Journal of Cardiovascular Translational Research
https://doi.org/10.1007/s12265-022-10273-6

REVIEW

Use of Digital Health Technology in Heart Failure and Diabetes: a Scoping Review

Dania Kallas[1] · Navroop Sandhu[2] · Christina Gandilo[3] · Mary Schleicher[4] · Laura Banks[5,6] · Mariam Jabara[7] · Luiz Alberto Cerqueira Batista Filho[8] · Tracey J. F. Colella[6,9] · Kim Connelly[10] · Varinder Kaur Randhawa[8,10,11]

Received: 10 February 2022 / Accepted: 5 May 2022

Abstract

Use of digital health technologies (DHT) in chronic disease management is rising. We aim to evaluate the impact of DHT on clinical outcomes from randomized controlled trials (RCTs) of patients with heart failure (HF) and diabetes mellitus (DM). Electronic databases were searched for DHT RCTs in patients with HF and DM until February 2021. Patient characteristics and outcomes were analyzed. One published ($N=519$) and 6 registered ($N=3423$) eligible studies were identified, with one study exclusively including HF and DM patients. Median DHT monitoring was 12 months, with six studies using mobile platforms as their key exposure. Clinical outcomes included quality-of-life or self-care surveys ($n=1$ each), physical activity metrics, changes in biomarkers, and other clinical endpoints ($n=3$). Limited data exist on RCTs evaluating DHT in patients with concomitant HF and DM. Further work should define standardized clinical endpoints and platforms that can manage patients with multiple comorbidities.

Keywords Chronic diseases · Diabetes mellitus · Heart failure · Digital health technologies · Randomized controlled trials

Abbreviations

HF	Heart failure
DM	Diabetes mellitus
DHT	Digital health technologies
QoL	Quality of life
RoB	Risk of bias
RCT	Randomized clinical trial

Introduction

Heart failure (HF) and diabetes mellitus (DM) account for substantial morbidity and mortality worldwide, with over 500,000 and 2.3 million afflicted with HF and DM in Canada alone, corresponding, respectively, to an annual incidence of over 50,000 and 200,000 [1, 2]. Moreover, these chronic illnesses can occur and modulate each other: among diabetic adults (> 64 years), the prevalence of HF is reported to be 22% [3, 4]. Historically, many advances in medical and/

Associate Editor Abhinav Sharma oversaw the review of this article

✉ Varinder Kaur Randhawa
varinder.randhawa@gmail.com

1 Department of Pediatrics, BC Children's Hospital, University of British Columbia, Vancouver, BC, Canada

2 Department of Medicine, Queen's University, Kingston, ON, Canada

3 Ottawa, Canada

4 Floyd D. Loop Alumni Library, Cleveland Clinic, Cleveland, OH, USA

5 Faculty of Health Sciences, Ontario Tech University, Oshawa, ON, Canada

6 KITE, Toronto Rehabilitation Institute, University Health Network, Toronto, ON, Canada

7 Department of Medicine, McGill University Health Centre, Montreal, QC, Canada

8 Department of Critical Care Medicine, Temerty Faculty of Medicine, Sunnybrook Health Sciences Centre, University of Toronto, Toronto, ON, Canada

9 Lawrence S Bloomberg Faculty of Nursing, Faculty of Rehabilitation Sciences Institute, University of Toronto, Toronto, ON, Canada

10 Department of Cardiology, St Michael's Hospital, Toronto, ON, Canada

11 Department of Cardiovascular Medicine, Kaufman Center for Heart Failure Treatment and Recovery, Heart, Vascular and Thoracic Institute, Cleveland Clinic, Cleveland, OH, USA

Published online: 31 May 2022

or device therapies for HF and DM care have focused on improving mortality or major adverse cardiovascular events [5–7]. In fact, the negative impact of certain anti-diabetic therapies on cardiovascular health prompted the requirement for cardiovascular outcomes trials to be undertaken for regulatory approval [8]. Similarly in HF, poor adherence, adverse clinical outcomes, and readmission burden suggest the need for robust evaluation in this population [9]. It is therefore crucial to consider interventions to improve the multidimensional aspects of patient health and quality-of-life (QoL) metrics.

The growth of digital health technologies (DHT) has been accelerated by the coronavirus pandemic, transforming the delivery of medical care along with highlighting the positive impact and need for persistent advancement in this field. DHT consist of the use of information and communication technologies (e.g., wearables, mobile applications, telehealth, and text messaging platforms) to support health and play an emerging role in managing patients with chronic diseases [10, 11]. However, some barriers to the use of DHT include lack of access, financial burden, loss of patient follow-ups or medication adherence, device failure, and end-point validity [11]. DHT in clinical studies has become more prevalent in evaluating different aspects of care and evaluation of patient-related outcomes in their normal daily routines. Despite the high prevalence of multiple chronic diseases or multimorbidity, most DHT platforms focus on managing a single disease [12]. In fact, the prevalence and effectiveness of DHT use among patients with HF and DM is unknown. Therefore, in patients with HF and DM, we sought to investigate the impact of DHTs on clinical disease variables such as QoL, medication adherence, health behaviors, and clinical biomarkers.

