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Patient-centered mobile health technology intervention to improve self-care in patients with chronic heart failure: Protocol for a feasibility randomized controlled trial

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Abstract

This randomized controlled trial aims to determine the feasibility and preliminary efficacy of a patient-centered, mobile health technology intervention (iCardia4HF) in patients with chronic HF. Participants (n=92) are recruited and randomized 1:1 to the intervention or control group. The intervention group receives a commercial HF self-care app (Heart Failure Storylines), three connected health devices that interface with the app (Withings weight scale and blood pressure monitor, and Fitbit activity tracker), and a program of individually tailored text-messages targeting health beliefs, self-care self-efficacy, HF-knowledge, and physical activity. The control group receives the same connected health devices, but without the HF self-care app and text messages. Follow-up assessments occur at 30 days and 12 weeks. The main outcome of interest is adherence

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Declaration of interests
The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.
The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Supplementary data
Supplementary material

to HF self-care assessed objectively through time-stamped data from the electronic devices and also via patient self-reports. Primary measures of HF self-care include medication adherence and adherence to daily weight monitoring. Secondary measures of HF self-care include adherence to daily self-monitoring of HF symptoms and blood pressure, adherence to low-sodium diet (spot urine test), and engagement in physical activity. Self-reported HF self-care and health-related quality of life are assessed with the Self-care Heart Failure Index and the Kansas City Cardiomyopathy Questionnaire, respectively. Hospitalizations and emergency room visits are tracked in both groups over 12 weeks as part of our safety protocol. This study represents an important step in testing a scalable mHealth solution that has the potential to bring about a new paradigm in self-management of HF.

Keywords

heart failure; self-care; mHealth; smartphones; text messages; randomized controlled trial

1. Introduction

Heart failure (HF) is a serious chronic condition associated with high mortality, frequent hospitalizations, and poor health-related quality of life (HRQoL). An estimated 6.2 million Americans have HF and approximately 1 million new cases are reported annually in the United States (US) [1]. Despite major improvements in clinical outcomes with surgery and pharmacotherapy, mortality rates and hospital readmissions remain high [1]. Approximately 25% of patients are readmitted to the hospital within 30 days and up to 50% within 6-months following a HF hospitalization [1]. This results in significant, potentially avoidable costs to our already strained healthcare system since hospitalizations account for 65-70% of annual HF management costs [2–4].

Much of the healthcare utilization costs and deaths are thought to be preventable if patients engage in better HF self-care [5]. HF self-care is a naturalistic decision-making process that involves three main concepts [6]: maintenance (routine behaviors associated with treatment adherence); symptom perception (daily self-monitoring and interpretation of signs and symptoms), and management (response to symptoms when they occur). Clinical guidelines stress the importance of effective HF self-care as part of a successful treatment [5 7 8], but lack of patient engagement in these routine self-care behaviors remains challenging. Nonadherence to daily self-monitoring of weight and HF symptoms is remarkably high (>50%), even among recently discharged patients [9]. Previous research shows that in 20% to 64% of HF readmissions, nonadherence to prescribed medications and low-sodium diet are implicated as proximate causes of readmission [10–14]. As a result, improvement of HF self-care behaviors remains a priority for research and clinical practice.

Consumer-facing mHealth technologies such as mobile health applications (apps) and wearables offer unprecedented opportunities for engaging HF patients in daily self-monitoring and healthy lifestyle behaviors, including self-management of HF outside of hospital settings [15]. However, the feasibility, safety, and efficacy of such commercial mHealth products is largely underexplored in patients with HF [16 17]. Despite the existence

of numerous standalone mobile apps and digital health devices, research on their effectiveness for HF self-management is limited [16 18]. Most clinical trials to date have evaluated research-based mobile apps that are not commercially available (e.g., [19 20]) or apps that are part of a larger remote patient monitoring system in which the main recipients of the patient data and alerts are physicians and nurses. The involvement of clinicians in daily monitoring of vital signs and symptoms interferes with the patients' role as primary decision-makers in managing their own condition and the development of independent self-care skills (e.g., [21 22].

This study aims to address this research gap by assessing the feasibility, acceptability, and preliminary efficacy of *iCardia4HF* – a patient-centered mHealth intervention that integrates a number of commercially available mobile apps and connected health devices, with a theory-based program of individually tailored text messages [23 24] to improve self-care in patients with HF [23]. This study will provide intervention feasibility and preliminary clinical trial data for a full-scale randomized controlled trial (RCT) that will determine the efficacy of the iCardia4HF intervention as an adjunct therapy to standard care for adults with chronic HF. In this paper, we describe the study design, methodology, and procedures of the iCardia4HF trial.

2. Methods

2.1 Study design

This study is a single-site, prospective, parallel group feasibility RCT in which 92 adult patients with HF are randomized to the iCardia4HF intervention or control group for 12 weeks. The intervention group receives a patient-centered HF self-care app named Heart Failure Storylines and three connected health devices (weight scale, blood pressure monitor, and activity tracker) for daily self-monitoring of HF signs and symptoms, as well as 4 individually tailored text-messages per week. The control group receives the same connected health devices (to establish equipoise), but without the HF self-care app and text-messages. In addition, both groups receive a Medication Event Monitoring bottle for objective assessment of medication adherence (primary outcome). As shown in Figure 1, the study includes the following phases: (1) participant screening; 2) informed consent; 3) baseline assessment (visit 1); 4) randomization; 5) 30-day assessment (visit 2); and 6) post-intervention assessment at 12 weeks (visit 3). The follow-up times for the assessments were chosen because improvements in HF self-care have occurred at similar times in other studies [25–28]. Also, the 30-day period corresponds with the time identified in the literature as the period of greatest risk for re-hospitalization [29–31].

2.2 Trial Registration and Funding

The trial is funded by the Office of the Director of the National Institutes of Health (NIH) and the National Institute of Nursing Research. It is approved by the University of Illinois at Chicago Institutional Review Board (protocol 2019-0790), and is registered at ClinicalTrials.gov (NCT04262544).

2.3 Specific aims and hypotheses

The iCardia4HF trial has the following specific aims:

Aim 1: Determine the feasibility and acceptability of the iCardia4HF intervention over 12 weeks.

Aim 2: Estimate the effects of the iCardia4HF intervention on objectively assessed measures of HF selfcare (medication adherence; self-monitoring of weight, blood pressure [BP], and symptoms; sodium-restricted diet; and physical activity [PA]) measured with the multiconnected app-based devices, and self-reported HF self-care measured with the Self-care of Heart Failure Index (SCHFI) at 30 days and 12 weeks.

Aim 3: Examine the mediating effect of intervention target variables (health beliefs, self-care efficacy, and HF-knowledge), and the impact of individual patient factors (age, gender, cognition, depression, comorbidities, left ventricular ejection fraction (LVEF) and New York Heart Association (NYFIA) class), on both objectively assessed and self-reported measures of HF self-care.

Central Hypothesis: Compared with the control group, HF patients who receive the iCardia4HF intervention will have greater improvement in both objective and subjective measures of HF self-care adherence at 12 weeks.

3.4 Eligibility criteria

Participants are recruited from inpatient cardiology and the outpatient HF Clinic of the University of Illinois Hospital and Health Sciences System (UI Health) in Chicago. Table 1 enumerates the inclusion and exclusion criteria. The study focuses on patients who have HF with reduced ejection fraction (HFrEF, ≤40% LVEF), given the differences in pathophysiology, clinical representation, and medication treatment of patients with preserved ejection fraction (≥50%)[7]. Exclusion criteria are applied to ensure participants' ability to safely perform HF self-care, complete the study requirements, minimize error associated with the primary outcome, and prevent possible missing data. The race/ethnicity composition of the enrollment population, based on the demographics of the HF population at the study recruitment site and inclusion/exclusion criteria, is expected to be approximately 80% Black or African American, 10% White, 5% Hispanic or Latinx, and 5% other. We plan on enrolling equal numbers of women and men to improve health equity for women who are under-represented in HF research [32].

2.5 Patient recruitment and enrollment

Recruitment begins by querying the electronic medical record to screen potentially eligible patients who are hospitalized at UI Health with a primary or secondary diagnosis of HF and also ambulatory HF patients with upcoming appointments at the Heart Failure Outpatient Clinic. Potentially eligible patients are approached in person before they are discharged from the hospital or contacted via telephone by a trained researcher, who briefly explains the study, invites participation, responds to any questions, and completes eligibility screening, including the Montreal Cognitive Assessment (MoCA) [33] and other criteria requiring an interview with the patient (e.g., ability to perform self-care and write/read in English).

Eligible patients are provided written informed consent and are scheduled to complete baseline assessment and 1-hour study orientation, which includes setting up the devices and apps and training on how to use them.

