SUPeRFOOD: enhanced SUPport for initiation and paRticipation in a FOOD is medicine program

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Community Partner: Project Open Hand (POH)

Sponsor: American Heart Association (AHA)

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Version History

Version	Date	Summary of Changes
1.0	2/16/2024	Initial version submitted to IRB
1.1	3/22/2024	Modified data sharing language to match sponsor language. Modified primary objective and endpoint of phase 2 to be acceptability based on sponsor feedback. Original outcomes are retained as secondary outcomes. Added potential recruitment through fliers, phone calls, or in-person contact. Removed collection of electronic health record data by FHIR. Clarified inconsistencies, typos, references.
1.2	07/3/2024	Added measurements to include AHA common data elements. Modified recruitment procedures to comply with UCSF requirements.

1.3	10/11/2024	Added additional exclusion to exclude patients who are currently receiving services from Project Open Hand.
1.4	11/26/2024	Added clinicaltrials.gov number Modified inclusion criteria to include patients who have had at least one CR session within the last year at UCSF or ZSFG, and to include patients who have internet or smartphone access. Added language describing new recruitment methods. Updated Table 2 to include additional data collection on FIM meal units for participants' insurance authorization period and dependents.

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Abbreviations

AHA	American Heart Association
CR	Cardiac Rehabilitation
CV	Cardiovascular
EHR	Electronic Health Record
FHIR	Fast Health Interoperability Resource
FIM	Food is Medicine
MTG	Medically tailored groceries
MTM	Medically tailored meals
POH	Project Open Hand
UC	Usual Care
UCSF	University of California, San Francisco

Protocol Synopsis

Title	SUPeRFOOD: enhanced SUPport for initiation and paRticipation in a FOOD is medicine program
Sponsor	American Heart Association (AHA)
Site	UCSF
Rationale	Food is Medicine (FIM) interventions improve quality of life, improve cardiovascular risk factors, reduce hospitalizations, and reduce healthcare costs, but questions remain about optimal approaches for referral, initiation, engagement, and retention in FIM programs to improve participation and ultimately health outcomes.
Study Design	Two phase study: • Phase 1: Human-centered design • Phase 2: 2x2 factorial randomized clinical trial

Objectives	• Phase 1: Optimize the design of the text-messaging and navigation interventions.
	• Phase 2:
	  ▪ To determine the acceptability of navigation to encourage participation in a FIM program.
	  ▪ To determine the acceptability of text messaging to encourage participation in a FIM program.

Target Participant Enrollment (Total)	• Phase 1: up to 6 per session, up to 18 participants total • Phase 2: 84
Participant Selection Criteria	**Inclusion Criteria** 1. Age 18 or older 2. Attended at least 1 cardiac rehabilitation session in the last year at UCSF or ZSFG 3. Has access to the internet or a smartphone 4. Able to communicate in English or Spanish 5. Resident of San Francisco County **Exclusion Criteria** 1. Enrolled in hospice 2. Unable to consent for self 3. Currently receiving Project Open Hand services
Duration of Participant Participation	• Phase 1: 1-6 2-hour sessions over 3 months • Phase 2: 3 months
Comparators	• Navigation • Text-messaging • Usual care (UC)

Study Visits	• Phase 1: 1-6 2-hour sessions over 3 months • Phase 2: Entirely remote study visits through Eureka
Primary Endpoint	• Satisfaction with the intervention.
Secondary Endpoints	• Number of FIM meals received within 3 months, the proportion of patients initiating and engaged in the FIM program (received at least 1 and 8 FIM meals in 3 months, respectively), number of CV events in 3 months, and changes from baseline to 3 months in self-efficacy, food security, healthy eating, quality of life, and cardiovascular risk factors.

Study Hypotheses	• Primary:
	  ○ Navigation + UC (±text messaging) [experimental] will result in mean overall satisfaction of >3.5 (scale of 1-5, with 5 being very satisfied).
	  ○ Text messaging + UC (±navigation) [experimental] will result in mean overall satisfaction of >3.5 (scale of 1-5, with 5 being very satisfied).
	• Secondary:
	  ○ Navigation + UC (±text messaging) [experimental] will result in a greater mean number of FIM meals received in 3 months than UC (± text messaging) [control].
	  ○ Text messaging + UC (±navigation) [experimental] will result in a greater mean number of FIM meals received in 3 months than UC (± navigation) [control].

Background and Rationale

Healthy eating prevents cardiovascular (CV) events.[1–4] Food is Medicine (FIM) interventions include medically tailored meals (MTMs), medically tailored groceries (MTGs), and nutritious food referrals.[2,5] In people with chronic disease, FIM interventions improve quality of life, improve CV risk factors, reduce hospitalizations, and reduce healthcare costs.[2,5–9] **Many questions remain about optimal approaches for referral, initiation, engagement, and retention in FIM programs to improve participation and ultimately health outcomes.**[2]

Cardiac rehabilitation (CR) is a guideline-recommended, multi-disciplinary program for people with heart conditions that includes nutrition counseling.[10,11] The 12-week program is an opportune time for people to establish long-term habits. The CR population is well-suited for integrating and studying FIM programs because 1) CR patients are at risk for CV events, 2) FIM programs benefit people with CV conditions,[5–7] and 3) CR patients are actively engaging in behavior change, which may be a beneficial time for engaging with a FIM program.[12]

Connecting CR and FIM programs offers a scalable opportunity to improve healthy eating and health outcomes in people with heart conditions. Our long-term goals are to optimize approaches for patients to engage in FIM programs and to examine the effects on health outcomes. Our central hypothesis is that **enhanced support for patients in addressing barriers to participation in FIM programs will improve engagement in FIM programs and health outcomes.** Formative and pilot studies are needed to adapt enhanced support interventions to diverse heart condition patients to inform future larger scale studies to test the effects of these interventions on health outcomes.

