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Telehealth care and remote monitoring strategies in heart failure patients: A systematic review and meta-analysis

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ABSTRACT

Background: Heart failure (HF) is a cardiac clinical syndrome that involves complex pathological aetiologies. It represents a growing public health issue and affects a significant number of people worldwide.
Objectives: To synthesize evidence related to the impact of telemonitoring strategies on mortality and hospital readmissions of heart failure patients.
Methods: A systematic literature review was conducted using PubMed, Scopus, CINAHL, IEEE Xplore Digital Library, Engineering Source, and INSPEC. To be included, studies had to be in English or Italian and involve heart failure patients of any NYHA class, receiving care through any telecare, remote monitoring, telemonitoring, or telehealth programmes. Articles had to contain data on both mortality and number of patients who underwent rehospitalizations during follow-ups. To explore the effectiveness of telemonitoring strategies in reducing both one-year all-cause mortality and one-year rehospitalizations, studies were synthesized through meta-analyses, while those excluded from meta-analyses were summarized narratively.
Results: Sixty-one studies were included in the review. Narrative synthesis of data suggests a trend towards a reduction in deaths among monitored patients, but the number of rehospitalized patients was higher in this group. Meta-analysis of studies reporting one-year all-cause mortality outlined the protective power of care models based on telemonitoring in reducing one-year all-cause mortality. Meta-analysis of studies reporting the number of rehospitalized patients in one-year outlined that telemonitoring is effective in reducing the number of rehospitalized patients when compared with usual care strategies.
Conclusion: Evidence from this review confirms the benefits of telemonitoring in reducing mortality and rehospitalizations of HF patients. Further research is needed to reduce the heterogeneity of the studies.

Introduction

Heart failure (HF) is a cardiac clinical syndrome that can arise as a consequence of various conditions, even those not directly associated with the myocardium.[1–4] HF poses a significant public health issue as it is a chronic condition that generally worsens over time, usually cannot be cured, and available data highlight that millions of people (ranging from 23 to 64.3 million) are affected worldwide.[5–8] The prevalence is generally 1% to 2% of the general adult population in developed countries, rising to up to 10% in people aged over 70.[1,9,10] In Europe, cardiovascular diseases were responsible for 1.83 million deaths (36% of all deaths) in 2016, accounting for approximately 2% of healthcare expenditure, which translates to about 29 billion dollars.[11–14] Notably, European 12-month all-cause mortality rates for hospitalized and outpatient patients were 17% and 7%, respectively, and hospitalization rates were 44% and 32 %, indicating a significant burden on healthcare systems.[1,15] Additionally, HF adversely affects the living and working abilities of patients, leading to a deterioration in their overall quality of life.[1,2,4,10,16]

Despite the substantial human and economic resources employed, rehospitalization and mortality rates in HF patients remain alarming due to the increasing incidence and improved prognosis.[8,17] Furthermore, HF is associated with the highest 30-day readmission rate among all diagnoses (about 20–25%), and approximately half of newly diagnosed patients are admitted to hospital within one year of HF diagnosis.[8,18,19] Patient self-monitoring or self-management of medications, periodic visits to outpatient departments, and entrusting patients to caregivers may not be sufficient to prevent the onset of secondary pathological

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events.[20–22] Caring models that enable the early detection of signs and symptoms of worsening HF and promote long-term health by reducing mortality and rehospitalizations are recommended. To achieve these goals, remote monitoring has become one of the most adopted tools for HF management.[20,23] With telemonitoring, it is possible to better classify the clinical condition of patients and tailor nursing and medical interventions.[20] However, evidence about the effectiveness of remote clinical management of HF patients is not entirely convincing. Despite a significant reduction in all-cause mortality and rehospitalizations in patients cared for with telemonitoring strategies, the effects were relatively small and not entirely positive in terms of outcomes.[1,16,20] In addition, a heterogeneity of telemonitoring models has been highlighted, making it difficult to assert with certainty what its better application modality is. This could justify the fact that a large-scale implementation of remote monitoring is not yet recommended by guidelines.[7,16,20,23]

In this context, an extensive systematic literature review was needed to synthesize evidence related to the impact of telemonitoring strategies on mortality and rehospitalizations of HF patients. The research questions that this study aims to address are: a) Can telemonitoring strategies reduce one-year all-cause mortality in patients with HF? b) Can telemonitoring strategies reduce the number of one-year rehospitalizations in patients with HF?

Methods

Aim

The aim of this study was to synthesize evidence related to the effectiveness of telemonitoring strategies in influencing both one-year all-cause mortality and the number of one-year rehospitalizations in patients with HF.

Study design

A systematic literature review with meta-analyses was conducted, and its reporting was checked against the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist.[24] This literature review was based on a research protocol that was not registered in any international database; however, it is available upon reasonable request to the authors.

Search strategy

To be included in the review, studies had to: a) be primary quantitative, b) be available in full text, c) be written in English or Italian, d) include heart failure patients of any New York Heart Association class (NYHA) cared for with any type of telehealth or remote monitoring strategies, and e) report mortality and rehospitalizations as outcomes. In this study, telehealth, or remote monitoring (telemonitoring) is defined as any strategy utilizing technology, including wearable devices, mobile applications, and secure online platforms, to remotely monitor and manage the health of patients with heart failure. A pilot search was performed on PubMed to identify the most relevant keywords and refine the electronic search strategy.[25] The following keywords were retrieved 'heart failure' 'telenursing' 'telehealth nursing' 'telemetry, nursing', 'remote monitoring', 'remote patient monitoring', 'telemonitoring', 'survival rate', 'survival, mortality, 'patient readmission', 'patient compliance', 'medication adherence', 'quality of life'. Details about search strategy are reported in Table 1 of the supplementary file.

The consulted electronic databases were PubMed, Scopus, CINAHL, IEEE Xplore Digital Library, Engineering Source, and INSPEC. The search was performed in August 2021, and no limitations were utilized to ensure a high sensitivity of the search strategy.[26] The full search strings are available in Table 2 of the supplementary file. All the retrieved references were collected and managed with EndNote X7.8 for Windows (Thomson Reuters, New York). Given the broad search strategy and the multitude of consulted databases, we did not carry out additional search strategies, such as screening citations and reference lists of included manuscripts.

Selection of studies

Studies were independently screened for both eligibility (AM and LB) and inclusion (FF and VC) by two raters each. During these processes, any disagreements between raters were resolved through discussion with a third author (VM) until consensus was reached. Studies with mixed samples were excluded if it was not possible to obtain separate data on patients' outcomes.

Risk of bias of included studies

To evaluate the risk of bias in included studies, the Joanna Briggs Institute's (JBI) critical appraisal tools for the evaluation of randomized controlled trials and observational studies were utilized.[27] Following the JBI Manual, decisions about the scoring system and cutoffs were made in advance and agreed upon among reviewers before critical appraisal commenced. Studies were judged for risk of bias according to the following cutoffs: low risk, if the percentage of answers scoring 'yes' was above 70%; moderate risk if 'yes' scores counted between 50% and 69%; high risk if 'yes' scores were below 49%.

Data extraction and analysis

Data extraction was performed using an electronic Microsoft Excel spreadsheet previously piloted by two researchers (FF and FC). Piloting involved building an electronic spreadsheet with data extraction fields and extracting related data from some included manuscripts. A discussion on emerged concerns or disagreements took place among authors, ultimately providing researchers with an instrument that allows for the extraction of data of interest, as described in the review protocol. This also ensures consistency among researchers during formal data extraction.

Details about extracted data are reported in Table 3 of the supplementary file. One researcher extracted data (LB) in an unblinded manner, and a second reviewer (AM) checked the correctness of the data. A discussion with a third author (VM) was used to resolve any inconsistencies. This cross-verification process guaranteed the reliability of data extraction. General information, study characteristics, and data related to the research questions of the review were preliminarily and descriptively synthesized. To explore the effect of telemonitoring strategies on both one-year all-cause mortality and one-year rehospitalization, studies were synthesized through meta-analyses using ProMeta® free software when feasible, i.e., when at least two studies with the same outcomes could be pooled. The Odds Ratio (OR) or Risk Ratio (RR) were calculated as the principal effect size using the random-effect model as a conservative approach to account for different sources of variation among studies. The level of heterogeneity was explored and quantified through Cochran's Q-test and I^2, respectively. In this regard, a significant Q-test value ($p \leq 0.05$) indicates the presence of heterogeneity, while the threshold for considering heterogeneity as substantial was 50%.[26] To explore the robustness of results, a sensitivity analysis was performed by removing each study from the meta-analysis.[26] To detect the possible role of the study design in determining the heterogeneity, a subgroup analysis was performed testing this variable.

