Cover Page for IRB Protocol

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"Implementing a digitally-enabled community health worker intervention for patients with heart failure"
NIH-NHLBI; K23HL150287

PARTNERS HUMAN RESEARCH COMMITTEE
PROTOCOL SUMMARY

Answer all questions accurately and completely in order to provide the PHRC with the relevant information to assess the risk-benefit ratio for the study. Do not leave sections blank.

PRINCIPAL/OVERALL INVESTIGATOR
Jocelyn A. Carter, MD, MPH

PROTOCOL TITLE
Implementing a Digitally- Enabled Community Health Worker Program for Patients with Heart Failure

FUNDING
NIH/NHLBI is the funding source for all funding except digital platform hard/software
Biofourmis is the funder of all digital platform hard/software

VERSION DATE
August 01, 2022

SPECIFIC AIMS

Concisely state the objectives of the study and the hypothesis being tested.

This study consists of three aims focused on examining the effectiveness of pairing patients that are at high risk for readmission with a Community Health Worker (CHW) and a digital platform designed to help promote wellness outside the hospital. The objectives are 1) identification of 30 patient and 20 community health worker perspectives on barriers to heart failure care via qualitative interviews; 2) perform an open pilot trial assessing the usability, workflow, and integration of a digitally-enabled CHW intervention; and 3) perform a randomized controlled trial assessing the feasibility, acceptability and preliminary effectiveness of a digitally enabled community health worker intervention. In Aim 1 we will perform concise 25-minute qualitative interviews with 30 adults with heart failure (HF) among inpatients hospitalized at MGH or via phone. We will also conduct 1.5-hour focus groups with community health workers (10 community health workers per focus group; 2 focus groups total) with CHWs that care for patients with heart failure. Outcomes will include heart failure knowledge, as well as the impact of social (e.g., socioeconomic status, social support, living situations), behavioral (e.g., diet, activity), clinical (e.g., care plan adherence), communication-based (e.g., connection to care teams), digital (e.g., messaging of biometrics), human (e.g., CHW interactions), disease-based (e.g., HF and other comorbidities), cultural (e.g., health beliefs), or environmental (e.g., work, home) factors on heart failure care. Common themes will be identified and used to inform Aim 2. The hypothesis is that

interviews with patients with HF and CHW focus groups can improve HF interventions

In Aim 2, we will conduct a 30-day open pilot trial with 30 patients (10 patients at a time for 3 consecutive cycles) orient patients to the use of the digital platform, and pair patients with CHWs trained to use the digital platform and care for patients with heart failure. We will also identify patients with heart failure by contacting patients through research invitations and direct MGH primary care/cardiology physician team referrals. Outcomes will include usability (ability to implement the interventions, enroll patients, and collect data). Also, the rate of patient biosensor, mobile application, symptom assessment, Everion sensor, digital blood pressure monitor, and digital weight scale use will be assessed. In general, we will review digital platform patient use to determine the rates of total and proportional patient time spent engaged with the digital platform (e.g., time spent with the arm biosensor in place, frequency of blood pressure monitor use, frequency of weight scale use, frequency of digital platform video or text interactions per day, frequency of symptoms assessment completion). The frequency of CHW in-person or phone interactions will also be tracked. CHW exit interviews (15-minute) will be conducted after each patient study interval ends. The hypothesis is that qualitative data (collected during patient and CHW interviews), along with usability data in an open pilot trial can inform digitally-enabled CHW intervention design refinement prior to performing a clinical trial.

In Aim 3, we will conduct a randomized controlled trial among 50 patients with heart failure. Twenty-five patients (n=25) will be randomized to the digitally-enabled CHW intervention + usual care (explored in Aim 2) and 25 patients will be randomized to CHW care + usual care. Outcomes will include patient acceptability (defined by patient satisfaction, willingness to engage in the intervention again, etc.), feasibility (rate of patient biosensor, mobile application, symptom assessment, Everion sensor, digital blood pressure monitor, digital weight scale, and CHW interaction use) and preliminary effectiveness (30-day readmissions, ED visits, missed primary care and cardiology appointments). CHW exit interviews (15-minute) will also be conducted after each patient study interval ends. The hypothesis is that a 30-day digitally-enabled CHW intervention can generate high acceptability, feasibility, and preliminary effectiveness among patients with heart failure.

Aim1

Identification of 30 patient and 20 community health worker perspectives on barriers to heart failure care through semi-structured interviews and focus groups

Outcomes: The domains of the interview and focus group guides: HF knowledge, social (e.g., socioeconomic status, social support, living situations), behavioral (e.g., diet, activity), clinical (e.g., medication reconciliation, care plan adherence), communication-based (e.g., connection to care teams), digital (e.g., medication reminders, appointment reminders), human (e.g., CHW home visits, accompaniment to clinic visits), disease-based (e.g., HF and other comorbidities), cultural (e.g., health beliefs), or environmental (e.g., work, home) factors

Hypothesis: Interviews with patients with HF and CHW focus groups can improve a HF intervention

Aim 2
Conduct a 30-day open pilot trial with 30 patients (10 patients at a time for 3 consecutive cycles) at hospital discharge by orienting patients to the use of the digital platform and pairing patients with community health workers trained to use the digital platform and care for patients with heart failure.

Outcomes: Digital CHW intervention usability: the usability outcome will be defined by facilitators and barriers to platform use (the ability to implement the intervention, enroll patients, and collect data). These data will be collected via qualitative interviews with patients and CHW staff participating in the open pilot trial. Rates of Everion biosensor, phone application, symptom assessment, frequency of CHW in-person or phone interactions, total and proportional patient time spent engaged with the digital platform (e.g., time spent with the arm biosensor in place, frequency of blood pressure monitor use, and frequency of digital platform video interactions per day) will also be tracked.

Hypothesis: Use of qualitative data (collected during patient and CHW interviews), along with usability data in an open pilot trial can inform intervention design refinement for a digitally-enabled CHW in a clinical trial.

Aim 3:
Conduct a 30-day randomized controlled trial with HF patients randomized to either the digitally-enabled CHW intervention + usual care (n=25) or to CHW care + usual care (n=25).

Outcomes: Outcomes will include patient acceptability (defined by patient satisfaction, willingness to engage in the intervention again, etc.), feasibility (rate of patient biosensor, mobile application, symptom assessment, Everion sensor, digital blood pressure monitor, digital weight scale, and CHW interaction use) and preliminary effectiveness (30-day readmissions, ED visits, missed PC and cardiology appointments). CHW exit interviews (15-minute) will also be conducted after each patient study interval ends.

Hypothesis: A 30-day digitally-enabled CHW intervention can generate high acceptability, feasibility, and preliminary effectiveness for patients with HF.

BACKGROUND AND SIGNIFICANCE

Provide a brief paragraph summarizing prior experience important for understanding the proposed study and procedures.

There were approximately 3.3 million adult 30-day all-cause hospital readmissions in the USA, generating $41.3 billion in hospital costs.[1] Up to 20% of these readmissions or $8.26 billion in health care expenditures were potentially

preventable.[2] Reasons for preventable readmission are multifactorial and associated with disease conditions, age, and healthcare utilization.[3,4]

Patients with congestive heart failure are the leading population of patients re-admitted within thirty days of a previous hospitalization.[5] Ongoing efforts to reduce readmission rates for heart failure patients have included public reporting and readmission penalties instituted by the Centers for Medicare & Medicaid Services (CMS) as well as numerous national campaigns focused on supporting programming to assist hospitals in this effort.[6,7,8] Despite AHA goals to reduce readmissions by 20% by 2016, the goal has yet to be achieved. [9]

Community Healthcare Worker (CHW) care delivery is one of very few health interventions demonstrated to reduce health care utilization among populations with chronic disease.[10] As embedded members of healthcare teams, CHWs function as expert coaches voiced in motivational interviewing and goal-setting. CHWs also call/visit patients or even show up outside patient homes in a hired car to take them to medical appointments. Despite noted improvement in healthcare outcomes by as much as 18-65% with the use of CHW interventions,[11] studies exemplifying that CHW models can improve specific outcomes targeted by the Centers for Medicare and Medicaid (i.e. 30-day readmission rates) have been scant and no studies have been completed examining a digitally-enabled CHW intervention for patients with heart failure. Data analysis performed on 550 patients enrolled in a small randomized controlled trial, pairing patients at high risk for readmission with CHWs, indicated that intervention study participants as compared to controls had 40% lower 30-day readmission rates, 20% less emergency room visits, 30% less missed post-discharge appointments.[14] Thirty-three percent of these enrolled participants had a diagnosis of heart failure.

Even with this noted improvement in a core CMS-designated outcome, scalability has not been well demonstrated for CHW programming in part because one of the most significant historical barriers to CHW care delivery is difficulty reaching patients for telephone and home visits. Historically, CHW programs have relied on direct communication with patients as the only method of informing care delivery which has limited the ability of these programs to scale and demonstrate return on investment in general. Despite this known weakness and strong evidence demonstrating the effect of digital platforms as a viable solution to staying in touch with patients in the field,[12,13] a digital platform specifically tailored to meet the needs of patients and CHWs that care for them has never been studied.

With our partnership with the developers at Biofourmis, a biotechnology company focused on health care, Biofourmis has expanded upon their current heart failure digital platform to deliver a prototype designed for community health workers to use with patients that have heart failure. This digital platform (for iOS/ Android mobile phone application) is paired with Biovation's Everion arm band a Bluetooth enabled blood pressure monitor, and a Bluetooth enabled weight scale. This technology has been deployed in remote care settings outside the United States since 2016.