Medically Tailored Meals (MTM): MTMs improve outcomes for those with heart conditions, especially those unable to plan, shop for and/or prepare healthy food. Studies of MTM show improvements in health-related quality of life, diet quality, self-efficacy, food security, and cardiovascular (CV) risk factors (e.g., blood pressure and cholesterol).[7,13,14] Because of these results and pilot programs,[15] California now includes MTMs as a Community Supports benefit through its state Medicaid program.

Medically Tailored Groceries (MTG) and Nutritious Food Referrals: MTGs and food referrals (e.g., produce prescriptions and nutrition incentives) support people who can prepare their own meals. MTG and food referrals, among those who maintain engagement with the programs, can increase diet quality and reduce food insecurity.[9,16] Though trial-based evidence regarding MTGs and produce prescriptions is less robust, modeling suggests that incentives for fruits and vegetables could prevent over 1.9 million lifetime cardiovascular disease events and save approximately $40 billion in healthcare costs.[17]

Known barriers to FIM programs: Barriers that impact access to and engagement with FIM interventions exist at both the health care and participant levels.[18] Health care barriers include provider awareness, buy-in and institutional workflows, and staffing capacity that support referral to and discussion of FIM interventions during encounters. Fractured coordination of

care between the FIM organization and the referring provider/organization can result in loss to follow-up or incomplete applications for services. Communication with potential participants as the conduit between the referring provider and the FIM organization places burden on the participant, who may already be experiencing significant complexity in managing their health. During enrollment and throughout FIM service, participants experience a range of access issues (e.g., inadequate housing, cooking facilities, and transportation). Cultural appropriateness, taste preferences, and language preferences can also influence access and engagement. Interventions that include FIM alongside supports that increase knowledge, confidence, and enhance the accessibility of services are of critical value for FIM programs.[12]

Project Open Hand (POH), the community partner for this project, provides nutritious meals to support medical treatment for people with chronic conditions, such as coronary artery disease, heart failure, diabetes, recent surgery, and HIV. POH provides both MTM and MTG to participants. MTM or MTG can be picked up once per week from the POH facility or mobile van. For participants who are unable to pick-up MTM or MTG, the food will be delivered to the participant's home. POH also operates a community nutrition program where people can receive meals in-person at the POH facility. POH works with participants to identify and meet dietary needs, including counseling and education from a dietician. Sample meals can be viewed on the POH website.

Intervention A: Navigation: Similar to FIM programs, CR is a beneficial, but underutilized service.[19–21] Among the interventions that improve participation in CR,[22] patient navigation may be the most adaptable to FIM programs. A navigator can guide patients through the system and help patients overcome barriers to accessing services. A structured approach to navigation in CR includes: 1) explain the program, 2) explain the benefits, 3) provide positive endorsement, 4) describe process to enroll, 5) welcome questions, 6) address barriers to attendance, and 7) provide follow-up information; this approach may be adapted to FIM.[23] Navigation often employs behavioral science strategies, such as motivational interviewing, to promote self-efficacy.[24–26] Navigation can be individualized with regard to patient needs, capabilities, and cultural preferences. To our knowledge, there are no randomized trials of patient navigation as a strategy to improve initiation and engagement in FIM programs.

Intervention B: Text messaging: Behavioral science-based text messaging for promotion of health behaviors can improve self-efficacy, health behaviors (e.g., diet quality, steps, tobacco use), and CV health outcomes, including blood pressure, cholesterol, and weight.[27–30] Text messages can be individualized based on programmable algorithms, and the approach may have advantages with regard to cost and scalability. Behavioral science-based text messaging to improve participation in FIM programs has not been previously studied.

This study will proceed in two phases. In Phase 1, we will conduct human-centered design sessions in CR participants to understand barriers to participating in a FIM program and optimize the design of navigation and text-messaging interventions for addressing these barriers. In Phase 2, we will conduct a 2x2 randomized factorial study in people participating in

CR comparing navigation to usual care and text messaging to usual care with regard to number of FIM meals received.

Preliminary Studies

In 2022, Project Open Hand (POH) served >477,000 MTM or MTG to almost 3,200 people (15% with CV disease). Participants are 35% female and 1% transgender with 27% Latino/Hispanic, 21% African American/Black, and 5% Asian American/Pacific Islander. Over 80% have an income less than $2400/month. Of those enrolled, 64% take home at least seven MTMs each week. Outcomes include 89% reporting more balanced nutrition, 55% helping them reach health-related goals, 51% better energy levels, 80% better able to manage their health condition, and 66% able to take medications as instructed.