The publication bias was assessed through funnel plots, the test for their asymmetry (Begg and Mazumdar's rank correlation and Egger's linear regression method), and the computation of the failsafe number, if needed. Data that could not be included in the quantitative synthesis were narratively synthesized.

Results

The electronic searches in the scientific databases identified 2347 potentially relevant records. Duplicates and references without abstracts were removed, and 1284 titles and abstracts were assessed for eligibility. One hundred and seven available full texts were then analysed and 61 of them were included in the systematic review, with 17 included in the meta-analyses. The PRISMA flowchart (Fig. 1) provides detailed information about the search and selection process.

Characteristics of the included studies

The 61 included studies (Table 1) were published from 2004 to 2020 and conducted mainly in USA (n = 16, 26.2%), Italy (n = 10, 16.4%), and the Netherlands (n = 7, 11.5%). Most of them were randomized controlled trial (n = 39, 63.9%), followed by prospective (n = 8, 13.1%) and retrospective (n = 7, 11.5%) observational studies. Overall, 22198 heart failure patients were involved in the research experiences, with a size of study samples ranged from 20 to 1653.

The mean and median age were reported for 16782 and 3942 patients, respectively.

The average age ranged from 52.0 to 81.4 years while the median age

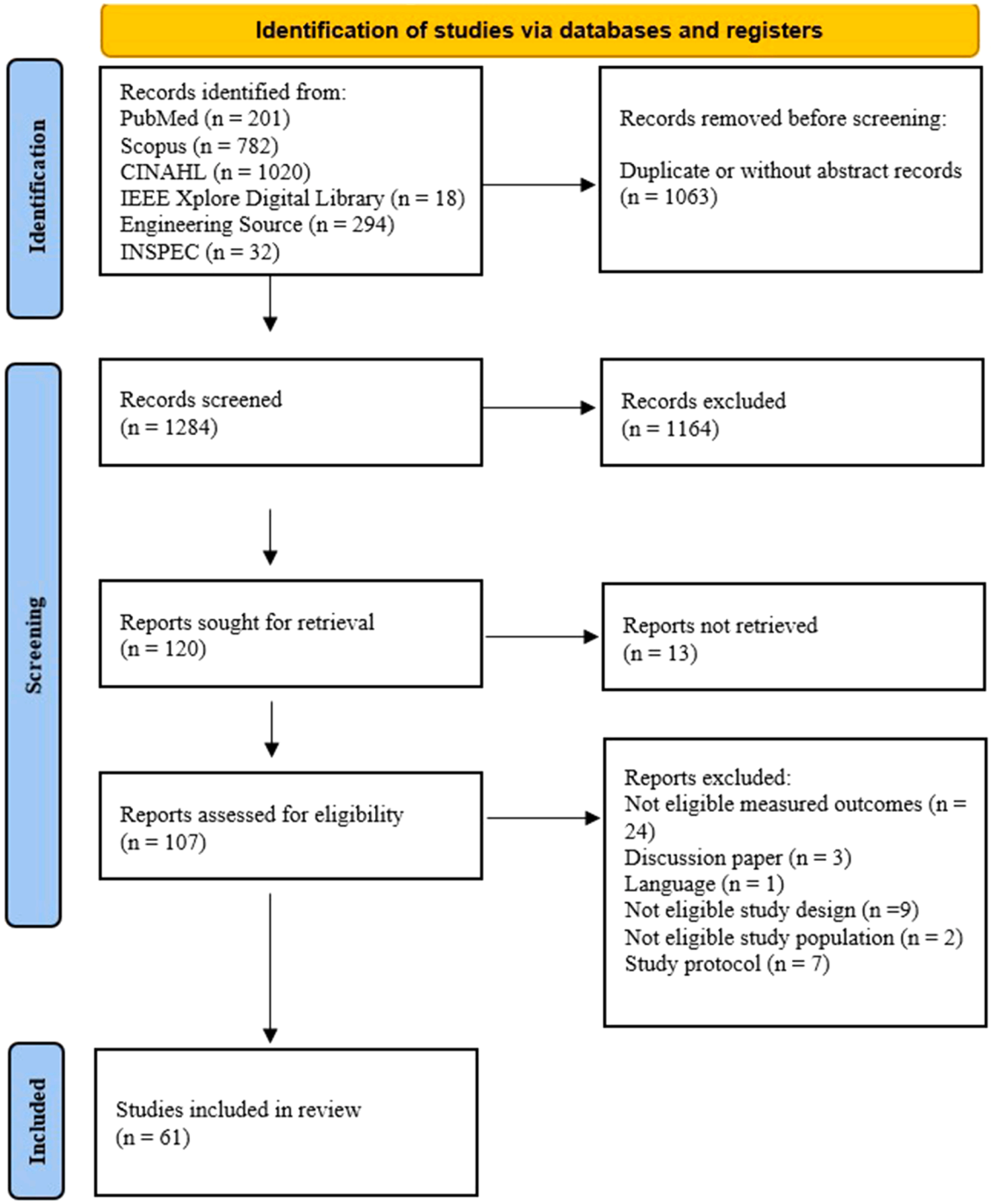

Fig. 1. PRISMA flow chart.

Table 1
Characteristics of included studies ($n = 61$).

ID	Author	Year	Country	Study design	Aim	Setting	Care model case	Care Model Control	Sampling
1	Agboola	2015	USA	Observational retrospective	To evaluate the effect of a heart failure telemonitoring program, Connected Cardiac Care Program (CCCP), on hospitalization and mortality.	Massachusetts General Hospital	CCCP	Usual care	Convenience
2	Antonicelli	2010	ITA	RCT	To explore adherence to prescription of b-blockers over time in elderly CHF patients undergoing home telemonitoring compared with those receiving standard care from a specialized CHF management team and to determine if there were any differences in mortality and rate of re-admission to hospital between these two groups.	Centre of Telemedicine of the Italian Research Centre on Aging in Ancona and the Italian Institute for Auxology in Milan, Italy	Telemonitoring	Contacted monthly by telephone, seen in the CHF outpatient clinic every 4 months	Randomized
3	Antonicelli	2008	ITA	Prospective study	To explore whether, as compared to standard care from a specialized CHF management team, the addition of home telemonitoring to an integrated CHF patient care system may reduce mortality and rate of re-admission to hospital in elderly CHF patients.	Italian National Research Centre on Ageing Hospital	Telemonitoring	Usual care	Convenience
4	Balk	2008	NL	RCT	To evaluate the effects of guidance provided by the MOTIVA system, in patients with chronic heart failure.	8 Dutch hospitals	Motiva system	Usual care	Randomized
5	Blum	2014	USA	RCT	To address a number of shortcomings of the early studies of home telemonitoring. As one of the projects, we hypothesized that centrally monitoring weight, blood pressure, and heart rate, and being able to act on that information quickly, would prevent many hospitalizations related to fluid overload. Furthermore, we looked at the effect of home monitoring on 30-day readmission rates, mortality, and health-related quality of life measures.	University of Maryland Medical Center	Remote monitoring	Usual care	Randomized

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Table 1 (*continued*)