Methods

Sources, Study Selection, Risk of Bias, and Data Extraction

We conducted a systematic search of relevant databases (Ovid MEDLINE®, Embase, Cochrane Central Register and Clinical Trials.Org) from 1946 to February 2021 incorporating Medical Subject Headings or "MeSH" terms and integrated validated search filters [13]. Appendix 1 provides the search strategies and search terms applied to the database evaluations [14]. Additional randomized controlled trials (RCTs) were manually identified by reviewing individual citations and ClinicalTrails.gov. Identified studies underwent title and abstract (C.G. and V.K.R.) and full-text (D.K., C.G., L.B., and V.K.R.) screening for study inclusion by at least two independent reviewers. All English RCTs reporting on the use of DHT in adult patients (≥ 18 years) with HF and DM were included, with the intent that this could potentially identify the highest level of evidence and between study standardization. We excluded duplicate studies, abstracts, non-randomized studies, case series with ≤ 5 cases, and/or non-human studies. Studies were managed using the Covidence systematic review software (Veritas Health Innovation, Melbourne, Australia). Studies were categorized into two groups based on RCT status: published or "registered" (i.e., active but unpublished or planned) RCTs. The risk of bias (RoB) of complete RCTs were assessed by two independent reviewers (D.K and N.S.) using the Cochrane Collaboration's Tool for Assessing Risk of Bias 2 (RoB2, version 9, August 2019) [15]. The risk of bias for studies was assessed based on five RoB domains and can be given a bias score of "low," "some concerns," or "high." Any discrepancies related to study inclusion and risk of bias or certainty of evidence assessments were resolved by consensus or by a third reviewer where required. Study design, inclusion criteria, patient characteristics, DHT utilized, and clinical outcomes were extracted and assessed where applicable. Sex, age, type of DHT utilized, and efficacy of DHT intervention were sought.

Results

Our search strategy identified 1,913 unique records after removal of citations that did not adhere to our inclusion criteria and duplicate records (Fig. 1). After title and abstract screening, 26 underwent full-text review and 7 were included in the qualitative synthesis. Of these, one was a published RCT, and 6 were "registered" RCTs. Clinical results of each published and registered trial are reported in Tables 1 and 2, respectively.

Outcome Measures in HF and DM DHT Trials

Focus on Published DHT RCT

The published RCTs in patients with both HF and DM exclusively utilizing a DHT tool were limited to the Renewing Health Project. In this study, the aim was to assess whether a one-year structured telephone-based health coaching program supported by a self-managed remote monitoring system improved QoL and reduced HbA1c over time among patients with type II DM and heart disease (inclusive of HF) versus standard quality of care. Participants in the intervention group received a mobile phone with a personal health record (PHR) app, and a set of medical devices linked the patient's PHR account via Bluetooth. In addition, patients in the intervention group were also assigned a health coach who called them every 4–6 weeks to evaluate health behaviors and recommend a behavior management plan according

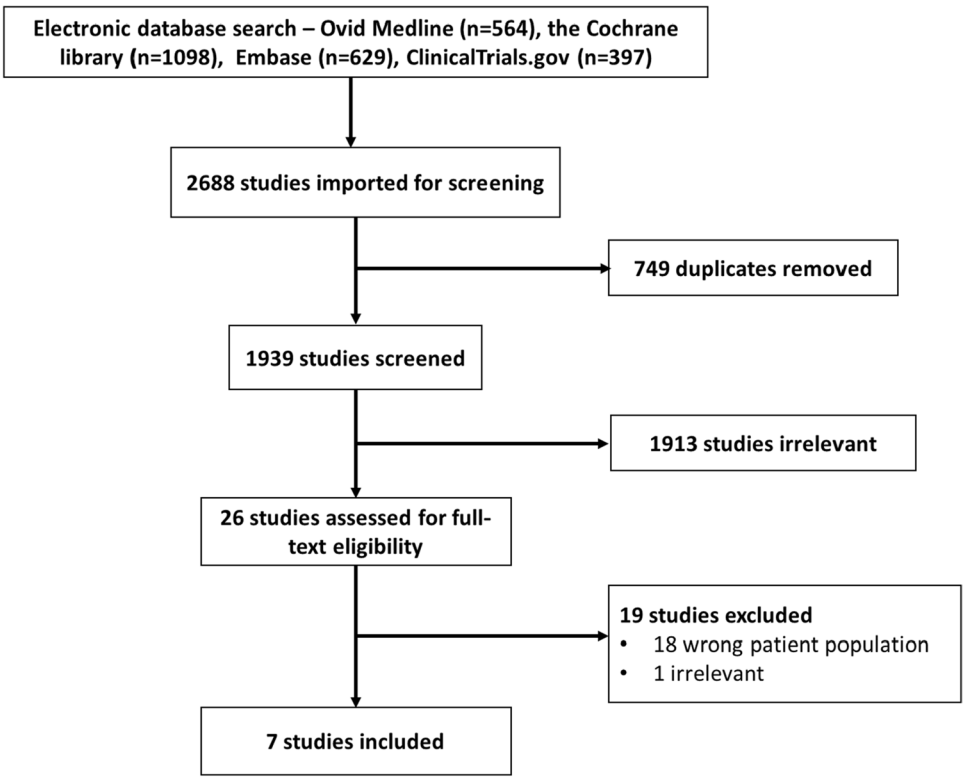

Fig. 1 Study Selection PRISMA flow diagram. The electronic database search identified 1,939 eligible studies for title and abstract screening after removing 749 duplicate studies from 2,688 initially identified studies. Of these, 1,913 studies were excluded, and 26 studies underwent further full-text review. Of these, 7 studies met the inclusion criteria

to a structured training program ("Pfizer's health coaching model"). Health-related QoL was assessed via the SF-36 health survey. A total of 519 participants with an age of 18 years or older were recruited and consisted of predominantly males ($n=317/519$, 61%). The mean age of patients did not differ between intervention (68.1 years) and the control group (66.9 years) nor between diabetic (66.1 years) or heart disease (68.1 years) patients. Although patients consistently received health coaching calls throughout the study and the majority of the patients (91.6% in heart disease group and 95% in diabetes group) adhered to the home telemonitoring plan, the study found no benefit in their study intervention. This one-year program did not improve QoL or the clinical condition in comparison to patients with standard of care. Nonetheless, beneficial trends in blood pressure (BP) and cholesterol levels for all patients was reported with more improvements in clinical variables (weight, waist circumference, BP, and LDL-cholesterol) being more apparent in the type II DM patient group (weight change = −0.9; systolic BP change = −6.1; diastolic BP change = −2.61; LDL change = −0.40) than in the heart disease patient group (weight change = 0.04, systolic BP change = −5.43, diastolic BP change = −0.27; LDL change = −0.34) [17].

