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# Association of a remote monitoring programme with all-cause mortality and hospitalizations in patients with heart failure: National-scale, real-world evidence from a 3-year propensity score analysis of the TELESAT-HF study

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Aims	To examine the association of a remote monitoring programme (RMP) with all-cause mortality and hospital admissions for heart failure (HF) within the French healthcare system.
Methods and results	A national-scale, real-world, propensity-weighted cohort study was conducted using the SNDS French database from August 2018 to December 2022 (NCT06312501). Patients receiving standard of care (SoC) were compared with those receiving RMP (Satelia <sup>®</sup> Cardio, NP Medical). The Satelia <sup>®</sup> Cardio algorithm adjusted the monitoring frequency based on symptom and weight changes, and provided tailored web-based patient education. The RMP included a digital interface for proficient patients and phone monitoring by nurses for those uncomfortable with digital technology. Data were sourced from over 300 healthcare centres across France. A propensity-weighted Cox regression model was used, supplemented by sensitivity analyses across subgroups. In total, 5357 RMP patients and 13 525 SoC patients were included after weighting. Weighted/adjusted analyses showed lower all-cause mortality for RMP patients (hazard ratio [HR] 0.64; 95% confidence interval [CI] 0.59–0.70; $p < 0.0001$ ), persisting across hospitalization and/or long-term illness status subgroups (HR 0.52 to 0.75). RMP was neutrally associated with HF hospitalization rates (rate ratio [RR] 0.95; 95% CI 0.89–1.02) but linked to less time in hospital (–2.1%, $p < 0.0001$ ) and fewer emergency visits (RR 0.83; 95% CI 0.75–0.92; $p = 0.001$ ).
Conclusion	In France, RMP with customized monitoring frequencies and educational strategies was associated with lower all-cause mortality, emergency visits, and time spent in hospital in patients with HF which may enhance nationwide HF management.

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#### **Graphical Abstract**



Association of a remote monitoring programme (RMP) with all-cause mortality and hospitalization in heart failure (HF) patients. COPD, chronic obstructive pulmonary oedema; HR, hazard ratio; ICU, intensive care unit; LTI, long-term illness; RR, rate ratio; SoC, standard of care.

Keywords Heart failure • Remote monitoring programme • Mortality • Real-world evidence • Propensity score

## Introduction

Heart failure (HF) is a common yet critical syndrome with a growing global incidence.<sup>1</sup> The condition is responsible for considerable societal and economic costs, both nationally and internationally, and has involved continuous therapeutic advances to improve patient survival in the last decade.<sup>2,3</sup> HF represents one of the leading expenditure items for health insurance in France with €3.1 billion in 2021 and an 18.0% increase between 2015 and 2021.<sup>4</sup> Repeated hospitalizations contribute to increasing the economic burden of HF which represents approximately 2.0% of the total healthcare expenditure in Europe.<sup>5,6</sup>

The latest European Society of Cardiology (ESC) guidelines have underscored the importance of remote monitoring programmes (RMPs) in HF management, along with a Class IIb recommendation.<sup>7</sup> Despite encouraging findings on RMPs in the existing literature,<sup>8</sup> there remains a paucity of large-scale, real-world assessments of such systems.<sup>9</sup> This is particularly relevant since RMPs can be complex to deploy and typically operate with a connected scale or other device logistics and maintenance system.<sup>10–12</sup> In addition, medication management, education and health promotion, which are primary pillars in HF management, are sometimes neglected by RMPs.<sup>7,13</sup> Notwithstanding, RMPs may play a crucial role in facilitating regular follow-ups and mitigating healthcare access disparities, particularly in medically underserved regions.<sup>14</sup> This is particularly significant for systems that operate via telephone rather than apps, catering effectively to the needs of often elderly patients who may face challenges with digital literacy. Despite their increasing interest, there is a gap in large-scale, multicentre clinical and real-world evidence assessing the effectiveness of telemedicine tailored for both digitally literate and illiterate patients.

In 2014, the French healthcare system launched the ETAPES programme to explore the use of RMP across several patient groups, including those with HE.<sup>9,12,15</sup> The programme approved more than 26 different RMP systems, positioning France as one of the first countries to implement non-invasive RMP in real-world HF settings, even before the 2021 ESC guidelines recommended non-invasive telemonitoring.<sup>9,12,15</sup> Additionally, under the post-ETAPES programme framework, RMP solutions that monitor symptoms and weight, as well as provide therapeutic

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education, are now reimbursed and available to HF patients through medical prescription.<sup>16</sup> This study aimed to investigate all-cause mortality using a comprehensive, multi-dimensional RMP for HF, which integrates phone-based monitoring for patients with digital illiteracy alongside standard care. This approach was designed to bridge the digital divide and enhance HF management across diverse populations.