During the "stay-at-home" order in Illinois that went into effect March 21st due to the COVID-19 pandemic, recruitment and enrollment was temporarily suspended, until our team transitioned and received IRB approval for all of the above procedures to be conducted remotely via telephone and Internet. Specifically, all potentially eligible patients were contacted by telephone only; cognitive assessment was performed using the MoCA BLIND version [34], which comprises the same items as the full MoCA except the visual ones, with scores converted back to 30 using the following equation: (19x30)/22; and informed consent was obtained using the Research Data Electronic Capture (REDCap) eConcent Framework [35]. Additional measures are described below in the Participant Safety section.

2.6 Randomization and allocation concealment

After completion of baseline assessment, enrolled study participants are randomly assigned in a 1:1 ratio to the intervention or control group (n=46 per arm). Using Pocock and Simon's "minimization" procedure [36], randomization assures better-than-chance group balance at baseline for the following essential stratification variables with equal weight: age (18-44, 45-64, >65), gender (male, female), NYHA class (I-IV), and days between discharge of last HF admission and randomization (≤30 days, 31-90 days, and >90 days). We use QMinim [37], a free web-based minimization application hosted in a secure server at the University of Illinois at Chicago, to dynamically allocate participants in one of the two arms. QMinim's computational algorithm automatically randomizes new participants based on the selected baseline characteristics of all the participants who have been previously randomized to each arm, thus minimizing the potential total covariate imbalance between study arms after each new patient is randomized. The algorithm uses the "biased coin" probability method, recommended by Efron [36 38], to protect allocation predictability. Specifically, for each new patient who completes baseline assessment and is ready to be randomized, the system automatically calculates an imbalance score for each of the baseline covariates, as the excess or deficit of previously randomized patients in either arm matching the current patient on that covariate. Randomization with QMinim is performed by a designated study staff person who is not involved in patient screening and recruitment and does not have the ability to influence the execution of the minimization procedure. Investigators enrolling participants do not have access to QMinim or knowledge of the randomization method and therefore, they are not able to foresee assignments.

2.7 Intervention

Participants in the intervention group receive a smartphone-enabled multiconnected app kit, in addition to usual care, consisting of: (1) a patient-centered mobile health app, named Heart Failure Storylines; (2) three connected health devices (Withings Body Composition weight scale and BP monitor, and Fitbit Charge 3 activity tracker) along with their respective mobile apps (Health Mate and Fitbit); and (3) individually tailored text-messages targeting health beliefs (perceived benefits and barriers of adherence to HF self-care), HF knowledge, and HF self-care efficacy.

Below, we present the theoretical framework that guides the intervention and describe the multiconnected app and text-messaging components as well as the goal-setting approach that is used to promote HF self-care in the intervention group.

2.7.1 Theoretical Basis of the Intervention—Poor HF self-care occurs for a variety of reasons. Important modifiable factors influencing patient decisions about HF self-care include health beliefs (perceived benefits and barriers of HF self-care) [6 39–41], self-care efficacy [6 42–44], and knowledge about HF [39 45 46]. Individual factors such as age [47 48], gender [48 49], cognitive decline [50 51], depression [52 53], stress/anxiety[49], and comorbidities [54], also affect HF self-care. Figure 2 provides the conceptual framework of the iCardia4HF intervention and selection of outcome measures. Our framework reflects an integration of the Health Belief Model [55] and the Situation Specific Theory of HF Self-Care [6]. The Heart Failure Storylines app incorporates a number of digital health tools (e.g., self-monitoring of vital signs and symptoms, medication adherence tracking and patient reminders) that target three constructs of the Situation Specific Theory of HF Self-care: *self-care maintenance* (routine behaviors associated with treatment adherence), *symptom perception* (monitoring of signs and recognition of symptoms), and *self-care management* (response to symptoms). The text-messaging component of the intervention further promotes adherence to HF self-care strategies and self-management of symptoms by influencing the two main constructs underlying the Health Beliefs Model (*perceived barriers and perceived benefits about medication, diet, and selfmonitoring adherence), as well as self-care efficacy* (confidence in the ability to be adherent and respond to HF symptoms) *and HF knowledge*. Guided by patients' responses to validated instruments at different timepoints, tailored text-messages aim to address patients' perceived barriers to adhering with HF self-care regimens, enhance *self-care efficacy*, and improve HF-related knowledge. We hypothesize that the iCardia4HF intervention will improve HF self-care and subsequently lead to better health outcomes. The intervention's effect on self-care is mediated by intervention targets (health beliefs, self-care efficacy, and self-care knowledge). The intervention's effect on HF self-care is moderated by person, problem-specific, and environmental factors (gender, age, NYHA class, race, marital status, education, comorbidities and social support) [56].

(HF: Heart Failure, HRQoL: Health Related Quality of Life; ER: Emergency Room)

2.7.2. Heart Failure Storylines app and connected health devices—Heart Failure Storylines (Figure 3) is a cross-platform, self-care mobile app that allows patients with HF to monitor and manage their health. It has been developed by Self-Care Catalysts in collaboration with the Heart Failure Society of America (HFSA), and is available for free via the Apple and Google Play stores [57]. Heart Failure Storylines includes a variety of tools that help patients track their medications, symptoms, vital signs, diet, PA, water consumption, and healthcare appointments, among other things. These tools can be enabled or disabled as needed to provide users with a personalized profile for HF self-management. Heart Failure Storylines allows users to connect their app with third-party wearable activity trackers and digital health devices. Data collected from these devices are presented in a weekly calendar format with color-coding schemes to help patients identify pre-clinical measures of worsening HF between time periods, correlate lifestyle behavior with changes

in their health and modify their behavior accordingly to self-manage HF symptoms. For the purpose of this study, the Heart Failure Storylines app is configured to connect via Web Application Programming Interfaces (API) to the three devices mentioned above (Withings weight scale and BP monitor, and Fitbit PA tracker), and provide study participants with the following electronic tools: medication tracker, HF symptoms tracker, vital signs tracker, PA tracker, low sodium guidelines, and My Storylines Report. Appendix 1 provides further details about each feature and how it is used in the study. All the other tools that are available in the Heart Failure Storylines app (e.g., water consumption, diet diary, and appointment tracker) are disabled from the patient dashboard to reduce complexity and participant burden.

Figure 4 depicts the overall architecture and components of the iCardia4HF intervention, and Table 2 provides further details about the types of monitored data, devices and apps used to facilitate selfmonitoring of HF signs and symptoms, types of self-monitoring (passive/active), and notifications/reminders to engage participants in daily HF self-care adherence.

Briefly, the three connected health devices are provided at no cost for daily self-monitoring of weight, body composition (e.g., water mass, fat mass, bone mass, and muscle mass), BP, continuous and resting heart rate, PA (steps and intensity), exercise, sedentary time, and sleep (duration, stages, and oxygen variation). The Medication Event Monitoring System (MEMS) bottle is used to objectively assess medication adherence. Each device (except MEMS) interfaces with its native mobile app via Bluetooth and with the Heart Failure Storylines app via the cloud. Specifically, the Withings Health Mate app interfaces with the Cardio Body scale and BP monitor, while the Fitbit Charge 3 interfaces with the Fitbit app. Every time a patient steps on the scale or measures his/her BP, the measurement data are transferred to the Health Mate app via Bluetooth, and then to the Heart Failure Storylines app via an application programming interface with the Withings cloud server. The same applies to Fitbit. Both Health Mate and Fitbit provide participants with a number of visualization and graphic feedback tools that allow them to review and understand their data. Heart Failure Storylines comprises a number of self-monitoring, patient education, and adherence reminder tools, targeted at supporting HF self-care maintenance, monitoring, and management.

As shown in Figure 2, the iCardia platform [58] is used to remotely collect, in real-time, all patientgenerated health data captured by the devices and apps, and also to send individualized text messages to study participants in the intervention group. iCardia is a digital health platform that collects continuous biosensor data from third-party applications and connected health devices and provides researchers with a number of data visualization, analytics, and communication tools to support personalized and adaptive health behavior interventions. It has been developed by the principal investigator of this study (SK) and is hosted on a HIPAA compliant server at the University of Illinois at Chicago. iCardia is currently utilized by numerous NIH-funded studies, supporting research in the area of hypertension [59], heart failure [23], asthma [60 61], chronic obstructive pulmonary disease [62], and PA promotion [63 64].

