoring for HF. Among enrolled participants, adherence was robust: device wear-time substantially exceeded the minimum threshold for reliable physiological data capture, task completion rates were high across all modalities, and the safety profile was favorable—with no significant age-related decline in engagement. However, the prescreening-to-enrollment cascade demonstrates that technology-related concerns prevented the large majority of clinically eligible patients from ever participating, highlighting that the primary barrier to scalable remote monitoring is adoption, not adherence.

Addressing this adoption gap will require a fundamental shift in platform design: from systems that demand patient technical proficiency to architectures that absorb technological complexity on the patient's behalf.

This study demonstrates that intensive multimodal digital monitoring can achieve high levels of adherence among a small, highly selected subgroup of patients with HF who are willing to engage with wearable and smartphone-based technologies. Among enrolled participants, device wear-time substantially exceeded predefined quality thresholds, completion rates for active monitoring tasks were high, and no meaningful decline in engagement was observed with increasing age. These findings indicate that once technology-receptive patients are successfully enrolled, sustained participation in a relatively complex remote monitoring program is achievable.

However, the recruitment experience provides an equally important and perhaps more clinically relevant finding. Only

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about 1 in 8 clinically eligible patients agreed to participate, with technology-related concerns representing the dominant barrier to enrollment. Accordingly, the principal conclusion of this study is not that digital monitoring is broadly feasible across the HF population, but rather that it is feasible within a small self-selected subset of patients who are already receptive to digital health technologies. The major obstacle to large-scale implementation appears to be adoption rather than adherence.

Future efforts should therefore focus less on improving adherence among engaged users and more on expanding accessibility among the much larger population currently excluded by technology-related barriers. Simplified user interfaces, passive data acquisition, caregiver integration, automated device management, and emerging AI-enabled support systems may help reduce these barriers and broaden participation. Whether such approaches can meaningfully increase enrollment among typical patients with HF and thereby improve the population-level effectiveness of remote monitoring remains an important question for future research.

Acknowledgments

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Data Availability

Deidentified data from this study may be available upon reasonable request to the corresponding author, subject to institutional and regulatory approvals.

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Generative AI Use

The authors declare that generative AI was not used in the preparation of this manuscript.

Conflicts of Interest

KSR, SJLV, FD, CH, and YH are past employees of Biofourmis. Biofourmis had no role in the preparation of this manuscript, the interpretation of the data, and the analysis. JSR currently receives research support through Yale University from Johnson & Johnson to develop methods of clinical trial data sharing, from the Food and Drug Administration for the Yale–Mayo Clinic Center for Excellence in Regulatory Science and Innovation (CERSI) program (U01FD005938), from the National Institutes of Health (R01AA032254), from the Greenwall Foundation, and from Arnold Ventures. The other authors report no conflicts of interest.

References

1. Benjamin EJ, Blaha MJ, Chiuve SE, Cushman M, Das SR, Deo R, et al. Heart disease and stroke statistics-2017 update: a report from the American Heart Association. Circulation. Mar 07, 2017;135(10):e146-e603. [FREE Full text] [doi: 10.1161/CIR.0000000000000485] [Medline: 28122885]
2. Heidenreich PA, Albert NM, Allen LA, Bluemke DA, Butler J, Fonarow GC, et al. Forecasting the impact of heart failure in the United States: a policy statement from the American Heart Association. Circ Heart Fail. May 2013;6(3):606-619. [FREE Full text] [doi: 10.1161/HHF.0b013e318291329a] [Medline: 23616602]
3. Kim JH, Cisneros T, Nguyen A, van Meijgaard J, Warraich HJ. Geographic disparities in access to cardiologists in the United States. J Am Coll Cardiol. Jul 16, 2024;84(3):315-316. [FREE Full text] [doi: 10.1016/j.jacc.2024.04.054] [Medline: 38986673]
4. Curtis JP, Rathore SS, Wang Y, Krumholz HM. The association of 6-minute walk performance and outcomes in stable outpatients with heart failure. J Card Fail. Feb 2004;10(1):9-14. [doi: 10.1016/s1071-9164(03)00705-x]
5. ATS Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories. ATS statement: guidelines for the six-minute walk test. Am J Respir Crit Care Med. Jul 01, 2002;166(1):111-117. [doi: 10.1164/ajrccm.166.1.at1102] [Medline: 12091180]
6. Steinhubl SR, Muse ED, Topol EJ. The emerging field of mobile health. Sci Transl Med. Apr 15, 2015;7(283):283rv3. [FREE Full text] [doi: 10.1126/scitranslmed.aaa3487] [Medline: 25877894]
7. Stevenson LW, Ross HJ, Rathman LD, Boehmer JP. Remote monitoring for heart failure management at home. J Am Coll Cardiol. Jun 13, 2023;81(23):2272-2291. [FREE Full text] [doi: 10.1016/j.jacc.2023.04.010] [Medline: 37286258]