POH collects data on barriers and facilitators using a multi-dimensional approach based on participant activities, participant surveys, and interactions with staff.[31] Barriers include appropriateness (available only to limited diagnoses), availability/accommodation (limited care coordination, operating hours, location, challenges in reaching staff), acceptability (food not meeting preferences), facilitating conditions (lack of knowledge about cooking, inadequate housing/cooking facilities, lack of social support), and other factors (medical illnesses). Facilitators include appropriateness (tailoring service to needs, variety of diets, nutritionist), availability/accommodation (relationships with referring partners, mobile sites, home delivery services, bilingual staff, interpreter services, telehealth options), acceptability (ongoing development of culturally appropriate meals/groceries, dietary preferences, treated with respect [98%], deliveries on-time [92%], deliveries accurate [93%]), and responsive client services. These barriers and facilitators will guide the initial development of the interventions.

Objectives

Phase 1: Optimize the design of the text-messaging and navigation interventions.

Phase 2:

- To determine the acceptability of navigation to encourage participation in a FIM program.
- To determine the acceptability of text messaging to encourage participation in a FIM program.

Study Hypotheses

Phase 1: Not applicable

Phase 2:

- Primary:
  - Navigation + UC (±text messaging) [experimental] will result in mean overall satisfaction of >3.5 (scale of 1-5 with 5 being very satisfied).
  - Text messaging + UC (±navigation) [experimental] will result in mean overall satisfaction of >3.5 (scale of 1-5 with 5 being very satisfied).
- Secondary:

- Hypothesis A: Navigation + UC (±text messaging) [experimental] will result in a greater mean number of FIM meals received in 3 months than UC (± text messaging) [control].
- Hypothesis B: Text messaging + UC (±navigation) [experimental] will result in a greater mean number of FIM meals received in 3 months than UC (± navigation) [control].

Study Design

Phase 1: Conduct **human-centered design sessions** with CR patients to adapt two enhanced support interventions to FIM programs: **A) navigation and B) text messaging**. Navigation will be adapted from approaches known to work for enhancing enrollment and participation in CR.[22] Text messages will be based on behavioral science to promote initiation and engagement and adapted from previously studied text message libraries.[32]

Phase 2: We will conduct a 2x2 factorial design **pilot randomized trial** in 84 CR participants to compare the efficacy of navigation and text messaging interventions for increasing participation in a FIM program (Table 1). All participants will experience usual care (UC): a MyChart message with links to the FIM program and study measurement-related text messaging in the Eureka Research Platform. Additionally, participants will be co-randomized 1:1 to A) navigation (present/absent) and B) enhanced text messaging (present/absent), such that 25% of participants will be allocated to each of the four intervention arms. The primary outcome will be the number of MTMs or MTGs for meals (termed "FIM meals") received during the 3-month study period. We will also **evaluate the implementation** of the interventions through interviews, review of "artifacts" of implementation (e.g., meeting minutes, materials), and data on implementation inputs, activities, outputs, and outcomes using a logic model framework.[33]

Table 1. Four arms of the 2x2 factorial trial

Usual care (UC)	UC + Navigation
UC + Text messaging	UC + Navigation + Text messaging

Endpoints

Phase 1: Not applicable

Phase 2:

- Primary endpoint: Satisfaction with the intervention.
- Secondary endpoints include the number of FIM meals received in 3 months, the proportion of patients initiating and engaged in the FIM program (received at least 1 and 8 FIM meals in 3 months, respectively), number of CV events in 3 months, and changes from baseline to 3 months in self-efficacy, food security, healthy eating, quality of life, and Life's Essential 8 CV risk factors.

Participant Selection

Inclusion Criteria:

1. Age 18 or older
2. Attended at least one cardiac rehabilitation session within the last year at UCSF or ZSFG
3. Has access to the internet or a smartphone
4. Able to communicate in English or Spanish
5. Resides in San Francisco County

Exclusion Criteria:

1. Enrolled in hospice
2. Unable to consent for self
3. Currently receiving Project Open Hand services

Study Procedures

Phase 1 Recruitment

We will send a MyChart message to current UCSF CR patients inviting them to participate in human-centered design sessions.

Phase 1 Screening and Consent

Patients who respond to the recruitment email will be screened for eligibility based on inclusion and exclusion criteria. Participants will be asked to provide written, informed consent.

Phase 1 Human-Centered Design Sessions

Participants will complete a brief REDCap survey about demographics. We will conduct human-centered design sessions with CR patients. The human-centered design process will iteratively proceed through 4 phases: discover, define, develop, and deliver. The process will follow principles of technology design for health equity.[34] We will conduct 3 design sessions with groups of 2-6 CR patients each, audio and video-recorded and transcribed for rapid qualitative template analysis.[35] Groups will be language-concordant. The first session will focus on discovery and definition of patient needs and behaviors related to FIM in the context of the Theory of Planned Behavior, following an interview guide.[36] Based on this information, we will refine the interventions. The second session will focus on feedback on drafts of the developed materials. If significant revisions are needed, an additional session will be added. The third session will focus on refining the intervention materials by asking participants to "walk-through" the experiences of navigation and receiving text messages. If significant revisions are suggested, additional sessions of iterative revision will continue.

Phase 1 Participant Compensation

Participants will receive $200 per design session.