The Biofourmis platform will offer the following features in this study:

1) interval symptom-based questionnaires which is accessed by the patient via the Biofourmis mobile app
2) seamless artificial intelligence-enabled monitoring of physio-data including heart rate, blood pressure wave, respiration rate and activity data via a lightweight biosensor attached to an armband worn by patients
3) educational videos that may be viewed by patients via the mobile Biofourmis application
4) direct communication with CHW providers
5) use of a patient profile by CHW providers to identify artificial intelligence-generated aberrancies in physio-data in anticipation of clinical decline, to monitor medication/appointment compliance, adherence to completion of questionnaires

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[13] Merchant et al. 2017. Digital health intervention for asthma: patient perception of usability and value for self-management. *American Journal of Respiratory and Critical Care Medicine 2017;195:A3326.*

[14] Carter J, Hassan S, Walton A, Yu L, Donelan K, Thorndike AN. Effect of Community Health Workers on 30-Day Hospital Readmissions in an Accountable Care Organization Population: A Randomized Clinical Trial. *JAMA Netw Open*. 2021;4(5):e2110936. Published 2021 May 3. doi:10.1001/jamanetworkopen.2021.10936

RESEARCH DESIGN AND METHODS

Briefly describe study design and anticipated enrollment, i.e., number of subjects to be enrolled by researchers study-wide and by Partners researchers. Provide a brief summary of the eligibility criteria (for example, age range, gender, medical condition). Include any local site restrictions, for example, "Enrollment at Partners will be limited to adults although the sponsor's protocol is open to both children and adults."

This study consists of three aims focused on examining the effectiveness of pairing patients that are at high risk for readmission with a Community Health Worker (CHW) and a digital platform designed to help promote wellness outside the hospital. In Aim 1, 30 inpatients with heart failure will be enrolled along with 20 community health workers from MGH inpatient settings and MGH community clinics that work with heart failure patients. In Aim 2, 30 patients will be enrolled in an open pilot trial investigating the usability of a digital community health worker intervention. In Aim 3, 50 patients will be randomized to the digitally-enabled CHW intervention + usual care (n=25) or to CHW care + usual care (n=25) to examine the acceptability, feasibility, and preliminary effectiveness of the intervention.

Aim 1

Patients

Thirty patients admitted to MGH in the last 24 months prior to enrollment and who have a diagnosis of heart failure (HF) will be identified. Interview guides based upon existing literature will include open-ended questions to facilitate inductive analyses, specific probes related to *a priori* clinically, culturally-relevant patient characteristics, and patient and CHW barriers and facilitators. The domains of the interview guides will include HF knowledge, social (e.g., socioeconomic status, social support, living situations), behavioral (e.g., diet, activity), clinical (e.g., medication reconciliation, care plan adherence), communication-based (e.g., connection to care teams), digital (e.g., medication reminders, appointment reminders), human (e.g., CHW home visits, accompaniment to clinic visits), disease-based (e.g., HF and other comorbidities), cultural (e.g., health beliefs), or environmental (e.g., work, home) factors. The interview instruments will be pre-tested with a convenience sample of 4 patients to refine the timing, appropriateness, and utility. This will ensure that the intended understanding of all questions is clear and that response options are fitting.

Twenty-five-minute qualitative interviews with patients will be performed by the PI and a HIPPA-certified study coordinator via phone. A chart review will also be completed by study coordinators. All patient interviews will be audio recorded and transcribed verbatim for analysis and identification of key themes.

The duration of patient involvement will be the length of the 25- minute qualitative interview via phone.

Due to the current focus and precautions related to the COVID-19 pandemic that may limit contact with inpatients, inpatients may be approached, introduced to the Aim 1 study and verbally consented in the hospital prior to the administering the interview guide via phone after patients return home after hospital discharge. All patient interviews will be audio recorded and transcribed verbatim.

Also, due to COVID-19 related restrictions on the inpatient floors, patients eligible for Aim 1 enrollment may also be identified from a pool of 62 heart failure respondents from a previous randomized controlled trial (PI, Jocelyn Carter;Protocol #2016P002768) who agreed to be contacted for future additional research activities. These patients may be contacted by phone and introduced to study Aim 1. If interested, and if verbal consent is obtained after the participant has reviewed the study fact sheet, these patients may be interviewed by phone. All patient interviews will be audio recorded and transcribed verbatim.

In addition, two independent 1.5 hour focus groups with MGH community health workers (10 community health workers per focus group) will be conducted by the PI and a study coordinator.

All transcription and interviewer/moderator notes will be uploaded into Dedoose for analysis. The PI will independently code patient data followed by CHW focus group data. A trained research coordinator will also independently code the same data. The framework used will include an approach where two researchers will familiarize themselves with the raw data, independently identify key themes raised by respondents, and reapply this thematic framework by rearranging the raw data into themes and relationships. Associations between themes, user characteristics, and outcomes will be identified. Each coder will perform content analysis to capture themes associated with each focus group and patient interview. These will be compared by gender and age. Intercoder reliability will be achieved through an iterative process of comparing each level of coding (themes and codes) while discussing discrepancies and comparing results to the raw data. Themes will be reviewed, and discrepancies discussed with a third researcher, with expertise in qualitative data. The PI will review patient transcripts weekly with interviewer staff to discuss emerging themes, modify the patient interview instrument as needed, and assess for theoretical saturation. If necessary, the PI will make modifications to increase the contextual relevance. This analysis will be used to refine Aim 2.

Inclusion/Exclusion Criteria are as listed here;
Eligibility amongst adult patients at the Massachusetts General Hospital (MGH) who meet all eligibility criteria will be considered. The following inclusion criteria will be applied. Patients must:

1) be between the ages of 18-95
2) have a diagnosis of heart failure
3) have been admitted to MGH in the 24 months prior to being enrolled
4) own a smart phone and be familiar with common user features
5) live within a 35 mile radius of MGH (55 Fruit Street, Boston, MA 02114)
6) have a working home/mobile telephone number where they can be reached
7) be English speaking
8) be able to consent to study participation
9) have a primary care provider
10) have unmet needs for outpatient support identified during the screening process multidisciplinary case management rounds (e.g., assistance with

medication management, appointment scheduling, transportation, social support)

The following exclusion criteria will be applied. Exclusion will apply to patients that:

1) are homeless at the time of admission
2) do not have cognition to complete the survey or require caregiver prompting or response for questionnaire completion
3) have a history of known lack of capacity to consent (due to guardianship or invoked health care proxy)
4) visual, motor or hearing deficits that precludes engagement

CHWs

CHWs working in MGH inpatient and outpatient settings will be identified for one of two focus groups (n=10/focus group) lasting 1.5 hours each. All CHWs will have experience providing direct care for HF patients. Focus group interview guides based upon existing literature will include open-ended questions to facilitate inductive analyses, specific probes related to *a priori* clinically, culturally-relevant CHW barriers and facilitators to delivery care in hear failure populations. The domains of the focus group interview guides will include HF knowledge, social (e.g., socioeconomic status, social support, living situations), behavioral (e.g., diet, activity), clinical (e.g., medication reconciliation, care plan adherence), communication-based (e.g., connection to care teams), digital (e.g., medication reminders, appointment reminders), human (e.g., CHW home visits, accompaniment to clinic visits), disease-based (e.g., HF and other comorbidities), cultural (e.g., health beliefs), or environmental (e.g., work, home) factors. The interview and focus group instruments will be pre-tested with a convenience sample of 2 CHWs to refine the timing, appropriateness, and utility. Focus groups will be recorded and later transcribed. Transcription and interviewer/moderator notes will be uploaded into Dedoose for analysis. The PI will independently code CHW focus group data. A trained research coordinator will also independently code the same data. The framework used will include an approach where two researchers will familiarize themselves with the raw data, independently identify key themes raised by respondents, and reapply this thematic framework by rearranging the raw data into themes and relationships. Associations between themes, user characteristics, and outcomes will be identified. Each coder will perform content analysis to capture themes associated with each focus group and patient interview. These will be compared by gender and age. Intercoder reliability will be achieved through an iterative process of comparing each level of coding (themes and codes) while discussing discrepancies. Themes will be reviewed and discrepancies discussed with another co-investigator with expertise in qualitative data. The PI will review patient transcripts weekly with interviewer staff to discuss emerging themes. Due to the small number of focus groups used (n=2), no modifications will be made to the CHW focus group instrument after the first focus group occurs. The analysis will be used to refine Aim 2.

The duration of CHW involvement will be the 1.5-hour length of the focus group.

Inclusion and exclusion criteria are as listed below.

1) Employed as an MGH community health worker working with experience with heart failure populations in inpatient or outpatient settings

Exclusion Criteria

1) Unable to attend scheduled focus group

The Aim 1 sample sizes are defined as the maximum number of participants we can enroll with resources available as well as the minimum number of individuals that would be required to demonstrate value or statistical significance regarding care perspectives as compared to historical controls.

Aim 2

The pairing of CHWs with patients along with the use of the Biofourmis digital platform may assist with patient engagement and substantially improve post-discharge care. The pairing of CHWs with patients along with the use of the Biofourmis digital platform may also create feedback systems for the CHW and primary care/cardiology teams to promote early identification of patients that are moving away from their healthy baseline due to increased risk for a recurrent HF exacerbation requiring readmission. The CHWs participating in Aim 2 are paid members of the research study team.