## **Methods**

### Study design and data sources

A national-scale cohort study was conducted in France from 1 August 2018 to 31 December 2022 (NCT06312501). The ETAPES programme, supported by the French government to promote remote monitoring, along with ethical concerns in light of emerging French<sup>17,18</sup> and ESC<sup>7</sup> guidelines advocating for RMPs, guided our decision to conduct a real-world cohort analysis rather than a randomized controlled study. This methodology ensured that no patients were disadvantaged against the potential benefits of using an RMP as the literature suggests.<sup>19</sup> Patients were retrospectively selected from the French national health data system (Système National des Données de Santé; SNDS) and categorized into two groups based on clinical characteristics; (i) the intervention group referred to as the RMP group, and (ii) the control group referred to as the standard of care (SoC) group comprised of a sample of HF patients who did not benefit from any remote monitoring.

The SNDS covers approximately 99% of the French population,<sup>20</sup> contains outpatient data (such as disabilities, drugs, medical procedures, and deaths) as well as public and private hospitalization data. Diagnoses are coded according to the International Classification of Diseases, 10th revision (ICD-10) and medical procedures according to the Classification Commune des Actes Médicaux (CCAM). This database has proven to be a useful and reliable source for the assessment of drug safety and effectiveness in previous literature.<sup>21</sup>

#### Interventional group

Patients in the RMP group were provided with a personalized telemedicine solution named Satelia<sup>®</sup> Cardio (NP Medical, Bordeaux, France) which monitors clinical signs (HF symptoms and weight)<sup>15</sup> and provides web-based personalized education and training through its digital application. The patient journey within the RMP followed four steps, as outlined in Figure 1. Initially, patients were enrolled in the Satelia<sup>®</sup> Cardio RMP with their physician's assistance. Within 48 h, they received an onboarding call from a Satelia  ${}^{\textcircled{R}}$  Cardio nurse, who helped complete their medical file and provided detailed instructions on how to use the system. Following onboarding, patients were asked to complete a weekly questionnaire and monitor their weight regularly. The RMP used a score-based algorithm to analyse patient answers, trigger alerts to physicians when needed,<sup>22</sup> and automatically tailor the frequency of follow-ups adapted to the patient's risk profile. Details regarding alert handling using the RMP system studied here were previously reported.<sup>22</sup> Data from the questionnaires were directly entered by the patients on a voluntary basis via the web application, or collected by a Satelia<sup>®</sup> Cardio nurse via a phone call (Télesphore<sup>®</sup> platform) for those who were digitally illiterate or could not use the application (Figure 1).

The Satelia $^{\textcircled{B}}$  Cardio RMP intervention involved an average of 18 nurses dedicated to phone monitoring throughout the study,

with the team expanding over time to accommodate the growing patient population, especially those with limited digital literacy. The programme started in August 2018 with 2 part-time nurses, expanded to 5 in 2019, grew to 15 in 2020, and reached 28 by 2022. These nurses were primarily responsible for onboarding patients within 48 h of inclusion, conducting phone calls to collect responses to the HF questionnaire (including weight and clinical symptoms) for patients who were not digitally literate, and providing educational sessions by phone as requested by cardiologists.

The Satelia<sup>®</sup> Cardio RMP system does not utilize a connected scale; instead, patients record their weight using their personal scales and manually input the measurements into the system. This approach allows for consistent monitoring without the need for integrated devices, empowering patients to be self-sufficient once they are no longer under the RMP.

The Satelia<sup>®</sup> Cardio RMP system provides digital telemonitoring and therapeutic support, beginning 21 days after patient inclusion. Patients start by selecting their expertise level—A ('I prefer to be guided'), B ('I am eager to learn'), or C ('I consider myself an expert')—through a simple self-assessment. They then complete an educational diagnostic assessment covering five key areas: signs of deterioration, diet, medications, physical activity, and weight management, each scored out of 5.

After each follow-up, patients receive a web-based 'Daily Challenge' quiz with two true/false questions and a helpful tip. Each cycle includes six themes, with 18 questions per cycle. The cycle typically lasts 9 weeks, with twice-weekly responses, ensuring comprehensive coverage through 40 different questions. At the end of each cycle, a satisfaction quiz evaluates patient feedback on the Satelia<sup>®</sup> Cardio RMP. For non-responsive patients, Satelia nurses conduct follow-up calls. For patients without digital access, three phone sessions per semester cover critical topics such as alert signs, weight management, salt intake, physical activity, and medication adherence. Each session includes an educational diagnosis, with a new cycle starting each semester, and satisfaction questionnaires administered at the end.

The educational programme addresses key health themes at three levels: knowledge, skills, and attitudes, prioritizing incorrect diagnostic responses in subsequent quizzes. The Satelia<sup>®</sup> Cardio RMP system's comprehensive approach ensures ongoing patient engagement, education, and improved health outcomes through tailored telemonitoring support.

The Satelia  $^{I\!\!R}$  Cardio RMP was previously evaluated in the literature as being easy to use, reassuring, and well-accepted by patients with  $\rm HE^{23,24}$ 

Patients in the RMP group were linked using deterministic linkage on the French National Health Insurance fund (Caisse Nationale de l'Assurance Maladie, CNAM).