2.7.3 Text Messages for HF Self-care—Patients allocated to the intervention group also receive a theory-based program of individually tailored text messages via the iCardia platform. The text messaging program aims to improve HF self-care behaviors and PA by targeting patients' health beliefs (perceived benefits and barriers of HF self-care), self-care efficacy, and HF knowledge in a culturally sensitive manner. The content and tailoring algorithm of the text messaging program are based on the "*Heart Messages*" program which was originally developed and validated by Pressler et al [65]. Our research team translated the Heart Messages into short message service (SMS) text messages and refined their content with input from clinicians and HF patients [23]. The Flesch-Kincaid test was used to ensure that readability of the text messages is ≤12th grade. Tailoring of the text messages is guided by patients' responses to the following validated scales administered at baseline and 4 weeks: 1) Health Belief Scales [66 67]; 2) HF Self-care Self-efficacy Scale [68]; and 3) Dutch HF knowledge Scale [69]. For example, questions on the Health Belief Scales are divided into perceived benefits and barriers about medication adherence, low-sodium diet compliance, and self-monitoring compliance. Each item on the scale receives a five-point score ranging from 1 (strongly disagree) to 5 (strongly agree). Participants who score ≥3 on a barrier question or ≤3 on a benefit question, receive weekly text messages tailored to that specific barrier or benefit item. If a participant scores >3 on a benefit question or <3 on a barrier question, then a message is not sent because it is presumed that the patient already understands the barriers or benefits identified in that question. Culturally appropriate content to enhance patients' self-care efficacy as well as tactical ("how to") and situational skills ("what to do when") is also incorporated into the messages. Participants can respond to text messages if they have any questions or concerns, but are advised to call their healthcare provider or go to the emergency room in case of an acute exacerbation or other health issues they might face during the study. Participants are informed that this is not a clinical telehealth system or substitute for clinical care.

2.7.4 Evidence-based intervention goals—A goal-based approach is used to promote HF self-care via the iCardia4HF kit. The primary goals are daily adherence to: (1) taking all prescribed HF medications at the right time and dose; (2) self-monitoring of weight, body composition, and BP each morning before breakfast and medication taking; (3) checking for HF symptoms; (4) following a sodium-restricted diet (2000-3000 mg of sodium/day); and (5) engaging in PA to gradually increase the number of steps above baseline by a minimum of 3,000 steps per day over 12 weeks, an increase that approximates the 30 minutes of PA at a moderate walking pace recommended by clinical guidelines for patients with HF [7]. Personalized reminders for medication, vital signs, and symptom monitoring, as well as weekly PA goals in concurrence with the study cardiologis's recommendations are entered in the patients' mobile apps by study personnel. These can be updated during the study by the patient or research assistants (RA) through the app's web interface and iCardia. Discussion with the study cardiologist at the beginning of the study regarding the appropriate level of PA and target heart rate address the particular needs of patients with an implantable cardioverter defibrillator or pacemaker, and promote maintained PA. Participants are informed that the mobile app is not a substitute for usual care and does not serve as a telemonitoring system or for reporting emergencies.

2.8 Control Group

Participants assigned to the control group receive usual care, plus the same connected health devices as the intervention group, but without the Heart Failure Storylines mobile app, motivational text-messages, and notifications/reminders. The connected health devices are set up to automatically transmit data via the patients' smartphone to the iCardia server every time a measurement is taken. This allows us to collect directly comparable measures of HF self-care adherence between the two groups. Usual care at UI Health includes patient education before hospital discharge, and follow-up visits at the outpatient HF clinic at 1-2 weeks after discharge and monthly thereafter depending on the patien's condition. Patient education includes literacy-sensitive material about HF self-care developed by the Sheps Center for Health Services Research [70 71], and a 40-minute session with an Advance Practice Registered Nurse (APRN) and a dietician.

2.9 Participant safety

Patients are carefully screened, and individuals who do not meet the eligibility criteria or for whom the intervention is deemed medically inappropriate or unsafe are excluded. To ensure the safety of our study participants and research staff through the COVID-19 pandemic, we use a number of good practices described in Bikson et al [72] as well as risk mitigation measures recommended by the Centers for Disease Control and Prevention. Specifically, we have converted the study consent, baseline assessment, study onboarding, and follow up assessments to virtual study visits using videoconferencing (e.g. Zoom), YouTube videos, telephone, and REDCap. Participants are provided with a secure link to the study consent form via email or text message; are walked through the consent form with study staff remotely (telephone or video); and can sign the informed consent form through a secure online signature process implemented in REDCap. For setting up the devices/apps and training participants on how to use them, we created a number of user-friendly videos, and make these available to participants via a secure link. Furthermore, we contact participants via phone to address any questions and technical issues. For follow up assessments conducted remotely, we use telephone or Zoom calls. We have also established strict safety and sanitization procedures for all in-person interactions, trained staff in execution of these procedures, and implemented all institution required safety procedures.

To ensure unbiased ascertainment between the intervention and control groups, we systematically review enrolled patients' medical record at baseline, 4 weeks, and 12 weeks to confirm continuous eligibility and to identify any adverse events occurring during the study. In addition, we provide participants with a standardized sheet at baseline to record any hospitalizations or emergency room visits they have during the study, and ask them to text iCardia in case they experience a hospitalization or other adverse event. An adverse event is defined as any untoward physical or psychological event experienced by a study participant during or as a result of their participation in the research study. All events are recorded and then reviewed by the study team and the independent data safety monitor person for seriousness, study relatedness, and expectedness. Finally, we have established patient safety protocols for participants who report frequently contemplating suicidal ideation and those whose Patient Health Questionnaire (PHQ-9) scores are suggestive of moderately severe or severe depressive symptoms (scores>14)[73].

2.10 Retention

Attrition can be a challenge for follow-up data collection in patients with chronic conditions, especially during the COVID-19 pandemic. Patients with HF or other chronic conditions may be reluctant to seek in person care or participate in study procedures that require in-person visits due to fear of contracting COVID-19, especially given their increased risk of severe illness with infection [57]. Therefore, in addition to the patient safety measures described above, we also use a number of successful retention strategies to minimize loss to follow up [23 63 64]. First, all research-related visits are offered both in-person and virtually at a time that is convenient for the participants and, if feasible, on days and hours that coincide with their follow up appointment at UI Health as part of usual care to reduce the number of visits. Second, we provide transportation and parking vouchers as needed to those who prefer to attend the study visits in-person. Third, participants receive monetary reimbursement for data collection ($40 at the beginning and $40 at the end of the study for a total of $80). Fourth, participants get to keep the connected health devices for free after completion of the study. Fifth, we collect and use the names and contact information of two family members or friends in case participants cannot be reached by phone, mail, or email. Sixth, we use periodic calls every 30 days to verify address and phone data, and send text message reminders 24 hours prior to data collection appointments.

2.11 Study measures and data collection schedule

All outcome measures and assessment schedules are listed in Table 5. Below we provide details for each measure.

2.11.1 Clinical characteristics and demographics—Sociodemographic information are collected at baseline via patient interviews using the National Institute of Nursing Research Common Data Elements Demographics form. Clinical information are extracted from the electronic medical record by trained research assistants. Comorbid conditions are scored using an updated version of the Charlson comorbidity index [74]. Depression is assessed using the Patient Health Questionnaire-9 (PHQ-9) [73] and cognition is assessed with the Montreal Cognitive Assessment (MoCA) scale [33].

2.11.1 Feasibility and acceptability measures (Aim 1)—With respect to feasibility and acceptability measures, we collect recruitment process data (e.g., number of patients screened, called, and eligible), and keep track of the recruitment length of time, participation declines and withdrawals along with reasons for withdrawing, retention rates, and recruitment issues that may arise. With respect to the intervention, we collect data on the proportion of scheduled, successfully delivered, and read text messages; frequency of use of the devices and apps; and technical issues that may arise.

The final assessment visit at Week 12 includes an exit interview to evaluate participants' perceived usefulness, ease of use, and satisfaction with the devices, mobile apps, and text messages (intervention group only), as well as intention to continue using the iCardia4HF multi-connected app kit for daily selfmonitoring and self-management of HF symptoms. Evaluation is guided by the Technology Acceptance Model (TAM) [75], which has been used in numerous studies in healthcare [76], including mHealth interventions for patients

with HF [77]. Participants are asked about any problems they encountered during the study with the use of the mHealth technologies, and suggestions for improvement in a subsequent full trial.

2.11.2 Primary outcome measures (Aim 2)—The primary outcomes of interest are: (1) medication adherence; and (2) adherence to daily self-monitoring of weight.

Medication adherence, defined as the extent to which a patien's medication-taking behavior corresponds with the prescribed medication regimen [78], is measured by electronic monitoring. We use AARDEX's MEMS, a medication bottle cap fitted with a microelectronic chip that records the time and date the bottle is opened and closed. Real-time data are recorded in the chip and transferred to a secure web-based server via an electronic reader at follow up research visits 2 and 3 (30 days and 12 weeks, respectively). Data are collected for 1 HF medication for each patient because it is impractical and may be burdensome to patients to use multiple MEMS. Previous research has demonstrated that monitoring of 1 medication with the MEMS provides a valid indicator that patients took all of their medications even when they are prescribed multiple medications per day [78–81]. Three indicators of medication adherence are assessed with the MEMS: (1) dose-count (taking adherence), defined as the percentage of prescribed number of doses taken and measures deviation from the physician's prescription; (2) dose-days, defined as the percentage of days the correct number of doses were taken; and (3) dose-time (scheduling adherence), defined as the percentage of doses taken on schedule.