In Aim 2, 30 patients will be enrolled in a 30-day open pilot trial after hospital discharge or through contacting patients with heart failure through research invitations in Patient Gateway and by mail, by primary care physician team or cardiology physician team referral. A chart review will also be completed for all enrolled participants. At the time of enrollment, participants will be instructed on use of the Biofourmis mobile application with the aid of a study coordinator. All enrolled participants will also be given and taught how to use a Bluetooth enabled digital blood pressure monitor (for blood pressure monitoring each day), digital weight scale (for body weight monitoring each day), as well as an Everion biosensor with associated arm band (used to monitor and heart rates, oxygenation, activity levels, etc.). Participants will wear the arm band every day for 30 days, take their blood pressure with the digital blood pressure monitor, and weigh themselves with the weight scale monitor at least once a day. Participants will also be encouraged to view educational videos within the Biofourmis application about heart failure and wellness.

While the Biofourmis application can be downloaded by anyone, the application may only be used by those that have a profile/access code for the application. All enrolled participants are expected to complete all questionnaires associated with the study and return the loaned Everion and digital blood pressure and weight scale at the study end. Data collected during the study will reside in secured data settings (all data generated from Biofourmis app use/ digital blood pressure monitor/digital weight scale/Biofourmis armband) or REDCap (questionnaire responses).

Inclusion/Exclusion Criteria

Eligibility amongst adult patients who meet all eligibility criteria will be considered. The following inclusion criteria will be applied. Patients must:

11) be between the ages of 18-95

12) have a diagnosis of heart failure
13) have been admitted to MGH in the 24 months prior to being enrolled
14) own a smart phone and be familiar with common user features
15) have insurance
16) live within a 35-mile radius of MGH (55 Fruit Street, Boston, MA 02114)
17) have a working home/mobile telephone number where they can be reached
18) be English speaking
19) able to consent to study participation
20) have a primary care provider
21) have unmet needs for outpatient support identified during screening for study enrollment (e.g., assistance with medication management, appointment scheduling, transportation, social support)

The following exclusion criteria will be applied. Exclusion will apply to patients that:

5) are homeless at the time of admission
6) do not have cognition to complete the survey or require caregiver prompting or response for questionnaire completion
7) have a history of known lack of capacity to consent (due to guardianship or invoked health care proxy)
8) visual, motor or hearing deficits that precludes engagement with the intervention.

For Aim 2, each participant will join the study following enrollment for a typical study duration of approximately 30 days.

The Aim 2 sample size is defined as the maximum number of people that we can enroll with the equipment resources available as well as the minimum number of individuals that would be required to demonstrate value or statistical significance regarding care outcomes as compared to historical controls.

Aim 3
In Aim 3, 50 patients will be enrolled in a 30-day randomized control trial. The CHWs participating in Aim 3 are paid members of the research study team.

Eligible patients will be identified by identifying patients cared for by MGH cardiology and primary care team panels who are eligible for the study. Eligible patients will be contacted with permission from bedside nursing while inpatient. They will have the option to complete all enrollment procedures and study instructions by returning to MGH 55 Fruit Street at a convenient time. Enrolled participants will join the study following enrollment for a typical study duration of approximately 30 days. Eligible patients may also be contacted through Patient Gateway Personalized Letter, Patient Gateway Targeted Research Announcement, and mail. If interested in enrollment, these patients will have the option to complete all enrollment procedures and study instructions by returning to MGH at a convenient time.

We will limit the possibility of contacting patients that do not meet our study criteria by: 1) Making sure that patients who opt-out of research invitation contact are filtered out of recruitment lists from RPDR and are not sent research invitations; 2)

selecting criteria so that only those most likely to meet study inclusion criteria are sent invitations; 3) regularly monitor patient responses (twice weekly) to ensure the criteria are identifying the correct patients; 4) report any patient complaints about this method of recruitment as an "Other Event" to the IRB within 1 month of occurrence. Enrolled participants will begin their 30 days at the time that all enrollment procedures are complete.

If interested in enrollment after hearing about the study, these patients will have the option to complete all enrollment procedures and study instructions by returning to MGH 55 Fruit Street at a convenient time.

Patients may be referred to us by a MGH primary care provider/physician or cardiologist. These patients may contact us by phone after reviewing our study fact sheet which will be posted and available for viewing in MGH primary care and cardiologist offices. If contacted by a patient interested in participating in the study, we will describe the study enrollment and consent procedures. If interested in enrollment after hearing more about the study, these patients will have the option to complete all enrollment procedures and receive all equipment and study instructions by returning to MGH at a convenient time.

A chart review will also be completed for all enrolled participants.

For intervention participants, at the time of enrollment, participants will be instructed on use of the Biofourmis mobile application with the aid of a study coordinator. All enrolled participants will also be given and taught how to use a Bluetooth enabled digital blood pressure monitor (for blood pressure monitoring each day), digital weight scale (for body weight monitoring each day) as well as a Everion biosensor with associated arm band (used to monitor and heart rates, oxygenation, activity levels, etc). Participants will wear the arm band every day for 30 days; they will also take their blood pressure, weigh themselves with the digital blood pressure monitor and weight scale monitor, respectively, at least once a day. Participants will also be encouraged to view educational videos within the Biofourmis application about heart failure and wellness.

While the Biofourmis application can be downloaded by anyone, the application may only be used by those that have a profile/access code for the application. All enrolled participants are expected to complete all questionnaires associated with the study and return the loaned Everion and digital blood pressure and weight scale at the study end. Data collected during the study will reside in secured data settings (all data generated from Biofourmis app use/ digital blood pressure monitor/digital weight scale/Biofourmis armband) or REDCap (questionnaire responses).

Inclusion/Exclusion Criteria
Eligibility amongst adult patients admitted who meet all eligibility criteria will be considered. The following inclusion criteria will be applied. Patients must:

22) be between the ages of 18-95
23) have a diagnosis of heart failure
24) admitted to MGH within 24 months of the time of enrollment

25) own a smart phone and be familiar with common user features
26) live within a 35-mile radius of MGH (55 Fruit Street, Boston, MA 02114)
27) have a working home/mobile telephone number where they can be reached
28) be English speaking
29) able to consent to study participation
30) have a primary care provider
31) have unmet needs for outpatient support identified during screening for study enrollment (e.g., assistance with medication management, appointment scheduling, transportation, social support)

The following exclusion criteria will be applied. Exclusion will apply to patients that:

9) are homeless at the time of admission
10) do not have cognition to complete the survey or require caregiver prompting or response for questionnaire completion
11) have a history of known lack of capacity to consent (due to guardianship or invoked health care proxy)
12) visual, motor or hearing deficits that precludes engagement with the intervention.

For Aim 3, each participant will join the study following enrollment for a typical study duration of approximately 30 days.

The Aim 3 sample size is defined as the maximum number of people that we can enroll with the equipment resources available as well as the minimum number of individuals that would be required to demonstrate value or statistical significance in terms of preliminary effectiveness.

Briefly describe study procedures. Include any local site restrictions, for example, "Subjects enrolled at Partners will not participate in the pharmacokinetic portion of the study." Describe study endpoints.

Aim 1
Patients
Patients with heart failure that are hospitalized may be approached, introduced to the Aim 1 study and verbally consented in the hospital prior to the administering the interview guide via phone after patients return home after hospital discharge. Also, patients eligible for Aim 1 enrollment may also be identified from a pool of 62 heart failure respondents from a previous randomized controlled trial (PI, Jocelyn Carter;Protocol #2016P002768) who agreed to be contacted for future additional research activities. These patients may be contacted by phone and introduced to study Aim 1. All study criteria will be confirmed with patients directly and an informational letter introducing the qualitative study purpose and payment for participation ($50 per patient) will be given to eligible patients (via email or snail mail). If interested, patients will be able to review the informed consent document. All questions will be answered about all aspects of the study listed on the

information sheet and the informed consent document. If interested in enrolling in the study, patients will then give verbal consent and be interviewed by a study coordinator via phone (25 min). All patient interviews will be audio recorded and transcribed verbatim. Dedoose will be used to analyze themes generated by the interviews. A chart review for readmitted study participants will also be performed by study staff. A REDCap database will be used to store all questionnaire and chart review data.

Thirty enrolled participants will participate in a 25-minute semi-structured interview designed to illicit responses focused on the following domains: heart failure knowledge, social (e.g., socioeconomic status, social support, living situations), behavioral (e.g., diet, activity), clinical (e.g., medication reconciliation, care plan adherence), communication-based (e.g., connection to care teams), digital (e.g., medication reminders, appointment reminders), human (e.g., CHW home visits, accompaniment to clinic visits), disease-based (e.g., HF and other comorbidities), cultural (e.g., health beliefs), or environmental (e.g., work, home) factors. A chart review will also be completed for all participants.

