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Review

Telemonitoring of Real-World Health Data in Cardiology: A Systematic Review

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Abstract: (1) Background: New sensor technologies in wearables and other consumer health devices open up promising opportunities to collect real-world data. As cardiovascular diseases remain reason number one for disease and mortality worldwide, cardiology offers potent monitoring use-cases with patients in their out-of-hospital daily routine. Therefore, the aim of this systematic review is to investigate the status quo of studies monitoring patients with cardiovascular risks and patients suffering from cardiovascular diseases in a telemedical setting using not only a smartphone-based app, but also consumer health devices such as wearables and other sensor-based devices. (2) Methods: A literature search was conducted across five databases and the results were examined according to the study protocols, technical approaches and qualitative and quantitative parameters measured. (3) Results: Out of 166 articles, 8 studies were included in this systematic review. These cover interventional and observational monitoring approaches in the area of cardiovascular diseases, heart failure and atrial fibrillation using various app, wearable and health device combination. (4) Conclusions: Depending on the researcher's motivation a fusion of apps, patient reported outcome measures and non-invasive sensors can be orchestrated in a meaningful way adding major contributions to monitoring concepts for both, individual patients and larger cohorts.

Keywords: telemonitoring; telemedicine; telecardiology; cardiology; wearable; sensors; consumer health devices; cardiovascular disease; heart failure; atrial fibrillation

1. Introduction

Within the last decade, advances in sensor technology made a large number of wearables and further consumer health devices ready for the market. Both, leading technology companies and specialized manufacturers acknowledged a need for affordable and accessible integrated sensor technologies for fitness and health. They are serving this trend with significant investments in the emerging market [1]. One result is a progressive penetration of these technologies into a large proportion of the general public given that consumer health devices allow individuals to measure cardiac vital signs while working out or to self-monitor their own health status potentially promoting an individual's health behavior [2]. As these technologies becomes more widespread and sophisticated, there are many potential applications and use cases. Several of these involve monitoring individual patients' and entire cohort's physiology in the context of everyday life. This potential has been recognized by both, researchers and health care professionals as remote patient monitoring opens up new sustainable ways to support and care for patients in their homes [3–5]. Especially the field of cardiology can be considered as one of the most important fields of application, as integrated sensor technologies allow a variety of use cases following up with a patient's cardiovascular health status under real-world conditions avoiding clinical biases like white coat hypertension [6–8]. On the other hand, cardiovascular diseases is the leading cause of death in the European countries and therefore avoiding these have a huge impact of public health and the health system. For

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example, heart failure affects approximately 26 million people worldwide [9]. Once hospitalized, up to 25% of heart failure patients are readmitted within 30 days [10,11]. So, recognizing the worsening of heart failure and avoiding hospital admissions is a key quality metric for managing heart failure patients.

This also influenced the researchers of the Use Case Cardiology (UCC) of the HiGHmed [12] consortium when planning the integration of both institutional and cross-sectional heart failure (HF) related health care data in 2017. As part of an affiliated telemonitoring (TM) study the application of wearables in the follow-up care of HF patients is planned. The aim is to support patients and their physicians in the HF disease management while simultaneously aggregating health data from the "black box" home setting by equipping patients with wearables, complementary devices and patient-reported outcome measures (PROMs). The aggregated data will then be transferred into a Medical Data Integration Center and merged with the hospitals' electronic health records (EHR) to create a longitudinal dataset of HF patients. Therefore, it is the consortium's premise to develop and deploy low-threshold state of the art solutions. In doing so our premise is to passively observe the patients' disease progression retrospectively without requiring any additional intervention. Thus, our study focuses on latest consumer technologies which are suitable for everyday use.

In order to get an overview of recent research and technology related developments in the field the main objective of this systematic review is to investigate the status quo of studies monitoring patients with cardiovascular risks and patients suffering from cardiovascular diseases in a telemedical setting using not only a smartphone-based app, but also consumer health devices such as wearables and other sensor-based devices.

2. Materials and Methods

We performed a systematic review in order to identify published articles regarding telecardiological studies using consumer health devices to monitor patient's health status reported via a mobile app. We identified and evaluated the available literature in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) guidelines [13].

2.1 Search Strategy

We conducted this comprehensive and systematic search of five databases on literature published between 1st January 2001 and 31st March 2021. We identified relevant English-language publications searching *PubMed*, *Web of Science*, *CINAHL*, *Cochrane Library* and *Scopus*. We were searching for ("telemedicine" OR ("telecardiology" AND "cardiology" OR "cardiovascular disease") AND "app" OR "mobile application") as mandatory keywords. We provide detailed queries in *Table 1*.