Phase 2 Recruitment

We will give a recruitment flyer to current UCSF CR patients and newly initiating CR participants informing them about Food is Medicine and offering the opportunity to participate in the study. Participants may also be recruited to the study from referrals from health care providers, phone call from a clinical research coordinator, or contact from a clinical research coordinator in the CR center. We will also send a MyChart message to UCSF patients who have had a CR visit within the last year. Participants who do not use MyChart will be mailed a paper letter. Participants will be informed that they are 1) eligible for referral to a Food is Medicine program, 2) potentially eligible for a research study testing different ways to help people participate in a Food is Medicine program, 3) able to participate in the Food is Medicine program, even if they do not

participate in the study. Participants interested in the study will be given a link to join the study, which will take them to the Eureka Research Platform.
In addition, we will recruit participants who have completed at least one CR session at Zuckerberg San Francisco General Hospital (ZSFG) within the last year. Participants at ZSFG may also be recruited to the study from flyers, word of mouth, or contact from a clinical research coordinator.

Phase 2 Screening and Consent

Participant screening, consent, and subsequent study participation will occur on the Eureka Research Platform. The participant will answer screening questions based on inclusion and exclusion criteria for eligibility confirmation. The participant will provide eConsent for this minimal risk study in Eureka.

Phase 2 Randomization

Consented participants will undergo two randomizations:

A) Randomization to navigation or usual care (1:1)
B) Randomization to text messages or usual care (1:1)

Participants will be considered enrolled in the study after randomization.

Phase 2 Blinding

The randomization groups of the participant will not be explicitly disclosed to the participant. However, since the interventions are different from usual care, it is possible that the participant may infer randomization group. Study staff delivering the navigation intervention will not be blinded to group allocation for navigation, since this will not be possible for the delivery of the intervention. Study staff will be blinded to text-messaging intervention. POH staff determining the number of meals received will be blinded to participant randomization groups.

Phase 2 eVisits

Participants will complete 2 study eVisits on Eureka. eVisit 1 will occur at the time of randomization. eVisit 2 will occur 3 months after randomization. Participants will complete questionnaires in Eureka (Table 2). If participants have connected health data (e.g., Fitbit, Apple Watch), they will be asked to contribute this optional data. In addition, study staff will abstract the electronic health record (EHR) for additional data (Table 2). After the final eVisit, the meals outcome data will be entered into Eureka via a coordinator form based on POH records. If participants are unable to complete eVisits on Eureka, a clinical research coordinator may call participants to complete surveys over the phone and enter data into Eureka via proxy data entry.

Table 2. Study Measurements

Measurement	**Rationale**	**Source**	**Month**	
			0	**3**
Demographics and Health literacy[37,38]	Understand characteristics of participants.	Eureka	x	

Medical conditions	Understand characteristics of participants.	Eureka	x	
Subjective social status[39]	Important social determinant of health.	Eureka	x	
Income and financial security	Important social determinant of health	Eureka	x	
Barriers to healthy eating (adapted)	Directly relevant to effects of intervention.	Eureka	x	x
Food security[40,41]	Important social determinant of health, directly relevant to potential effects of FIM programs.	Eureka	x	x
Mediterranean Eating Pattern Assessment (MEPA)[42]	Validated measure of diet quality, included in Life's Essential 8.	Eureka	x	x
Quality of Life (EQ-5D-5L)	Validated quality of life questionnaire that can be used to support cost effectiveness analysis.[43]	Eureka	x	x
General health status	Measure of general health status.	Eureka	x	x
Cardiac Self-efficacy[44]	Important behavioral science construct that may be influenced by the interventions.	EHR	x	x
Patient Health Questionnaire – 9[45]	Validated measure of depressive symptoms	EHR	x	x
General Anxiety Disorder - 7[46]	Validated measure of anxiety symptoms	EHR	x	x
Tobacco use	Important CV risk factor in Life's Essential 8.	Eureka	x	x
Sleep hours	Important CV risk factor in Life's Essential 8.	Eureka	x	x
Blood pressure	Important CV risk factor in Life's Essential 8.	EHR	x	x
Weight/Body Mass Index (BMI)	Important CV risk factor in Life's Essential 8.	EHR	x	x
Cholesterol	Important CV risk factor in Life's Essential 8.	EHR	x	x
Hemoglobin A1c	Important CV risk factor in Life's Essential 8.	EHR	x	x
Self-reported minutes/week of moderate to vigorous physical activity	Important CV risk factor in Life's Essential 8.	Eureka	x	x
Steps/day	Objective measure of physical activity in people with available data.	Eureka	x	x
Six-minute walk distance[47]	Objective exercise capacity measure collected routinely as an outcome in CR programs.	EHR	x	x
Satisfaction with the intervention(s)[48]	Measure of acceptability.	Eureka		x
Net promoter score	Measure of acceptability	Eureka		x
Time and costs	Custom questionnaire to help estimate costs.	Eureka		x
Consumption of food	Custom questionnaire to report consumption of distributed food	Eureka		x
Cardiovascular Events	Events include CV hospitalizations for myocardial infarction, heart failure, stroke, and deaths.	EHR		x
Number of CR sessions attended	Attending a greater number of CR sessions is associated with greater benefit.[49]	EHR		x
Number of FIM meal units	Primary outcome of study. We will be able to determine this outcome in all participants. Because some participants will receive groceries and some participants will received meals, we will define this outcome as a meal "unit" received from POH. A meal unit is defined as 7 packaged meals (delivery), 1 grocery box (delivery), 1 set (5 or 7) of packaged meals (pick-up), or 1 grocery distribution (pick-up). We will collect number of FIM meal units throughout participants' 3-month study participation and throughout their insurance authorization period.	POH		x

	We will also collect number of FIM meal units for their dependents, if applicable.			