Community Health Workers

Community health workers (n=20) working in MGH inpatient and outpatient settings will be identified for one of two focus groups (n=10/focus group) lasting 1.5 hour each. All CHWs will have experience providing direct care for HF patients. MGH CHWs will be emailed an informational letter and introduced to the study at their CHW weekly departmental meetings. CHWs interested in participating will be enrolled and after giving verbal consent, they will be scheduled for a focus group at MGH (55 Fruit Street, Boston, MA), via virtual meeting accessed via MGB generated Zoom link, or at a MGH community clinic. Payment for participation will be $50 per CHW. Focus group domains will include CHW functionalities for clinical (e.g., medication reconciliation, care plan adherence), communication-based (e.g., connection to care teams), digital (e.g., medication reminders, appointment reminders), human (e.g., CHW home visits, accompaniment to clinic visits), disease-based (e.g., HF and other comorbidities), cultural (e.g., health beliefs), or environmental (e.g., work, home) factors.

Common narrative themes from patients and community health workers will be identified via coding of all responses by the PI, one study coordinator trained in coding/qualitative research, and a study co-investigator. These findings will be used to inform Aim 2.

Aim 1 patient participants may be given the option to participate in future research studies including Aim 2 of this study.

Aim 2

An open pilot trial will be performed of the 30-day intervention among 30 patients with HF. While total of 30 patients will be enrolled, 10 patients will be enrolled at a time to enhance learning and optimize study process for a total of 3 cycles of enrollment. Enrolled participants will receive the 30-day digitally-enabled CHW intervention (usual care + digitally-enabled CHW care). A chart review will also be

completed for all participants. All patient participants will also complete 10-minute exit interviews with completion of a questionnaire in person or via phone at study day 25 and at the end of the 30-day interval. CHWs will also complete an exit interview at the end of each 30-day study interval pairing.

Eligible patients may also be contacted through Patient Gateway Personalized Letter, Patient Gateway Targeted Research Announcement, and mail. If interested in enrollment, these patients will have the option to complete all enrollment procedures and receive all equipment and study instructions by returning to MGH at a convenient time. We will limit the possibility of contacting patients that do not meet our study criteria by: 1) Making sure that patients who opt-out of research invitation contact are filtered out of recruitment lists from RPDR and are not sent research invitations; 2) selecting criteria so that only those most likely to meet study inclusion criteria are sent invitations; 3) regularly monitor patient responses (twice weekly) to ensure the criteria are identifying the correct patients; 4) report any patient complaints about this method of recruitment as an "Other Event" to the IRB within 1 month of occurrence. Enrolled participants will begin their 30 days at the time that all enrollment procedures are complete.

If interested in enrollment after hearing about the study, these patients will have the option to complete all enrollment procedures and receive all equipment and study instructions by returning to MGH at a convenient time.

Patients may be referred to us by a MGH primary care provider/physician or cardiologist. These patients may contact us by phone after reviewing our study fact sheet which will be posted and available for viewing in MGH primary care and cardiologist offices. If contacted by a patient interested in participating in the study, we will describe the study enrollment and consent procedures. If interested in enrollment after hearing more about the study, these patients will have the option to complete all enrollment procedures and receive all equipment and study instructions by returning to MGH at a convenient time.

After completing the enrollment questionnaire, participants will be given the Everion biosensor, digital weight scale, and digital blood pressure cuff. Participants will be instructed to wear the Everion biosensor on their non-dominant arm and how it will track several body metrics including heart rate, oxygenation and activity levels. A study team member will guide the participant through downloading the Biofourmis app, and setup of the Biofourmis app as well as demonstrating all features. Patients will be instructed on how to use the digital weight scale and digital blood pressure cuff as well as the Biofourmis app. The Everion biosensor and digital weight scale and digital blood pressure monitor will be linked to the Biofourmis mobile phone application. To promote privacy of health information, a login will be required for access to app and all mobile phones will be set to password protected mode/touch ID activated (if not already).

At the time of enrollment, application permissions will be given. For the Biofourmis application to access any information on an iOS/Android smartphone, the application must ask the user for permission and only if that permission is granted, can the application access that information. This is inherently enforced on all

applications by the operating system. In our case, we only will ask for permissions to access:

- Relevant digital-health data from Biofourmis platform physical/metabolic activity metrics including heart rate, oxygenation and activity levels
- Display notifications
- All clinical support team notifications

Participants will be advised that they will need to return the Everion device, digital weight scale, and digital blood pressure monitor after the 30-day enrollment period ends. They will be advised that the app can be used freely after the study is concluded.

Participants will complete an enrollment questionnaire at the time of enrollment. A chart review will also be completed by study coordinators. Participants will also be asked whether they own a home weight scale and blood pressure cuff. The study team will also assess the level of adherence based on self-reported symptom data collected in questionnaires as well as the Quality of Life Questionnaire and exit questionnaire administered on day 25 and day 30 after enrollment.

Patient participants will complete exit interviews in-person or via phone after the 30-day study interval ends. Patient participants will be contacted by phone on day 25 and within 3 days of completing the 30-day intervention and exit interviews (25 minutes in length) will be scheduled either in-person (at MGH, 55 Fruit street) or via phone. CHW study staff will also complete exit interviews in-person 3-5 days after each 30-day patient participant intervention ends.

All interviews will be audio recorded and transcribed verbatim. Interviews will be performed by the PI and a study coordinator trained in semi-structured interview administration. Expected completion of each iteration of 10 exit interviews will occur within 2 weeks of participants completing the 30-day intervention.

Patients that are admitted within 30 days of hospital discharge will be approached during their hospital admission to complete a short readmission questionnaire (10 minutes). An admission chart review will also be completed prior to discharge.

In addition, when patients are offered or trained in the intervention but decline to participate, reasons for non-participation will be assessed to inform enrollment barriers.

When the study aim ends or a participant's participation ends prematurely, those participants may keep their app (in which case their use will continue to be tracked), but will be asked to return the Everion device, the digital weight scale, and digital blood pressure monitor.

Aim 2 participants may be given the option to participate in future research studies.

Aim 3

A randomized controlled trial will be performed of the 30-day intervention among 50 patients with HF randomized to the intervention arm (digitally-enabled CHW + usual care) or the control arm (CHW care + usual care). Participants randomized to the intervention arm will be enrolled(n=25) and participants will receive the 30-day digitally-enabled CHW intervention (usual care + digitally-enabled CHW care). Participants randomized to the control arm will be enrolled (n=25) and participants will receive the 30-day CHW intervention (usual care with CHW care). A chart review will also be completed for all participants. All patient participants will also complete 10-minute exit interviews with completion of a questionnaire in person or via phone at study day 25 and at the end of the 30-day interval. CHWs will also complete an exit interview at the end of each 30-day study interval pairing.

Eligible inpatients will be identified through a number of different ways. Inpatients presenting with congestive heart failure exacerbation as the primary diagnosis and hospitalized on a relevant MGH inpatient units and meeting all eligibility criteria will be recruited. All study criteria will be confirmed with patients directly and an informational letter introducing the study purpose and payment for participation ($250 per patient) will be given to eligible patients. After agreeing to the study and providing written informed consent, patients meeting study criteria will be enrolled and CHW staff will meet and establish patient- centered goals for the study interval prior to hospital discharge. Patients unable to be fully enrolled and given study equipment prior to discharge will be contacted via phone and if interested have the option of returning to MGH at a convenient time.

Eligible patients may be contacted through Patient Gateway Personalized Letter, Patient Gateway Targeted Research Announcement, and mail. If interested in enrollment, these patients will have the option to complete all enrollment procedures and receive all equipment and study instructions by returning to MGH at a convenient time. We will limit the possibility of contacting patients that do not meet our study criteria by: 1) Making sure that patients who opt-out of research invitation contact are filtered out of recruitment lists from RPDR and are not sent research invitations; 2) selecting criteria so that only those most likely to meet study inclusion criteria are sent invitations; 3) regularly monitor patient responses (twice weekly) to ensure the criteria are identifying the correct patients; 4) report any patient complaints about this method of recruitment as an "Other Event" to the IRB within 1 month of occurrence. Enrolled participants will begin their 30 days at the time that all enrollment procedures are complete.

If interested in enrollment after hearing about the study, these patients will have the option to complete all enrollment procedures and receive all equipment and study instructions by returning to MGH at a convenient time.

Patients may be referred to us by a MGH primary care provider/physician or cardiologist. These patients may contact us by phone after reviewing our study fact sheet which will be posted and available for viewing in MGH primary care and cardiologist offices. If contacted by a patient interested in participating in the study, we will describe the study enrollment and consent procedures. If interested in enrollment after hearing more about the study, these patients will have the option to complete all enrollment procedures and receive all equipment and study instructions by returning to MGH at a convenient time.

After completing the enrollment questionnaire, participants randomized to the digitally-enabled intervention arm will be given the Everion biosensor and digital weight scale and blood pressure cuff. Participants will be instructed to wear the Everion biosensor on their non-dominant arm and how it will track several body metrics including heart rate, oxygenation and activity levels. A study team member will guide the participant through downloading the Biofourmis app, and setup of the Biofourmis app as well as demonstrating all features. Patients will be instructed on how to use the digital weight scale and digital blood pressure cuff as well as the Biofourmis app. The Everion biosensor, digital weight scale and digital blood pressure monitor will be linked to the Biofourmis mobile phone application. To promote privacy of health information, a login will be required for access to app and all mobile phones will be set to password protected mode/touch ID activated (if not already).