Table 1. Our search queries as we executed them per database.

Database	Query
Pubmed	((telemedicine OR telecardiology [Title/Abstract]) AND (cardiology OR "cardiovascular disease"[Title/Abstract]) AND (app OR mobile application[Title/Abstract])) AND (("2001/01/01"[Date - Publication] : "2021/03/31"[Date - Publication]))
CINAHL	((telemedicine OR telecardiology [Title/Abstract]) AND (cardiology OR "cardiovascular disease"[Title/Abstract]) AND (app OR mobile application[Title/Abstract])) AND (("2001/01/01"[Date - Publication] : "2021/03/31"[Date - Publication]))
Cochrane	(telemedicine OR telecardiology):ti,ab AND (cardiology OR "cardiovascular disease"):ti,ab AND (app OR mobile application):ti,ab" with Cochrane Library publication date Between Jan 2001 and Mar 2021
Web of Science	(AB =((telemedicine OR telecardiology) AND (cardiology OR "cardiovascular disease") AND (app OR mobile application))) OR (TI=((telemedicine OR telecardiology) AND (cardiology OR "cardiovascular disease") AND (app OR mobile application)))[1]
SCOPUS	((ABS (telemedicine OR telecardiology) AND ABS (cardiology OR "cardiovascular disease") AND ABS (app OR mobile AND application))) OR ((TITLE (telemedicine OR telecardiology) AND TITLE (cardiology OR "cardiovascular disease") AND TITLE (app OR mobile AND application))) AND (LIMIT-TO (SRCTYPE , "j") OR LIMIT-TO (SRCTYPE , "p"))[2]

2.2 Inclusion and Exclusion Criteria

We intended to include articles matching the following criteria: (1) Primary studies dealing with (2) Telemedical concepts in (3) cardiovascular disease monitoring which used (4) consumer health devices such as wearables (5) or other none invasive sensors to (6) track patients' health data (7) with a smartphone app as a central user interface. Studies not considering both wearable and sensor generated data were excluded.

2.3 Selection and Data Extraction

We managed the retrieved articles of each search in before mentioned databases with Citavi 5[3]. First, we removed duplicates. Then, we identified relevant articles by screening all keywords, titles and abstracts based on our selection criteria. We excluded all records that did not clearly meet the eligibility criteria. Subsequently one experienced expert in the field of medical informatics assessed all potentially relevant and freely available full-text publications regarding the inclusion and exclusion criteria. In case of ambiguity, the articles were discussed with a second expert in the domain. While we conducted the full-text review, we identified potentially relevant references in the first-level results based on the context.

Studies which we considered ambiguous, with respect to the inclusion criteria, were discussed with a second expert in the field. For all articles included, consensus between both authors was reached through discussion.

2.4 Comparison criteria

[1] Search period was set via the UI of Web of Science.
[2] Search period was set via the UI of SCOPUS.
[3] Swiss Academic Software GmbH Citavi 5 Version 5.7.1.0.

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In order to compare the studies, we determined various comparison criteria and divided them into the three groups (1) study protocol, (2) technical parameters and (3) qualitative and quantitative parameters.

Study Protocol

This group includes the framework conditions of the publications giving an overview of the relevant studies. As this review focuses on cardiological diseases, the disease related use cases form an important criterion together with both sample sizes and study cohort sizes, study types and the minimum participation duration. In addition, the country in which the study was conducted as well as the application area distinguishing between local (e.g. Munich), regional (e.g. Bavaria) or national (e.g. Germany) were selected.

Technical Parameters

Comprising of whether study staff monitored inlcuding intervention i.e., actively intervene by adjusting a participant's treatment/therapy plan (e.g. due to changing measures or vital signs) or without intervention i.e., a passive observing character. Additionally, the platforms on which the patients' app was offered were included. The third and fourth technical criteria include the applied wearables and other none-wearable consumer health devices connected to the patients' app.