### Inclusion and exclusion criteria

The inclusion criteria for analysed patients in both RMP and control groups were adults residing in France and who were hospitalized for HF between 1 August 2018 and 31 December 2021 (online supplementary *Table S 1*). HF hospitalizations were categorized into two definitions, either strict or expanded, and were identified according to the ICD-10 diagnosis codes. The strict definition included the main diagnosis of HF (150), or secondary diagnosis (150) associated only with one of the selected codes in the main diagnosis: hypertensive heart and renal disease with (congestive) HF (113.0), hypertensive heart and renal disease, unspecified (113.9), hypertensive heart disease (1110), chronic passive congestion of liver (K761) and



**Figure 1** Patient journey overview with remote monitoring programmes (RMPs) in the TELESAT-HF study. BNP, B-type natriuretic peptide; HF, heart failure; NT-proBNP, N-terminal pro-B-type natriuretic peptide; NYHA, New York Heart Association.

pulmonary oedema (181). This validated strict definition stems from the CNAM cartography version G10. The expanded hospitalization definition was a primary or secondary HF diagnosis (150) irrespective of other diagnosis codes. Exclusion criteria were: (i) patients with inconsistent or incomplete SNDS data, (ii) patients affiliated in the French overseas territories (due to lack of reliability of data in these territories), and (iii) patients with severe hepatic dysfunction. For patients in the RMP group who opted out of the solution during the study period, the date they ceased using the RMP was recorded. Importantly, during the COVID-19 pandemic (closure of some HF hospitalization units), the inclusion criteria evolved on 15 April 2020 with the inclusion of patients being treated for HF and being symptomatic (New York Heart Association (NYHA) class >II and high peptide levels: B-type natriuretic peptide >100 pg/ml or N-terminal pro-B-type natriuretic peptide [NT-proBNP] >1000 pg/ml), in addition to patients hospitalized for HF. As biological data are not available in the SNDS, inclusion criteria of controls were being labelled as HF long-term illness (LTI, known as affection de longue durée in France) in the Social Security system and/or being treated with a combination of angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) or sacubitril/valsartan with beta-blockers (potentially associated with a mineralocorticoid receptor antagonist [MRA]). Patients receiving treatment with ACE inhibitors, ARBs, or sacubitril/valsartan together with beta-blockers likely represented a subgroup of HF management where RMP may have been proposed since their medication regimen indicated a level of specialized care.

A three-step process was implemented to design the SoC group. First, the French National Health Insurance extracted a sample from the SNDS database that met the HF criteria and was representative of the RMP group in terms of age and sex. From this sample, patients who matched the inclusion criteria of the RMP group (hospitalized for HF between 1 August 2018 and 15 April 2020, or hospitalized for or treated for HF between 15 April 2020 and 31 December 2022) were selected. To further ensure comparability between the SoC and RMP cohorts, patients in the SoC group were selected based on their hospitalization history, treatment periods, and HF severity to reflect the distribution observed in the RMP group. For patients with multiple hospitalizations or treatment dates during the inclusion period, a random selection was performed within a range minimizing the difference in index date, ensuring that the chosen date aligned with the appropriate time frame before the RMP intervention.

### Inclusion period and index date

Patients were included between 1 July 2018 and 31 December 2021 and followed until 31 December 2022. The index date was the entry date in the cohort and was defined as the following: (i) for the RMP group, as the date of hospital admission for HF (for hospitalized patients) and/or the date of HF treatment (for patients not hospitalized) before the implementation of the RMP, and (ii) for the SoC group as the date of hospital admission for HF (for hospitalized patients) and/or the date of HF treatment (for patients not hospitalized). This definition was the same for both groups, aside from the implementation of the RMP to ensure the accuracy of the results. Hospitalization could occur up to 12 months prior to the inclusion period or subsequently. The index date of patients with more than one hospitalization date and/or HF treatment was randomly selected from 2018 to 2021 to match according to the clinical and baseline similarities of patients (for example, residing in the same region, having the same level of severity). Patients were followed until the first of the following events: (i) death, (ii) admission to a nursing home known as EHPAD in France, (iii) loss to follow-up defined as the absence of healthcare use for more than 6 months, or until index date +30 months.

#### Study outcomes

The primary outcome of this study was all-cause mortality. Secondary outcomes included the number of unplanned HF-related hospitalizations, emergency unit and intensive care unit (ICU) admissions, and time spent at the hospital. Analyses on mortality and hospitalization were reported in this study in the overall population as well as in subgroups of specific interest (those with and without a history of HF admission, and those under long-term treatment or not).