For participants randomized to the intervention, at the time of enrollment, application permissions will be given. For the Biofourmis application to access any information on an iOS/Android smartphone, the application must ask the user for permission and only if that permission is granted, can the application access that information. This is inherently enforced on all applications by the operating system. In our case, we only will ask for permissions to access:

- Relevant digital-health data from Biofourmis platform physical/metabolic activity metrics including heart rate, oxygenation and activity levels
- Display notifications
- All clinical support team notifications

Participants randomized to the intervention arm will be advised that they will need to return the Everion device, digital weight scale and digital blood pressure monitor after the 30-day enrollment period ends. They will be advised that the app can be used freely after the study is concluded.

Participants will complete an enrollment questionnaire at the time of enrollment. A chart review will also be completed by study coordinators. Participants will be asked whether they own a home weight scale and blood pressure cuff. The study team will also assess the level of adherence based on self-reported symptom data collected in questionnaires as well as the Quality of Life Questionnaire and exit questionnaire administered on day 25 and day 30 after enrollment.

Patient participants will complete exit interviews in-person or via phone after the 30-day study interval ends. Patient participants will be contacted by phone on day 25 and within 3 days of completing the 30-day intervention and exit interviews (25 minutes in length) will be scheduled either in-person (at MGH, 55 Fruit street) or via phone. CHW study staff will also complete exit interviews in-person 3-5 days after each 30-day patient participant intervention ends.

All interviews will be audio recorded and transcribed verbatim. Interviews will be performed by the PI and a study coordinator trained in semi-structured interview administration. Expected completion of each iteration of 10 exit interviews will occur within 2 weeks of participants completing the 30-day intervention.

Patients that are admitted within 30 days of hospital discharge will be approached during their hospital admission to complete a short readmission questionnaire (10 minutes). An admission chart review will also be completed prior to discharge.

In addition, when patients are offered or trained in the intervention but decline to participate, reasons for non-participation will be assessed to inform enrollment barriers.

When the study arm ends or a participant's participation ends prematurely, those participants may keep their app (in which case their use will continue to be tracked), but will be asked to return the Everion device, the digital weight scale, and digital blood pressure monitor.

For studies involving treatment or diagnosis, provide information about standard of care at Partners (e.g., BWH, MGH) and indicate how the study procedures differ from standard care. Provide information on available alternative treatments, procedures, or methods of diagnosis.

Aim 1

This aim does not involve diagnostic processes. This use of qualitative interviews which may improve patient engagement and favorably effect outcomes including reduced rates of hospital readmission, ED visits, improved medication compliance and improved care plan adherence.

This Aim will complete the following in addition to standard of care:

1) Completion of qualitative interviews with patients
2) Completion of focus groups with community health workers

Aim 2

This aim does not involve diagnostic processes. The standard of care and excellence at Partners/MGH institutions may be enhanced with the use of the proposed mobile application and/or community health worker care delivery which may improve patient engagement and favorably effect outcomes including reduced rates of hospital readmission, ED visits, and improved medication compliance and care plan adherence.

This Aim will complete the following in addition to standard of care:

3) Distribution of the Everion biosensor, digital BP monitor, and digital weight scale
4) Distribution of the Biofourmis mobile Application
5) Completion of study questionnaires (schedule of completion in supplemental documents)
    a. Enrollment questionnaire for patients
    b. Quality of Life Questionnaire for patients
    c. Usability exit interviews with patients

d. Post- study exit interviews with CHWs

Aim 3
This aim does not involve diagnostic processes. The standard of care and excellence at Partners/MGH institutions may be enhanced with the use of the proposed mobile application and/or community health worker care delivery which may improve patient engagement and favorably effect outcomes including reduced rates of hospital readmission, ED visits, and improved medication compliance and care plan adherence.

This aim will complete the following in addition to standard of care for patients randomized to the intervention arm:

6) Distribution of the Everion biosensor, digital BP monitor, and digital weight scale
7) Distribution of the Biofourmis mobile Application
8) CHW care
9) Completion of study questionnaires (schedule of completion in supplemental documents)
   a. Enrollment questionnaire for patients
   b. Quality of Life Questionnaire for patients
   c. Usability exit interviews with patients

This aim will complete the following in addition to standard of care for patients randomized to the control arm:

10) CHW Care
11) Completion of study questionnaires (schedule of completion in supplemental documents)
   a. Enrollment questionnaire for patients
   b. Quality of Life Questionnaire for patients
   c. Usability exit interviews with patients

Describe how risks to subjects are minimized, for example, by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk or by using procedures already being performed on the subject for diagnostic or treatment purposes.

Aim 1
Minimal risk is anticipated in this study since no drugs or biologics are involved. All adverse events in association with the study will be reported to the Partners Institutional Review Board and according to Partners Healthcare/MGH policy.

Aim 2
As in any clinical study, there are risks related to privacy and confidentiality.

While the use of any mobile application has some potential security risk, measures will be taken to mitigate the risk of any possible breach of privacy. As part of the Biofourmis registration within the Biofourmis mobile application, patients will be

instructed on how to minimize the risk of any possible breach of confidentiality. Patients will be instructed to limit personal identifiers entered into mobile application, review the privacy/security settings often, and restrict any unnecessary access.

Aim 3
As in any clinical study, there are risks related to privacy and confidentiality.

While the use of any mobile application has some potential security risk, measures will be taken to mitigate the risk of any possible breach of privacy. As part of the Biofourmis registration within the Biofourmis mobile application, patients will be instructed on how to minimize the risk of any possible breach of confidentiality. Patients will be instructed to limit personal identifiers entered into mobile application, review the privacy/security settings often, and restrict any unnecessary access.

Describe explicitly the methods for ensuring the safety of subjects. Provide objective criteria for removing a subject from the study, for example, objective criteria for worsening disease/lack of improvement and/or unacceptable adverse events. The inclusion of objective drop criteria is especially important in studies designed with placebo control groups.

Aim 1
Participants will continue to receive usual healthcare from their physicians regardless of participation. While minimal safety risk is expected during this study, this study aim is not designed to detract from or interfere with clinical care. Individuals unable or unwilling to participate in the semi-structured interview will be withdrawn from the study aim.

Aim 2
Participants will continue to receive usual healthcare from their physicians along with CHW and digital platform support. While minimal safety risk is expected, this study aim is not designed to detract from or interfere with clinical care. Individuals unable or unwilling to participate in questionnaires, CHW interactions, mobile application or arm band wear or interviews will be withdrawn from the study aim. Study aim records that identify subjects will be kept confidential as required by law. Subject data will de- identified in study aim records disclosed among MGH study co-investigators. Subjects will be encouraged to limit personal identifiers they enter into mobile applications.

Aim 3

Participants will continue to receive usual healthcare from their physicians along with CHW and digital platform support. While minimal safety risk is expected, this study aim is not designed to detract from or interfere with clinical care. Individuals unable or unwilling to participate in questionnaires, CHW interactions, mobile application or arm band wear or interviews will be withdrawn from the study aim. Study aim records that identify subjects will be kept confidential as required by law.

Subject data will de- identified in study aim records disclosed among MGH study co-investigators. Subjects will be encouraged to limit personal identifiers they enter into mobile applications.

FORESEEABLE RISKS AND DISCOMFORTS

Provide a brief description of any foreseeable risks and discomforts to subjects. Include those related to drugs/devices/procedures being studied and/or administered/performed solely for research purposes. In addition, include psychosocial risks, and risks related to privacy and confidentiality. When applicable, describe risks to a developing fetus or nursing infant.

Aim 1

No drugs or biologic procedures will be administered. There are no foreseeable discomforts or psychosocial risks to subjects. If after consenting to the study, study participants are no longer interested in being included in the study or are unable to complete the study for any reason, they will be withdrawn from the study. If there are any questions that make study participants uncomfortable, they may skip these questions.

To mitigate the risk to privacy and confidentiality, all study participants will be assigned a unique study identification number as part of a Partners password protected REDCap database. Only de-identified data will be analyzed and published. Data will only be assessable to authorized study staff including the PI, co-investigators and statistical staff.

Aim 2

No drugs or biologic procedures will be administered. There are no foreseeable discomforts or psychosocial risks to subjects. If after consenting to the study, study participants are no longer interested in being included in the study or are unable to complete the study for any reason, they will be withdrawn from the study. If there are any questions that make study participants uncomfortable, they may skip these questions.

To mitigate the risk to privacy and confidentiality, all study participants will be assigned a unique study identification number as part of a Partners password protected REDCap database. Only de-identified data will be analyzed and published. Data will only be assessable to authorized study staff including the PI, co-investigators and statistical staff.

In terms of device or mobile application use, the following processes will mitigate the risk to privacy and confidentiality.

- A login will also be required for access to the Biofourmis application and the smart phone will be set to password protected mode / touch ID activated. At the time of enrollment, app permissions will be given.
- For an application to access any information on an iOS/Android smartphone, the application must ask the user for permission and only if that permission

is granted, can the application access that information. This is inherently enforced on all applications by the operating system.

- In our case, we only will ask for permissions to access:
    - Relevant digital-health data from Biofourmis platform including physical/metabolic activity metrics including heart rate, oxygenation and activity levels
    - Display notifications
    - All clinical support team notifications

Any mobile app that is downloaded carries potential security risks and while a guarantee that this mobile application is risk free cannot be made, every effort has been taken to ensure that risk has been mitigated as listed above. In addition, weekly monitoring by the PI, Jocelyn Carter, MD will occur to help identify and prevent any security issues.

Aim 3
No drugs or biologic procedures will be administered. There are no foreseeable discomforts or psychosocial risks to subjects. If after consenting to the study, study participants are no longer interested in being included in the study or are unable to complete the study for any reason, they will be withdrawn from the study. If there are any questions that make study participants uncomfortable, they may skip these questions.