Qualitative and Quantitative Parameters

Following the group of technical parameters, this group focuses on parameters provided by (i) the patients, (ii) measured via a wearable or other consumer health device and (iii) data collected in a hospital setting by a physician including examinations and surveys. We further differentiated patient-reported data in patient-reported outcome measures (PROMs) and patient-generated health data (PGHD). PROMs, following the definition of Weldring et al., describe tools or instruments (e.g. standardized questionnaires) developed to ensure a valid and reliable measurement of patient-reported outcomes [14]. Accordingly, these can further be subdivided into the PROMs that (a) measure functional status, capture (b) health-related quality of life, (c) symptom and symptom burden, (d) personal experience of care, (e) health-related behaviors such as anxiety and depression as well as PROMS that cannot be assigned to any of the above mentioned groups because they are e.g. none-disjunct, summarized into (f) others. While according to Sharpio et al. patient-generated health data (PGHD) is defined as ‚health-related data including health history, symptoms, biometric data, treatment history, lifestyle choices, and other information created, recorded, gathered or inferred by or from a patient', in this review we focus on patient data documented into an app [15]. Finally, the specific vital signs provided by wearables and other consumer health devices were also included as a criterion while the frequency in which device-tracked parameters were captured was also taken into account.

3. Results

We identified 166 articles in our initial search (see supplementary materials). After we removed duplicates, a total of 157 articles were included for the title and abstract screening process. Among these, 31 articles seemed relevant and we performed a full-text review/evaluation, resulting in a total of seven articles being eligible and included in the study [16–22]. After we did a backward reference screening we included one additional article [23]. Finally, eight articles were included in this systematic review. The detailed selection process is illustrated as PRISMA flow diagram in *Figure 1*.

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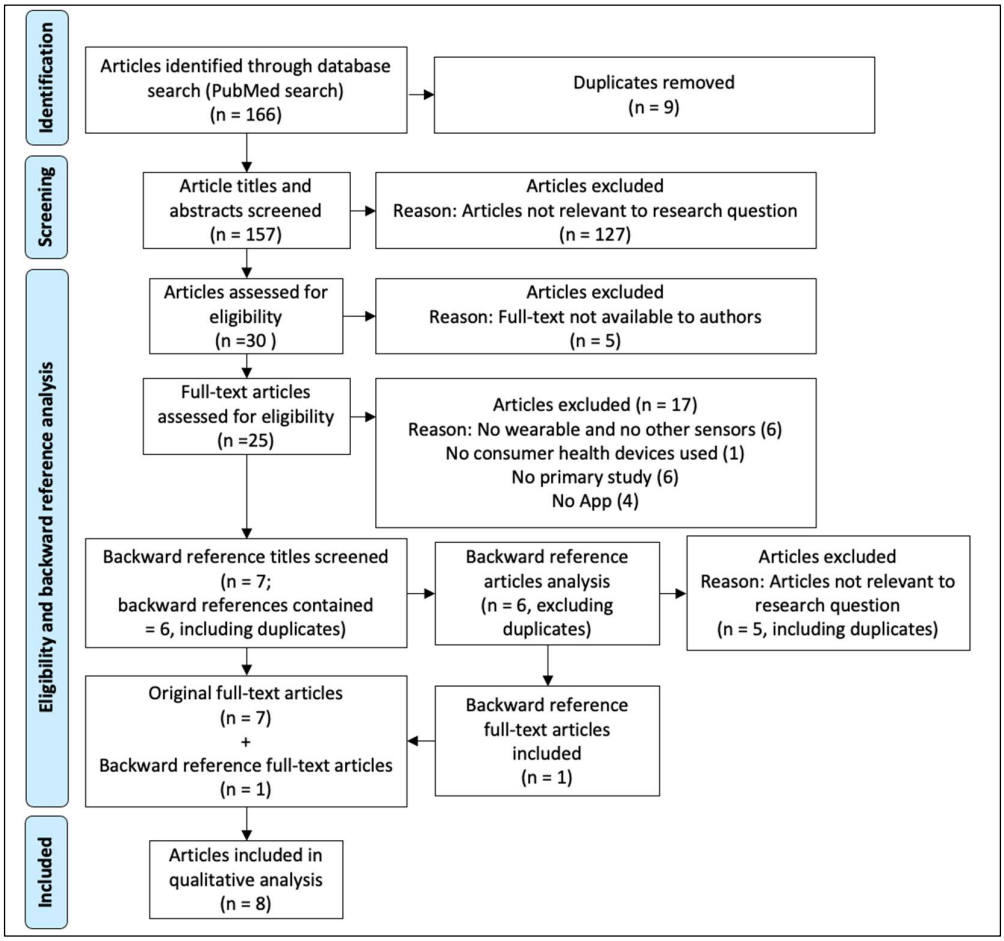

Figure 1. PRISMA flow diagram of the literature screening process.