We will conduct optional individual semi-structured interviews in a convenience sample of study participants and staff with regard to implementation of the interventions. Participants will be asked to provide verbal consent for the interviews. Interviews will be audio-recorded and transcribed without reference to the participant identify.

Phase 2 Participant Compensation

Participants will receive $50 for completing eVisit 1 (Month 0) and $50 for completing eVisit 2 (Month 3) and $50 for completing the optional interview.

Comparators

Intervention A: Navigation: Navigation will occur at both the health system and FIM program levels. The health system navigator will be separate personnel from CR program staff to limit effects on usual care. Navigation will include: motivational interviewing,[24] patient-determined visits (i.e., phone, video, or in-person visits depending on patient preference), and delivery of a structured approach to participation: 1) explain the program, 2) explain the benefits, 3) provide positive endorsement, 4) describe process to enroll, 5) welcome questions, 6) address barriers to attendance, and 7) provide with follow-up information.[23] Health system navigation will include at least 3 attempts to contact participant for each individual session. Participants will have 1 weekly navigation session until the participant enrolls in the FIM program or declines further contact. Scripts will be refined based on Phase 1 activities. FIM program navigation will include individual in-person, video, or telephone contacts by FIM staff to participants to address participation barriers. FIM navigation contacts will occur on a weekly basis until the participant has achieved sufficient engagement (receipt of 8 FIM meals) or the participant declines further contact. Scripts will be refined based on Phase 1 activities.

Intervention B: Text-messaging: The text-messaging intervention will be informed by behavioral science.[32] Text messages will promote healthy eating and participation in a FIM program through behavior change techniques: provide information about behavior-health link ("Did you know that joining a Food is Medicine program like Project Open Hand can lower your chance of being hospitalized?), provide instruction ("When cooking, use olive oil or canola oil instead of butter"), prompt intention formation ("Write a list of 3 reasons you want to eat healthy foods, and put the list somewhere you will see it often"), and provide general encouragement ("Did you eat a heart-healthy meal today?)[32] The initial text messaging library will be adapted from messages found acceptable in our previous research. Text messaging will be refined in Aim 1. Text messages will be tailored based on a programmed algorithm (e.g., before initiating the FIM program will receive messages about enrolling and after initiating the program will receive messages about engagement). Participants will receive 2-4 text messages per week (frequency to be determined in Aim 1)[28] until the end of the 3-month intervention or until the participant opts out of text messages.

Usual Care: All participants will receive a MyChart message with written instructions about how to enroll in a Food is Medicine program.

Adverse Experience Reporting and Documentation

For this minimal risk study, the risks related to participation in the research are related to the potential loss of privacy due to participation in research and potential discomfort related to sensitive questions on questionnaires. However, we recognize that this population may experience adverse events due to their underlying health conditions, and that reporting of these adverse events may be relevant to understanding the effects of the interventions and Food is Medicine programs more broadly. Thus, we plan to collect data on adverse events as part of this study.

Adverse Events

Following definitions from the US Department of Health and Human Services,[50] an adverse event is any untoward or unfavorable medical occurrence in a human participant, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. An unexpected AE is defined as any adverse event occurring in one or more participants, the nature, severity, or frequency of which is **not** consistent with either:

1. the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol-related documents, such as the IRB-approved research protocol and the current IRB-approved informed consent document; or
2. the expected natural progression of any underlying disease, disorder, or condition of the participant experiencing the adverse event and the participant's predisposing risk factor profile for the adverse event.

Expected adverse events (EAE) are defined as anticipated events based on the prior experience with the assessments and/or intervention that are listed in the participant consent and protocol; these can be attributed to an underlying health condition, the participant population being studied, or normal consequences of an intervention. Within this study, events such as sore muscles, minor muscle/ joint pain, fatigue, sleep disturbance, appetite disturbance, pain, cough, heartburn, constipation or diarrhea, rashes, nocturia, mood or anxiety, and tinnitus are common among older adults with cardiovascular disease who are expected to enroll. In cardiovascular disease patients there are often events associated to their health condition that do not require discontinuing the study intervention or components of the intervention. Participants in CR may experience events such as shortness of breath; new pain, pressure or aching in chest, arms, jaw, neck, shoulder, or back; fatigue; light-headedness; irregular heart rhythm or heart fluttering; worsening and/or new joint or muscle pain. Participants in this research may also experience loss of privacy.

Adverse events will be recorded in the Eureka data collection platform. Adverse events will be described by duration (start and stop dates and times), severity, outcome, treatment, and relation to study intervention, or if unrelated, the cause.

AE Severity

The guidelines shown in Table 3 below should be used to grade severity. It should be pointed out that the term "severe" is a measure of intensity and that a severe AE is not necessarily serious.