Adherence to daily self-monitoring of weight is assessed with the Withings Body Cardio scale based on time-stamped data that are automatically transmitted from the scale to the patien's smartphone and then to the iCardia study server. Daily adherence to self-monitoring of weight is defined as the percentage of days with one or more weight measurements between 12:00 am and 11:59 pm over 12 weeks.

2.11.3 Secondary outcome measures (Aim 2)—*Adherence to daily self-monitoring of BP* is measured with the Withings Blood Pressure monitor. We use time-stamped data automatically transmitted from the patien's phone to the iCardia server to calculate the percent of days patients complete at least one BP measurement between 12:00 am and 11:59 pm over a period of 12 weeks. Days with multiple BP measurements count as one measurement for that day.

Adherence to daily self-monitoring of HF symptoms (intervention group only) is assessed with the Heart Failure Storylines app. We use time-stamped data from the app to count the number of days patients in the intervention group completed the 8-item HF symptoms assessment between 12 am and 11:59 pm over a period of 12 weeks. Days with incomplete data (e.g., unanswered symptom questions) are labeled as "incomplete" and reported separately.

Adherence to low-sodium diet is assessed with a spot morning urine sample test. The Kawasaki formula will be used to estimate the 24-hour urinary excretion from a fasting morning urinary sample [82]. This approach has been proven to provide a valid estimate of

the sodium intake in several populations, including patients with HF, and in large-scale epidemiological studies [83–85].

Physical activity is assessed with the Fitbit Charge 3 activity tracker over 12 weeks. Physical activity measures include mean number of daily (1) steps, (2) minutes of light, moderate, and vigorous activity, and (3) sedentary minutes by week over a period of 12 weeks. To be included in the weekly analysis, ≥10 hours of daily Fitbit wear-time has to be available for ≥4 days of each 7-day time frame.

HF self-care is measured with the Self-Care Heart Failure Index (SCHFI) version 7.2 [6]. The SCHFI consists of 29-items divided into three scales measuring self-care maintenance, symptom perception, and self- care management. Each SCHFI scale uses Likert-type response and is scored separately. Scores on each scale are standardized to range from 0 to 100. Higher scores indicate better self-care. A score of ≥70 on each scale is considered to be an adequate level of HF self-care. The minimal clinically important change is an improvement of 8 points or one-half standard deviation in the standardized score [86].

Health-related Quality of Life (HRQoL) is measured with the Kansas City Cardiomyopathy Questionnaire (KCCQ) [87], a 23-item self-administered scale that quantifies in a disease-specific fashion physical limitations, symptoms (frequency, severity, and recent change over time), quality of life, social interference, and self-efficacy in patients with HF. Scale scores are transformed to a 0 to 100 range. Lower scores indicate worse symptoms and quality of life.

Number of hospitalizations and Emergency room visits. As part of our safety protocol, we record the number of hospitalizations (all-cause and HF-related) and emergency room visits during the study via both self-reports and data abstraction from the UI Health electronic health record (EHR). Monthly telephone calls and patient diaries capture self-reported hospitalizations outside of UI Health. Also, the HF clinic at UI Health contacts other hospitals and routinely requests discharge summaries and medical records when established patients are admitted to another hospital.

2.11.3 Intervention target measures (Aim 3)—*Health Beliefs* are measured with three validated scales: 1) Beliefs about Medication Compliance Scale (BMCS); 2) Beliefs about Dietary Compliance Scale (BDCS); and 3) Beliefs about Self-monitoring Scale (BSMCS). Each scale consists of a benefit and barrier subscale that describes the potential benefits or barriers to taking HF medications (diuretics), following a sodium-restricted diet, or self-monitoring for HF signs and symptoms. Both benefit and barrier items in the three subscales use a 1 to 5 Likert-scale, with 1 corresponding to “strongly disagree” and 5 corresponding to “strongly agree”.

Self-care Self-efficacy is assessed by participant report via interview using the self-care self-efficacy subscale (10 items) of the SCHFI 7.2v instrument to measure the perceived ability and confidence of patients to engage in each phase of the self-care process. Scores on the Self-care Self-efficacy Scale are standardized to range from 0 to 100. Higher scores indicate higher confidence.

HF-knowledge is assessed with the Dutch Heart Failure Knowledge scale (DHFK)[69]. The DHFK is a 15- item multiple-choice test that covers items concerning HF knowledge in general, knowledge on HF treatment including diet and fluid restriction, and HF symptoms recognition. For each item patients choose from three options, with one of the options being the correct answer. The scale score ranges from 0 to 15 points with higher scores indicating better knowledge.

2.12 Statistical analysis

2.12.1 Analytic plan—Statistical analysis will be conducted using intention-to-treat principles and results will be presented according to the Consolidated Standards of Reporting Trials (CONSORT) statement for randomized pilot and feasibility trials [94 95]. We will evaluate between-group differences in primary and secondary outcomes by intention-to-treat using tests of group by time interactions in repeated measures. We will collect information about reasons for missing data and use pattern mixture models and sensitivity analyses to investigate and adjust for potential missing mechanisms. Data that are not missing at random are expected, but all missing data will be monitored regularly to ensure there are no unforeseen biases that might affect results.

Aim 1 is to test the feasibility and acceptance of the iCardia4HF intervention. We will use descriptive statistics to summarize recruitment/retention, acceptance scores, and study measures at baseline. Between-group differences in patient characteristics will be tested using χ^2 and *t*-tests. Linear regression analysis will be used to examine the relationship between “acceptance” of iCardia4HF and the main constructs of the TAM [76].

Aim 2 is to determine the effects of iCardia4HF on objective measures of HF self-care, including self-reported self-care, HRQL, hospitalizations, and emergency room (ER) visits over 12 weeks. Two sample t-tests or the Wilcoxon test will be used to assess between-group differences in mean percentage of days patients adhered to daily self-monitoring (weight and BP) and medication use. We will calculate the mean change from baseline to 12 weeks between groups in number of daily steps, weekly MVPA minutes, 24-hour urine sodium excretion, SCHFI and HRQL scores, and calculate Cohen’s d as a standardized index of effect size with 95% CI. Poisson regression with robust variance will be used to study the incidence of hospital readmission and ER visits.

Aim 3 is to explore the mediating effect of intervention target variables and the impact of independent patient factors on the primary and secondary measures of HF self-care. Driven by our conceptual framework, we will test whether health beliefs, self-care efficacy, and HF-knowledge serve as mediators of intervention effects on the primary HF self-care measures, and further identify the direct association between intervention and outcomes as well as indirect association through the mediator [96 97]. Next, we will use multiple regression analyses to examine the impact of patient factors (age, gender, cognition, depression, comorbidities, LVEF, NYHA, and days between discharge of last HF hospital admission and randomization) on the primary and secondary measures of HF self-care. We will apply generalized mixed models to identify time-varying pattern differences between arms and account for variabilities.

2.12.2 Sample size and data interpretation—An efficacy-based power analysis is beyond the scope of a feasibility study [98]. Therefore, following the paradigm of Ma et al [99], we will use a confidence interval approach to interpret the results of our RCT by considering the variability of the comparative measure and confidence interval (CI) width in reference to conventional effect size standards of clinical significance [100]. A follow-up sample of 40 participants in each arm, accounting for a projected 13% loss to follow-up (n=12) at 12 weeks will achieve 90% power for the expected 2-sided 95% CI to have a standardized half-width no greater than 0.5. With this level of precision, it is unlikely to miss a between-group mean difference in medication adherence and weight self-monitoring adherence that has a Cohen's d≥0.5 (medium or large effect), because the confidence interval in these scenarios (A-B, Figure 5) will exclude the no effect (null) value. Such findings will convincing enough to justify a full RCT. In case the 95% CI overlaps the line of no effect (Scenarios C-E, Figure 4), we will consider the location of the point estimate relative to the null and consider the results in the context of other secondary outcomes (e.g., SCHFI and HRQoL) to decide whether a full trial is warranted. If we encounter Scenario F (Figure 5), where Cohen's d is less than zero and the upper 95% CI is less than 0.2 (small effect), then we will conclude that a larger trial is not warranted without substantive modifications to the intervention approach and study design.

2.13 Quality Control

2.13.1 Data collection and management—In order to protect the privacy of study participants and to maintain confidentiality of the collected data, all datasets created in this study are stored electronically on secure, password-protected, and encrypted databases that are continuously backed up and compliant with the Health Insurance Portability and Accountability Act (HIPAA). In addition, we use anonymous study ID codes for data storing, tracking, and reporting of patient data. Only key research personnel have access to patients' protected health information. Several electronic resources and databases are used for data collection and management. The EPIC UI Health Electronic Health Record is used to identify potentially eligible patients and to extract clinical information from enrolled study participants, including hospitalizations and emergency room visits. The REDCap platform [101 102] is used to record patient screenings, participant enrollment, scheduled follow-up visits, intervention process data entry and verification, and interviewer-administered questionnaire data. REDCap is also be used to produce weekly progress reports that allow us to track patient recruitment and follow-up completion, participant retention, key baseline characteristics of enrolled patients, and other important study information. The iCardia platform [58] is used for the remote collection of all Fitbit and Withings data captured by the connected health devices and to manage the delivery of personalized text messages. The AARDEX platform is used for the collection of medication adherence data, and the Quest Diagnostics platform is used for the collection of urine test results.