ID	Author	Year	Country	Study design	Aim	Setting	Care model case	Care Model Control	Sampling
6	Bogyi	2019	HUN	Observational retrospective	To investigate the effects of remote monitoring on mortality in an optimally treated heart failure patient population undergoing CRT-D implantation.	Medical Centre of the Hungarian Defence Forces	Remote monitoring	The control group consisted of CRT-D recipients, who were followed up in our outpatient device clinic without remote monitoring.	Convenience
7	Boriani	2017	ITA	RCT	To evaluate whether RM may be of higher clinical and/or economic value compared with standard follow-up strategies.	Europe and Israel	Carelink monitor	the Standard arm received only in-office visits every 4 months.	Randomized
8	Bowles	2009	USA	Prospective study	To compare the effects of evidence-based disease management guidelines delivered to patients with HF and diabetes using three different modalities: in-person visits alone (Control), in-person visits and telephone intervention (Telephone) and in-person visits and telemonitoring (Telemonitoring).	Four agencies in Pennsylvania	Sentry III, Honeywell hommed, Inc.; Vitelcare Turtle, Visual Telecommunications Network, Inc.; Aviva 1010, American telecare Inc.; digital stethoscope and videoconferencing	All patients, regardless of group assignment, received home nursing guided by the appropriate evidence-based disease-management protocol for HF, diabetes or both	Randomized
9	Boyne	2014	NL	RCT	To analyze the effects of telemonitoring on disease specific knowledge, self-efficacy, self-care and adherence.	Outpatient clinic of one of three hospitals in the South of the Netherlands	Health Buddy system	Usual care	Randomized
10	Boyne	2012	NL	RCT	There is a need for innovative strategies to reduce heart failure hospitalizations.	Three hospitals in The Netherlands	The patients in the intervention arm received a device, with a liquid crystal display and four keys, connected to a landline phone.	Usual care	Randomized
11	Capomolla	2004	ITA	RCT	To evaluate the outcomes of this approach and compare them with those of the usual program of care after discharge from an HFU.	NA	Telemonitoring	Usual care	Randomized
12	Chaudhry	2010	USA	RCT	Determine whether telemonitoring would reduce the combined endpoint of readmission or death from any cause among patients recently hospitalized for heart failure.	33 cardiology practices across the US	Telemonitoring	Usual care	Randomized
13	Cleland	2005	UK	RCT	We sought to identify whether home telemonitoring (HTM) improves outcomes compared with nurse telephone support (NTS) and usual care (UC) for patients with heart failure.	Germany, the Netherlands, UK	Nurse telephone support + home telemonitoring	Usual care	Randomized
14	Comín-Cole	2015	ESP	RCT	To evaluate the impact of adding	Hospital del Mar Research Institute	Tele health	Usual care	Randomized

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Table 1 (*continued*)

ID	Author	Year	Country	Study design	Aim	Setting	Care model case	Care Model Control	Sampling
					telemedicine to a multidisciplinary HF programme.				
15	Dar	2009	UK	RCT	To determine if home telemonitoring of the signs and symptoms of typical heart failure patients recently discharged from hospital could reduce the risk of all-cause re-hospitalization, when compared with usual specialist care (UC).	Three acute hospitals in urban, multi-ethnic Northwest London	Honeywell hommedtm	Usual care	Randomized
16	De Simone	2015	ITA	Quasi-experimental	Test the hypothesis that remote monitoring can reduce death from any cause and cardiovascular hospitalizations in HF patients who receive ICD/CRT-D.	25 Italian centres	Remote monitoring	Usual care	Convenience
17	Delaney	2010	USA	Pre–post study	The primary aim of this pilot study was to gather preliminary information regarding the feasibility of a nurse-directed multicomponent home care intervention using evidence-based protocols designed in previous trials to teach HF self-management and to prevent/reduce depression and a telemonitoring (TM) system in preparation for a larger randomized trial. The secondary aim of this study was to investigate the possibility that such an Intervention might improve quality of life (QOL), prevent/reduce depressive symptoms, and reduce hospitalizations.	Large multibranch Medicare certified non-profit home care agency in Connecticut	The HEART program	Usual care	Convenience
18	Delaney	2013	USA	RCT	To examine the influence of an Intervention combining telemonitoring (TM) and self-care education on the frequency hospitalization in adults with HF following home care. Secondary outcomes included quality of life (QOL) and HF knowledge.	Large multibranch home care agency in Connecticut	Telemonitoring	Usual care	Randomized
19	Delaney	2014	USA	Quasi-experimental	The purpose of this study was to develop,	A large multibranch home care agency	Home care education, Assessment, Remote-	Usual care	Convenience

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Table 1 (*continued*)

ID	Author	Year	Country	Study design	Aim	Setting	Care model case	Care Model Control	Sampling
					implement, and test the efficacy and feasibility of the Home Care Education, Assessment, Remote-Monitoring, and Therapeutic Activities (HEART) program.	with two urban and two suburban offices	monitoring, Therapeutic activities		
20	Dierck	2015	UK	Observational retrospective	The aim of the present analysis was to investigate the impact of HTM compared to usual care on prescription rates of guideline HF medication, hospitalisation rates and all-cause mortality.	National (UK) Health Service	HTM	Usual care	Convenience
21	Ding	2020	AUS	RCT	This study aimed to examine whether the ITEC—CHF program improved patient compliance with weight monitoring as well as other self-management behaviors and health outcomes.	Two trial sites in Australia: one in Victoria (VIC) and one in Western Australia (WA)	ITEC-CHF	Usual care	Randomized
22	Domingues	2011	BRA	RCT	To compare two nursing intervention groups among patients hospitalized due to decompensated HF.	Tertiary university hospital in Porto Alegre, Brazil	Telephone monitoring	Usual care	Randomized
23	Frederix	2018	BEL	RCT	Whether an initial six-month CHF telemonitoring programme could induce long-term health benefits and cost savings once the tele intervention stopped.	Belgium	Telemonitoring	Usual care	Randomized
24	Galinier	2020	FRA	RCT	To assess the effect of a telemonitoring programme vs. standard monitoring in preventing all-cause deaths or unplanned hospitalisations over 18 months of follow-up in patients with HF.	France	Telemonitoring	Usual care	Randomized
25	Geller	2019a	GER	RCT	The present IN-TIME subanalysis explores difference between ICD and CRT-D patients in the endpoint rate and in the benefit of telemonitoring.	Heart Center Leipzig, Germany. 36 investigational sites in seven countries	Lumax ® dual-chamber ICD capable of automatic daily multiparameter telemonitoring	Usual care	Randomized
26	Geller	2019b	GER	RCT	The present IN-TIME subanalysis explores difference between ICD and CRT-D patients in the endpoint rate and in the benefit of telemonitoring.	Heart Center Leipzig, Germany. 36 investigational sites in seven countries	Lumax ® CRT-D capable of automatic daily multiparameter telemonitoring	Usual care	Randomized
27	Gingele	2017	NL	Observational retrospective	To investigate potential long-term	Three hospitals in the Netherlands	Health Buddy system	Control patients had four	Convenience

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Table 1 (*continued*)

ID	Author	Year	Country	Study design	Aim	Setting	Care model case	Care Model Control	Sampling
					effects of telemonitoring.	(Maastricht, Heerlen, Sittard)		personal contact moments with a HF specialist.	
28	Giordano	2009	ITA	RCT	To determine whether a multidisciplinary home-based telemanagement programme would reduce hospital readmission rate and costs in CHF patients.	Cardiovascular rehabilitation departments of "Salvatore Maugeri" Foundation	Home-based telemanagement (HBT)	Usual care	Randomized
29	Hale	2016	USA	RCT	The primary goal of this randomized controlled pilot study is to compare the MedSentry medication monitoring system versus usual care in older HF adults in patients who recently completed a HF telemonitoring program.	Massachusetts General Hospital (MGH) or Brigham and Women's Hospital (BWH)	The medsentry Medication Management System	Usual care	Randomized
30	Hansen	2018	GER	Prospective study	We aimed to provide more evidence that quarterly automated follow-ups are non-inferior to follow-ups which involve personal physician contact in HF patients with recently implanted ICD/CRT-D devices over 12 months. Secondly, we aimed to determine whether the type of physician contact affected outcomes.	17 sites across Germany	Telemetry Merlin@home transmitter	Phone or visit	Randomized
31	Hindricks	2014	GER	RCT	We did the fluence of home moniToring on mortality and morbidity in heart failure patients with IMpaired lEft ventricular function (IN-TIME) trial to evaluate the incremental benefit of automatic multiparameter telemonitoring for patients with heart failure treated with an ICD or a CRT-D.	36 tertiary clinical centres, in Australia (1), Europe (33), and Israel (2)	Telemonitoring	Usual care	Randomized
32	Hoban	2013	USA	Prospective study	The purpose of this research study was to determine if there is a difference in hospital readmission rates, patient's perception of quality of life, and self-care behaviors, in HF patients who were telemonitored and those who were not.	Large, not-for profit HHA, which services five counties in the Philadelphia area	Telemonitoring	Usual care	Randomized
33	Kalter-Leibovici	2017	ISR	RCT	We aimed to evaluate the long-term effect of a countrywide comprehensive	Heart failure centers	Disease management	Usual care	Randomized

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Table 1 (*continued*)