#### **Statistical analysis**

Patient demographics and comorbidities were described by calculating the frequency and percentage for categorical variables, and mean, standard deviation, median, interquartile range (IQR), minimum and maximum for continuous variables. Patient severity status, treatment and index date characteristics were also described. To ensure comparability between the RMP and SoC groups and to limit confounding factors, a propensity score was used to estimate the probability that patients receive a remote monitoring solution conditional to their baseline characteristics (classic logistic regression model). Weights were calculated using the standardized mortality ratio weighting (SMRW) methodology described by Hirano et al.<sup>25</sup>; the SoC group was weighted to represent the RMP group. Covariate imbalance between groups was assessed by calculating standardized differences for each covariate included in the propensity score. These standardized differences were also calculated before and after weighting by the SMRW.

A standardized difference of >0.1 (10%) and >0.2 (20%) was selected as a threshold for moderate or significant imbalance, respectively, between groups. All statistical analyses were performed using SAS software V9.4 (SAS Institute, Carry, NC, USA). A weighted and adjusted Cox proportional hazards model was used to compare all-cause mortality between groups. The analyses examining associations based on HF hospitalization history and LTI status were adjusted for age, gender, deprivation index (defined using data from the population census and household tax income data<sup>26</sup>), and type of inclusion criteria (strict or expanded hospitalization, or  $\geq 2$  HF treatments). The RMP was designed to accommodate varying levels of digital literacy among patients. Digitally literate patients interacted with the programme through a digital interface, allowing them to self-report HF symptoms. For patients who were less comfortable with digital technology, typically reflecting the older HF population, the RMP provided phone-based monitoring by a nurse. This dual approach ensured that all patients, regardless of their technological proficiency, received the necessary monitoring and support.

Sensitivity analyses were conducted to account for immortal time bias. Patients in the RMP group needed to be alive at the time of RMP implementation, whereas there was no such constraint for the control group. To address this issue, a sensitivity analysis was performed using the date of RMP implementation as the index date for the RMP group. Additional sensitivity analyses included censoring at 6 months, as well as an intention-to-treat (ITT) analysis without censoring at cessation. Further analyses were conducted using the strict definition of HF hospitalization, as well as limiting the analysis to the 2020–2021 COVID-19 period.

#### **Ethical considerations**

In accordance with French medical data privacy laws, this study received ethics approval by the Comité d'Expertise pour les Recherches, les Etudes et les Evaluations dans le domaine de la Santé (CESREES) and the Commission Nationale de l'Informatique et des Libertés (CNIL) (DR-2022-140, No. 922055). Patients using Satelia<sup>®</sup> Cardio were individually informed of the study and provided their consent prior to the study. With regard to SoC patients linked from the SNDS, no individual consent was required since the data were anonymous in accordance with European General Data Protection Regulation 2016/679.

## Results

#### Study population

A total of 35 275 patients were analysed, 5467 of whom were receiving RMP and 29 808 were receiving standard care. Following the propensity score procedure (SMRW approach), 5357 patients in the RMP group and 13 525 patients in the SoC group were analysed (*Figure 2*). The median follow-up duration [IQR] was 912 [440–913] days overall, with 911 [402–913] days in the RMP group and 912 [553–913] days in the SoC group. Patients were mostly male (RMP: 67.8% vs. SoC: 68.3%) and aged 70–79 years (RMP group: 29.8% vs. SoC group: 29.5%). Following the statistical analyses for the SoC group, patient distribution was comparable in terms of year of inclusion from the index date and according to inclusion criteria (online supplementary *Table S2*), baseline characteristics and treatment prior to the index date (*Table 1*) as well as in terms of deprivation index distribution (online supplementary *Table S3*).

The most frequent comorbidities were hypertension, rhythm disorders, coronary heart diseases and diabetes. HF severity, reflected by the number of HF-related hospitalizations within 12 months prior to the inclusion date, was comparable in both groups. Most patients were incident cases with no HF hospitalization and no LTI scheme for HF before inclusion (*Table 1*). The inclusion criteria were comparable between the RMP and SoC groups, including between the strict definition of HF hospitalization and treatment. A comparable proportion of patients were included in this study with none, one, or two HF-related hospitalizations within 12 months of study inclusion (*Table 1*).

# Analysis of the primary outcome in the entire cohort

Patients receiving RMP had significantly lower all-cause mortality compared to the SoC group (hazard ratio [HR] in the SMRW analysis 0.64; 95% confidence interval [CI] 0.59–0.70, p < 0.0001) (*Table 2*). Event rate curves began to diverge from day 45 and continued to separate over time (*Figure 3*).

## Analysis of the primary outcome according to heart failure history and long-term illness status

The association between RMP and lower mortality remained consistent across all analysed subgroups. This association was particularly strong in patients with a history of one or more



HF hospitalizations, where the RMP group exhibited over a 40% reduction in mortality compared to the SoC group (*Figures 3* and 4).

## Sensitivity analysis of the primary outcome

A sensitivity analysis was performed to address a potential immortal time bias. The analysis confirmed the association of RMP on mortality, with an estimated 32.0% lower mortality rate in the RMP group compared to the SoC group. Additional sensitivity analyses included censoring at 6 months as well as an ITT analysis without censoring at cessation which showed an estimated 30.0% and 29.0% lower mortality in the RMP group and the SoC group, respectively.