The included articles describe studies with several different types of study design such as Proof-of-Concept studies (2 of 8; 25.0%) [19,22], Randomized Controlled Trials (2 of 8; 25.0%) [20,23], Cluster Randomized Trials (1 of 8; 12.5%), Longitudinal Cohort Studies (1 of 8; 12.5%) [16], Pilot Studies (1 of 8; 12.5%) [21], and Screening Studies (1 of 8; 12.5%) [17]. These studies were conducted in four different countries: three in the United States (37.5%) [18,19,21], two in China (25.0%) [16,17], two in Germany (25.0%) [22,23], and one in Canada (12.5%) [20]. Four studies enrolled on national (50.0%) [16,17,19,23] and four on local (50.0%) [18,20–22] levels while none of the included studies were conducted at the regional level. In terms of the use cases, Heart Failure was represented in three (37.5%) [20,22,23], cardiovascular disease in three (37.5%) [18,19,21] and Atrial Fibrillation in two studies (25,0%) [16,17]. The smallest study cohort comprised 10 partici.pants. The largest study included 246.541 participants. The minimum participation duration of all eight studies ranged from 14 days to 393 days. We provided an overview of the results *Table 2*.

 doi:10.20944/preprints202107.0702.v1

Table 2. Overview of the studies included in the systematic review with a focus on the study protocols.

Ref.	Country	Application Area	Study type	Disease	Sample size (Population size)	Participation Duration
Werhahn et al., 2019 [22]	Germany	local	Proof-of-Concept Study	Heart Failure	10 (10)	2 months
Wenger et al., 2019 [21]	USA	local	Pilot Study	Cardiovascular disease	14 (14)	6 months
Seto et al., 2020 [20]	Canada	local	RCT [1]	Heart Failure	74 (144)	3 months
Modena et al., 2018 [19]	USA	national	Proof-of-Concept Study	Cardiovascular disease	250 (250)	17 weeks
McManus et al., 2019 [18]	USA	local	Longitudinal Cohort Study	Cardiovascular disease	790 (4.095)	≥3 months
Guo et al., 2019a [17]	China	national	Screening Study	Atrial Fibrillation	187.912 (246.541)	≥14 days
Guo et al., 2019 [16] [24]	China	national	CRT [2]	Atrial Fibrillation	32.259 (32.259)	≥14 days
Koehler et al., 2018 [23]	Germany	national	RCT [1]	Heart Failure	796 (1.571)	365–393 days

[1] RCT, Randomized Controlled Trial; [2] CRT, Cluster Randomized Controlled Trial.

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With respect to the technical characteristics of the included studies, we identified six studies following an interventional monitoring approach (75.0%) [16,17,20–23] while two studies used the applied app and technology to log patient's health status for further research (25.0%) [18,19]. The operating systems for the patient apps included Google Android and Apple iOS. The latter was used as a platform for conducting two studies (25.0%) [18,22], one study was carried out using multiple platforms (12.5%) [19] and one relied on the use of an Android-based app (12.5%) [17]. The remaining four articles (50.0%) provided no further information about the platform(s) used [16,20,21,23]. When it comes to the wearables used, two articles stated the use of Smartwatches from Apple (25.0%) [18,22], one article reported the use of a FitBit wearable (12.5%) [21], one study relied on the use of a Withings Smartwatch device and Withings Fitnesstracker (12.5%) [19], while two articles reported the use of the Honor Band 4, Honor Watch as well as the Huawei Watch GT (25.0%) [16,17]. Two study protocols did not plan the use of any wearables (25.0%) [20,23]. Furthermore, it was analyzed whether the participants were provided with other consumer health devices connected to the patients' app. The authors found that five study protocols included different types of Bluetooth blood pressure monitors (62.5%) [18–21], four the use of Bluetooth scales (50.0%) [19–21,23] and one study each included the use of a glucometer (12.5%) [21], one a sleep tracking system (12.5%) [19], one an electrocardiography device (12.5%) [23] and one a pulse oximeter (12.5%) [23].Some studies used a combination of several of the before mentioned devices. Three studies did not use additional devices besides the wearables (37.5%) [16,17,22]. We provided an overview of the results in *Table 3*.

Table 3. Overview of the studies included in the systematic review with a focus on the technical approaches.