ID	Author	Year	Country	Study design	Aim	Setting	Care model case	Care Model Control	Sampling
					disease management program among patients with chronic heart failure.				
34	Koehler	2011	GER	RCT	To investigate whether RTM would reduce mortality and hospitalizations in ambulatory chronic HF patients compared with usual care.	Clinical Trial Center Leipzig	Remote monitoring	Usual care	Randomized
35	Kotooka	2018	JPN	RCT	NA	A total of 27 centers participated in this study: 3 outpatient clinics, 4 provincial hospitals, 6 general hospitals in urban areas, 1 national center, and 13 university hospitals in Japan	Telemonitoring	Usual care	Randomized
36	Koulaouzidis	2018	UK	Observational retrospective	We hypothesised that the patients at high risk, and, hence, potentially with most to benefit, were those who had recently been diagnosed with HF, and we therefore assessed the effects of TM in patients who were recently diagnosed with HF with reduced ejection fraction (HFrEF) and had New York Heart Association (NYHA) class II–III symptoms.	Kingston-upon-Hull	Motiva system	Usual care	Convenience
37	Kraai	2016	NL	RCT	The aim of this study is to assess the effect of telemonitoring on top of an ICT-guided-DMS with an CDSS in patients with worsening HF on the combined endpoint of death, readmission and HR-QoL, compared to patients treated with ICT-guided-DMS and CDSS alone.	Ten Dutch hospitals	Telemonitoring	ICT-guided-DMS	Randomized
38	Krum	2013	AUS	RCT	The aim of this study was therefore to determine whether an automated telephone support system would improve quality of life and reduce death and hospital admissions for rural and remote heart failure patients.	Rural and remote areas of Australia	Usual care + Intervention	Usual care	Randomized
39	Kulshreshtha	2010	USA	Pilot study	The objective of this pilot study was (1) to determine whether RM could be successfully implemented in non-homebound HF patients, (2) to assess	Massachusetts General Hospital (MGH)	Remote monitoring	Usual care	Randomized

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Table 1 (*continued*)

ID	Author	Year	Country	Study design	Aim	Setting	Care model case	Care Model Control	Sampling
					satisfaction with RM among ambulatory HF patients, and (3) to obtain preliminary estimates of the 6-month hospital readmission rate between non-homebound patients who participated in an RM program and patients who either declined (non-participants) or were not offered the opportunity to participate (control).				
40	Kurek	2017	POL	Prospective study	This study aimed to analyze the impact of RM on mortality and hospitalization rate using an all-comers prospective observational registry from a high-volume cardiovascular center.	Department of Electrophysiology Hearth Centre, Leipzig (Germany)	The RM group included the following devices: carelinktm (Medtronic, Minneapolis, merlintm MN, USA): 5.1 % (St. Jude Medical, St. Paul, MN, Monitoringtm USA): 72 % and Home (Biotronik, Berlin, Germany): 22.9 %	NA	Convenience
41	Lehmann	2006	USA	Pilot study	To measure the impact of managing CHF patients via telehealth technology on overall healthcare utilization, including physician visits, ED visits, and hospital readmissions.	Centers for Medicare and Medicare Services	Vital sign technology	Telephone to report vital signs	Randomized
42	Leng Chow	2019	SGP	Quasi-experimental	Our study aimed to compare the effectiveness of telemonitoring over structured telephone support in reducing heart failure-related healthcare utilization.	Changi General Hospital (CGH)	Telemonitoring	Structured Telephone Support (STS)	Convenience
43	Mizukawa	2019	JPN	RCT	The purpose of the present study was to compare the effectiveness of CM and SM with usual care in improving psychosocial status (as assessed by QOL, self-efficacy, and self-care behavior scores) among patients who experienced hospitalization for HF. We also compared their effectiveness in reducing rehospitalization and all-cause mortality within 24 months.	Five acute care hospitals in Hiroshima Prefecture, Japan	Collaborative Management (CM)	Usual care / Self-Management (SM)	Randomized
44	Mortara	2009	ITA	RCT	The objectives were as follows: (i) to evaluate the feasibility of this system in patients with HF; (ii) to compare the efficacy	Eleven centres in three European countries (UK, Italy, and Poland)	Telemonitoring	Usual care	Randomized

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Table 1 (*continued*)

ID	Author	Year	Country	Study design	Aim	Setting	Care model case	Care Model Control	Sampling
					of HT vs. usual care to reduce the cardiac events in HF patients at high risk of re-admission; (iii) to define the prevalence and the clinical relevance of home breathing disorders and abnormalities of heart rate variability.				
45	Myers	2006	USA	Prospective study	We implemented a home telemonitoring intervention among recently discharged patients with class III or IV CHF that consisted of daily patient self-monitoring and a daily phone call to the patient. We then compared use outcomes to a similar cohort of usual care patients within the same health care system.	Partners Home Care, Boston Massachusetts	Home telemonitoring	Usual care	Convenience
46	Negarandeh	2019	IRN	RCT	The aim of this study was to assess the effects of monitoring through telephone (tele-monitoring) on self-care behaviors and readmission of patients with HF after discharge.	The Grand Hospital of Dezful	Telemonitoring	Usual care	Randomized
47	Nouryan	2018	USA	RCT	The purpose of the present study was to attempt to isolate the effects of telemonitoring by enrolling patients in the outpatient setting, after completion of home care, when their condition was no longer being closely followed by a nurse monitor.	Biostatistic Department	Telemonitoring	Usual care	Randomized
48	Nunes-Ferreira	2020	PRT	Prospective study	To assess the feasibility and effectiveness of a telemonitoring (TM) programme in reducing hospitalization and mortality in a population with HF and reduced ejection fraction.	Tertiary hospital (Centro Hospitalar Universitário Lisboa Norte, Lisbon, Portugal)	Patients followed up prospectively with the support of non-invasive TM facilities	Usual care	Convenience
49	Olivari	2018	ITA	RCT	We aimed to explore the effectiveness of remote monitoring in elderly patients with heart failure, in Italy and Greece, early after hospital discharge.	Veneto Region	Telemonitoring	Usual care	Randomized
50	Ong	2016	USA	RCT	The objective of the Better Effectiveness After Transition–Heart failure (BEAT-HF) study was to	Six academic medical centers in California	Telemonitoring	Usual care	Randomized

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Table 1 (*continued*)

ID	Author	Year	Country	Study design	Aim	Setting	Care model case	Care Model Control	Sampling
					evaluate the effectiveness of a care transition intervention using remote patient monitoring in reducing 180-day all-cause readmissions.				
51	Pedone	2015	ITA	RCT	The current study was planned to evaluate whether a telemonitoring system providing information directly to the physician in charge of individuals' care and including telephone support could prevent hospital readmissions and death in elderly adults with HF.	Geriatric acute care ward of a teaching hospital, and outpatient clinic of the same hospital	Telemonitoring	Usual care	Randomized
52	Piotrowicz	2020	POL	RCT	To determine whether potential improvements in functional and quality of- life outcomes after a 9-week training period translate into improvement in clinical outcomes during the extended follow-up of 12 to 24 months, compared with usual care (UC).	Five centers in Poland: the Institute of Cardiology in Warsaw (coordinating center), the Silesian Center for Heart Diseases in Zabrze (site 2), Medical University of Gdansk (site 3), Medical University of Lódz (site 4), and Medical University of Warsaw (site 5)	Hybrid Comprehensive TeleRehabilitation (HCTR)	Usual care	Randomized
53	Radhakrishnan	2013	USA	Observational retrospective	We have investigated the associations between the characteristics of patients with HF and re-hospitalization during a 60-day period of telemonitoring after discharge from hospital.	New England	Tele health	NA	
54	Scalvini	2005	ITA	Prospective study	The aim of the present study was to analyse the costs of a home-based intervention with a telecardiology system in CHF patients.	Division of Cardiology "Salvatore Maugeri" Foundation, Brescia	Home-Based Telecardiology (HBT)	Usual care	Convenience
55	Seto	2012	CAN	RCT	The objective of our randomized controlled trial was to perform an in-depth investigation of the effects of a highly automated and user-centered mobile phone-based telemonitoring system on self-care and clinical management, with the aim of improving heart failure outcomes.	University Health Network (UHN) Heart Function Clinic in Toronto, Ontario	Telemonitoring	Usual care	Randomized
56	Sohn	2012	GER	Observational retrospective	The aim of this article was to perform a health	Germany	Telemedicine for the Heart	Usual care	Convenience

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Table 1 (*continued*)

ID	Author	Year	Country	Study design	Aim	Setting	Care model case	Care Model Control	Sampling
					economic cost–cost analysis by comparing an intervention group of program participants with a matched control group.				
57	Veenstra	2015	NL	Pre–post study	The first objective of this study was to assess the impact of telehealth-based disease management on unplanned admissions, disease severity and quality of life in CHF patients.	CHF outpatient unit of a local community hospital in the north of the Netherlands	Motiva system	NA	Convenience
58	Vuorinen	2014	FIN	RCT	The objective of this study was to investigate whether the multidisciplinary care of HF patients could be improved with telemonitoring at the Cardiology Outpatient Clinic of Helsinki University Central Hospital (HUCH), primarily in terms of reducing HF-related hospitalizations.	Cardiology Outpatient Clinic of HUCH	Telemonitoring	Usual care	Randomized
59	Wade	2011	USA	RCT	The goal was to assess impact on outcomes and quality of life, and also to assess the feasibility of utilizing an Internet-based telemonitoring technology to facilitate CM in an elderly HF population with multiple comorbidities.	Aetna Medicare Advantage	Tele health	Usual care	Randomized
60	Wagenaar	2019	NL	RCT	In our study we evaluated (i) an interactive platform for HF disease management (the e-Vita platform) with telemonitoring facilities, replacing routine consultations, and (ii) the HFM website. Both were compared to UC. The primary outcome was self-care and the secondary outcomes health status, hospitalizations and all-cause mortality.	Nine Dutch HF outpatient sclinics	'Heartfailurematters.org' website group + *E*-health adjusted care pathway group	Usual care	Randomized
61	Yanicelli	2020	ARG	RCT	To validate the HTS for the first time in a real setting, its effectiveness to improve self-care and treatment adherence of HF patients.	Not reported	Telemonitoring	Usual care	Randomized

ranged from 61 to 77 years.