Similar associations were observed when analysing only hospitalized patients using the strict definition of HF hospitalization (HR 0.60; 95% CI 0.54–0.66). Additionally, the association of RMP with mortality remained consistent when considering only the COVID period (2020–2021) (HR 0.61; 95% CI 0.55–0.67).

#### Analysis of hospitalization outcomes

In the global population, the RMP was associated with a non-significant reduction in HF hospitalizations (rate ratio [RR] 0.95; 95% Cl 0.89–1.02; p = 0.13) although significantly reduced the amount of time spent in the hospital (-2.09%; 95% Cl -2.62 to -1.56; p < 0.0001) (*Table 3*). Furthermore, the RMP significantly decreased the rates of emergency unit visits (RR 0.83; 95% Cl 0.75–0.92; p = 0.001) and ICU admissions (RR 0.84; 95% Cl 0.74–0.97; p = 0.01).

The most consistent benefits of the RMP were observed in patients with prior hospitalizations. Those with one prior HF hospitalization showed a significant reduction in both ICU admissions (RR 0.67; 95% CI 0.49–0.91; p = 0.01) and emergency visits (RR 0.64; 95% CI 0.52–0.79; p < 0.0001). Similarly, patients with two or more prior hospitalizations experienced notable decreases in ICU admissions (RR 0.66; 95% CI 0.50–0.87; p = 0.003) and emergency visits (RR 0.77; 95% CI 0.63–0.95; p = 0.01). In contrast, outpatients without LTI status experienced an increase in HF hospitalizations (RR 1.30; 95% CI 1.16–1.45; p < 0.0001) and a higher incidence of both ICU admissions and emergency visits.

## Discussion

The results of this study indicate a beneficial association between the use of an RMP and all-cause mortality among HF patients within the French healthcare system. Our analysis showed that HF patients monitored with Satelia® Cardio (French ETAPES/post-ETAPES RMP) exhibited a 36.0% lower mortality rate compared to those receiving standard care. This significant reduction in mortality may underscore the considerable value of implementing tailored monitoring and educational strategies in HF management. Additionally, the RMP was associated with significant reductions in emergency department visits, in ICU admissions, and the percentage of time spent in the hospital, even though the reduction in HF hospitalizations was not statistically significant (Graphical Abstract). These findings suggest that RMPs could be highly effective in improving outcomes across a broad HF population, potentially extending healthcare access and quality on a large scale.

	RMP group ( <i>n</i> = 5357)	SoC group ( <i>n</i> = 13 525)	ASMD <sup>a</sup>
Age at index date (years)			
Mean $\pm$ SD	71.8 ± 13.2	$71.8 \pm 5.4$	0.004
Median (IQR)	73.0 (64.0-82.0)	74.0 (65.0-82.0)	
Min-max	[20–100]	[21–101]	
Age range (years), n (%)			
<60	918 (17.1)	2394 (17.7)	-0.012
60-69	1113 (20.8)	2962 (21.9)	-0.028
70–79	1596 (29.8)	3989 (29.5)	0.009
80-89	1429 (26.7)	3476 (25.7)	0.01
≥90	301 (5.6)	703 (5.2)	0.033
Sex, n (%)			-0.001
Female	1724 (32.2)	4287 (31.7)	
Male	3633 (67.8)	9237 (68.3)	
Comorbidities, n (%)			
Coronary heart disease	2981 (55.6)	7628 (56.4)	-0.001
Hypertension	4631 (86.4)	11 699 (86.5)	-0.005
Dyslipidaemia	1793 (33.5)	4490 (33.2)	0.005
Stroke	438 (8.2)	1095 (8.1)	0.004
Rhythm disorders	3522 (65.7)	8994 (66.5)	0.011
Moderate or severe renal insufficiency	1067 (19.9)	2705 (20.0)	0.011
Diabetes	1703 (31.8)	4341 (32.1)	0.003
Obstructive sleep apnoea-hypopnoea syndrome	188 (3.5)	500 (3.7)	-0.004
Myocardial infarction	1143 (21.3)	2962 (21.9)	0.009
Chronic pulmonary diseases	1235 (23.1)	3124 (23.1)	0.008
Obesity	1515 (28.3)	3841 (28.4)	-0.003
Categorization according to LTI and HF hospitalization history, n (	(%)		
Outpatients, no LTI status	3320 (62.0)	8209 (60.7)	-0.093
Outpatients, LTI status	779 (14.5)	2001 (14.8)	-0.002
One prior hospitalization <sup>b</sup>	758 (14.1)	1988 (14.7)	0.034
2 or more prior hospitalization <sup>b</sup>	500 (9.3)	1325 (9.8)	0.083
Number of HF-related hospitalizations within 12 months prior to	the inclusion date <sup>b</sup> , <i>n</i> (%)		
0	4099 (76.5)	10211 (75.5)	
1	758 (14.1)	1988 (14.7)	
≥2	500 (9.3)	1325 (9.8)	
HF medication, n (%)			
Angiotensin II receptor blocker	2255 (42.1)	5829 (43.1)	-0.019
ACE inhibitor	2084 (38.9)	5194 (38.4)	0.011
Sacubitril/valsartan	1200 (22.4)	3219 (23.8)	-0.033
MRA	1693 (31.6)	4436 (32.8)	-0.026
Beta-blocker	3943 (73.6)	9968 (73.7)	-0.002
SGLT2i	129 (2.4)	365 (2.7)	-0.015