Ref.	Monitoring (interventional/ observing)	Operating System/ Platform	Wearable	Other Consumer Health Devices
Werhahn et al., 2019 [22]	Interventional	iOS Versions 10.2.1–11.2.1	(1) Apple Watch 1st Gen.	/
Wenger et al., 2019 [21]	Interventional	Unknown	(1) FitBit	(1) Weight-scale (2) Glucometer (3) Sphygmomanometer
Seto et al., 2020 [20]	Interventional	Unknown	/	(1) A&D Medical Bluetooth Weigh-scales (2) A&D Medical Bluetooth BP [1] monitors
Modena et al., 2018 [19]	Observing	Android/ iOS	(1) Withings Fitnesstracker (2) Withings Watch	(1) mHealth BP [1] monitor (2) Smart weight scale (3) Sleep tracking system
McManus et al., 2019 [18]	Observing	iOS Versions 9 or higher	(1) Apple Watch	(1) Nokia Withings Digital BP [1] cuff
Guo et al., 2019a [17]	Interventional	Android 5.0 or higher	(1) Honor Band 4 (2) Honor Watch (3) Huawei Watch GT	/
Guo et al., 2019 [16]	Interventional	Unknown	(1) Honor Band 4 (2) Honor Watch (3) Huawei Watch GT	/
Koehler et al., 2018 [23]	Interventional	Unknown	/	(1) Three-channel ECG device: PhysioMem PM 1000, GETEMED (2) A&D BP [1] measuring device (UA767PBT) (3) Seca 861 Weighing scales (4) SpO2 [2] Signal Masimo Extraction Technology

[1] BP, Blood Pressure; [2] SpO2, Oxygen Saturation.

Based on previously defined groups of PROMs, we could categorize two PROMs as outcomes measuring functional statuses (2 of 17; 11.76%) [18,23] , five as describing health-related quality of life (29.41%) [20,22,23], three to symptom and symptom burden (17.65%) [16,20], one as personal experience of care (5.88%) [20], four to health-related behaviors such as anxiety and depression (23.53%) [18,19,22] and two none-disjunct PROMs (11.76%) [18,22]. The exact allocation of the PROMs can be found in *Supplementary Materials*.

In *Table 4* we provide an overview of quantitative and qualitative parameters described within the reviewed studies. Overall, seventeen PROMs could be identified with two studies using one PROM (25.0%) [18,21], five studies using two or more types of PROMs (62.5%) [16,18,20,23] and not using PROMs was reported in one study (12.5%) [17].

When it comes to PGHD, five studies (62.5%) [16–18,21,22] collected various parameters while three studies did not foresee the documentation of any additional data by the patient (37.5%) [19,20,23]. These five studies took a variety of self-documented lifestyle factors like diet (2 of 8; 25,0%) [16,21], smoking behavior (2 of 8; 25.0%) [18,21] or alcohol use (1 of 8; 12.5%) [18] into account. Furthermore, therapy compliance factors like medication adherence (6 of 8; 75.0%) [16–18,21,22] were documented, while also unspecified health surveys (1 of 8; 12.5%) [18], self-reported risk factors (1 of 8; 12.5%) [18], information about cardiovascular disease history (1 of 8; 12.5%) [18], sociodemographic data (1 of 8; 12.5%) [18], Atrial fibrillation-related hospital visits (1 of 8; 12.5%) [17] and hospitalizations (1 of 8; 12.5%) [17] were requested to be entered into the patients' app or paper-based questionnaire respectively. One study asked the patients to enter their blood pressure and weight manually into the app (12.5%) [22] using non-connected conventional devices. Besides mentioned patient-reported data, three studies reported the assessment of laboratory parameters at the beginning and in the course of the respective study (37.5%) [16,20,23]. One further study used a clinical questionnaire to collect data by clinical staff (12.5%) [17]. One study conducted a six-minute-walk test and an ECG examination by study personnel (12.5%) [22]. Based on the wearables and devices to be found in *Table 3*, a wide range of self-tracked parameters could be identified including seven studies measuring the patient's heart rate (87.5%) [22], [18,19,19,20], [16,17,23] six studies the patient's blood pressure (75.0%) [16,18–21,23], four studies asked the patients to track their weight (50.0%) [20,21,23] and two used the devices to track the daily steps or mean daily steps (25.0%) [19,21]. Finally, the device-based self-tracking of a six-minute-walk-test (6MWT) [22], no further described physical activity [19], the measurement of blood glucose [21], pulse wave velocity (PWS) [19], sleep duration [19] and oxygen saturation (SpO2) [23] were performed each in one study (12.5%).