Heart failure classification based on NYHA class was reported for 20249 patients. Fourteen studies included patients ($n = 7360$) with all NYHA classes, 19 included only II, III, and IV classes ($n = 6496$), and 16 included 5205 patients with I, II, or III classes.

Narrative results on patient outcomes

Of the 22198 patients included in the review, 15922 patients were included in the narrative synthesis. Patients included in telemonitoring were 7791 (Case), while 7845 were involved in usual care path for heart failure treatment (Controls) (Table 4 of the supplementary file).

Telemonitoring and mortality

When considering mortality, 1026 death were reported among patients exposed to telemonitoring and 1106 among controls. An overall heterogeneity was detected on both telemonitoring application modalities and follow-up periods. Nevertheless, some authors found telemonitoring to be protective against mortality.[28–31] In details, when telemonitoring was based on the daily transmission of some clinical data (pacing impedances, bradycardia, tachycardia, and cardiac resynchronization therapy statistics, mean heart rates, patient activity, and heart rate variability, as well as relevant clinical events) it showed to reduce the patients' mortality at six months (HR = 0.368, 95% CI = 0.186–0.72; $p = 0.004$) as showed by Bogyi and colleagues. A similar effect was reported after 30 days of observation by Ong and colleagues through a daily physiological parameters transmission and telephone coaching (RR = 0.53, 95% CI = 0.31–0.93; $p = 0.03$). Sohn and colleagues showed a reduction of mortality rates in patients cared with a telemonitoring technology based on nurses' telephone calls and recording of blood pressure, pulse, and body weight (8.5% vs. 13.2%; $p < 0.05$). Finally, De Simone and colleagues (2015) reported an improvement in patient survival likelihood after 12 months of utilization of implanted cardiac devices (HR = 0.53, 95% CI = 0.31–0.88; $p = 0.015$).

Conversely to these positive results, most of studies documented a general lack of effectiveness of telemonitoring in reducing patients' mortality (Table 5 of the supplementary file).

Telemonitoring and rehospitalization

The total number of rehospitalized patients included in telemonitoring programs were 824, while those rehospitalized during the usual care programs were 764. Anyway, some authors found telemonitoring to be effective in preventing rehospitalization.[29,32–34] Comi'n-Colet and colleagues (2016) showed the protective power of telemonitoring based on the collection of patients' biometric data (weight, heart rate and blood pressure) and symptoms reporting against rehospitalization during 6 months of follow-up on 188 patients (HR = 0.39, 95% CI = 0.19–0.77; $p = 0.007$).

De Simone and colleagues (2015) reported similar results at 12 months follow-up of 987 patients exposed to implanted cardiac devices (HR = 0.59, 95% CI = 0.41–0.86; $p = 0.006$). Also, telemonitoring based on a remotely monitored electronic pillbox showed to be protective against rehospitalization (RR = −82%; $p = 0.04$) on 25 patients observed for 90 days.[33]

Finally, Mizukawa and colleagues, showed the protective power of telemonitoring based on self-management education and non-invasive daily measurement of physiological parameters in reducing number of patients rehospitalized during a follow-up lasted up to 24 months on 57 patients ($p = 0.048$). Also in this case, most of the studies showed a lack of effectiveness of telemonitoring models in reducing the considered outcome (Table 6 of the supplementary file).

Meta-analyses of studies documenting one-year all-cause mortality

All studies reporting one-year all-cause mortality (Table 7 of the supplementary file) were included in the meta-analysis.[35–48] Meta-analysis confirmed data documented by other authors[28–31] in supporting the protective power of care models based on telemonitoring regarding one-year all-cause mortality (OR = 0.54, 95% CI = 0.39–0.76) with sensitivity analysis showing a stability in the effect size (range 0.50–0.59) meaning that the overall result was not significantly influenced by a single study (Fig. 2).

The meta-analysis demonstrated a substantial and significant level of heterogeneity (Q-test $p < 0.05$; $I^2 = 56.39$).

To explore the heterogeneity, a subgroup analysis based on study designs was performed (Fig. 3). The analysis showed no significant differences in the effect size obtained using different study designs (ANOVA Q-test = 1.99; $p = 0.37$) that means heterogeneity was not affected by this variable.

Meta-analyses of studies documenting one-year number of rehospitalized patients

All studies reporting one-year number of rehospitalized patients (Table 7 of the supplementary file) were included in the meta-analysis.[36–38,40–42,45–51] Meta-analysis result confirmed the data documented by other authors[29,32–34] in supporting the protective power of care models based on telemonitoring regarding one-year rehospitalization (OR = 0.56, 95% CI = 0.40–0.80) with sensitivity analysis showing a stability in the effect size (range 0.53–0.69) meaning that the overall result was not significantly influenced by a single study (Fig. 4). However, a substantial and significant level of heterogeneity was detected (Q-test $p < 0.05$; $I^2 = 77.79$).

To explore the heterogeneity, a subgroup analysis based on study design was performed (Fig. 5). The analysis showed that study designs did not affect heterogeneity (ANOVA Q-test = 2.83, $p = 0.24$)

Further explorative analysis

Since it was not possible to identify the cause of heterogeneity through subgroup analysis, the authors hypothesized that the content of the telemonitoring care models could have played a crucial role in determining the observed level of heterogeneity in the meta-analyses presented in this manuscript (Tables 8 and 9 of the supplementary file). Therefore, a series of meta-analyses were conducted by aggregating the studies for common telemonitoring strategy (Table 2).

Care models and one-year all-cause mortality

Patients cared with electrocardiogram remote transmission[36,38,45–47] reported a reduced probability of one-year all-cause mortality (RR = 0.56, 95% CI = 0.41–0.78; Q-test $p = 0.34$, $I^2 = 10.85$). This result emerged also considering remote transmission of patient's physiologic parameters (OR = 0.56, 95% CI = 0.40–0.78; Q-test $p = 0.33$, $I^2 = 12.26$).[35,36,41,44–46,48] Finally, aggregating studies providing the remote evaluation of patients with implanted cardiac devices,[37,40] a reduced probability of death at one-year was confirmed (RR = 0.37, 95% CI = 0.23–0.61; Q-test $p = 0.99$, $I^2 = 0.00$). Studies describing telephone monitoring[35,36,38,42,47] and studies in which patient was cared based on a website educational program[39,48] showed not statistically significant protective results (RR = 0.61, 95% CI = 0.36–1.02; Q-test $p = 0.06$, $I^2 = 55.39$ and RR = 2.01, 95% CI = 0.86–4.67; $p = 0.107$, respectively). The meta-analyses based on care models did not demonstrate any significant level of heterogeneity except for care model including telephone monitoring. The sensitivity analysis performed by removing one study at time, showed substantial stability in results of performed meta-analyses except for that related to models including telephone monitoring, in which the non-significant results was conditioned by the study of Krum and colleagues.[42] (Table 10 of the supplementary file)