 Table 1 Baseline patient characteristics including heart failure medications given to patients prior to the index date after propensity score weighting

ACE, angiotensin-converting enzyme; ASMD, absolute standard mean difference; HF, heart failure; IQR, interquartile range; LTI, long-term illness; MRA, mineralocorticoid receptor antagonist; RMP, remote monitoring programme; SD, standard deviation; SGLT2i, sodium–glucose cotransporter 2 inhibitor; SoC, standard of care. <sup>a</sup>If <0.10 minimal difference.

<sup>b</sup>Within 12 months before the inclusion date.

To our knowledge, the TELESAT-HF study is the largest national-scale real-world study designed to assess the association between tailored RMPs for HF and outcomes. Previous studies have reported conflicting results, with some heterogeneity in methodologies and limited multicentre real-world data.<sup>27,28</sup> For instance, Knoll et  $al.^{29}$  demonstrated that a comprehensive RMP with tele-coaching significantly reduced HF hospitalizations (17.9)

vs. 21.8 per 100 patient-years, p < 0.001) and all-cause mortality (5.8 vs. 11.0%, p < 0.001) in a large cohort of 6065 severe HF patients compared to standard care over 1 year. Similarly, the most recent meta-analyses by Scholte *et al.*<sup>8</sup> and Umeh *et al.*<sup>30</sup> reported that remote monitoring in HF patients was associated with reductions in all-cause mortality, HF-related hospitalizations, and total hospitalizations. These meta-analyses highlight the

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 Table 2 Association of the remote monitoring programme with all-cause mortality overall and according to heart failure hospitalizations and long-term illness status for heart failure

Characteristics	RMP group	SoC group	All-cause mortality HR <sup>a</sup> (95% Cl)	p-value
Global population	5357	13 525	0.639 (0.586-0.696)	< 0.0001
Outpatients, no LTI status	3320	12873	0.617 (0.546-0.696)	< 0.0001
Outpatients, LTI status	779	1467	0.745 (0.581-0.952)	0.01
One prior hospitalization	758	1350	0.563 (0.463-0.681)	< 0.0001
$\geq 2$ prior hospitalizations	500	668	0.518 (0.415-0.644)	< 0.0001

CI, confidence interval; HR, hazard ratio; LTI, long-term illness; RMP, remote monitoring programme; SoC, standard of care. <sup>a</sup>Weighted hazard ratio.



**Figure 3** Kaplan–Meier survival curves of patients in the remote monitoring programme (RMP) group versus the standard of care (SoC) group, overall (A) and according to heart failure (HF) hospitalizations and long-term illness (LTI) status (B-E). Hazard ratio (HR) in the overall population corresponds to weighted HR; HR in the subgroups are derived from models adjusted for sociodemographic (age, sex and deprivation index) and clinical characteristics (comorbidities and severity of HF).

complexity of remote monitoring in HF management, given the diverse approaches and healthcare systems involved.

However, evidence in the field has been further complicated by the lack of standardization in alert management and the challenges of implementing sophisticated monitoring systems such as the TIM-HF2 study.<sup>13</sup> This German study used 24/7 alert responsiveness and detailed monitoring (e.g. oximetry), which exceeds the capabilities of the current post-ETAPES approach, which is primarily based on weight and symptom monitoring with limited business hour management. When isolating non-invasive telemonitoring in the meta-analysis performed by Scholte *et al.*,<sup>8</sup> the association of RMP with all-cause mortality or recurring HF-related hospitalizations showed no significant reductions. However, the association with a first HF hospitalization was significant, albeit with high heterogeneity. The effectiveness of RMP may hence rely on its inclusion within a comprehensive multi-dimensional programme consisting of personalized education and tele-coaching for HF patients.

In France, the OSICAT randomized clinical trial, which included 941 patients between 2013 and 2016, produced more neutral results regarding all-cause mortality and unplanned HF-related hospitalizations, despite being conducted within the same healthcare system.<sup>12</sup> However, the study did show a reduction in all-cause death or first unplanned hospitalization in NYHA class III/IV patients. The differences in outcomes between the OSICAT and TELESAT-HF studies may be attributed to several factors. At the

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Figure 4 Forest plot of all analyses produced for the mortality endpoint according to severity of heart failure (HF). CI, confidence interval; LTI, long-term illness; RMP, remote monitoring programme; SoC, standard of care. \*Weighted hazard ratio (HR). \*\*Models were adjusted for sociodemographic (age, sex, and deprivation index) and clinical characteristics (comorbidities and severity of HF), Proportional hazards assumptions for all models were verified.