2.13.2 Intervention Fidelity—Evidence that the intervention has been delivered as intended is monitored using strategies recommended by the Treatment Fidelity Workgroup of the National Institutes of Health Behavior Change Consortium (BCC) [103]. These strategies focus on study design, training of key research personnel, treatment delivery, treatment receipt, and enactment of treatment skills.

Study Design: We have established standard procedures to monitor and decrease the potential for contamination between the intervention and control group, to monitor interactions with study participants (e.g., number and frequency of text messages and contacts), and also to address foreseeable issues in implementing the study design. We have standardized all training sessions, user manuals, handouts, and educational content (videos) to ensure that both groups receive the same informational content and training at baseline on how to use the connected health devices and mobile apps provided to them. A trained research assistant calls each study participant a week after training, and once a month thereafter, in order to inquire about and address any technical issues that may interfere with the use of the devices or apps. The research assistant also uses the iCardia platform to monitor the incoming data and delivery of text messages to ensure participants' receipt of and adherence to the intervention.

Training: Key research personnel (recruiters, trainers, interventionists, and outcome assessors) are provided with rigorous training and oversight to minimize contamination, drift in skill over time, and/or deviations from the study protocol. We use standardized and pretested training materials, including role-playing to ensure consistent and adequate training of all key research personnel before and during the study. Adequacy of training to implement the study procedures is evaluated and monitored weekly throughout the study.

Intervention delivery, receipt, and enactment: To ensure consistent and satisfactory delivery of the iCardia4HF intervention, we employ a number of techniques, including checklists, direct observation of participant training sessions, weekly review of scheduled and delivered text messaging reports, and participant exit interviews. Checklists and direct observation of participant training sessions ensures that all devices and mobile apps are properly set up for each group at baseline and that there are no deviations from the protocol. Weekly review of text messaging reports ensures that intervention participants are receiving the proper number and type of messages. Exit interviews are used to assess whether intervention participants received, read, and understood the text messages; the degree to which the mobile apps and devices were useful and easy to use; and to what extend the intervention motivated them to improve self-care. Treatment enactment (i.e., the extent to which intervention participants apply the HF self-care maintenance and management skills at the appropriate time in their daily life) is captured by the iCardia platform based on time-stamped data collected from the mobile apps and connected health devices.

3. Discussion

Self-care is fundamental to achieving optimal HF outcomes, but adherence is commonly poor among HF patients. Previous clinical trials have demonstrated that self-management interventions, including face-to-face patient education [104 105], telephone case management [106 107], and home visits [108] can improve self-care adherence and reduce the risk of HF-related hospitalizations. However, most of these interventions have limited reach due to lack of healthcare system investment and patient resources [109]. There is a critical need to develop and test novel HF self-care interventions that are scalable, and patients can manage themselves at a low cost. Even modest reductions in resource use would be beneficial because of HF prevalence and high costs of care.

The proliferation of commercially available mHealth technologies such as mobile apps, wearable activity trackers and other connected health devices [110 111] that permit collection and analysis of large amounts of patient generated health data in real-time, offer scalable and affordable opportunities for improving adherence to HF self-care, engaging individuals in healthy lifestyle behaviors, and expanding delivery of care services to communities that are difficult to reach. Mobile technologies have witnessed unprecedented penetration among adults in the US: 81% of Americans now own a smartphone (non-Hispanic Whites 82%, Blacks 80%, and Hispanics 79%), with lower-income Americans and those over 50 years of age exhibiting a sharp uptick in ownership [112 113]. Because of their portability, connectivity, and sophistication, mobile health apps offer an ideal platform for promoting adherence to HF self-care and delivering behavior change intervention at any time and any place. Mobile apps can support collection and analysis of physiological data in real-time, actionable feedback, adherence reminders, behavioral prompts, interactive patient education, and a host of other features including health information exchange between healthcare providers and patients. Wearable activity trackers and other connected health devices that interface with smartphones can help patients to increase daily selfmonitoring of HF-related parameters without major effect, become more aware of how their bodies work and what is normal, be alerted to health changes that need medical attention, and stay motivated while making lifestyle changes [114]. Text messaging is also shown to be effective in promoting adherence to self-care and healthy lifestyle behaviors in areas such as diabetes, obesity, and cardiovascular disease [115–119]. Systematic reviews on the effectiveness of mHealth interventions for long-term conditions (e.g., diabetes, and hypertension) support their potential for improving management and health outcomes through self-care [15 117 120–122]. These technologies provide exciting opportunities for improving health outcomes in patients with chronic disease, but their utility is underexplored in the area of HF. The vast majority of randomized controlled trials have focused primarily on testing the efficacy of telehealth approaches that are not targeted at improving patients' self-care skills. Additionally, a key translation challenge is that many mHealth apps with empirical data are not commercially available, while many commercially available apps which patients are already experimenting with on their own have not been tested empirically or rigorously studied [15].

This study aims to provide useful information in three important areas. First, it will provide useful information regarding the feasibility of recruitment, methods, and deployment of commercially available mHealth tools to promote better self-care in patients with HF. A recent systematic review found 30 commercial apps supporting HF symptom monitoring and self-care [16]. These have been downloaded by more than 52,000 people [16]. However, no prior trials have assessed their efficacy [16]. The proposed study attempts to address this important research gap and respond to recent recommendations from the *American Heart Association* for future trials to include commercial mHealth products to determine their efficacy in improving health outcomes [15]. Our study uses Heart Failure Storylines (HFS), a free app that has been developed in partnership with the *Heart* Failure Society of America (HFSA) and is actively used by ~2000 people. The app is ranked as one of the highest performing apps in the review of Creber et al [123], based on the Mobile Application Rating Scale (MARS) [124], the IMS Institute for Health Informatics functionality scores [125],

and the HFSA guidelines for nonpharmacological management of HF [126]. In addition, we use the Fitbit and Withings apps and devices. Second, our study will provide useful information regarding the feasibility and preliminary efficacy of using text messages to promote HF self-care adherence. Text-messaging is a low-cost intervention that has shown to be efficacious in diabetes self-management [117], smoking cessation [127], and medication adherence [115]. However, the potential efficacy of text messages in underexplored in the area of HF. Only one small (n=6), single-arm study has tested the feasibility of using text messages for HF self-management [128]. Third, our study will provide valuable information about the feasibility of mHealth intervention in minority HF patients. The University of Illinois Hospital and Health Sciences System (UI Health) serves a diverse population in Chicago and therefore, we are uniquely positioned to address the health disparity in health outcomes for African Americans and Hispanic/Latinos patients. This is critical as minorities have the highest incidence of HF across all age groups and worse adherence to self-care [129]. Most trials of mHealth interventions for HF have been conducted in Europe, Canada, or Asia, and therefore have not involved African Americans or Hispanic/Latino patients.

In summary, the current study aims to provide important information on the feasibility, safety, and potential efficacy of the iCardia4HF intervention among patients with HF. Specifically, we will collect pilot data needed to (1) determine whether it is feasible and safe to use consumer-grade mHealth technologies to support daily self-monitoring and self-management of HF signs and symptoms in patients with HF, (2) determine whether adherence to using the iCardia4HF multiconnected app intervention is achievable in the target study population, (3) estimate accrual and attrition rates, (4) justify whether a full trial is warranted, (5) identify the need and potential for further improvement of the intervention components, and (6) explore potential effect modifiers and mechanisms to guide further investigation. Data collected from this RCT will enable us to refine the design, materials, operating procedures, and intervention components for a full-scale clinical trial that will be adequately powered to determine the efficacy of the iCardia4HF intervention in improving adherence to HF selfcare and reducing hospitalizations and mortality rates in patients with HF.