The overall risk of bias was considered "high risk" when assessed with the Cochrane RoB tool (Fig. 2). The measurements of the secondary outcomes (BP, weight, activity) were self-reported by participants in the intervention group using remote monitoring tools resulting in more evidence to support a high-risk bias.

Focus on Registered DHT RCTs

ClinicalTrials.gov identified another 6 "registered" RCTs utilizing DHT in patients with HF and DM along varying time horizons (Table 2). Together, these trials aim to recruit a total of 3,423 participants, with a median recruitment of 423 participants per study. Of these, 5 studies plan to recruit patients ≥ 18 years of age with no further characterization or categorization based on age groups (young adults versus older adults). All studies are to be based out of developed countries: 3 North American (Canada and USA [$n=2$]) sites and 3 European (Germany, Sweden, Denmark). The specificity of the inclusion criteria for patient groups differed among these studies: some were restricted to only patients with HF and DM ("Target HF-DM", NCT02918175), whereas others included patients also diagnosed with other chronic diseases such as ischemic heart disease and obstructive pulmonary disease. One study ("MODEL," NCT02957513) aimed to recruit African American patients in underserved communities, while others did not restrict inclusion criteria to a specific ethnic cohort.

Most studies ($n=5$ of 6) used telemedicine/mobile platforms as their key exposure: mobile applications were used in 3 studies, personalized text messaging in 2, and telemedicine in 2. One

Table 1 Characteristics of the published randomized controlled trial using a digital health technology

Authors (year), source (NCT)	Device (manufacturer)	Intervention vs. comparator	Primary outcome (s)	Secondary outcome (s)	Measure	Inclusion	Monitoring duration	Sex	Subjects	Mean age (years)	Estimated proportion of patients with heart disease and diabetes	Summary of findings
Renewing Health Project: Karhula et al. (2015), Finland NCT01310491	Remote monitoring toolbox (mobile phone with software, mobile personal health record (PHR) app, and a set of measurement devices connected to the patient's PHR account	Health coaching: telemedicine using mobile phones and self-monitoring of health parameters with remote patient monitoring app vs usual care: information booklet, standard clinical testing	Health-related QoL (assessed via SF-36 health survey) and HbA1c among diabetic patients	Mediation compliance, blood pressure reduction, weight reduction activity increase, smoke cessation, alcohol use reduction, cost for the organization, satisfaction and usability of the technology	For diabetics: weight, blood pressure (via blood pressure meter), blood glucose once per week For heart disease patients: steps once per week	Age > 18 years with one or both of the following: (a) type II diabetes (HbA1c > 6.5%) diagnosed 3 months prior to enrollment; (b) heart disease (ischemic heart disease or heart failure)	12 months	Intervention, females = 147 (40%) Control, females = 55 (37%)	Intervention: $n = 370$ (190 with heart disease and 180 with diabetes Control: $n = 149$ (79 heart disease and 70 with diabetes) Total = 519	Intervention: 68 years Control: 66.8 years	Heart disease group (patients with heart failure and/or ischemic heart disease): 64 had diabetes Diabetes group: 62 had heart disease (heart failure and/or ischemic heart disease) Total: 126 with heart disease and diabetes	Health coaching program supported with telemonitoring did not improve heart disease patients' or diabetes patients' QoL or their clinical condition

Table 2 Characteristics of registered randomized controlled trials of digital health technologies

Trial name (NCT)	Key exposure/device	Country of origin	Primary inclusion	Recruitment target	Intervention model	Exposure outcome/device-related unit	Primary outcome	Secondary outcomes	Monitoring duration
TARGET HF-DM: Mobile Health Behavioral Intervention in Patients With Heart Failure and Diabetes Mellitus NCT02918175	Personalized text messages and medication adherence teaching tool app (Duke PillBox)	USA	≥ 18 years old with chronic heart failure and prior diabetes mellitus diagnosis; clinical stability with no plan for revascularization	~ 200	Parallel assignment	Step count	Change in mean weekly step count (health behaviors)	Change in medication adherence, fill and refill rate, step count, NT-proBNP levels, HbA1C, Kansas City Cardiomyopathy Questionnaire (KCCQ) score and plasma metabolic profile	6 months
LeIKD: Lifestyle Intervention in Chronic Ischemic Heart Disease and Diabetes NCT03835923	Telemedicine-supported lifestyle intervention through individual structured exercise training	Germany	≥ 18 years with chronic ischemic heart disease, and type II diabetes	~ 1500	Parallel assignment	Daily physical activity	Change in HbA1c in 6 months	Change in HbA1c in 12 months, health literacy, daily physical activity, steps per day, eating behaviour, QoL, medical care expenses, weight, waist circumference, low density lipoprotein, high density lipoprotein, triglyceride, blood pressure, combined endpoint	12 months

Table 2 (continued)