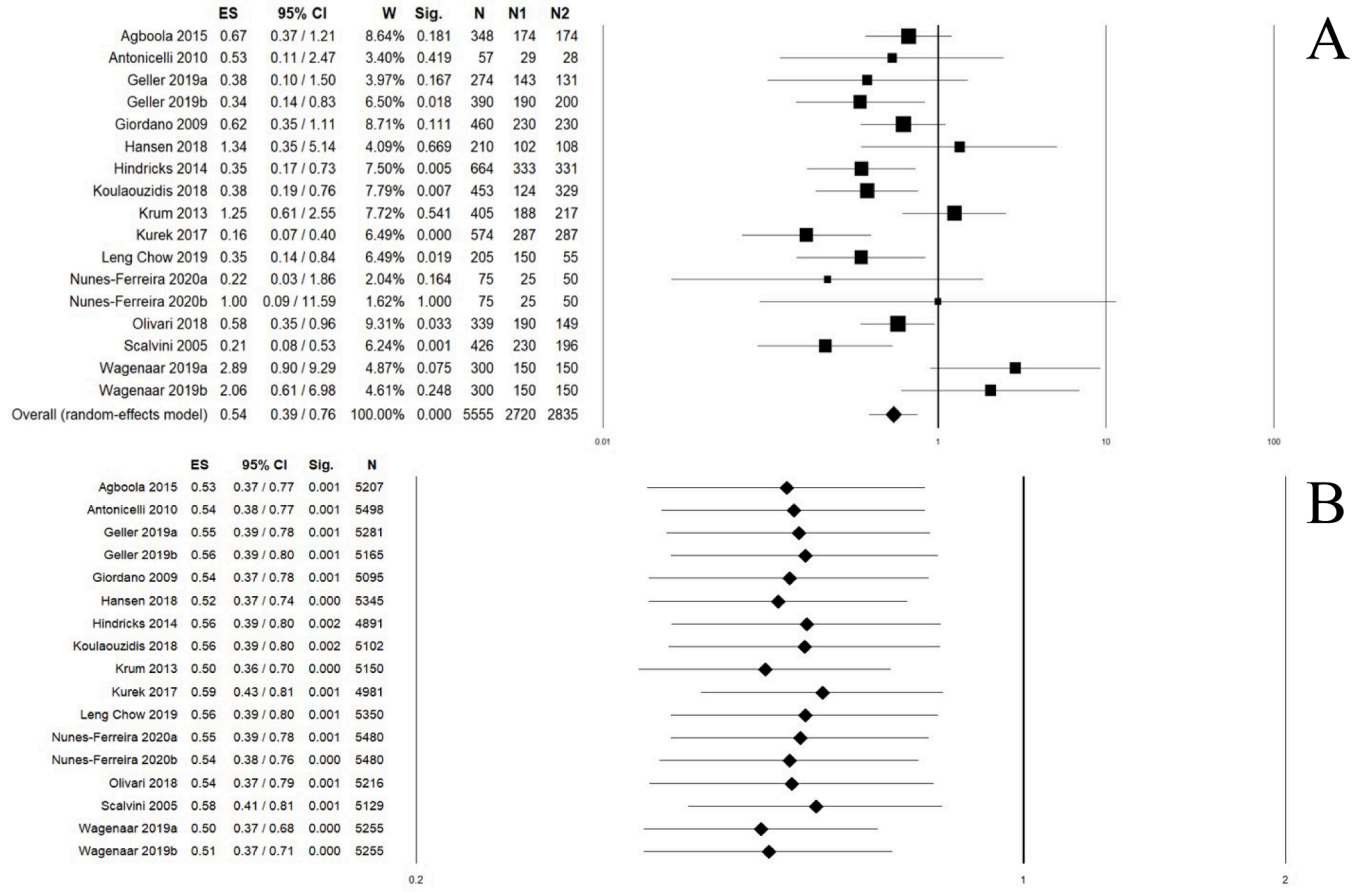

Fig. 2. A. Meta-analysis of studies reporting one-year all-cause mortality; B. Sensitivity analysis of studies reporting one-year all-cause mortality
Legend. ES = Effect size (Odds Ratio), 95 % CI = 95 % Confidence Interval, *W* = Weight, Sig. = Statistical significance, *N* = Total sample, N1 = Case, N2 = Controls; Heterogeneity statistics: Q-test = 36.69, df = 16, $p < 0.05$, $I^2 = 56.39$).

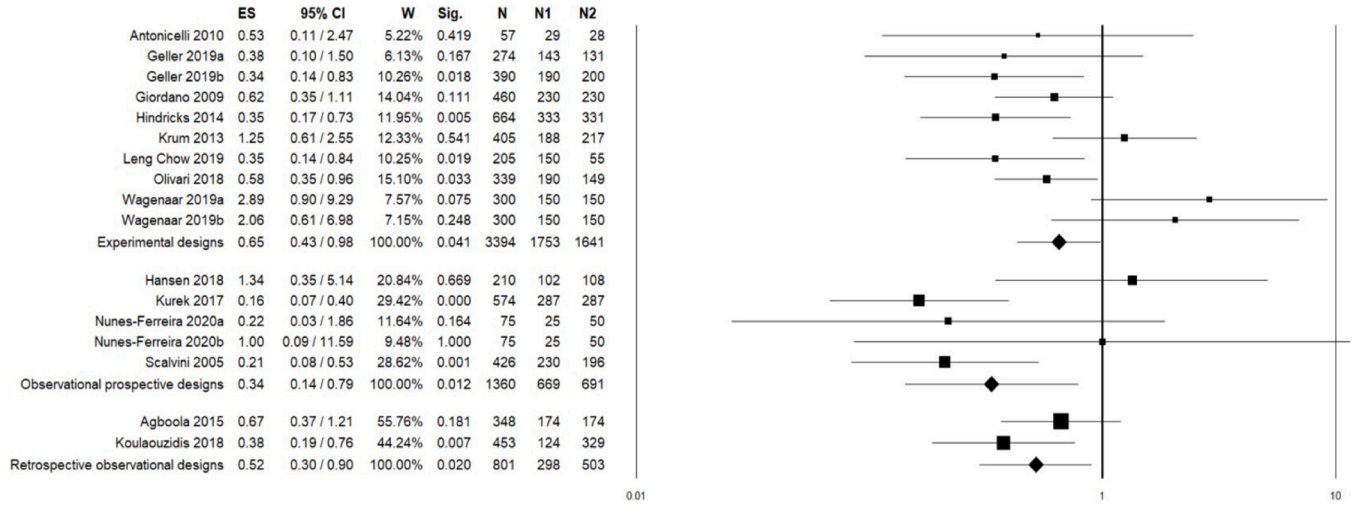

Fig. 3. Subgroup analysis based on study design (mortality)
Legend. ES = Effect size (Odds Ratio), 95 % CI = 95 % Confidence Interval, *W* = Weight, Sig. = Statistical significance, *N* = Total sample, N1 = Case, N2 = Controls; Heterogeneity statistics: ANOVA Q-test = 1.99, df = 2, $p = 0.37$.

Care models and one-year number of rehospitalized patients

Studies reporting electrocardiogram remote transmission[36,38,45,46,50] reported a reduced number of patients rehospitalized at one year (RR = 0.65, 95% CI = 0.49–0.86; Q-test $p < 0.05$, $I^2 = 63.31$). This result emerged also in studies describing the remote transmission of patient's physiologic parameters (RR = 0.40, 95% CI = 0.19–0.81; Q-test $p < 0.05$, $I^2 = 87.21$).[36,41,45,46,48–51] Finally, aggregating studies describing telephone monitoring,[36,38,42,47] a reduced number of patients rehospitalized at one-year was confirmed (RR = 0.62, 95% CI = 0.44–0.87; Q