iCardia4F represents a meaningful advance in promoting and assessing HF self-care. To our knowledge, no other study has integrated real-time data from multiple connected health devices and MEMS bottles to provide direct and objective assessment of HF self-care behaviors. Process measures from the feasibility and, if warranted, subsequent efficacy trial will inform the intervention’s potential as an adjunct to usual care. The combination of smartphones and low-cost mHealth technologies that are commercially available make the proposed intervention portable to different clinical settings and create exciting opportunities for scalability and broader impact. If ultimately proven efficacious, iCardia4HF has the potential to support HF self-management by offering an affordable and scalable mHealth solution that can be used as a supplement to routine care to improve HF self-care adherence among patients with chronic HF.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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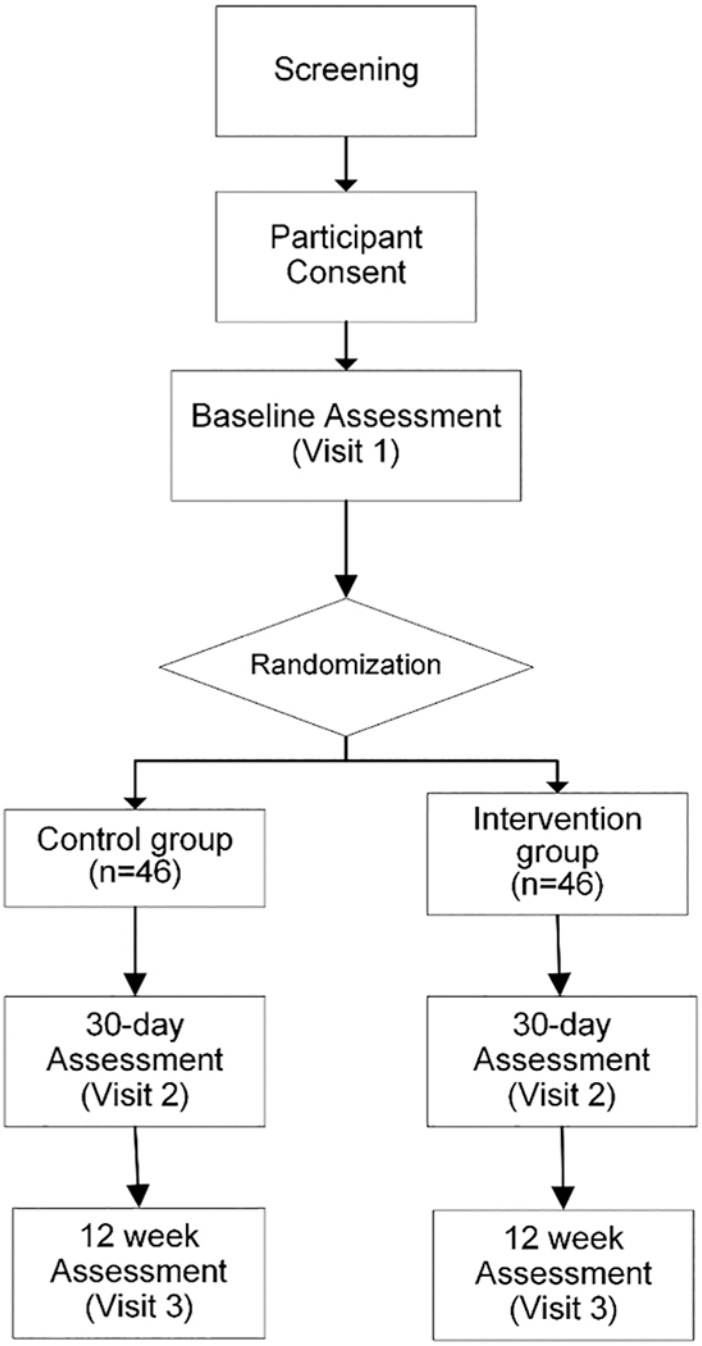