Trial name (NCT)	Key exposure/device	Country of origin	Primary inclusion	Recruitment target	Intervention model	Exposure outcome/device-related unit	Primary outcome	Secondary outcomes	Monitoring duration
Empire HF: Empagliflozin in Heart Failure Patients With Reduced Ejection Fraction NCT03198585	Empagliflozin 10 mg and accelerometer (accelerometer intended for sub-analysis to categorize patients into a low and high daily physical activity groups) [16]	Denmark	Age > 18 years, heart failure (left ventricular ejection fraction of ≤ 0.40; eGFR > 30 ml/min/173 m^2; BMI < 45) and/or type II diabetes (HbA1c 6.5–10%, on optimal treatment, stable doses of anti-glycemic treatment for 30 days)	190	Parallel assignment	NT-proBNP and daily average accelerometer units [16]	Change in plasma levels of NT-proBNP	Change in daily activity level, body composition on DXA scan, extracellular volume, plasma, metabolism, ketone supply, renal function, uric acid, albumin/creatine ratio, cardiac biomarkers, blood pressure, ejection fraction, cardiac hemodynamics via pulmonary capillary wedge and catheterization, health related QoL via questionnaire KCCQ and EQ-5D-5L	90 days
Medium Term Health Coaching and Life-long Monitoring in Cardiovascular Disease in Norrbotten NCT01478672	Telemedicine supported by digital health platform (HealthPals app) linked to blood pressure meter, pedometer, pulse watch, 2-channel electrocardiograph equipment provided to patient	Sweden	≥ 18 years with arterial hypertension ischemic heart disease, congestive heart failure, HbA1c > 53 mmol/mol, arrhythmia	741	Parallel assignment	Blood glucose levels, blood pressure, weight and other	Health Status (SF-36 survey)	HbA1c (for DM patients) and blood pressure (for heart disease patients), blood lipids, bodyweight, smoking habits, alcohol consumption, sense of coherence, EQ-5D to assess health outcomes	12 months

Table 2 (continued)

Trial name (NCT)	Key exposure/device	Country of origin	Primary inclusion	Recruitment target	Intervention model	Exposure outcome/device-related unit	Primary outcome	Secondary outcomes	Monitoring duration
MODEL: The Management of Diabetes in Everyday Life Program NCT02957513	Text messaging, health coaching and enhanced usual care	USA	African-American adults (≥18 years) with uncontrolled diabetes (HbA1c > 8) and one or more chronic condition (congestive heart failure, hypertension, coronary artery disease, cardiac arrhythmias, dyslipidemia, stroke, arthritis, asthma, cancer, chronic kidney disease, chronic obstructive pulmonary disease, depression, and osteoporosis), willing to receive care in identified clinical site, has cellphone and not planning to move	646	Parallel assignment	Self-care survey	Diabetes self-care activities over the previous 7 days for 7 core behaviors: smoking, diet, exercise, blood sugar testing, foot care, smoking, and medication adherence	Diabetes-specific QoL: diabetes control, anxiety, worry, social burden, sexual functioning, energy and mobility; primary care engagement, quality of care and average blood sugar	12 months
Effects of remote patient monitoring on chronic disease management NCT03127852	Medly application on a smartphone linked to electronic medical devices, such as a blood pressure monitor, weight scale and blood glucose meters provided to patient	Canada	≥18 years diagnosed with one or more of the following: heart failure, COPD, chronic kidney disease, and/or uncontrolled hypertension (including diabetics)	146	Parallel assignment	Daily weight, blood pressure, heart rate, symptom, and blood sugar levels	Change in QoL measured with SF-36 survey and change in cost of healthcare	Change in combined hospitalizations; left ventricular ejection fraction; BNP; heart failure: self-care, QoL, blood work, prognosis; change in dyspnea; forced expiratory volume; COPD: QoL, knowledge, self-efficacy, severity; GFR; blood pressure; HbA1c	6 months

Abbreviations: *NT-proBNP* N-terminal pro-brain natriuretic peptide; *COPD* chronic obstructive pulmonary disease; *HbA1c* hemoglobin A1c; *GFR* glomerular filtration rate; *EQ-5D* European Quality of Life Five Dimension; *KCCQ* Kansas City Cardiomyopathy Questionnaire; *SF-36* Short Form Health Survey; *QoL* quality of life

study ("Empire HF", NCT03198585) had a drug intervention with Empagliflozin and an associated sub-study that utilized an accelerometer to categorize patients into those who had either on average a high or low physical activity level [16]. The average duration for monitoring will be 9 months (range 3 to 12 months) among all studies. The primary exposures for the studies are aimed to assess aspects of QoL or self-care surveys ($n=1$ each), physical activity ($n=3$), and change in serum biomarkers ($n=2$, HbA1c and NT-proBNP levels) and clinical endpoints such as weight and BP ($n=2$).

Discussion

HF and DM are two chronic diseases that can modulate each other. Patients with HF are at increased risk of DM, and vice-versa, patients with DM are at higher risk of developing HF [4]. Despite the large incidence of patients with both diseases, a uniform approach to disease management in this population via digital health tools is absent. Among the studies that received full-text review but were excluded, the majority focused on DHT in patients with either DM or HF alone. As a result, this scoping review identified only one published RCT integrating DHTs in patients with both HF and DM, as well as 6 "registered" RCTs that were ongoing. Overall, there was a limited number of studies assessing DHTs exclusively in HF and DM patients. Therefore, 6 of 7 studies included in this review had patients with DM and > 1 cardiovascular comorbidity (but inclusive of HF) in their study population (Tables 1 and 2). In addition, we report significant heterogeneity among these studies with regard to the type of DHT utilized, study design, endpoint evaluations, and clinical outcomes (Fig. 3).

The lack of standardization among studies has potential implications when interpreting, managing, and generalizing study results. For instance, inclusion criteria in some studies were specific but relatively broad in others, which can lead to challenges in generalizing the results. The lack of a defined diagnosis in the inclusion criteria may also lead to varying outcomes as disease severity may not be controlled in a study. Among the registered RCTs (Table 2), half (3 of 6) defined the clinical conditions required for a diagnosis of either HF or DM. In addition, the methodology used to evaluate an outcome differed among the studies despite some studies having similar primary outcomes. For instance, accelerometers, exercise training, and health apps all assessed aspects of physical activity with no clear indication of why each device/intervention was utilized. Moreover, different questionnaires were used to assess QoL (e.g., the "KCCQ" or Kansas City Cardiomyopathy Questionnaire, "EQ-5D-5L" or EuroQoL Health Questionnaire, versus "SF-36" or Short Form 36 Health Survey Questionnaire). Many of the studies included in this review had multiple interventions. The implementation of more than one intervention (telemedicine supported by an app and linked to electronic medical devices; trial NCT01478672) may lead to potential difficulty when determining which intervention contributes to the efficacy of the study outcomes. Overall, standardization of methods across DHT studies will improve the interpretation of outcomes and the ability to adopt digital health interventions into clinical care of patients with HF and DM [18].