Werhahn et al. equipped patients with the Apple Watch to measure their heart rate. They used built-in pedometer functions of both Smartphone and Apple Watch to capture daily steps calculated as an arithmetic mean of 14 days. During three planned study site visits, the device-based 6MWT was validated by simultaneously carrying out a regular 6MWT [22]. Wenger et al. report that their trial participants captured their blood glucose level daily using a glucometer as well as their daily steps using the FitBit's build-in pedometer. Besides, they collected participants' blood pressure and bodyweight once a week on the same day using a Bluetooth BP monitor and weight-scale [21]. Seto et al. did not use any wearables, but Bluetooth BP monitors and weight-scales to daily measure heart rate, blood pressure and bodyweight [20]. Modena et al. included patients already owning a Withings Fitnesstracker or Withings Watch and BP monitor, weight scale or sleep tracking system to track their participants' pulse wave velocity, blood pressure, heart rate and bodyweight at least two days a week while the participant's physical activity level was captured using the build-in activity trackers on the participants smartphone. Additionally, Modena et al. described measuring the participants sleep

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duration via a Withings smartwatch or a sleep tracking system if available [19]. McManus et al. report that they equipped a subpopulation of their study cohort with an Apple Watch and an additional Bluetooth BP cuff to weekly log their blood pressure as well as the daily measured heart rate [18]. Guo and Wang et al. included participants owning a Huawei Watch GT, Honor Watch or Honor Band 4 to frequently capture their heart rate every 10 minutes [17]. Guo and Lane et al. used the same selection of devices to capture both heart rate and blood pressure, but did not provide further information about the frequency [16]. No other consumer health devices were used in either setting described by Guo et al [16,17]. In contrast, Koehler et al. outline the application of only non-wearable based sensors including ECG monitors, BP measuring devices, weighing scales and SpO2 sensors. These four devices were used to daily track the participants heart rate, blood pressure, weight and capillary oxygen saturation [23].

Table 4. Overview of the studies included in the systematic review with a focus on the qualitative and quantitative parameters.

Ref.	PROM	PGHD	Clinical parameters & scales	Self-tracked follow-up parameters	Frequency
Werhahn et al., 2019 [22]	(1) Minnesota Living with Heart Failure Questionnaire (MLHFQ) (2) Kansas City Cardiomyopathy Questionnaire (KCCQ) (3) Patient Health Questionnaire Depression Scale (PHQ-9) (4) Cardiac Anxiety Questionnaire (CAQ) (5) eHealth literacy (questionnaire similar to the eHealth Literacy Scale)	(1) Self-measured blood pressure (2) Self-measured body weight (before breakfast) (3) Confirmation of medication intake	(1) 4 day Holter electrocardiograms (ECGs) (2) Six-minute walk test (6MWT)	(1) Mean daily step count (MDSC) (2) Heart rate (3) Six-Minute Walk Test (6MWT)	(1), (2) Daily (3) Three times at site visits
Wenger et al., 2019 [21]	(1) Individualized Questionnaires (e.g. for medication adherence in case of missing BP measurements)	(1) Taking insulin or oral diabetes medication (2) Cholesterol medication (3) Following a diabetic healthful diet (4) Smoking cessation	/	(1) Blood glucose (2) Blood pressure (3) Weight (4) Daily steps	(1) Daily (every morning) (2) (3) Weekly (on the same day) (4) Daily
Seto et al., 2020 [20]	(1) Self-Care of Heart Failure Index (SCHFI) (2) Kansas City Cardiomyopathy Questionnaire-12 (KCCQ-12) (3) 5-level EQ-5D (EQ-5D-5L) (4) Shortness of breath Scale	/	(1) Routine blood test (creatinine, sodium and potassium levels) (2) Brain natriuretic peptide (BNP)	(1) Weight (2) Blood pressure (3) Heart rate	(1), (2), (3) Daily
Modena et al., 2018 [19]	(1) Perceived Stress Scale Survey	/	/	(1) Pulse wave velocity (PWV) (2) Physical activity level (3) Blood pressure (4) Heart rate (5) Sleep duration (6) Weight (BMI)	(1), (3), (4), (6) ≥2 days per week (2) Tracked using built-in activity trackers on the participants' smartphone (5) Daily