Table 3Association of the remote monitoring programme with heart failure hospitalizations, time spent in hospitalfor heart failure, emergency room and intensive care unit admissions, overall and according to heart failurehospitalizations and long-term illness status

Characteristics	HF hospitalization		Time spent in hospital for HF		Emergency room admissions		ICU admissions	
	Rate ratio (95% CI)	p-value	Percentage of time spent in hospital for HF	p-value	Rate ratio (95% CI)	p-value	Rate ratio (95% CI)	p-value
Global population	0.95 (0.89-1.02)	0.13	-2.09% (-2.62 to -1.56)	<0.0001	0.83 (0.75-0.92)	0.001	0.84 (0.74-0.97)	0.01
Outpatients, no LTI status	1.30 (1.16-1.45)	< 0.0001	-1.98% (-2.56 to -1.40)	< 0.0001	1.18 (1.00-1.37)	0.04	1.25 (1.02-1.54)	0.03
Outpatients, LTI status	1.32 (1.07-1.62)	0.009	1.05% (-0.42 to 2.52)	0.16	1.04 (0.77-1.41)	0.78	1.61 (1.10-2.36)	0.02
One prior HF hospitalization	0.85 (0.74-0.98)	0.02	-1.85% (-3.12 to -0.58)	0.004	0.64 (0.52-0.79)	< 0.0001	0.67 (0.49-0.91)	0.01
≥2 prior HF hospitalizations	0.89 (0.77-1.02)	0.09	-1.47% (-3.40 to 0.45)	0.13	0.77 (0.63-0.95)	0.01	0.66 (0.50-0.87)	0.003

CI, confidence interval; HF, heart failure; ICU, intensive care unit; LTI, long-term illness.

time OSICAT was conducted, general practitioners were primarily responsible for responding to HF alerts, whereas TELESAT-HF predominantly involved specialized centres with dedicated HF teams, including cardiologists and nurses, ensuring more focused and expert care. Additionally, the platform used in TELESAT-HF included proactive nurse calls for patients with digital difficulties and is not reliant on a connected scale, possibly increasing empowerment of the patients.

Several RMPs are currently implemented in France, with the Chronic Care Connect<sup>TM</sup> (CCC) being a particularly notable example. Recently, Roubille *et al.*<sup>9</sup> conducted a large, matched analysis involving approximately 1500 patients using CCC, which demonstrated a lower mortality rate after 6 months of telemonitoring, albeit with a higher risk of first HF hospitalization and

increased HF-related healthcare costs. Our study builds upon and complements the above findings in several critical ways. First, our analysis, encompassing over 5000 patients across more than 300 centres, represents the largest cohort studied to date, thereby enhancing the external validity of our results. Additionally, our study revealed a significant reduction in the percentage of time spent in the hospital for HF, along with fewer emergency department visits and ICU admissions, outcomes not observed in Roubille et al.'s analysis.<sup>9</sup> Importantly, Roubille et al. noted a 7-19% reduction in the risk of emergency department admissions among patients at the highest risk of hospitalization, with this benefit tending to increase with advancing age.<sup>9</sup> The more pronounced benefits observed in the TELESAT-HF study may be attributable to the inclusion of more severe patients and the additional support

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provided through phone contact by nurses for those less proficient with digital technology, as well as the absence of reliance on a connected scale, unlike the CCC system.

A similar large-scale study, the Whole System Demonstrator trial conducted in the UK, which included 3230 patients from 179 general practices and focused on diabetes, chronic obstructive pulmonary disease, and HF (HF accounting for 28% of patients), also reported similar outcomes.<sup>31</sup> This trial found that telehealth interventions significantly reduced both mortality (odds ratio 0.54, 95% CI 0.39-0.75; p < 0.001) and emergency department admissions (odds ratio 0.82, 95% CI 0.70–0.97; p = 0.017), aligning with the reductions observed in our TELESAT-HF study. The consistent benefit of telemonitoring across these studies underscores the potential of such interventions in improving patient outcomes and reducing the burden on healthcare systems. Collectively, our results, together with previous findings, suggest that RMPs have a significant role in enhancing HF management by not only reducing mortality but also by alleviating the strain on healthcare systems through reduced hospital utilization rates.