Figure 1:
Study Design

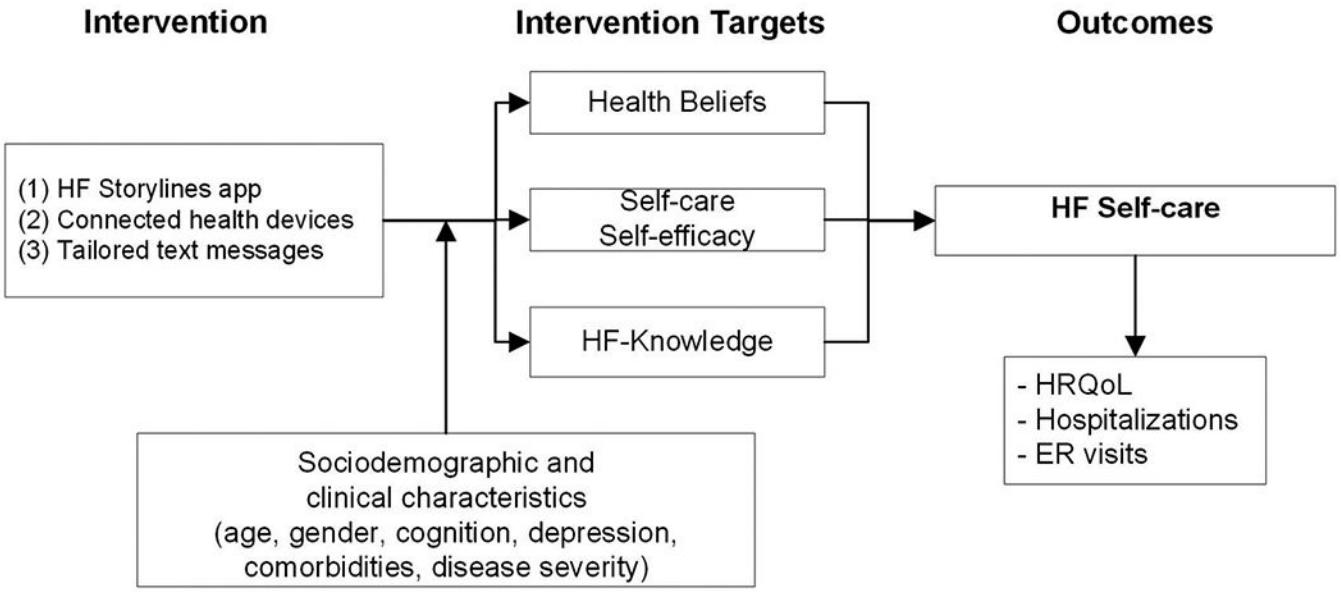

Figure 2:
Conceptual Framework

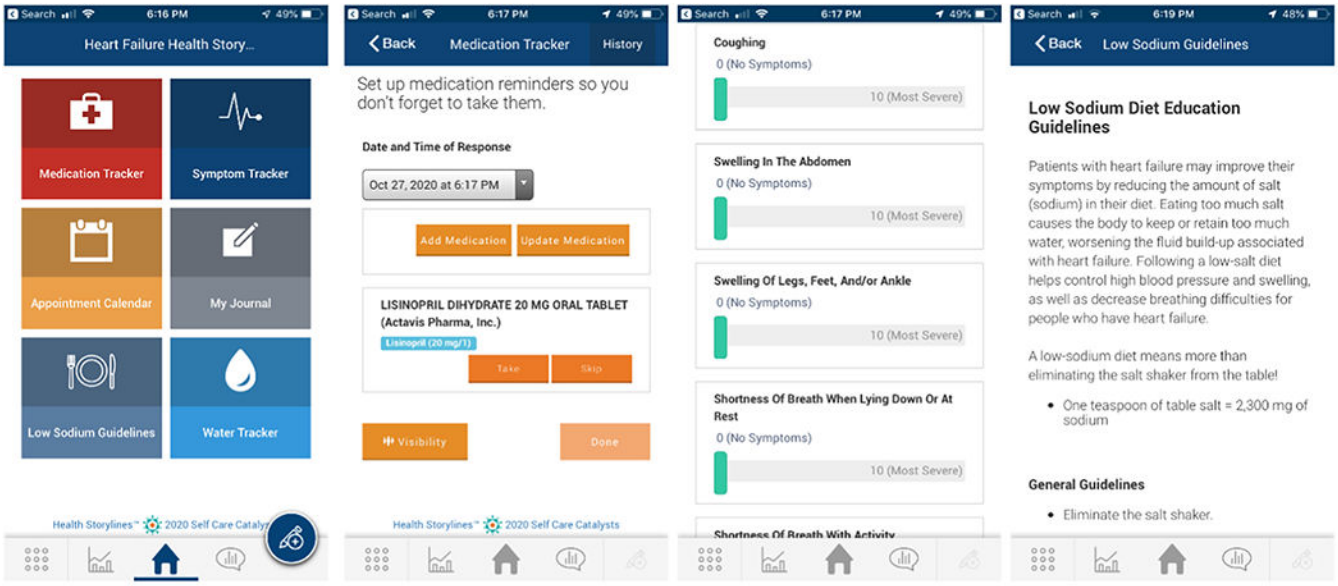

Figure 3:
Heart Failure Storylines app

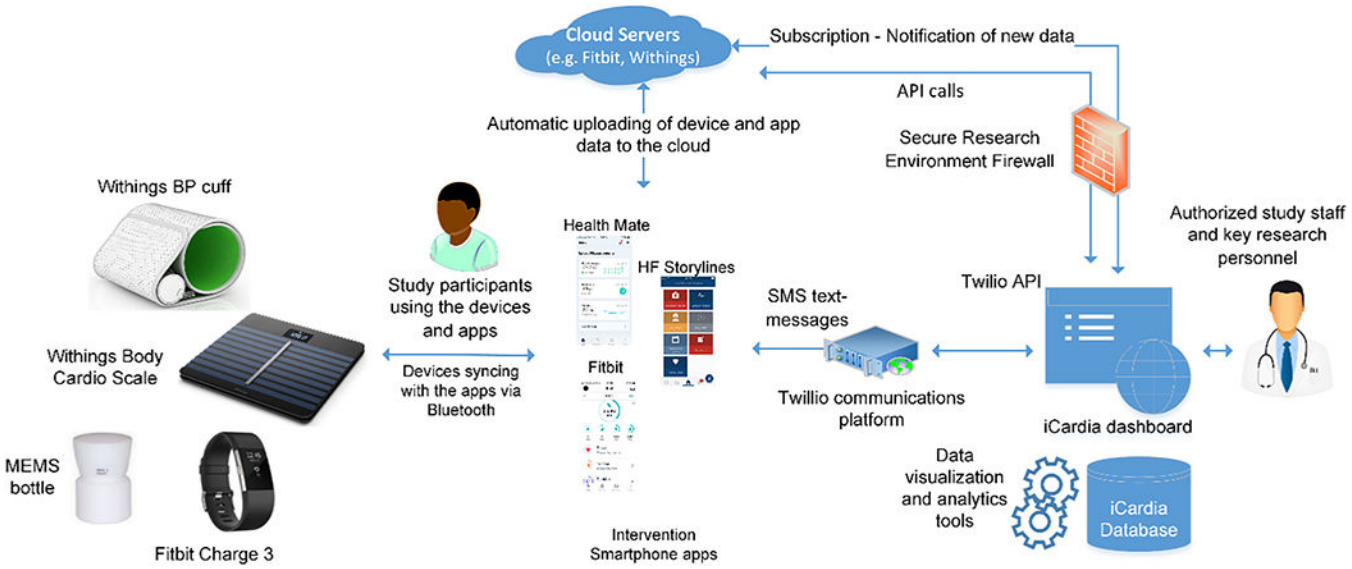

Figure 4:
iCardia4HF architecture and components

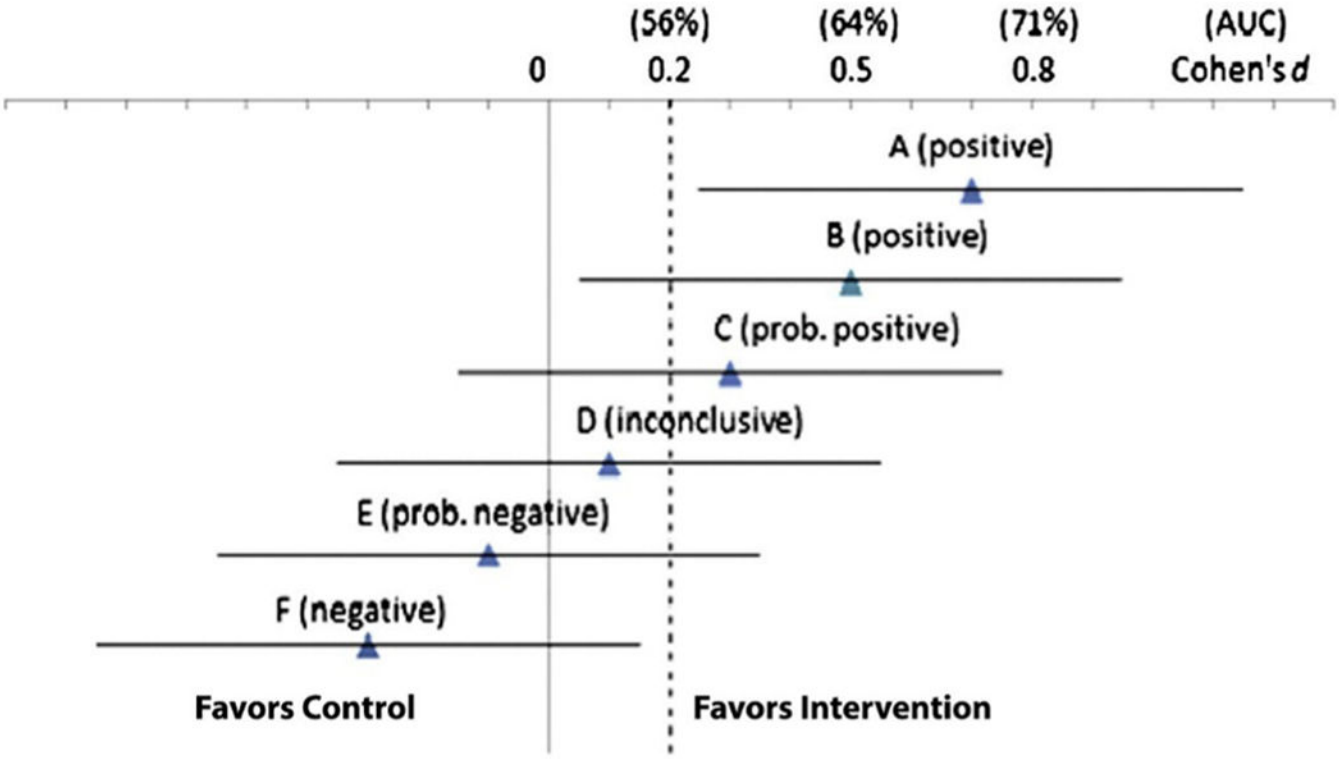

Figure 5:

Illustrative scenarios (A-F) of study results for the primary outcomes of interest (Adapted from [99]). Effect size estimates are expressed in Cohen's *d* along with the expected 2-sided 95% confidence intervals (standardized half-width = 0.5 at n=46/arm with a projected 13% attrition over 12 weeks). AUC (area under the receiver operating characteristic curve) values are given to indicate standards for assessing clinical significance corresponding to those for d. AUC measures the probability that a randomly selected participant in the intervention has a better response than a randomly selected participant in the control.

Table 1:

Participant inclusion and exclusion criteria

Inclusion criteria (patients are included if they meet all of the following)

- HF patients admitted to the hospital in the last 12 months with a primary or secondary diagnosis of HF as defined by the International Classification of Diseases (ICD-10) codes
- Left ventricular ejection fraction (LVEF) ≤40%, based on echocardiogram exam in the last 12 months
- ≥18 years of age as of date of enrollment
- Stage C, NYHA Functional Classification I-IV
- Being treated with at least one cardiovascular medication for HF (e.g., diuretics)
- Ability to speak and read English

Exclusion criteria (patients are excluded if they meet any of the following)

- Planned coronary revascularization, Transcatheter Aortic Valve Implantation (TAVI), Cardiac Resynchronization Therapy (CRT) - implantation, and/or heart transplantation (HTx) within the next 3 months.
- Coronary revascularization and/or CRT-implantation within the last 30 days
- Advanced renal disease (stage IV chronic kidney disease, glomerular filtration rate<30, or hemodialysis)
- Known alcohol or drug abuse
- Active cancer
- Pregnancy
- End-stage HF (hospice candidate with limited life expectancy)
- Not able to take care of self (eat, dress, walk, bath, take medications, or use the toilet independently)
- Discharged to or already living in a nursing home or other care facility
- Cognitive Impairment (Montreal Cognitive Assessment score <22 at baseline)
- Prior use of study devices for self-care or participation in a similar trial

Table 2:

Details about the types of monitored data, devices/apps, and reminders.

Monitored Data	**Weight and Body Composition**	**Blood Pressure**	**Symptoms**	**Medications**	**Physical activity (steps, intensity of activity), Heart Rate, Exercise (duration and type), Sedentary minutes, Sleep**
Devices used	Withings weight scale	Withings BP 801 cuff	No device	MEMS bottle	Fitbit Charge 3 - Wearable activity tracker with heart rate sensor and automatic detection of aerobic exercise
Mobile apps used	1. Health Mate 2. HF Storylines	1. Health Mate 2. HF Storylines	HF Storylines	HF Storylines	1. Fitbit 2. HF Storylines
Type of monitoring	Active *	Active	Active	Active (app) / Passive (MEMS)	Passive **
Reminders (Frequency)	Push notification to step on the scale (Daily)	Push notification to measure BP (Daily)	Push notification to record symptoms (Daily)	Push notification to take medication (Daily)	Push notification in the form of gentle vibration on the tracker if activity <250 steps/hour. Text-messages to remind participants to wear and charge Fitbit as needed based on the wear-time data collected from the iCardia server.

* Active monitoring: requires action by the patient (e.g., stepping on the scale);

** Passive monitoring: performed automatically by the device

MEMS: Medication Event Monitoring System

Table 3:

Sample of tailored text messages based on responses to the Health Belief Scales.