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8. Maddox TM, Albert NM, Borden WB, Curtis LH, Ferguson TBJ, Kao DP, et al. The learning healthcare system and cardiovascular care: a scientific statement from the American Heart Association. Circulation. Apr 04, 2017;135(14):e826-e857. [doi: 10.1161/CIR.0000000000000480] [Medline: 28254835]
9. Coravos A, Doerr M, Goldsack J, Manta C, Shervey M, Woods B, et al. Modernizing and designing evaluation frameworks for connected sensor technologies in medicine. NPJ Digit Med. Mar 13, 2020;3:37. [FREE Full text] [doi: 10.1038/s41746-020-0237-3] [Medline: 32195372]
10. Digital health technologies for remote data acquisition in clinical investigations. U.S. Food & Drug Administration. 2023. URL: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations [accessed 2026-09-21]
11. Heart Failure Society of America, Lindenfeld J, Albert NM, Boehmer JP, Collins SP, Ezekowitz JA, et al. HFSA 2010 comprehensive heart failure practice guideline. J Card Fail. Jun 2010;16(6):e1-194. [doi: 10.1016/j.cardfail.2010.04.004] [Medline: 20610207]
12. Cajita MI, Hodgson NA, Lam KW, Yoo S, Han HR. Facilitators of and barriers to mHealth adoption in older adults with heart failure. Comput Inform Nurs. Aug 2018;36(8):376-382. [FREE Full text] [doi: 10.1097/CIN.0000000000000442] [Medline: 29742549]
13. Chaudhry SI, Mattera JA, Curtis JP, Spertus JA, Herrin J, Lin Z, et al. Telemonitoring in patients with heart failure. N Engl J Med. Dec 09, 2010;363(24):2301-2309. [FREE Full text] [doi: 10.1056/NEJMoa1010029] [Medline: 21080835]
14. Koehler F, Winkler S, Schieber M, Sechtem U, Stangl K, Böhm M, et al. Impact of remote telemedical management on mortality and hospitalizations in ambulatory patients with chronic heart failure: the telemedical interventional monitoring in heart failure study. Circulation. May 03, 2011;123(17):1873-1880. [doi: 10.1161/CIRCULATIONAHA.111.018473] [Medline: 21444883]
15. McLeod CJ, Bruce C, Rajput K, Ross JS, Lou Velarde SJ, Dwiyasa F, et al. Estimating heart failure health status from multimodal wearables: implementation of a feature-engineering framework for KCCQ-12 prediction. Mayo Clin Proc Digit Health. Sep 2026:100403. [doi: 10.1016/j.mcpdig.2026.100403]
16. Airlie J, Forster A, Birch KM. An investigation into the optimal wear time criteria necessary to reliably estimate physical activity and sedentary behaviour from ActiGraph wGT3X+ accelerometer data in older care home residents. BMC Geriatr. Feb 17, 2022;22(1):136. [FREE Full text] [doi: 10.1186/s12877-021-02725-6] [Medline: 35177023]
17. Boyne JJ, Vrijhoef HJ, Crijns HJ, De Weerd G, Kragten J, Gorgels AP. Tailored telemonitoring in patients with heart failure: results of a multicentre randomized controlled trial. Eur J Heart Fail. Jul 2012;14(7):791-801. [FREE Full text] [doi: 10.1093/eurjhf/hfs058] [Medline: 22588319]
18. Soman P, Khouri MG, Lenihan D, Reyentovich A, Sperry BW, Sowalsky K, et al. Comparison of in-clinic assessment of 6MWT by conventional method and using wearable sensors for patients with ATTR-CM. Future Cardiol. Feb 2025;21(2):75-81. [FREE Full text] [doi: 10.1080/14796678.2025.2457881] [Medline: 39878480]
19. Gelles-Watnick R. Americans' use of mobile technology and home broadband. Pew Research Center. 2024. URL: https://www.pewresearch.org/internet/2024/01/31/americans-use-of-mobile-technology-and-home-broadband/ [accessed 2026-09-21]
20. Sokas D, Paliakaitė B, Rapalis A, Marozas V, Bailón R, Petrėnas A. Detection of walk tests in free-living activities using a wrist-worn device. Front Physiol. Aug 12, 2021;12:706545. [FREE Full text] [doi: 10.3389/fphys.2021.706545] [Medline: 34456748]
21. Tinggaard AB, Sørensen L, Vissing K, Jessen N, Nørrelund H, Wiggers H. Daily physical activity and prognostic implications in patients with heart failure: an accelerometer study. Clin Res Cardiol. May 2025;114(5):616-628. [doi: 10.1007/s00392-024-02508-0] [Medline: 39222281]
22. Docherty KF, Buendia Lopez R, Folkvaljon F, Boer RA, Chen J, Hammarstedt A, et al. Wearable accelerometer-derived measures of physical activity in heart failure: insights from the DETERMINE trials. J Card Fail. Apr 2025;31(4):689-703. [FREE Full text] [doi: 10.1016/j.cardfail.2024.10.439] [Medline: 39603408]
23. Schubert C, Archer G, Zelis JM, Nordmeyer S, Runte K, Hennemuth A, et al. Wearable devices can predict the outcome of standardized 6-minute walk tests in heart disease. NPJ Digit Med. Jul 09, 2020;3:92. [FREE Full text] [doi: 10.1038/s41746-020-0299-2] [Medline: 32665977]
24. De Cannière H, Corradi F, Smeets CJ, Schoutteten M, Varon C, Van Hoof C, et al. Wearable monitoring and interpretable machine learning can objectively track progression in patients during cardiac rehabilitation. Sensors (Basel). Jun 26, 2020;20(12):3601. [FREE Full text] [doi: 10.3390/s20123601] [Medline: 32604829]
25. de Jong AJ, Zuidgeest MG, Santa-Ana-Tellez Y, Hallgreen CE, van Sloten TT, de Boer A, et al. The impact of operational trial approaches on representativeness: comparison of decentralized clinical trial participants, conventional trial participants, and patients in daily practice. Drug Discov Today. Feb 2025;30(2):104304. [FREE Full text] [doi: 10.1016/j.drudis.2025.104304] [Medline: 39884338]
26. Khosla S, White R, Medina J, Ouwens M, Emmas C, Koder T, et al. Real world evidence (RWE) - a disruptive innovation or the quiet evolution of medical evidence generation? F1000Res. Jan 25, 2018;7:111. [FREE Full text] [doi: 10.12688/f1000research.13585.2] [Medline: 30026923]