The COVID-19 pandemic has expedited the use of DHT and yet has also highlighted the disparities that exist in medical care such as access to digital health devices. Socioeconomic status, education, sex and gender, and race and ethnicity are important baseline characteristics to consider in larger cohort studies of HF and DM patients given the lack of access to DHT that may exist in remote and underprivileged communities. The "Management of Diabetes in Everyday Life" (MODEL) study was the one study in our review that limited their population to a minority group (i.e., African Americans) to assess self-care activities associated to their diagnosis. In the same way, this study design enabled the assessment of a digital health intervention on a minority group, leveraging digital health tools to assess subgroups of patients or even phenotypic profiles of HF and DM which can be immensely beneficial and impactful in optimizing the clinical care for these chronic diseases.

DHTs have shown to be an effective tool in managing chronic diseases and possess great utility if adopted uniformly [19]. Future studies need to evaluate or introduce new DHT platforms that are capable of simultaneously evaluating patients with multiple chronic diseases. This will particularly be beneficial for DM and HF patients given that both these chronic diseases often coexist together. The ability to consolidate care using a single DHT platform may improve the QoL of patients while integrating a proactive model for patient involvement. For example, AliveCor is a portable heart monitor device capable of performing an electrocardiogram using 2 fingers to help detect atrial arrhythmias. While the published AliveCor device study (not included in this scoping review) did not focus on the incidence of atrial arrhythmias in only HF and DM patients, this could be an interesting future study given the validation of this tool over many published studies and the relative propensity of atrial fibrillation in patients with these comorbid conditions [20].

Consensus of which clinical endpoints should be assessed via DHT tools for patients with both HF and DM has yet to be determined. The design of studies can lend themselves to address endpoints such as HF severity or glycemic control. This is particularly important given the impact of certain medications on both endpoints in patients with or without HF and DM [4]: for instance, sodium glucose co-transporter 2 inhibitors (SGLT2i) have been implicated in modulating the recovery of left ventricular ejection fraction and reducing HF readmissions in patients with HF and in improving glycemic control in patients with DM. The safety and efficacy of medications, such as SGLT2 inhibitors, should be investigated in large cohort studies and possibly in clinical trials in the future. Telemonitoring can be used to encourage

Study	D1	D2	D3	D4	D5	Overall
Renewing Health Project: Karhula et al (2015)	!	+	+	-	!	-

+ Low risk
! Some concerns
- High risk

D1 Randomisation process
D2 Deviations from the intended interventions
D3 Missing outcome data
D4 Measurement of the outcome
D5 Selection of the reported result

Fig. 2 Randomized clinical trial risk of bias Cochrane risk assessment summary plot. The overall risk of bias for the Renewing Health Project study is assessed as high

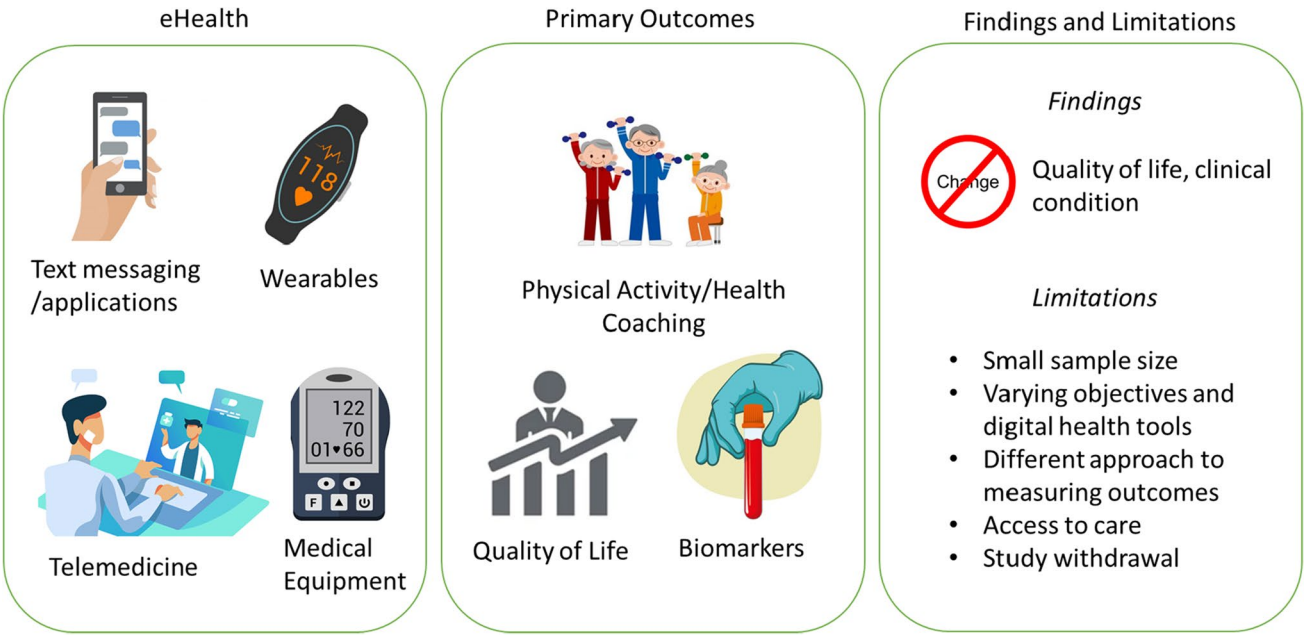

Fig. 3 Scope of digital health technologies in heart failure and diabetes mellitus. A summary of the digital health technologies (eHealth), primary outcomes, and findings and limitations of the identified randomized controlled trials