To mitigate the risk to privacy and confidentiality, all study participants will be assigned a unique study identification number as part of a MGB password protected REDCap database. Only de-identified data will be analyzed and published. Data will only be assessable to authorized study staff including the PI, co-investigators, and statistical staff.

In terms of device or mobile application use for participants randomized to the intervention arm, the following processes will mitigate the risk to privacy and confidentiality.

- A login will also be required for access to the Biofourmis application and the smart phone will be set to password protected mode / touch ID activated. At the time of enrollment, app permissions will be given.
- For an application to access any information on an iOS/Android smartphone, the application must ask the user for permission and only if that permission is granted, can the application access that information. This is inherently enforced on all applications by the operating system.
- In our case we only will ask for permissions to access:
    - Relevant digital-health data from Biofourmis platform including physical/metabolic activity metrics including heart rate
    - Display notifications
    - All clinical support team notifications

Any mobile app that is downloaded carries potential security risks and while a guarantee that this mobile application is risk free cannot be made, every effort has been taken to ensure that risk has been mitigated as listed above. In addition, weekly monitoring by the PI, Jocelyn Carter, MD will occur to help identify and prevent any security issues.

In terms of all participants including those randomized to the control arm, the following processes will mitigate the risk to privacy and confidentiality:

- A login will be required for access to all REDCap questionnaire and chart review data.
- A login will be required for access to all Dedoose transcriptions and analysis

EXPECTED BENEFITS

Describe both the expected benefits to individual subjects participating in the research and the importance of the knowledge that may reasonably be expected to result from the study. Provide a brief, realistic summary of potential benefits to subjects, for example, "It is hoped that the treatment will result in a partial reduction in tumor size in at least 25% of the enrolled subjects." Indicate how the results of the study will benefit future patients with the disease/condition being studied and/or society, e.g., through increased knowledge of human physiology or behavior, improved safety, or technological advances.

Aim 1
Study Aim subjects may not receive direct benefit from study aim enrollment. However, improved patient engagement or insights may be seen. The results of this aim will assist in the refinement of Aim 2 focused on developing a promising and innovative intervention for this population facing high morbidity and significant mortality.

Aim 2
Study aim subjects may or may not receive direct benefit from study enrollment. However, it is possible that enrollees will have potential benefits including increased patient compliance with medications and post- discharge appointments, improved engagement with care plans, reduced thirty-day readmissions, reduced ED visits, higher levels of patient perceived psychosocial support and satisfaction with care. If this study aim demonstrates the expected benefit, this type of intervention may be spread to other parts of the hospital and beyond.

Potential benefits are outlined below:

1) E-Learning Modules for Lifestyle Modification
    a) Improve lifestyle modification through education and access to resources – Tobacco Cessation, Heart Healthy Diet, Exercise
2) Symptom Checker and CHW pairing
    a) Able to use at baseline and throughout the study
    b) Pairing with CHW and create patient-centered care plan
    c) Guided creation of a profile within the Biofourmis mobile application
    d) Learn to use Biofourmis platform and participate in supervised practice sessions with opportunities for discussion and questions
3) The Biofourmis platform/ Digital blood pressure monitor/digital weight scale/ Everion biosensor is expected to engage participants by:
    a) Mobile app notifications to the patient regarding use of digital devices
    b) Engaging in video teaching patients about their disease
    c) Direct communication with CHWs within the platform and mobile phone

about care plans as it relates to medication/appointment adherence, video education and symptomatology and physiologic monitoring

Aim 3
Study aim subjects may or may not receive direct benefit from study enrollment. However, it is possible that enrollees will have potential benefits including increased patient compliance with medications and post- discharge appointments, improved engagement with care plans, reduced thirty-day readmissions, reduced ED visits, higher levels of patient perceived psychosocial support and satisfaction with care. If this study aim demonstrates the expected benefit, this type of intervention may be spread to other parts of the hospital and beyond.

Potential benefits for intervention patients are outlined below:

4) E-Learning Modules for Lifestyle Modification
   a) Improve lifestyle modification through education and access to resources – Tobacco Cessation, Heart Healthy Diet, Exercise
5) Symptom Checker and CHW pairing
   a) Able to use at baseline and throughout the study
   b) Pairing with CHW and create patient-centered care plan
   c) Guided creation of a profile within the Biofourmis mobile application
   d) Learn to use Biofourmis platform and participate in supervised practice sessions with opportunities for discussion and questions
6) The Biofourmis platform/ Digital blood pressure monitor/digital weight scale/ Everion biosensor is expected to engage participants by:
   a) Mobile app notifications to the patient regarding use of digital devices
   b) Engaging in video teaching patients about their disease
   c) Direct communication with CHWs within the platform and mobile phone about care plans as it relates to medication/appointment adherence, video education and symptomatology and physiologic monitoring

Potential benefits for control patients are outlined below:

7) E-Learning Modules for Lifestyle Modification
   a) Improve lifestyle modification through education and access to resources – Tobacco Cessation, Heart Healthy Diet, Exercise
   b) Direct communication with CHWs via mobile phone about care plans as it relates to medication/appointment adherence, symptomatology, and social support

EQUITABLE SELECTION OF SUBJECTS

The risks and benefits of the research must be fairly distributed among the populations that stand to benefit from it. No group of persons, for example, men, women, pregnant women, children, and minorities, should be categorically excluded from the research without a good scientific or ethical reason to do so. Please provide the basis for concluding that the study population is representative of the population that stands to potentially benefit from this research.

Aim 1/Aim 2/ Aim 3

Those that are unable to consent and those that have prisoner status (with implicit loss of ability to consent independently) will be systematically excluded from the study Aim. Additionally, patients that are Non-English speaking or have a visual, hearing, or motor impairment will not be enrolled in this study Aim. The remaining patients admitted to the pre-designated units during the study Aim period will be considered for eligibility and identified for potential enrollment. As such, the study Aim population is representative of the available population of cardiac patients that stand to benefit from this research.

When people who do not speak English are excluded from participation in the research, provide the scientific rationale for doing so. Individuals who do not speak English should not be denied participation in research simply because it is inconvenient to translate the consent form in different languages and to have an interpreter present.

Aim 1/Aim 2/ Aim 3
Active efforts are being made to create qualitative interview tools/questionnaires/mobile application in another language (Spanish). If this is developed during the timeline of the study, we will utilize interpreter services to obtain consent and conduct patient interviews to obtain the questionnaire data.

For guidance, refer to the following Partners policy:
Obtaining and Documenting Informed Consent of Subjects who do not Speak English
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Non-English_Speaking_Subjects.1.10.pdf

RECRUITMENT PROCEDURES

Explain in detail the specific methodology that will be used to recruit subjects. Specifically address how, when, where and by whom subjects will be identified and approached about participation. Include any specific recruitment methods used to enhance recruitment of women and minorities.

Aim 1
Patients
Patients with heart failure and meeting all eligibility criteria will be recruited in the inpatient setting or via a prior study. All study criteria will be confirmed with patients directly and an informational letter introducing the qualitative study purpose and payment for participation ($50 per patient) will be given to eligible patients. If interested, patients will be able to review the informed consent document. All questions will be answered about all aspects of the study listed on the information sheet and the informed consent document. If interested in enrolling in the study, patients will then provide verbal consent and will be interviewed by a study coordinator at MGH 55 Fruit Street (25 min). All patient interviews will be audio recorded and transcribed verbatim. Dedoose will be used to analyze themes generated by the interviews. A chart review for readmitted study participants will also be performed by study staff. A REDCap database will be used to store all questionnaire and chart review data. No other modes of recruitment will be utilized.

No specific recruitment methods will be used to enhance the recruitment of women or minorities.

Community Health Workers
CHWs (n=20) working in MGH inpatient and outpatient settings will be identified for one of two focus groups (n=10/focus group) lasting 1.5 hours each. All CHWs will have experience providing direct care for HF patients. MGH CHWs will be emailed an informational letter and introduced to the study at CHW weekly departmental meetings. CHWs interested in participating will be enrolled and, after giving verbal consent, will be scheduled for a focus group at MGH (55 Fruit Street, Boston, MA), via virtual meeting accessed via MGB generated Zoom link, or at 1-2 MGH community clinics.

Aim 2
Patients with heart failure and meeting all eligibility criteria will be recruited. All study criteria will be confirmed with patients directly and an informational letter introducing the study purpose and payment for participation ($250 per patient) will be given to enrolled participants completing the intervention. After agreeing to the study and providing written informed consent, patients meeting study criteria will be enrolled and CHW staff will meet and establish patient- centered goals for the study interval.

Modes of recruitment will be utilized. We will identify patients with heart failure by contacting patients through research invitations, accepting direct referrals from primary care physician/cardiology physician teams, and RDPR. No specific recruitment methods will be used to enhance the recruitment of women or minorities.