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27. Tegegne MD, Niakan Kalhori SR, Haas P, Sobotta VM, Warnecke J, Deserno TM. Wearable devices for remote monitoring of chronic diseases: systematic review. JMIR Mhealth Uhealth. Feb 11, 2026;14:e74071. [FREE Full text] [doi: 10.2196/74071] [Medline: 41671558]
28. Stehlik J, Schmalfuss C, Bozkurt B, Nativi-Nicolau J, Wohlfahrt P, Wegerich S, et al. Continuous wearable monitoring analytics predict heart failure hospitalization: the LINK-HF multicenter study. Circ Heart Fail. Mar 2020;13(3):e006513. [doi: 10.1161/CIRCHEARTFAILURE.119.006513] [Medline: 32093506]
29. Abraham WT, Adamson PB, Bourge RC, Aaron MF, Costanzo MR, Stevenson LW, et al. Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial. Lancet. Feb 19, 2011;377(9766):658-666. [doi: 10.1016/s0140-6736(11)60101-3]
30. Yancy CW, Jessup M, Bozkurt B, Butler J, Casey DEJ, Colvin MM, et al. 2017 ACC/AHA/HFSA focused update of the 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. Circulation. Aug 08, 2017;136(6):e137-e161. [doi: 10.1161/CIR.0000000000000509] [Medline: 28455343]
31. Ong MK, Romano PS, Edgington S, Aronow HU, Auerbach AD, Black JT, et al. Effectiveness of remote patient monitoring after discharge of hospitalized patients with heart failure: the Better Effectiveness After Transition -- Heart Failure (BEAT-HF) randomized clinical trial. JAMA Intern Med. Mar 2016;176(3):310-318. [FREE Full text] [doi: 10.1001/jamainternmed.2015.7712] [Medline: 26857383]
32. Dhingra LS, Aminorroaya A, Oikonomou EK, Nargesi AA, Wilson FP, Krumholz HM, et al. Use of wearable devices in individuals with or at risk for cardiovascular disease in the US, 2019 to 2020. JAMA Netw Open. Jun 01, 2023;6(6):e2316634. [FREE Full text] [doi: 10.1001/jamanetworkopen.2023.16634] [Medline: 37285157]
33. Odeh VA, Chen Y, Wang W, Ding X. Recent advances in the wearable devices for monitoring and management of heart failure. Rev Cardiovasc Med. Oct 28, 2024;25(10):386. [FREE Full text] [doi: 10.31083/j.rcm2510386] [Medline: 39484130]

Abbreviations

6MWT: 6-minute walk test
6MWD: 6-minute walk distance
ECG: electrocardiogram
ePRO: electronic patient-reported outcome
HF: heart failure
KCCQ-12: Kansas City Cardiomyopathy Questionnaire-12
NYHA: New York Heart Association
p6MWD: passive 6-minute walk distance

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