engagement with self-management (e.g., daily weights, medication adherence, clinical visit follow-ups), improve access to care for remote patients, and help coordinate care which may result in better QoL for patients. In addition, this can facilitate timely clinical visits in accordance with patient needs and disease severity while reducing the burden on healthcare systems. For this reason, leveraging DHT tools to help assess patients with concomitant DM and HF should be prioritized. Lastly, the ongoing studies in this space also provide the opportunity for researchers to consider subgroup analyses of patients that have both DM and HF.

Limitations

The limited number of studies identified in this scoping may be attributed to the rigor of our search strategy. We were strictly concentrated on studies evaluating DHT in patients with concomitant HF and DM, rather than focusing on global cardiovascular disease and/or risk factors. As such, we were not able to conduct a systematic review which may have encompassed more homogeneity in the field and consideration to sex and gender and race or ethnicity-based analyses. In addition, we restricted our search strategy to RCTs that were published in English. Although this enabled us to review robust standardized studies with the highest level of reported evidence, hypothesis-generating studies, and other published work in this field, some studies may have been overlooked. Majority of studies identified were registered RCTs (yet to be published), and therefore, future analysis of these studies' data and outcomes are warranted particularly for the HF and DM patient sub-groups. Lastly, we did not register our study protocol in PROSPERO since formal screening was initiated before consideration of protocol registration. This however provides opportunity for future extensive reviews in this space once ongoing studies are completed and published. The limited number of published studies in this space, however, precluded a meta-analysis of currently published data.

Conclusion

Digital health technologies offer a novel way to evaluate patient-centered outcomes and are particularly useful for chronic diseases that modulate each other, such as HF and DM. Given the limited number of studies that include both HF and DM populations, and the significant heterogeneity in existent DHT-based studies, further work should define standardized DHT endpoints and explore the utility, access, and cost-effectiveness in patients with chronic medical conditions.

Appendix 1

Search Strategy for Digital Health Technology Use in Patients with Heart Failure and Diabetes Mellitus

first Ovid MEDLINE, then EMBASE, then Clinicaltrials.gov, and finally Cochrane Central Register of Controlled Trials® ALL 1946 to February 01, 2021

	Searches
1	exp Accelerometry/ or Actigraphy/ or exp Fitness Trackers/ or (actigraph* or acceleromet* or actimet* or fitness tracker* or activity tracker*).tw,kw. or ((digital health or digital lifestyle or mobile health or mHealth or m-health) adj4 (technolog* or intervention* or app or apps or application*)).tw,kf
2	(((activ* or fitness) adj (monitor or monitors or tracker*)) or ((wearable or implant*) adj device* adj6 (activity or fitness or movement or steps or walking or walk)) or actical or activinsights or activpal or actiwatch or aw-64 or Basis Health Tracker or BodyMedia Fit or DirectLife or DynaPort MiniMod or emfit or fitbit* or Garmin Vivofit or geneactiv or GT1m or hexoskin or Jawbone UP or kinesia or (MisFit adj (Shine or Ray or Vapor)) or motionlogger sleep watch* or Nike FuelBand or phillips-respironics mini-mitter or Polar Loop or tremerometer or Withings Pulse).tw,kf
3	(exp Cell Phone/ or Smartphone/ or exp Mobile Applications/ or (cell phone* or smartphone* or mobile phone* or mobile app*).tw,kf.) and (health or fitness or exercise or activity or movement or steps or walk or walking).tw,kf
4	or/1–3
5	exp Heart Failure/
6	(((heart or ventric* or cardiac) adj2 (fail* or decompensat*)) or CHF).tw,kf
7	(HFpEF or diastolic failure or preserved ejection fraction).tw,kf
8	(HFrEF or systolic failure or ((reduced or depressed) adj2 ejection fraction)).tw,kf
9	exp Diabetes Mellitus/
10	(Type 1 diabetes or T1DM or T1D or IDDM).tw,kf
11	(Type 2 diabetes or T2DM or T2D or NIDDM).tw,kf.11diabetes).tw,kf
12	(gestational diabetes or pregnancy
13	or/5–12
14	4 and 13
15	14 and (randomly or randomized or randomised or RCT or RCTs).tw,kf
16	limit 15 to english language
17	limit 14 to (english language and randomized controlled trial)
18	16 or 17
19	(exp Animals/ or exp Models, animal/ or exp Disease models, animal/) not exp Humans/
20	((animal or animals or cat or cats or feline* or cow or cows or cattle or bovine or dog or dogs or canine* or hamster* or lamb or lambs or monkey* or primate* or simian or mice or mouse or murine or pig or pigs or piglet* or porcine or rabbit* or leporine or rat or rats or rodent* or sheep* or ovine or veterinar*) not (human* or patient*)).ti,kf,jw
21	19 or 20
22	18 not 21

ClinicalTrials.gov Search Strategy

	Searches
1	"digital health" OR "mobile health" OR mHealth OR "mobile applications" OR accelerometry OR accelerometer OR actigraphy OR actimeter OR actimetry OR "fitness tracker" OR "activity monitor" OR smartphone OR "cell phone" OR "mobile phone" AND "Heart Failure" OR diabetes OR HFpEF OR HFrEF OR "diastolic failure" OR "systolic failure" OR "preserved ejection fraction" OR "cardiac decompensation"