Table 3. AE Severity Grading

Severity	Description
Mild (1)	Transient or mild discomfort; no limitation in activity; no medical intervention or therapy required. The subject may be aware of the sign or symptom but tolerates it reasonably well.
Moderate (2)	Mild to moderate limitation in activity, no or minimal medical intervention/therapy required.
Severe (3)	Marked limitation in activity, medical intervention/therapy required, hospitalizations possible.
Life-threatening (4)	The subject is at risk of death due to the adverse experience as it occurred. This does not refer to an experience that hypothetically might have caused death if it were more severe.

AE Relationship to Study Intervention

The relationship of an AE to the study intervention should be assessed using the following the guidelines in Table 4.

Table 4. AE Relationship to Study Intervention

Relationship to Intervention	Comment
Definitely	Previously known side effect of intervention; or an event that follows a reasonable temporal sequence from the intervention; that follows a known or expected response pattern to the intervention; that is confirmed by stopping or reducing the intervention; and that is not explained by any other reasonable hypothesis.
Probably	An event that follows a reasonable temporal sequence from the intervention; that follows a known or expected response pattern to the intervention; that is confirmed by stopping or reducing the intervention; and that is unlikely to be explained by the known characteristics of the participant's clinical state or by other interventions.
Possibly	An event that follows a reasonable temporal sequence from the intervention; that follows a known or expected response pattern to the intervention; but that could readily have been produced by a number of other factors.
Unrelated	An event that can be determined with certainty to have no relationship to the study intervention.

In accordance with the standard operating procedures and policies of the Institutional Review Board (IRB)/Independent Ethics Committee (IEC), the site investigator will report Unexpected AEs that are Definitely, Probably, or Possibly related to study participation to the IRB/IEC and Principal Investigator.

Serious Adverse Experiences (SAE)

An SAE is defined as any AE occurring that results in any of the following outcomes:

- death
- a life-threatening adverse experience
- inpatient hospitalization or prolongation of existing hospitalization
- a persistent or significant disability/incapacity
- a congenital anomaly/birth defect

Other important medical events may also be considered an SAE when, based on appropriate medical judgment, they jeopardize the participant or require intervention to prevent one of the outcomes listed.

Serious Adverse Experience Reporting

We will document all SAEs that occur (whether or not related to study intervention). The collection period for all SAEs will begin after informed consent is obtained and end after procedures for the final study visit have been completed.

In accordance with the standard operating procedures and policies of the Institutional Review Board (IRB)/Independent Ethics Committee (IEC), the Principal Investigator will report SAEs to the IRB/IEC.

Discontinuation and Replacement of Participants

A participant may be discontinued from the study at any time if the participant or the Investigator feels that it is not in the participant's best interest to continue. The following is a list of possible reasons for discontinuation:

- Participant withdrawal of consent
- Participant does not meet final eligibility confirmation
- Participant not adherent to study procedures
- Adverse event occurs that indicates in the opinion of the investigator that it would be in the best interest of the participant to discontinue the study
- Protocol violation requiring discontinuation
- Lost to follow-up
- Death
- Funder or Institution request for early termination of study

A participant may be withdrawn from the study at any time if the participant or the investigator feels that it is not in their best interest to continue.

All participants are free to withdraw from participation at any time, for any reason, specified or unspecified, and without prejudice.

Reasonable attempts will be made by the investigator to document a reason for participant withdrawals. The reason for the participant's withdrawal from the study will be specified in the participant's file source documents.

Participants who withdraw from the study after randomization may not be replaced.

Protocol Violations

A protocol violation occurs when the participant or investigator team fails to adhere to significant protocol requirements affecting the inclusion, exclusion, subject safety and primary endpoint criteria.

When a protocol violation occurs, it will be discussed with the investigator and a Protocol Violation Form detailing the violation will be generated. This form will be signed by the Investigator. A copy of the form will be filed in the site's regulatory binder.

Data Safety Monitoring

This minimal risk study will not have an external Data Safety Monitoring Board. The Principal Investigator will monitor study data for completeness and monitor and report adverse events as described above.

Analysis Methods

Phase 1: We will qualitatively describe participant responses using rapid template analysis[35] based on the Theory of Planned Behavior[36] and emergent themes. At least two study staff members will review and code transcripts. Study staff members will meet to achieve consensus, with any disputes resolved by the Principal Investigator.

Phase 2: Respecting statistical norms for pilot studies, the proposed pilot randomized trial mimics the design we hope to use in the future and does not provide p-values or formal sample size calculations.[51] The pilot study will provide information on the acceptability of the interventions. The sample size represents 1/3 of CR patients seen at UCSF in 9 months.
With a sample size of 42 for each experimental condition, his pilot study would be able to estimate a mean satisfaction score of 3.5 (scale of 1 to 5, with 5 being very satisfied) with a 95% confidence interval from 3.2-3.8, assuming a standard deviation of 1.
This pilot study will address two hypotheses (N=42 each) for the secondary outcome (which we expect to be the primary outcome for the future larger study):
Hypothesis A: Navigation + UC (±text messaging) [experimental] will result in a greater mean number of FIM meals received in 3 months than UC (± text messaging) [control].