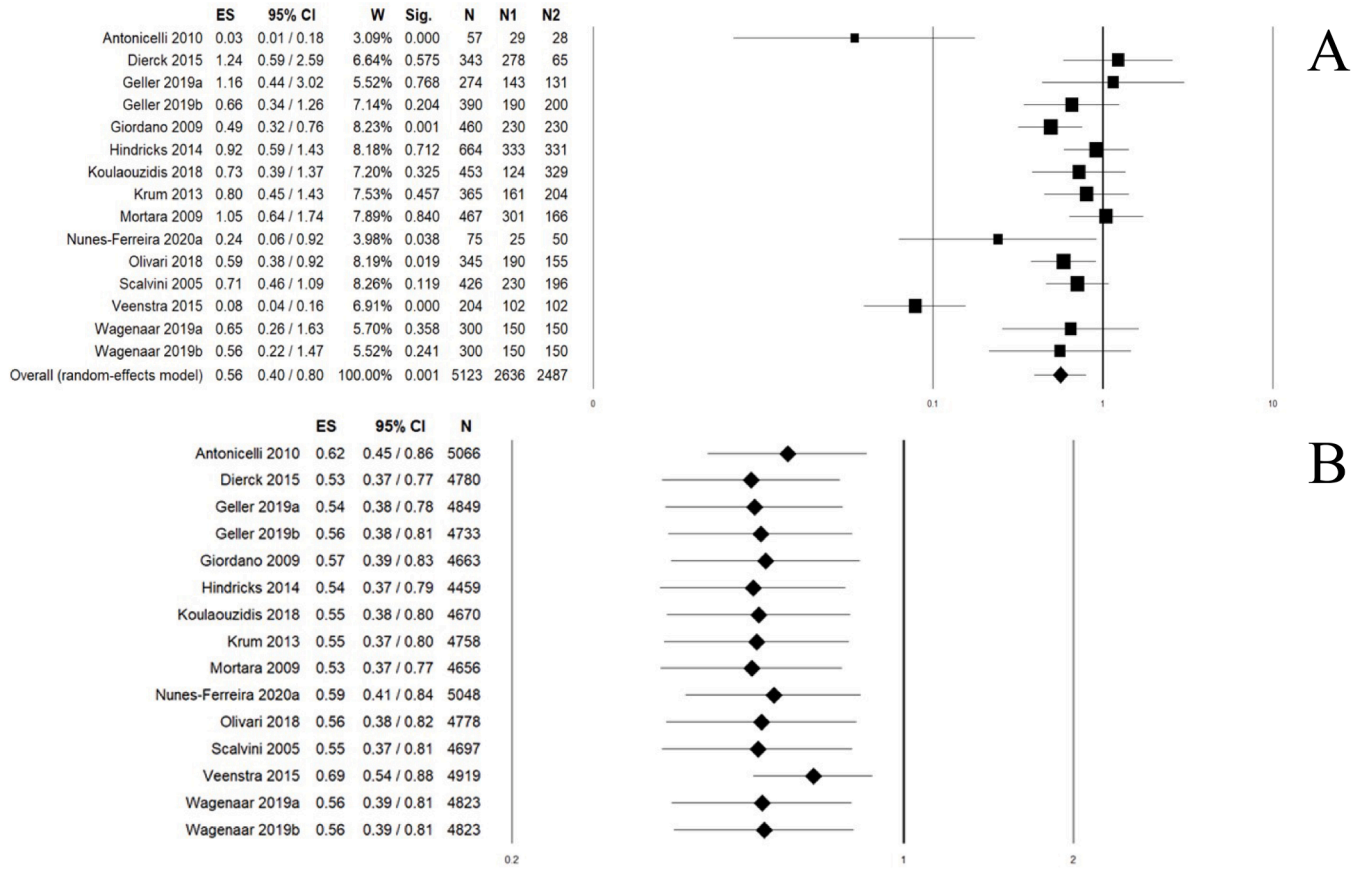

Fig. 4. A. Meta-analysis of studies reporting one-year number of rehospitalized patients; B. Sensitivity analysis of studies reporting one-year number of rehospitalized patients

Legend. ES = Effect size (Odds Ratio), 95 % CI = 95 % Confidence Interval, *W* = Weight, Sig. = Statistical significance, *N* = Total sample, N1 = Case, N2 = Controls; Heterogeneity statistics: Q-test = 63.04, df = 14, $p < 0.05$, $I^2 = 77.79$.

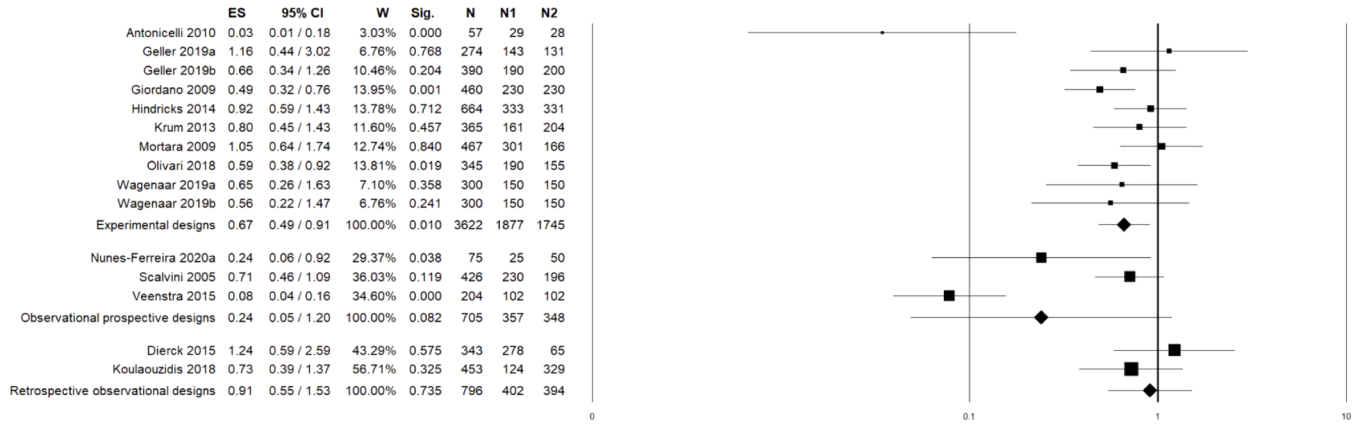

Fig. 5. Subgroup analysis based on study design (rehospitalized patients)

Legend. ES = Effect size (Odds Ratio), 95 % CI = 95 % Confidence Interval, *W* = Weight, Sig. = Statistical significance, *N* = Total sample, N1 = Case, N2 = Controls; Heterogeneity statistics: ANOVA Q-test = 2.83, df = 2, $p = 0.24$.

test $p < 0.05$, $I^2 = 63.89$). Even if studies have common care models, the heterogeneity remains substantial. Therefore, the protective effect of care models based on the transmission of the EKG and parameters, together with telephone intervention is confirmed although the result is influenced by a high heterogeneity. The sensitivity analysis performed by removing one study at time, showed a substantial stability in each performed meta-analyses except for that related to models including telephone monitoring, in which the non-significant results was conditioned by the study of Giordano and colleagues (Table 11 of the supplementary file).[38]

Risk of bias

Studies included in the meta-analyses were analyzed by Joanna Briggs Institute's critical appraisal tools specific for study design.[27] Judgement of risk of bias based on author's cut offs showed an average

Table 2
Common characteristics among care model of included studies.

One-year all-cause mortality
• Transmission and evaluation of patients' EKG. • Transmission and evaluation of physiologic parameters (at least blood pressure, heart rate, weight, and blood oxygen saturation). • Presence of implanted cardiac resynchronization therapy and defibrillator (CRT-D) or implantable cardioverter-defibrillator (ICD) devices. • Telephone monitoring. • Website-based educational programs.
One-year number of rehospitalized patients
• Transmission and evaluation of patients' EKG. • Studies reporting evaluation of relevant physiologic parameters (at least blood pressure, heart rate, weight, and blood oxygen saturation). • Telephone monitoring.

76% of 'yes' answers (Fig. 6). Specifically, six manuscripts showed a moderate risk of bias (50% – 69%) and eleven showed a low risk of bias (> 70%).

Publication bias in meta-analysis

The funnel plot and related test (Fig. 7) showed no evidence of publication bias (One year mortality: Egger's test, $t = 0.18$, $p = 0.869$, Fail Safe Number = 111; One year number of rehospitalized patients: Egger's test $t = -1.36$, $p = 0.198$, Fail Safe Number = 145).

Discussion

The results of meta-analyses have highlighted that, in general, the implementation of telemonitoring strategies in patients with heart failure can provide benefits. These include the reduction of all-cause mortality[35–48] and the number of hospital readmissions[36–38,40–42,45–51] within one year. Specifically, the positive prognostic impact of telemonitoring, which involves the transmission of clinical parameters such as electrocardiogram or vital signs, can be attributed to the capability to early recognize the patient's clinical deterioration and intervene promptly with personalized home-based care.[35–38,40,41,44–48] Recognizing early clinical signs of deterioration, contributes to the early identification of underlying causes which, in the absence of telemonitoring, might persist long enough to trigger a negative progression of physical conditions. This, in turn, permits the revision of the therapeutic plan and the implementation of additional educational interventions for the patient and family, ultimately decreasing the likelihood of dramatic disease progressions and inappropriate hospitalizations. However, evidence regarding the number of hospital readmissions within one year requires careful consideration. In contrast to findings related to mortality, meta-analyses on telemonitoring models, which involve the transmission of electrocardiogram or vital signs, even via telephone, have demonstrated substantial heterogeneity in effect sizes.[36,38,41,42,45–51]

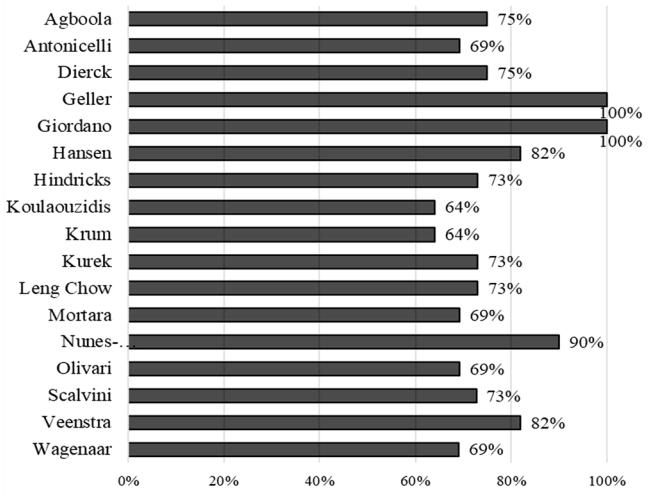

Fig. 6. Chart of risk of bias assessment.