Medication Adherence	
Benefit question: If I take my water pills, I will lower my chance of being in the hospital. Patient Response: Strongly Disagree (1), Disagree (2), or Undecided (3)	Barrier question: Taking water pills makes it hard to go away from home. Patient Response: Undecided (3), Agree (4), or Strongly Agree (5).
Text Message: Taking medications as your doctor or nurse tells you to, can help remove extra water from your body and can lessen your chance of being hospitalized.	Text Message: Taking water pills can make it hard to go away from home. One option is to take it several hours before you plan to go out or wait until after you return to take it
Low-sodium Diet	
Benefit question: Eating a low salt diet will keep my heart healthy. Patient Response: Strongly Disagree (1), Disagree (2), or Undecided (3)	Barrier question: Food does not taste good on the low salt diet. Patient Response: Undecided (3), Agree (4), or Strongly Agree (5).
Text Message: Sodium in salt acts like a sponge. It holds extra fluid in the body making the heart work harder. Cutting down on sodium is one of the most important parts of your treatment.	Text Message: You can flavor your food without using salt. You can use a salt substitute or other seasonings like pepper, lemon juice, garlic/onion powder, and basil. Talk to your doctor or nurse before using a salt substitute
Self-Monitoring	
Benefit question: If I weigh myself every day, I will lower my chance of being in the hospital. Patient Response: Strongly Disagree (1), Disagree (2), or Undecided (3)	Barrier question: I do not know how to check my feet and legs for swelling. Patient Response: Undecided (3), Agree (4), or Strongly Agree (5).
Text Message: Weighing yourself every day can lower your chance of being in the hospital. One reason for going to the hospital is because of fluid building up in your body.	Text Message: Use your thumb to push the skin on top of your foot or shin. Release your thumb and look and feel for indentation, a sign of swelling. Do the same for your other foot and leg. Tell your doctor or nurse if you find any swelling.

Table 4:

Sample tailored text messages based on responses to the Dutch Heart Failure Knowledge Scale

Question	Patient Response	Text Message
How much fluid are you allowed to take at home each day?	Patient responds other than "1.5 to 2.5 liters at the most".	Track your fluid intake with a 2 Liter soda bottle, for every cup you drink pour the same amount of water in the bottle, once it is full you have reached your fluid limit.
Why should someone with heart failure follow a low salt diet?	Patient responds other than "salt promotes fluid retention".	Salt increases the amount of fluid in the body! Limit your salt intake to 2-3,000 mg per day. One teaspoon of salt is approximately 2,300 mg of sodium.
Which statement about weight increase and heart failure is true?	Patient responds other than "in case of an increase of over 2 kilograms (4.4 lbs) in 2 or 3 days, you should contact your doctor or nurse".	Sudden changes in weight might lead to hospitalizations. If you notice a weight gain of 2-3 pounds in a day or 5 lbs in a week, please call your doctor or nurse and let them know.

Table 5:

Measures and Data Collection Schedule

Measures	Assessment tool/method	Reliability/validity	Schedule
Clinical Characteristics and demographics			
Demographics	Date of birth, gender, marital status, employment status, education, insurance status, and contact information.	-	Baseline
Cognition	Montreal Cognitive Assessment (16-items) [33]. Evidence suggests that MoCA is a suitable screening tool for patients with HF [88].	Cronbach's α = 0.83 [33].	Baseline
HF characteristics	Clinical HF characteristics including LVEF and NYHA class are extracted from the patien's electronic medical record.	-	Baseline
Depression	Patient Health Questionnaire (PHQ-9) [73] (9-items) is a dual purpose instrument that can establish provisional depressive disorder diagnosis as well as grade depressive symptom severity.	Cronbach's α = 0.86-0.89; Test-retest reliability, r=.84 [89].	Baseline
Comorbidities	Comorbid conditions are scored with the updated Charlson comorbidity index [74], which includes 12 comorbidities.	C statistic=0.825 [74].	Baseline
Aim 1: Feasibility and Acceptability of the iCardia4HF intervention (Process Measures)			
Recruitment/Retention	We keep track of the recruitment length, number of patients screened and enrolled in the study, refusal rates for participation and for randomization; retention and follow-up rates, and any recruitment issues.	-	Week 1 to 12
Acceptance	Participants' acceptance of and satisfaction with the iCardia4HF intervention components is evaluated with two questionnaires (41-items) that are based on the Technology Acceptance Model (TAM) [75].	-	Week 12
Aim 2: Preliminary efficacy on HF self-care (Primary and Secondary Outcome Measures) Primary outcomes			
Medication adherence	Assessed with the AARDEX Medication Event Monitoring System (MEMS). Two indicators of adherence are assessed for 1 HF medication: 1) dose-count, defined as the percentage of prescribed number of doses taken; and 2) dose-time, defined as the percentage of doses taken on schedule (±3 hours of the expected time interval).	Evidence from two previous studies [78 79] show that monitoring one medication with MEMS provides a valid indicator of adherence even when patients are prescribed multiple medications per day.	Week 1 to 12
Adherence to self-monitoring of weight	Assessed with time-stamped data from the Nokia Cardio Body Weight Scale. We count the number of days patients completed at least one measurement between 12:00 am and 11:59pm.	-	Week 1 to 12
Secondary outcomes			
Adherence to self-monitoring of HF symptoms	Assessed with time-stamped data from the Heart Failure Storylines mobile app. We count the number of days patients in the iCardia4HF group completed the HF symptoms assessment between 12:00 am and 11:59pm.	-	Week 1 to 12
Adherence to BP self-monitoring	Assessed with time-stamped data from the Nokia Health BP Monitor. We count the number of days patients completed at least one measurement between 12:00 am and 11:59pm.	-	Week 1 to 12
Adherence to low-sodium diet	Dietary sodium intake is assessed with a spot morning urinary test. The Kawasaki formula [82] is used to estimate 24-hour urine sodium excretion.	Validity demonstrated in [82 90], where correlations between Kawasaki's spot urine method and 24-h urine sodium exertion were high (r=0.78, p<0.001 and r=0.69, p<0.01, respectively).	Baseline, 12 weeks
Physical activity (steps, MVPA)	Daily steps and MVPA are assessed with Fitbit Charge 3 – a valid wrist-based monitor that records and remotely transmits to our study server time-stamped data, including wear-time based on heart rate.	Validity demonstrated with the gold standard (ActiGraph) by a correlation of 0.95 for steps and 0.74 for MVPA [91]. Interclass correlation coefficients (ICC) across studies for walking speeds	Week 1 to 12

Measures	Assessment tool/method	Reliability/validity	Schedule
		with validation criterion, ICC≥0.94 [92].	
Self-reported self-care	Measured with the Self-Care Heart Failure Index (SCHFI, v.7.2). SCHFI has 3 subscales: self-care maintenance scale (10-items), symptom perception scale (9-items), and selfcare management scale (8-items). Standardized scores in each scale range from 0 to 100. A score of ≥70 indicates adequate self-care [6].	Reliability estimates using the global reliability index (GRI): self-care maintenance = 0.75; symptom perception=0.85; and selfcare management=0.70 [86].	Baseline, 30 days, 12 weeks
Health-related Quality of life (HRQL)	HRQL is measured with the Kansas City Cardiomyopathy Questionnaire [87]. This 23-item scale has 5 clinically relevant domains: physical limitations, symptoms, quality of life, social interference, and self-efficacy. Lower scores indicate worse HRQL.	Validity of each KCCQ domain is documented by comparison with available criterion standards (r = 0.46 to 0.74; p < 0.001 for all) [87].	Baseline, 30 days, 12 weeks
Hospitalizations	Tracked via the UIH EHR and patient reports. Monthly telephone calls and patient diaries are used to capture hospitalizations outside of UIH.	-	Weeks 1 to 12
ER visits	The primary source of data is the UIH EHR system and patient self-reports. Monthly telephone calls and patient diaries capture self-reported hospitalizations outside of UIH.	-	Weeks 1 to 12
Aim 3: Intervention Target Measures (Exploratory)			
Health Beliefs	Health Beliefs will be assessed using three validated scales: (1) Beliefs about Medication Compliance Scale (BMCS, 12-items) [66 67]; (2) Beliefs about Dietary Compliance Scale (BDCS, 12 items) [66]; and (3) Beliefs about Self-Monitoring Scale (BSMS, 18 items [67].	Internal consistency reliability estimates: BMCS (r=0.87-0.91) [66 67]; BDCS (*r*=.69-.84) [66]; and BSMS (*r*=.83-.89) [67	Baseline, 30 days, 12 weeks
Self-care Self-Efficacy	Measured with the SCHFI Self-Care Self-efficacy Subscale (10-items). Standardized scores range from 0 to 100. A score of ≥70 indicates adequate self-care efficacy.	Internal consistency reliability estimates among studies range between 0.84 and 0.90 [93].	Baseline, 30 days, 12 weeks
HF-Knowledge	Assessed with the Dutch Heart Failure Knowledge Scale [69], which includes 15-items (multiple choice questions).	Cronbach's α = 0.62	Baseline, 30 days, 12 weeks