Hypothesis B: Text messaging + UC (±navigation) [experimental] will result in a greater mean number of FIM meals received in 3 months than UC (± navigation) [control].
For each intervention, the null hypothesis is the mean number of FIM meals received will not differ between experimental and control groups. Intervention-specific analyses will use separate generalized estimating equation (GEE) log-Poisson models with robust standard errors to estimate the mean (95%CI) count per group and experimental: control risk ratio (RR);[52] models will be adjusted for the opposite experimental arm and baseline 6MWD as a measure of health status. An exploratory GEE model adding the A*B interaction term to models will be conducted and displayed in a forest plot of RR (95%CI) of each intervention arm (n=21) versus UC alone (n=21). Log-Poisson models will be used to estimate mean satisfaction and the proportions who initiated and engaged. We will use standard ANCOVA models to analyze 3-month changes in continuous outcomes (e.g., self-efficacy) and rank-based ANCOVA for changes in discrete outcomes (e.g., Life's Essential 8).[53] All ANCOVA models include the baseline value of the outcome as a covariate, the opposite experimental arm, and 6MWD.

We will also describe inputs, activities, outputs, outcomes using descriptive quantitative measures (e.g., counts, proportion, mean, standard deviation) and narrative description. We will qualitatively describe participant and staff responses from interviews and study artifacts using a rapid analysis template[35] based on the Theory of Planned Behavior,[36] Consolidated Framework for Implementation Research,[54] and emergent themes.

Cost Estimation

As part of this project, we will estimate costs of usual care and the interventions.
Usual care (costs may apply to all participants):

- Staff (health system): we will estimate the time it takes for staff to complete the following activities:
    - Draft MyChart message
    - Send MyChart message to participant
    - Complete and send referral for to POH
- Staff (POH): we will estimate the time it takes for staff to complete the following activities:
    - Receive and review referral from health system
    - Schedule participant intake
    - Conduct participant intake
    - Engage with participant during the course of the usual care program
- Participant: we will ask participants to estimate time and costs using a custom questionnaire, administered at the 3-month eVisit. Time and costs will be related to scheduling POH visits and receiving POH meals or groceries.
- POH Supplies, Capital Equipment, Facilities, and Other costs: we will consider POH Supplies, Capital Equipment, Facilities, and Other costs on a per participant and/or per meal basis.

Intervention A – Navigation (costs will only apply to participants randomized to these groups):

- Staff (health system): we will ask staff to record or estimate the time it takes to:
    - Schedule session with participant
    - Prepare for session with participant
    - Engage in session with participant

    - Complete follow-up tasks from session with participant
    - Hand off to POH
- Staff (POH): we will estimate the time it takes for staff to:
    - Receive hand off from health system
    - Schedule session with participant
    - Prepare for session with participant
    - Engage in session with participant
    - Complete follow-up tasks from session with participant
- Participant: we will estimate participant time from the reported staff time for scheduling and engaging with participant.
- Supplies, Capital Equipment, Facilities, and Other costs: we will estimate overhead costs based on staff time per participant.

<u>Intervention B – Text Messaging (costs will only apply to participants randomized to these groups):</u>

- Staff (health system):
    - Time to draft text messages
    - Time to program messages into Eureka
- Cost of delivering messages through Twilio, the service used by Eureka
- Participants will report monthly cost of phone service, include text messaging on the Time and Costs questionnaire.

Data Collection, Retention, and Monitoring

Data for Phase 1 will be recorded in study records on UCSF REDCap or UCSF OneDrive.

The primary data collection source for Phase 2 will be the Eureka Research Platform. This platform includes participant-facing interfaces for data collection, along with investigator- and clinical research staff-facing interfaces for data entry and management.

Participant data for Phase 2 will also be collected from the UCSF Electronic Health Record and entered in the Eureka Research Platform.

Data Collection Instruments

The Investigator will prepare and maintain adequate and accurate source documents designed to record all observations and other pertinent data for each participant.

Where possible, the participant will be asked to supply information regarding participant-oriented outcomes via participant questionnaires in the Eureka Research Platform. If participants are not able to enter their own responses, study staff may enter participant responses through proxy data entry by interviewing the patient in-person or over phone or video.

Study personnel will enter data from source documents corresponding to a participant's visit or participant events into the study Eureka database when the information corresponding to that visit or event is available.

The Investigator is responsible for all information collected on participants enrolled in this study. All data collected during the course of this study must be reviewed and verified for completeness and accuracy by the Investigator.

Data Management Procedures

The data will be entered into the Eureka database. Database lock will occur once quality assurance procedures have been completed. All procedures for the handling and analysis of data will be conducted using good statistical and computing practices.

Data Quality Control and Reporting

After data have been entered into the study database, a system of computerized data validation checks will be implemented and applied to the database on a regular basis. The study database will be updated in accordance with the resolved queries. All changes to the study database will be documented.

Archival of Data

The database is safeguarded against unauthorized access by established security procedures, including two-factor authentication for investigator and study staff access; appropriate backup copies of the database and related software files will be maintained. Databases are backed up by the database administrator in conjunction with any updates or changes to the database. At critical junctures of the protocol (e.g., production of interim reports and final reports), data for analysis is locked and cleaned per established procedures.

Availability and Retention of Investigational Records

The Investigator must make study data accessible to authorized representatives of the Funder (or designee), IRB/IEC, and Regulatory Agency (e.g., FDA) inspectors upon request. A file for each participant must be maintained that includes the signed Informed Consent, HIPAA Authorization and Assent Form and copies of all source documentation related to that participant. The Investigator must ensure the reliability and availability of source documents from which the information in the study database was derived.