Ref.	PROM	PGHD	Clinical parameters & scales	Self-tracked follow-up parameters	Frequency
McManus et al., 2019 [18]	(1) Center for Epidemiologic Studies Depression Scale, (CES-D) (2) Physical activity index (FHS)	(1) Socio-demographics (2) Medication use (3) Self-reported risk factors (4) Smoking (5) Alcohol use (6) Health Survey (7) CVD history/ non-CVD Medical history	/	(1) Blood pressure (2) Heart rate	(1) 1 day per week at the same day (2) Daily
Guo et al., 2019a [17]	/	(1) Medicine usage (2) Visits for AF-related adverse outcomes (3) Hospitalizations	(1) HAS-BLED score [1] (2) Congestive Heart Failure, Hypertension, Age >=75, Diabetes, Stroke, Vascular Disease, Age 65 to 74 Years, and Sex Category (CHA2DS2-VASc) (3) Sex Female, Age, Medical History, Treatment, Tobacco Use, Race Score (SAMe-T2T2R)	(1) Heart rate	(1) Every 10 min
Guo et al., 2019 [16]	(1) Patient-reported thromboembolism or bleeding events (2) AF symptom assessment scale from the European Hearth Rythm Association (EHRA)	(1) Drug adherence (dose and drug use) (2) Patient-specific cost diary	(1) Haemoglobin, Liver, Renal function (2) HAS-BLED score [1]	(1) Blood pressure (2) Heart rate	Unknown
Koehler et al., 2018 [23]	(1) Minnesota Living with Heart Failure Questionnaire (MLHFQ) (2) Self-rated health status (scale range one to five)	/	(1) Follow Up Visit Biomarker (2) N-terminal prohormone brain natriuretic peptide (NT-proBNP) (3) Mid-regional proadrenomedullin (MR-proADM)	(1) Weight (2) Blood pressure (3) Heart rate (4) Heart rhythm peripheral capillary oxygen saturation (SpO2)	(1), (2), (3), (4) Daily

[1] HAS-BLED; Hypertension, Abnormal Renal/Liver Function, Stroke, Bleeding History or Predisposition, Labile International Normalized Ratio, Elderly, Drugs/Alcohol Concomitantly score

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4. Discussion

This systematic review summarizes the findings of studies using a patient app as an interface to document not only different sensor-based vital signs but also self-tracked and -documented real-world health data for the purpose of telemonitoring in cardiology and observational research including cardiologic telemedicine data. The results suggest that different types of commercially available wearables and other consumer health devices can be implemented in a meaningful way in order to gain major insights in health behaviors and the course of diseases in different cardiologic patient cohorts.

The comparison shows that although the studies primary focus was different, there are many similarities suggesting that the symbiosis of these new technologies in a cardiological context seems to be of interest for researchers worldwide. To achieve their respective objectives all studies relied on a combination of app and none-invasive devices. While the interventional studies approach was to monitor the daily management of disease progression or to provide active support preventing deterioration when serious symptoms occurred, the observational programs aimed to provide further real-world health data for medical research improving therapies and treatments in the long-term.

Furthermore, the comparison shows that the choice of non-invasive devices is crucial, when it comes to either monitoring high-frequency data or snapshots of a patient's health status. This also depends on the scientific question or the context of treatment. In the studies reviewed, sensor- and app-based monitoring was implemented on the basis of various cardiological use cases while some had intersections when it comes to the PROM or self-tracked follow up parameters collected. As vital signs like heart rate and blood pressure or weight were taken into account by almost all studies reviewed it can be assumed that these turn out to be physiological key signals to be monitored providing first insights into a patient's general condition. However, this is countered by the fact that the accuracy of commercial wrist-worn devices are part of current scientific discussions [25–27]. From a monitoring point of view, wearables have the advantage that they can provide high-frequency streaming data while worn. Although the market for consumer health devices is rapidly evolving, the types of sensors used in commercially available wearables are still limited, e.g. blood pressure, heart rate, SpO2, electrocardiogram or photoplethysmography. Thus, the need for both further development in current sensors (e.g. wrist worn ECG with more leads) and new sensor technologies was also recognized in the studies examined, which is why additional consumer health devices were applied to add follow-up parameters that cannot yet be captured by wearables in general or with sufficient quality. Adding to this, the review found that frequent surveys of standardized PROMs via a patient app seem to be another meaningful way to assess various aspects of a patient's health status at home by adding further assessment criteria. Moreover, the digitization of PROMs seems to be an meaningful step towards a more patient-centered treatment [28,29]. While from our point of view as for the analysis purpose the use of structured data acquisition is to be preferred, there is much to be said for expanding the data basis through simple surveys such as confirmation of medication intake or documentation of dietary behavior as practiced in some of the programs.

Werhahn et al.'s study required patients to manually enter self-measured body weight among other parameters into the app without fully exploiting the possibilities of automatically transferring measurements by using existing interfaces like Bluetooth. In contrast are Seto et al.'s, Moderna et al.'s and Koehler et al.'s approaches to reduce the hurdle for regular data transfers to the app by equipping patients with Bluetooth scales. Thus, the manual entry of patients' medical history by the patients themselves as described by McManus et al. has potential for improvement as this data could already be stored in the EHR or Personal Health Record (PHR). Seto et al. describe a practical example as they explicitly mentioned the import of laboratory parameters e.g. brain