Aim 3
A randomized controlled trial will be performed with a 30-day intervention among 50 patients with HF randomized to the intervention arm (digitally-enabled CHW + usual care) or the control arm (CHW care + usual care). Participants randomized to the intervention arm will be enrolled(n=25) and participants will receive the 30-day digitally-enabled CHW intervention (usual care + digitally-enabled CHW care). Participants randomized to the control arm will be enrolled (n=25) and participants will receive the 30-day CHW intervention (usual care with CHW care). A chart review will also be completed for all participants. Patients with heart failure and meeting all eligibility criteria will be recruited. All study criteria will be confirmed with patients directly and an informational letter introducing the study purpose and payment for participation ($250 per patient) will be given to enrolled participants completing the intervention. After agreeing to the study and providing written informed consent, patients meeting study criteria will be enrolled and randomized to intervention or control arms. CHW staff will meet and establish patient- centered goals for the study interval.

Modes of recruitment will be utilized. We will identify patients with heart failure on inpatient units, by contacting patients through research invitations, accepting direct referrals from primary care physician/cardiology physician teams, and RDPR. No

specific recruitment methods will be used to enhance the recruitment of women or minorities.

Provide details of remuneration, when applicable. Even when subjects may derive medical benefit from participation, it is often the case that extra hospital visits, meals at the hospital, parking fees or other inconveniences will result in additional out-of-pocket expenses related to study participation. Investigators may wish to consider providing reimbursement for such expenses when funding is available

Aim 1
Patients
Study coordinator approaching patients will present an informational letter introducing the qualitative study aim purpose and payment for participation ($50 per patient) will be given to eligible patients. Interested patients will be verbally consented and interviewed at the bedside or via phone (25 min).

Community Health Workers
CHWs interested in participating will be enrolled and scheduled for a focus group (1.5 hours) at MGH (55 Fruit Street, Boston, MA), via virtual meeting accessed via MGB generated Zoom link, or at 1-2 MGH community clinics. Payment for participation will be $50 per CHW.

Aim 2
Patients
Patients with heart failure and meeting all eligibility criteria will be recruited. All study criteria will be confirmed with patients directly and an informational letter introducing the study purpose and payment for participation ($250 per patient) will be given to eligible patients. After agreeing to the study and providing written informed consent, patients meeting study criteria will be enrolled and CHW staff will meet and establish patient- centered goals for the study interval.

The Biofourmis mobile application, Biofourmis arm band, digital blood pressure monitor, and digital weight scale will be provided at no cost to the participant for the duration of the study. Participants will be able to keep the Biofourmis mobile app access but will need to return the blood pressure monitor, weight scale, and Everion arm band following study completion.

No additional hospital visits or out of pocket expenses related to study participation will be incurred.

Community Health Workers
CHWs for this study aim will be paid study staff and no remuneration for study aim participation will be given.

Aim 3

Patients
Patients with heart failure and meeting all eligibility criteria will be recruited. All study criteria will be confirmed with patients directly and an informational letter introducing the study purpose and payment for participation ($250 per patient randomized to intervention or control) will be given to eligible patients. After agreeing to the study and providing written informed consent, patients meeting study criteria will be enrolled and randomized (block randomization, blocks of 3) to intervention or control. CHW staff will meet and establish patient- centered goals for the study interval at the time of enrollment.

For intervention patients, the Biofourmis mobile application, Biofourmis arm band, digital blood pressure monitor, and digital weight scale will be provided at no cost to participants in the intervention group for the duration of the study. Participants will be able to keep the Biofourmis mobile app access but will need to return the blood pressure monitor, weight scale, and Everion arm band following study completion.

No additional hospital visits or out of pocket expenses related to study participation will be incurred.

Community Health Workers
CHWs for this study aim will be paid study staff and no remuneration for study aim participation will be given.

For guidance, refer to the following Partners policies:

Recruitment of Research Subjects
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Recruitment_Of_Research_Subjects.pdf

Guidelines for Advertisements for Recruiting Subjects
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Guidelines_For_Advertisements.1.11.pdf

Remuneration for Research Subjects
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Remuneration_for_Research_Subjects.pdf

CONSENT PROCEDURES

Explain in detail how, when, where, and by whom consent is obtained, and the timing of consent (i.e., how long subjects will be given to consider participation). For most studies involving more than minimal risk and all studies involving investigational drugs/devices, a licensed physician investigator must obtain informed consent. When subjects are to be enrolled from among the investigators' own patients, describe how the potential for coercion will be avoided.

Aim 1
Patients

After identifying eligible patients, a member of the study team will interview inpatients at the bedside or reach out to patients via phone to introduce the study. (For those patients interviewed as inpatients, a study team member will ask a member of the care team for permission to approach. After permission is obtained, eligible patients who are willing to speak to a research team member about the study aim will be approached by the care team.) A research team member will describe the nature of the study aim and expected involvement. If interested, the study coordinator will offer to give or send (via email or snail mail) the patient the study fact sheet. The fact sheet will distill the purpose and main components of the study aim in a simplified way so that patients can get an idea of what the study aim will involve by reading a single page. Involvement will include a qualitative interview, and chart review procedures. Patients contacted via phone will have an opportunity to have the info sheet sent to them (via email or snail mail), read about the process and procedures, ask questions, and engage in discussion about all study aim details. Patients will have time to read and review the information as well as ask questions or to have the coordinator call them via phone later if necessary.

If the potential participant is not interested and/or verbal consent is not obtained for participation, the patient will not be enrolled. If after hearing about the study aim and reviewing the study aim fact sheet, a potential participant is interested in participating in the study aim and meets all eligibility criteria, the patient will be verbally consented and be enrolled in the study aim.

Patients that are undecided on study aim participation may take additional time to consider enrollment and study coordinators may connect with patients up to three times via phone to clarify any outstanding questions prior to enrollment.

Patients that are interested will be verbally consented prior to being enrolled and complete the qualitative interview while in patient or via phone.

The interview will be conducted by the PI and a study coordinator via phone or at the patient's bedside and this will last for 25-minutes. All interviews will be recorded prior to verbatim transcription via TranscribeMe.

All patients may keep paper copies of the study aim fact sheet for future reference.

Community Health Workers
CHWs (n=20) working in MGH inpatient and outpatient settings will be identified for one of two focus groups (n=10/focus group) lasting 1.5 hours each. All CHWs will have experience providing direct care for HF patients. MGH CHWs will be emailed an informational letter and introduced to the study at CHW weekly departmental meetings. CHWs interested in participating will be verbally consented, enrolled and scheduled for a focus group at MGH (55 Fruit Street, Boston, MA), via virtual meeting accessed via MGB generated Zoom link, or at 1-2 MGH community clinics.

Aim 2
After identifying eligible patients contacted by Research Invitation, or by MGH primary care provider/cardiologist referral, a member of the study team will introduce the study. If interested in enrollment after hearing about the study, these

patients will have the option to complete all enrollment procedures and receive all equipment and study instructions by returning to MGH at a convenient time. Patients will have an opportunity to ask questions and engage in discussion about CHWs care delivery, the use of a Biofourmis mobile application, Everion, digital blood pressure monitor, digital weight scale, and all study aim details. Patients will have time to ask questions or to have the coordinator call back later via phone if necessary.

If the potential participant is not interested and/or consent is not obtained for participation, the patient will not be enrolled. If after hearing about the study aim, reviewing the study aim fact sheet and consent form, a potential participant is interested in participating in the study aim and meets all eligibility criteria, the patient may sign the consent form and be enrolled in the study aim.

Patients that are undecided on study aim participation may take additional time to consider enrollment up to 6 weeks or 3 study coordinator contacts after study coordinator initial contact; or up to 6 weeks after patients express interest via research invitation, or referral contact).

Patients that are interested will sign a consent form. Informed consent will be obtained by a clinical research coordinator or an MD. Capacity to consent will always be assessed by the Licensed Physician Investigator.

Enrolled participants will then meet their paired CHW, establish a plan for contact and a plan to reach patient-established goals. Enrolled participants will also be taught how to use the Biofourmis mobile application which will be uploaded to their phone. Enrollees will also be given and taught how to use the Everion, digital weight scale, and the digital blood pressure monitor. All participants will continue to engage with their CHW and be instructed on how to use the Biofourmis app and all hardware with opportunities to ask questions. Enrolled participants will also benefit from supervised practice of hard/software use. The expectation is that participants will have an established contact plan with their assigned CHW and be expert users of the Biofourmis platform.

All patients may keep paper copies of the study aim fact sheet and consent for future reference.

The CHWs participating in Aim 2 are paid members of the research study team.

Aim 3:

After identifying eligible patients contacted in the inpatient setting, by Research Invitation, or by MGH primary care provider/cardiologist referral, a member of the study team will introduce the study. If interested in enrollment after hearing about the study, these patients will have the option to complete all enrollment procedures and receive all equipment and study instructions by returning to MGH at a convenient time.

Patients will have an opportunity to ask questions and engage in discussion about CHWs care delivery, the use of a Biofourmis mobile application, Everion, digital blood pressure monitor, digital weight scale, and all study aim details. Patients will have time to ask questions or to have the coordinator call back later via phone if necessary.

If the potential participant is not interested and/or consent is not obtained for participation, the patient will not be enrolled. If after hearing about the study aim, reviewing the study aim fact sheet and consent form, a potential participant is interested in participating in the study aim and meets all eligibility criteria, the patient may sign the consent form and be enrolled in the study aim.

Patients that are undecided on study aim participation may take additional time to consider enrollment up to 6 weeks or 3 study coordinator contacts after study coordinator initial contact; or up to 6 weeks after patients express interest via research invitation, or referral contact).

Patients that are interested will sign a consent form. Informed consent will be obtained by a clinical research coordinator or an MD. Capacity to consent will always be assessed by the Licensed Physician Investigator.