This highlights a potential paradoxical effect induced by telemonitoring, occurring when there is an asymmetry between the patients' actual clinical conditions and the service's practical ability to manage them at home. Healthcare providers responsible for remotely interpreting the patient's clinical parameters may perceive the need for hospitalization due to the inability to manage new clinical conditions at home, either because of their severity or the unavailability of appropriate resources or personnel. While a potential increase in hospital readmissions may appear unfavourable, it is not inherently negative, particularly when such readmissions contribute to improved patient survival.

Regarding the effectiveness of telemonitoring utilizing implantable devices (e.g., pacemakers, implantable defibrillators) on one-year all-cause mortality, a significant protective effect of these technologies has been observed.[37,40] This can be attributed to their ability to address potentially lethal cardiac rhythm disorders, optimize heart rate, and continuously monitor the heart's electrical activity.[37,40]

While there is currently no unanimous consensus on the components of the telemonitoring model that establishes the gold standard for patients with heart failure,[1,38] the results of this systematic literature review emphasize that systems relying on the remote transmission of clinical parameters are a valuable tool to be considered for the home management of patients with heart failure.The potential to reduce mortality in these patients is indicative of a patient- and family-centered care approach, considering individual needs and promoting proactive management of their health conditions. Furthermore, telemonitoring has the potential to enhance the efficiency of care by reducing hospitalizations and emergency room visits,[38] improving access to care, and reducing inequalities in access to healthcare services. Additionally, it can facilitate the transition of patients from hospitals to home, promoting remote care and disease awareness while maintaining personal connections between patients and their care team.[45]

More than half of included studies were randomized controlled trial, providing a high level of evidence on the considered outcomes. The overall low or non-substantial risk of bias, detected in both randomized controlled trials and studies with other designs, enhances the reliability of the results from the meta-analyses. Moreover, the absence of publication bias represents a further strength of this work. The consideration of various databases (including non-clinical ones) maximized the chances of finding relevant studies. However, the absence of additional search strategies may have led to the omission of potentially relevant studies. Another limitation is represented by the residual heterogeneity after the exploratory meta-analytic approach, particularly concerning the outcome of the number of rehospitalized patients.

Implications for future research and practice

The findings of this study suggest that telemonitoring strategies should rely on the accurate collection and transmission of clinical data, tailored to the patient's characteristics. This approach is crucial not only to ensure patient- and family-centered care but also to guarantee the effectiveness and sustainability of the healthcare system.[5,6,8]

Telemonitoring strategies based on web-based educational programs did not demonstrate significant efficacy in reducing one-year all-cause mortality and the number of rehospitalizations. Besides, there was substantial heterogeneity in the effect sizes of studies investigating the effectiveness of telemonitoring based on the transmission of clinical data in reducing rehospitalization. Hence, it is necessary to further investigate the effectiveness of these telemonitoring strategies. Moreover, it would be beneficial to establish an evidence-based standardization of telemonitoring strategies, follow-up periods, and outcomes reporting.

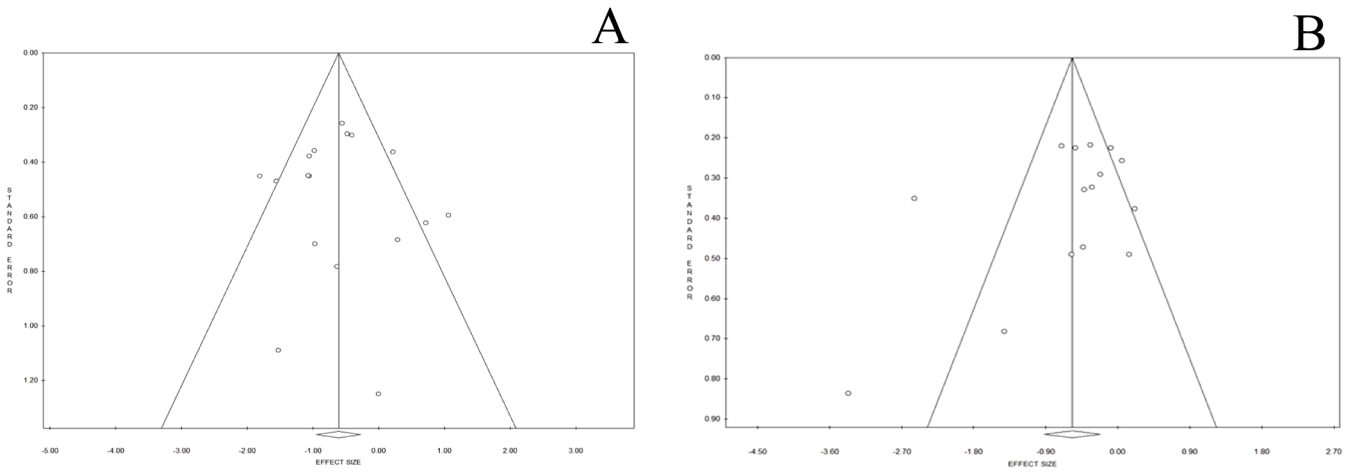

Fig. 7. A. Funnel plot to assess publication bias of meta-analized studies related to one-year all-cause mortality; B. Funnel plot to assess publication bias of meta-analized studies related to one-year rehospitalized patients.

Looking ahead, it is crucial to activate a virtuous circle in which literature informs clinical practice through high-quality studies,[1,16] and clinical practice stimulates research by implementing telemonitoring strategies tailored to specific patient characteristics (e.g., comorbidity, NYHA class) or organizational features (e.g., multidisciplinary service, skill-mix, nurses with advanced competence). This approach will enable a more robust meta-analytic synthesis before confidently asserting any hypotheses on the efficacy of telemonitoring.

Conclusion

Meta-analyses confirm the hypothesis that telemonitoring strategies are effective in reducing both all-cause mortality and the number of patients rehospitalized when compared with usual care strategies. Evidence from studies included in the narrative analysis partially confirms the effectiveness of telemonitoring in reducing mortality and the number of rehospitalized patients during the various follow-up periods investigated, despite their methodological heterogeneity. The heterogeneity detected in the meta-analyses needs to be overcome by performing studies that contemplate the application of similar monitoring strategies and care interventions in populations with similar clinical characteristics.

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CRediT authorship contribution statement

Vittorio Masotta: Data curation, Formal analysis, Investigation, Methodology, Validation, Visualization, Writing – original draft, Writing – review & editing. **Angelo Dante:** Data curation, Formal analysis, Methodology, Project administration, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing. **Valeria Caponnetto:** Data curation, Investigation, Validation, Visualization, Writing – original draft, Writing – review & editing. **Alessia Marcotullio:** Data curation, Investigation, Validation, Writing – original draft, Writing – review & editing. **Fabio Ferraiuolo:** Data curation, Investigation, Validation, Writing – original draft, Writing – review & editing. **Luca Bertocchi:** Data curation, Validation, Writing – original draft, Writing – review & editing. **Francesco Camero:** Data curation, Validation, Writing – original draft, Writing – review & editing. **Loreto Lancia:** Conceptualization, Investigation, Methodology, Project administration, Supervision, Validation, Writing – original draft, Writing – review & editing. **Cristina Petrucci:** Conceptualization, Investigation, Methodology, Project administration, Supervision, Validation, Writing – original draft, Writing – review & editing.

Declaration of competing interest

All authors declare no conflict of interest or competing interests.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.hrtlng.2024.01.003.

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