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natriuretic peptide (BNP) level from their hospital's EHR. Furthermore, Koehler et. al. also took the BNP level into account, while Guo et al. took haemoglobin, liver and renal function in both screened studies into consideration for the prediction of deterioration of the state of health. This review did not investigate how and whether laboratory parameters were transferred to the app, but again, it seems reasonable to do so by integrating the EHR. Among all the studies considered, Wenger et al. were the only one to use a point of care test as synchronized glucometers to measure patients' blood glucose were handed to the participants. This demonstrates that further laboratory parameters, which can currently only be measured by healthcare professionals, could in the future also be measured in the home setting. This would add a wider range of parameters to be monitored. The general advantages of mHealth technologies consist not only in bridging time and distance, but also as resource-intensive on-site monitoring can potentially be avoided. As soon as further over the counter sensors for measuring laboratory parameters reach market maturity, further scientific and clinical value could be gained when integrated in monitoring concepts. However, this is yet to be evaluated in further studies.

Finally, it is important to consider the platforms used, as the review revealed that only Modena et al. took a cross-platform approach integrating real-world health data from both Android and iOS devices. In the other studies, patients were provided with a compatible smartphone or were only eligible for study participation, if they already owned a suitable device. Consequently, this automatically leads to the exclusion of potential patients with unsupported device combinations. When considering a multi-platform approach the corresponding effort and associated resource consumption must be taken into account. While a less complex single platform approach allows to fully exploit features of wearables or other devices via native interfaces, a comprehensive and elaborate integration into a multi-platform application might be associated with limited access to all device features [30]. Koehler et al. for example integrated various consumer health devices from different manufacturers although the underlying platform is unknown to the authors.

In summary, although consumer health devices or wearables are rather evolving technologies, they are already able to bring a meaningful contribution in getting a more holistic insight into cardiological patients' health status and behavior while at the same time bridging the distance between patient and doctor.

4.1 Limitation

The results suggest that the search terms used were appropriate for the research question, but still some limitations of our study should be considered. For instance, our keywords telemedicine or telecardiology could limit the choice to studies that focused on interventional approaches while observational studies are left out. To weaken the impact, we added the keyword mHealth to our queries. This did not provide more results and was therefore dismissed.

Besides the selected search terms, the challenge was to create a category scheme in which all included studies could be meaningfully presented to provide a holistic overview without excluding relevant factors. Therefore, the scheme is limited to categories that are relevant from the authors' point of view. However, all information can be found in a Table in *supplementary materials*. The separation between PGHD, PROMs, and clinical parameters was also discussed and assessed in detail between the authors to accomplish it as disjunct as possible. Thus, we cannot ensure that everybody would evaluate this accordingly. Although prominent studies such as the Apple Heart Study [5,31] were not included in the literature review, we assume that our analysis covered studies in the clinical context of telecardiology. However, it indicates that there may be other studies in the field that we did not include.

4.2 Outlook

In the context of this review, we do not address the algorithms used, for example, by Guo et al. and Seto et al. to predict AF respectively decompensation in HF. Although there are already internationally agreed treatment standards, there is still a lack of transparent and uniform diagnostic algorithms as they are the subject of current research. It could be of interest to investigate which cardiological therapy guidelines or standards have been used to derive rules for algorithms and what is the status quo in cardiologic algorithm research. Thinking beyond study situations the possibilities for regular patients contributing their self-tracked health data into their EHRs. In addition, as we advocate the establishment of platforms through which users can donate their wearable data for public research purposes without being tied to a specific purpose, corresponding concepts could be of interest for further research.

In future studies it seems appropriate to replace the manual documentation of sensoric data (e.g., weight by integrating consumer health Bluetooth scales). Given this, suitable solutions satisfying regulatory, technical and medical requirements will be sought. As a second improvement the adaption of further or different questionnaires should be investigated.

5. Conclusions

In this systematic review we evaluated different approaches conducted by various researchers in the field of cardiological patient monitoring which apply an integrated combination of app-based surveys, wearables and other consumer health devices. Our review shows that depending on the researcher's motivation a fusion of apps, PROMS and non-invasive sensors can be orchestrated in a meaningful way adding major contributions to monitoring concepts for both, individual patients and larger cohorts. We suggest that different combinations of device-based vital sign monitoring combined with patient-reported outcomes and the documentation of lifestyle factors can contribute further insights into patients' disease progression, therapy compliance and general health behavior patterns. In the medium to long term, disease prevention will most likely depend on consumer health device-based cardiovascular risk monitoring as a tool to follow up patients.

Supplementary Materials: Figure S1: title, Table S1: Databases export, Table S2: Articles Excluded, Table S3:

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