A plausible explanation for the lower all-cause mortality observed in the RMP group is that RMP enhances the early detection of HF decompensation, reduces emergency readmissions for acute HF episodes, and facilitates timely access to specialized care. HF decompensation often goes undetected in its early stages, leading to a high risk of potentially avoidable HF-related rehospitalizations, as highlighted by Constantinou et al.,<sup>32</sup> who reported a 31.8% rehospitalization rate within 12 months. This explanation is further supported by the findings of Roubille et al.,<sup>9</sup> who observed higher rates of HF hospitalization but with shorter lengths of stay, suggesting less severe HF episodes. Our results show a similar pattern, with fewer emergency department admissions and an overall reduction in time spent in the hospital for HF. Of note, the early HF decompensation detection in our study was aided by the Satelia® Cardio score-based algorithm, which has been reported to have an excellent negative predictive value of 99%.<sup>23</sup> Alerts were sent to clinicians based on the scores, with an orange alert for scores  $\geq 12$  and a red alert for scores  $\geq 21$ . There are very few score-based detection algorithms that have been assessed in the literature and HF monitoring systems remain challenging for physicians due to their complexity and the frequency of alerts generated.<sup>33</sup> The present results suggest that the use of the rather straightforward algorithm (green-orange-red) herein with appropriate alert management may result in improved outcomes. However, we do not have available data on the management of alerts, which may have required face-to-face care in a sizeable proportion of cases. Notwithstanding, in our group experience, numerous alerts are managed over the phone or telemedicine by increasing diuretics and in uncertain cases, performing NT-proBNP measurements. However, actual management of alerts may vary across centres, and future studies should better delineate how alerts are managed in this RMP typology. Nevertheless, despite this variability, RMP was associated with better outcomes in a nationwide study.

The findings observed in our study do not allow delineating the underlying mechanisms explaining the better outcome associated with the RMP. Typically, an RMP is a complex intervention as defined in the epidemiology field.<sup>34</sup> Multiple aspects may incur benefit, including (but not limited to) patient education, early management of worsening HF, favouring guideline-directed medical therapy implementation/up-titration, better patient-centred framework, as well as enhancing communication between patients, general practitioners, ambulatory nurses and HF team. Dedicated mediation studies are warranted to further assess the proportion of effect underpinning these different mechanisms, including within a framework in which highly detailed information is collected regarding all of the above dimensions (a feature not available in the TELESAT-HF study).

#### **Strengths and limitations**

One of the key strengths of this study is its large scale, involving over 18 000 patients, including more than 5000 in the intervention group, with follow-up durations exceeding 12 months. These factors constitute one of the most extensive assessments of RMP in HF in France. Our findings suggest that a non-device-based algorithmic follow-up, coupled with coaching, could offer a practical and effective solution. An additional strength is the use of the SNDS database, which enhanced the validity of the study by providing comprehensive insights into outcomes such as all-cause mortality.<sup>21</sup> The inclusion of diverse patient demographics and settings, along with adjustments for temporal variations, further strengthens the robustness of our findings. Collectively, these aspects point toward the scalability of this RMP approach since it operates independently of connected devices and appears to be effectively implemented, underscoring its versatility and potential impact.

There are however inherent limitations due to the observational nature of the study. While the latter were minimized using the SMRW analysis method, which allowed considering the entire population meeting the selection criteria and enabled the groups to be comparable, residual bias nonetheless likely exists, which can only be addressed by future randomized studies. This is even more important in light of the nature of data extraction, which relied on harvesting administrative data from social security claims, which precluded a detailed phenotyping of the population that may have had an impact on addressing attribution bias. It also precludes having data internal to the telemonitoring follow-up such as adherence, which is key in assessing patient management. In light of the uncertainty regarding causality, a national group is currently involved in a large, randomized trial investigating the RMP effect at a national level in France. Funding was just obtained from the PHRC-N, the French Clinical Research Program, in 2024. The TELE-COMPASS-HF trial (Telemonitoring Evaluation to Lower Events-COMPrehensive Alert System) will provide more definite evidence regarding the effect of this approach to telemonitoring.

Additionally, our study relied on administrative data for HF identification, which may have overlooked nuanced patient characteristics. Furthermore, the present study included, as controls, patients likely to have HF based on their treatment with renin–angiotensin–aldosterone system (RAAS) inhibitors and beta-blockers, who would be considered for telemonitoring due to their regimen involving two or more HF medications. However, for patients not labelled as having HF under the LTI classification,

identifying HF cases solely based on the concurrent use of RAAS inhibitors and beta-blockers is less definitive. Nevertheless, this approach can be seen as a strength, as HF patients typically exhibit the poorest prognosis among cardiovascular patients. This may explain why more HF hospitalizations were observed in our analysis in patients without an LTI HF label who were not hospitalized under RMP, possibly due to certain patients in the control group not actually having HF. Lastly, our study lacked insights into the motivations of patients regarding RPM acceptance or refusal, which may have introduced potential bias. Future research could focus on comparing different RMPs to further delineate their respective effectiveness.

## Conclusion

Our findings suggest that an algorithm-based RMP with personalized frequency and tailored therapeutic education are associated with lower all-cause mortality and reduced hospital utilization compared to standard care within the French healthcare system. These findings may hold important implications for clinicians and policymakers, demonstrating the potential for RMP implementation across diverse patient populations in routine clinical practice. In light of the observational nature of this study, a national trial was very recently funded by the French Government to better ascertain the benefit of this approach. These RMP systems may be used in healthcare systems that have RMP reimbursement such as in France, Germany and the US, for example, although our results may further promote the reimbursement of such approaches in other systems.

## **Supplementary Information**

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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