All study documents (patient files, signed informed consent forms, Study File Notebook, etc.) must be kept secured for a period of two years following the conclusion of the study.

Monitoring

Monitoring visits may be conducted by the Funder (or designee), UCSF, or other regulatory bodies (e.g., IRB, FDA).

Participant Confidentiality

In order to maintain participant confidentiality, all participants will be assigned a unique participant number. That number will be used to identify the participant on all study materials.

Data Sharing

Participant data will be shared with Project Open Hand so that Project Open Hand can provide services to the participants.

The UCSF Coordinating Center will be responsible for creating analytic datasets for study investigators. Data generated within this study will be provided to the American Heart Association in a de-identified form, to be deposited within the Health Care x Food data repository on the Precision Medicine Platform, and subject to the Precision Medicine Platform Terms and Conditions. Data on the Precision Medicine Platform will be collated with data from other studies that are funded by the American Heart Association Health Care x Food initiative, and used by future investigators for analysis. In addition, data will be made available on Dryad, in alignment with agreed-upon Open Science Policies at the American Heart Association, whereby any factual data that is needed for independent verification of research results must be made freely and publicly available in an AHA-approved repository as soon as possible, and no later than the time of an associated publication or the end of the award period (and any no-cost extension), whichever come first.

Administrative, Ethical, and Regular Considerations

The study will be conducted according to the Declaration of Helsinki, Protection of Human Volunteers (21 CFR 50), Institutional Review Boards (21 CFR 56), and Obligations of Clinical Investigators (21 CFR 312).

To maintain confidentiality, all records will be identified by a coded number only. All study records will be kept in a secure electronic file or locked file cabinet and code sheets linking a patient's name to a patient identification number will be stored separately in another secure electronic file or locked file cabinet. Clinical information will not be released without written permission of the participant, except as necessary for monitoring by the FDA. The Investigator must also comply with all applicable privacy regulations (e.g., Health Insurance Portability and Accountability Act of 1996, EU Data Protection Directive 95/46/EC).

Protocol Amendments

Any amendment to the protocol will be written by the Principal Investigator. Protocol amendments cannot be implemented without prior written IRB/IEC approval except as necessary to eliminate immediate safety hazards to patients. A protocol amendment intended to eliminate an apparent immediate hazard to patients may be implemented immediately, provided the IRBs are notified within five working days.

Institutional Review Boards and Independent Ethics Committees

The protocol and consent form will be reviewed and approved by the IRB/IEC prior to study initiation. Serious adverse experiences regardless of causality will be reported to the IRB/IEC in accordance with the standard operating procedures and policies of the IRB/IEC, and the Investigator will keep the IRB/IEC informed as to the progress of the study. The Investigator will obtain assurance of IRB/IEC compliance with regulations.

Any documents that the IRB/IEC may need to fulfill its responsibilities (such as protocol, protocol amendments, Investigator's Brochure, consent forms, information concerning patient recruitment, payment or compensation procedures, or other pertinent information) will be submitted to the IRB/IEC. The IRB/IECs written unconditional approval of the study protocol and the informed consent form will be in the possession of the Investigator before the study is initiated. This approval must refer to the study by exact protocol title and number and should identify the documents reviewed and the date of review.

Protocol and/or informed consent modifications or changes may not be initiated without prior written IRB/IEC approval except when necessary to eliminate immediate hazards to the patients or when the change(s) involves only logistical or administrative aspects of the study. Such modifications will be submitted to the IRB/IEC and written verification that the modification was submitted and subsequently approved should be obtained.

The IRB/IEC must be informed of revisions to other documents originally submitted for review; serious and/or unexpected adverse experiences occurring during the study in accordance with the standard operating procedures and policies of the IRB; new information that may affect adversely the safety of the patients of the conduct of the study; an annual update and/or request for re-approval; and when the study has been completed.

Informed Consent

Informed consent will be obtained in accordance with the Declaration of Helsinki, ICH GCP, US Code of Federal Regulations for Protection of Human Subjects (21 CFR 50.25[a,b], CFR 50.27, and CFR Part 56, Subpart A), the Health Insurance Portability and Accountability Act (HIPAA, if applicable), and local regulations.

For Phase 1, we will obtain written informed consent via DocuSign.

For Phase 2, we will obtain eConsent via Eureka.

The Investigator will prepare the informed consent form prior to submission to the IRB/IEC. The consent form generated by the Investigator must be approved by the IRB/IEC. The written consent document will embody the elements of informed consent as described in the International Conference on Harmonisation and will also comply with local regulations. The Investigator will send an IRB/IEC-approved copy of the Informed Consent Form to the Funder (or designee) for the study file.

A properly executed, written, informed consent will be obtained from each participant prior to entering the participant into the study. Information should be given in both oral and written form and participants must be given ample opportunity to inquire about details of the study. If appropriate and required by the local IRB/IEC. A copy of the signed consent form (and assent) will be given to the participant and the original will be maintained with the participant's records.

Role of the Sponsor

This work was supported by the American Heart Association. All statements in this work, including its findings and conclusions, are solely those of the authors and do not necessarily represent the views of the American Heart Association.

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