Embase 1974 to 2021 February 01

	Searches
1	exp accelerometry/ or actimetry/ or exp activity tracker/ or (actigraph* or acceleromet* or actimet* or fitness tracker* or activity tracker*).tw,kw. or ((digital health or digital lifestyle or mobile health or mHealth or m-health) adj4 (technolog* or intervention* or app or apps or application*)).tw,kw
2	(((activ* or fitness) adj (monitor or monitors or tracker*)) or ((wearable or implant*) adj device* adj6 (activity or fitness or movement or steps or walking or walk)) or actical or activinsights or activpal or actiwatch or aw-64 or Basis Health Tracker or BodyMedia Fit or DirectLife or DynaPort MiniMod or emfit or fitbit* or Garmin Vivofit or geneactiv or GT1m or hexoskin or Jawbone UP or kinesia or (MisFit adj (Shine or Ray or Vapor)) or motionlogger sleep watch* or Nike FuelBand or phillips-respironics mini-mitter or Polar Loop or tremerometer or Withings Pulse).tw,kw
3	(exp mobile phone/ or exp mobile application/ or (cell phone* or smartphone* or mobile phone* or mobile app*).tw,kw.) and (health or fitness or exercise or activity or movement or steps or walk or walking).tw,kw
4	or/1–3
5	exp heart failure/
6	(((heart or ventric* or cardiac) adj2 (fail* or decompensat*)) or CHF).tw,kw
7	(HFpEF or diastolic failure or preserved ejection fraction).tw,kw
8	(HFrEF or systolic failure or ((reduced or depressed) adj2 ejection fraction)).tw,kw
9	exp diabetes mellitus/
10	(Type 1 diabetes or T1DM or T1D or IDDM).tw,kw
11	(Type 2 diabetes or T2DM or T2D or NIDDM).tw,kw
12	(gestational diabetes or pregnancy diabetes).tw,kw
13	or/5–12
14	4 and 13
15	14 and (randomly or randomized or randomised or RCT or RCTs).tw,kw
16	limit 15 to english language
17	limit 14 to (english language and randomized controlled trial)
18	16 or 17
19	(exp animal/ or exp animal model/ or animal disease model*.tw,kw.) not exp human/
20	((animal or animals or cat or cats or feline* or cow or cows or cattle or bovine or dog or dogs or canine* or hamster* or lamb or lambs or monkey* or primate* or simian or mice or mouse or murine or pig or pigs or piglet* or porcine or rabbit* or leporine or rat or rats or rodent* or sheep* or ovine or veterinar*) not (human* or patient*)).ti,kw,jw
21	19 or 20
22	18 not 21
23	conference abstract.pt
24	22 not 23

Cochrane Central Register of Controlled Trials Issue 2 of 12, February 2021

	Searches
1	MeSH descriptor: [Accelerometry] explode all trees
2	MeSH descriptor: [Actigraphy] this term only
3	MeSH descriptor: [Fitness Trackers] explode all trees

	Searches
4	(actigraph* or acceleromet* or actimet* or fitness tracker* or activity tracker* OR ("digital health" or "digital lifestyle" or "mobile health" or mHealth or m-health) NEAR/4 (technolog* or intervention* or app or apps or application*)):ti,ab,kw
5	(((activ* or fitness) NEXT (monitor or monitors or tracker*)) or ((wearable or implant*) NEXT device* NEAR/6 (activity or fitness or movement or steps or walking or walk)) or actical or activinsights or activpal or actiwatch or aw-64 or "Basis Health Tracker" or "BodyMedia Fit" or DirectLife or "DynaPort MiniMod" or emfit or fitbit* or "Garmin Vivofit" or geneactiv or GT1m or hexoskin or "Jawbone UP" or kinesia or (MisFit NEXT (Shine or Ray or Vapor)) or motionlogger sleep watch* or "Nike FuelBand" or "Phillips-respironics mini-mitter" or "Polar Loop" or tremerometer or "Withings Pulse"):ti,ab,kw
6	MeSH descriptor: [Cell Phone] explode all trees
7	MeSH descriptor: [Smartphone] this term only
8	MeSH descriptor: [Mobile Applications] explode all trees
9	((cell phone* or smartphone* or mobile phone* or mobile app*) AND (health or fitness or exercise or activity or movement or steps or walk or walking)):ti,ab,kw
10	[22-#9]
11	MeSH descriptor: [Heart Failure] explode all trees
12	(((heart or ventric* or cardiac) NEAR/2 (fail* or decompensat*)) or CHF):ti,ab,kw
13	(HFpEF or "diastolic failure" or "preserved ejection fraction"):ti,ab,kw
14	((HFrEF or "systolic failure" or ((reduced or depressed) NEAR/2 "ejection fraction"))):ti,ab,kw
15	MeSH descriptor: [Diabetes Mellitus] explode all trees
16	("Type 1 diabetes" or T1DM or T1D or IDDM):ti,ab,kw
17	("Type 2 diabetes" or T2DM or T2D or NIDDM):ti,ab,kw
18	("gestational diabetes" or "pregnancy diabetes"):ti,ab,kw
19	{OR #11-#18}
20	#10 AND #19
21	(randomly or randomized or randomised or RCT or RCTs):ti,ab,kw
22	#20 AND #21
23	#23 MeSH descriptor: [Animals] explode all trees
24	#24 MeSH descriptor: [Models, Animal] explode all trees
25	#25 MeSH descriptor: [Disease Models, Animal] explode all trees
26	#26 [17-#25]
27	#27 MeSH descriptor: [Humans] explode all trees
28	#28 #26 NOT #27
29	#29 ((animal or animals or cat or cats or feline* or cow or cows or cattle or bovine or dog or dogs or canine* or hamster* or lamb or lambs or monkey* or primate* or simian or mice or mouse or murine or pig or pigs or piglet* or porcine or rabbit* or leporine or rat or rats or rodent* or sheep* or ovine or veterinar*) not (human* or patient*)):ti,ab,kw
30	#30 #28 OR #29
31	#31 #22 NOT #30 in Trials