Enrolled participants will then meet their paired CHW, establish a plan for contact and a plan to reach patient-established goals. Enrolled participants will also be taught how to use the Biofourmis mobile application which will be uploaded to their phone. Enrollees will also be given and taught how to use the Everion, digital weight scale, and the digital blood pressure monitor. All participants will continue to engage with their CHW and be instructed on how to use the Biofourmis app and all hardware with opportunities to ask questions. Enrolled participants will also benefit from supervised practice of hard/software use. The expectation is that participants will have an established contact plan with their assigned CHW and be expert users of the Biofourmis platform.

All patients may keep paper copies of the study aim fact sheet and consent for future reference.

The CHWs participating in Aim 3 are paid members of the research study team.

NOTE: When subjects are unable to give consent due to age (minors) or impaired decision-making capacity, complete the forms for Research Involving Children as Subjects of Research and/or Research Involving Individuals with Impaired Decision-making Capacity, available on the New Submissions page on the PHRC website:
https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb

For guidance, refer to the following Partners policy:
Informed Consent of Research Subjects:
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Informed_Consent_of_Research_Subjects.pdf

DATA AND SAFETY MONITORING

Describe the plan for monitoring the data to ensure the safety of subjects. The plan should include a brief description of (1) the safety and/or efficacy data that will be reviewed; (2) the planned frequency of review; and (3) who will be responsible for this review and for determining whether the research should be altered or stopped. Include a brief description of any stopping rules for the study, when appropriate. Depending upon the risk, size and complexity of the study, the investigator, an expert group, an independent Data and Safety Monitoring Board (DSMB) or others might be assigned primary responsibility for this monitoring activity.

NOTE: Regardless of data and safety monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for protecting the rights, safety, and welfare of subjects under his/her care.

In addition to weekly data monitoring by the PI, a Data Safety Monitoring Board has been assembled that includes a NIH funded clinical trialist, a senior biostatistician and a NIH funded trialist and senior scientist that will meet annually to review all data and analysis, discuss progress, and challenges. All complaints about the study will be reviewed by the DSMB. The study may be stopped at any time if a safety or efficacy compromise occurs.

Describe the plan to be followed by the Principal Investigator/study staff for review of adverse events experienced by subjects under his/her care, and when applicable, for review of sponsor safety reports and DSMB reports. Describe the plan for reporting adverse events to the sponsor and the Partners' IRB and, when applicable, for submitting sponsor safety reports and DSMB reports to the Partners' IRBs. When the investigator is also the sponsor of the IND/IDE, include the plan for reporting of adverse events to the FDA and, when applicable, to investigators at other sites.

NOTE: In addition to the adverse event reporting requirements of the sponsor, the principal investigator must follow the Partners Human Research Committee guidelines for Adverse Event Reporting

Data review and database review will be completed by the PI, Jocelyn Carter, MD each week to ensure the validity and integrity of the data generated in accordance with all study procedures described in the IRB-approved protocol. Progress reports based on data review and database review will be completed and sent to the DSMB quarterly to ensure that all procedures and data collection are in compliance with details specified in the IRB protocol. All adverse events will be reported to the IRB directly by the PI.

MONITORING AND QUALITY ASSURANCE

Describe the plan to be followed by the principal investigator/study staff to monitor and assure the validity and integrity of the data and adherence to the IRB-approved protocol. Specify who will be responsible for monitoring, and the planned frequency of monitoring. For example, specify who will review the accuracy and completeness of case report form entries, source documents, and informed consent.

NOTE: Regardless of monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for ensuring that the study is conducted at his/her investigative site in accordance with the IRB-approved protocol, and applicable regulations and requirements of the IRB.

Data review and database review will be completed by the PI, Jocelyn Carter, MD each week to ensure the validity and integrity of the data generated in accordance with all study procedures described in the IRB-approved protocol.

For guidance, refer to the following Partners policies:

Data and Safety Monitoring Plans and Quality Assurance
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/DSMP_in_Human_Subjects_Research.pdf

Reporting Unanticipated Problems (including Adverse Events)
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Reporting_Unanticipated_Problems_including_Adverse_Events.pdf

PRIVACY AND CONFIDENTIALITY

Describe methods used to protect the privacy of subjects and maintain confidentiality of data collected. This typically includes such practices as substituting codes for names and/or medical record numbers; removing face sheets or other identifiers from completed surveys/questionnaires; proper disposal of printed computer data; limited access to study data; use of password-protected computer databases; training for research staff on the importance of confidentiality of data, and storing research records in a secure location.

NOTE: Additional measures, such as obtaining a Certificate of Confidentiality, should be considered and are strongly encouraged when the research involves the collection of sensitive data, such as sexual, criminal or illegal behaviors.

Privacy of study participants will be protected in the following ways. All patient information for the study will be stored in a locked study coordinator office at MGH. All medical records pertaining to the study that are no longer needed will be placed in HIPPA-compliant bins at MGH. All research team members for this study are CITI-certified and have a strong understanding of GCP.

All information and data concerning subjects or their participation in this study will be considered confidential. Only authorized personnel involved in the study will have access to these confidential files.

The electronic database generated will be password-protected and accessed only by authorized study staff trained on the importance data confidentiality and record security (limited to the PI, co- investigators and statistical lead). There are no foreseen risks to privacy and all study participants will be assigned a unique study identification number as part of a Partners password protected REDCap database. Only de-identified data will be analyzed and published.

SENDING SPECIMENS/DATA TO RESEARCH COLLABORATORS OUTSIDE PARTNERS

Specimens or data collected by Partners investigators will be sent to research collaborators outside Partners, indicate to whom specimens/data will be sent, what information will be sent, and whether the specimens/data will contain identifiers that could be used by the outside collaborators to link the specimens/data to individual subjects.

No data will be sent to research collaborators outside Partners. The PI and co-investigators will may have access to de-identified data solely for the purposes of routine data discussions contributing to the success of the study. Only de-identified data will be analyzed and published.

Specifically address whether specimens/data will be stored at collaborating sites outside Partners for future use not described in the protocol. Include whether subjects can withdraw their specimens/data, and how they would do so. When appropriate, submit documentation of IRB approval from the recipient institution.

RECEIVING SPECIMENS/DATA FROM RESEARCH COLLABORATORS OUTSIDE PARTNERS

When specimens or data collected by research collaborators outside Partners will be sent to Partners investigators, indicate from where the specimens/data will be obtained and whether the specimens/data will contain identifiers that could be used by Partners investigators to link the specimens/data to individual subjects. When appropriate, submit documentation of IRB approval and a copy of the IRB-approved consent form from the institution where the specimens/data were collected.

No data will be sent to research collaborators outside Partners. The PI and co-investigators will may have access to de-identified data solely for the purposes of routine data discussions contributing to the success of the study. Only de-identified data will be analyzed and published.

4.4 Statistical Design and Power

1. Statistical Analysis

For Aim 1, transcription and interviewer/moderator notes will be uploaded into NVivo 10 for analysis. Dr. Carter and a research coordinator will first independently code patient data followed by CHW focus group data. The framework used will include an approach where two researchers will familiarize themselves with the raw data, independently identify key themes raised by respondents, and reapply this thematic framework by rearranging the raw data into themes and relationships. Associations between themes, user characteristics, and outcomes will be identified. Each coder will perform content analysis to capture themes associated with each focus group and patient interview. These will be compared by gender and age. Intercoder reliability will be achieved through an iterative process of comparing each level of coding (themes and codes) while discussing discrepancies and comparing results to the raw data until Kappa> 0.80 is achieved. Themes will be reviewed and discrepancies discussed with a third researcher, Dr. Donelan, with expertise in qualitative data. Dr. Thorndike will also perform an expert review of the data analysis and interpretation. Dr. Carter will review patient transcripts weekly with interviewer staff to discuss emerging themes, modify the patient interview instrument as needed, and assess for theoretical saturation. If necessary, Dr. Carter will make modifications to the patient interview instrument to increase the contextual relevance. Due to the small number of focus groups used (n=2), no modifications will be made to the CHW focus group instrument after the first focus group occurs.

For Aim 2, interview transcriptions and interviewer notes will be reviewed weekly by Dr. Carter and themes will be categorized as described above in Aim 1 and in the Research Strategy section E.7. These themes will be used to refine the intervention prior to each new iteration (maximum of 3 study runs) informing the RCT intervention in Aim 3. Dr. Carter's review of the REDCap core competency/activity log checklists and digital platform patient use data will also inform intervention refinement.

For Aim 3, data analysis will include the following: Summary statistics for the acceptability and feasibility of the intervention will be reported with 95% confidence interval. For effectiveness of the intervention, the proportion with 30-day readmissions or missed appointments will be compared using Pearson's χ^2 tests and the number of ED visits will be compared using a Poisson model. Other variables in the post-study questionnaires will be compared between the two groups in a separate analysis. The relationship between potential predictors and outcomes will be explored. In Dr. Carter's prior CHW clinical trial, <3% of patients were lost to follow-up and similar rates are expected here. REDCap activity log and patient use assessments will also be summarized.

For Aim 3, power calculations will be based on a sample n=50. The study will have a minimum of 83% power to detect a 40% difference between the two groups with a two-sided significant level of 0.05. As a pilot study, the sample size is not powered to detect small differences between the two groups. However, the study will provide estimates for the effect size which can be used in the future R01 study.