Appendix 2

Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR) Checklist

Section	Item	PRISMA-ScR checklist item	Reported on page #
Title			
Title	1	Identify the report as a scoping review	1
Abstract			
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives	2
Introduction			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach	3
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives	3
Methods			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number	4 and 11
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale	4
Information sources*	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed	4
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated	4 and Appendix 1
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review	4 and Appendix 1

Section	Item	PRISMA-ScR checklist item	Reported on page #
Data charting process‡	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators	4
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made	5
Critical appraisal of individual sources of evidence§	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate)	n/a
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted	5
Results			
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram	5
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations	n/a
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12)	n/a
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives	5–7
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives	5–7
Discussion			
Summary of evidence	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups	7–10
Limitations	20	Discuss the limitations of the scoping review process	10
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps	11

Section	Item	PRISMA-ScR checklist item	Reported on page #
Funding			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review	11

JBI Joanna Briggs Institute; *PRISMA-ScR* Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.

*Where *sources of evidence* (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.

†A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with *information sources* (see first footnote).

‡The frameworks by Arksey and O'Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the process of data extraction in a scoping review as data charting.

§ The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document). *From*: Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMAScR): Checklist and Explanation. Ann Intern Med. 2018;169:467–473. https://doi.org/10.7326/M18-0850

Declarations

Human and Animal Subjects and Informed Consent Statement No human or animal studies were carried out by the authors for this article.

Conflict of Interest Dr. Kim Connelly holds the Keenan Chair in Research Leadership at St. Michael's Hospital and has received research grant support and speaker/consulting honoraria from the following companies that is not related to the work presented in this article: Abbott Vascular, AstraZeneca, Boehringer Ingelheim, Bristol Myers Squibb, Edwards, Eli Lilly, Janssen, Merck, Novo Nordisk, Sanofi, and Servier. The remaining authors report no relevant disclosures or conflicts of interest.

References

1. Benjamin, E. J., et al. (2018). Heart disease and stroke statistics-2018 update: A report from the american heart association. *Circulation, 137*(12), e67–e492.
2. Tousoulis, D., et al. (2014). Diabetes mellitus and heart failure. *Eur Cardiol, 9*(1), 37–42.
3. Bertoni, A. G., et al. (2004). Heart failure prevalence, incidence, and mortality in the elderly with diabetes. *Diabetes Care, 27*(3), 699–703.
4. Randhawa, V. K., Dhanvantari, S., & Connelly, K. A. (2021). How diabetes and heart failure modulate each other and condition management. *Canadian Journal of Cardiology, 37*(4), 595–608.
5. Curtis, L. H., et al. (2008). Early and long-term outcomes of heart failure in elderly persons, 2001–2005. *Archives of Internal Medicine, 168*(22), 2481–2488.
6. Rossignol, P., et al. (2019). Heart failure drug treatment. *The Lancet, 393*(10175), 1034–1044.
7. Allen, L. A., et al. (2009). End points for clinical trials in acute heart failure syndromes. *Journal of the American College of Cardiology, 53*(24), 2248–2258.
8. Ezekowitz, J. A., et al. (2017). 2017 Comprehensive update of the Canadian cardiovascular society guidelines for the management of heart failure. *Canadian Journal of Cardiology, 33*(11), 1342–1433.
9. Granger, B. B., et al. (2015). Results of the chronic heart failure intervention to improve medication adherence study: A randomized intervention in high-risk patients. *American Heart Journal, 169*(4), 539–548.
10. Vansimaeys, C., Benamar, L., & Balague, C. (2021). Digital health and management of chronic disease: A multimodal technologies typology. *The International Journal of Health Planning and Management, 36*(4), 1107–1125.
11. Qiu, Y., et al. (2021). The emerging role of digital health technology in cardiovascular care. *Canadian Journal of Cardiology, 37*(7), 939–942.
12. Doyle, J., et al. (2021). A digital platform to support self-management of multiple chronic conditions (ProACT): Findings in relation to engagement during a one-year proof-of-concept trial. *Journal of Medical Internet Research, 23*(12), e22672.
13. Arksey, H., & O'Malley, L. (2007). Scoping studies: Towards a methodological framework. *International Journal of Social Research Methodology, 8*(1), 19–32.
14. Tricco, A. C., et al. (2018). PRISMA extension for scoping reviews (PRISMA-ScR): Checklist and explanation. *Annals of Internal Medicine, 169*(7), 467–473.
15. Sterne, J. A. C., et al. (2019). RoB 2: A revised tool for assessing risk of bias in randomised trials. *BMJ, 366*, l4898.
16. Omar, M., et al. (2021). Hemodynamic determinants of activity measured by accelerometer in patients with stable heart failure. *JACC Heart Fail, 9*(11), 824–835.
17. Karhula, T., et al. (2015). Telemonitoring and mobile phone-based health coaching among Finnish diabetic and heart disease patients: Randomized controlled trial. *Journal of Medical Internet Research, 17*(6), e153.
18. Marquis-Gravel, G., et al. (2019). Technology-enabled clinical trials: Transforming medical evidence generation. *Circulation, 140*(17), 1426–1436.
19. Sharma, A., et al. (2018). Using digital health technology to better generate evidence and deliver evidence-based care. *Journal of the American College of Cardiology, 71*(23), 2680–2690.
20. Hall, A., et al. (2020). Effectiveness of a single lead AliveCor electrocardiogram application for the screening of atrial fibrillation: A systematic review. *Medicine (Baltimore), 99*(30), e21388.