Removing Surrogates' Uncertainty to Reduce Fear and Anxiety after Cardiac Events (RESURFACE): A Randomized Pilot Intervention Study

Protocol

NCT: NCT06048068

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1. Administrative Information

a. **Title**: Removing Surrogates Uncertainty to Reduce Fear and Anxiety after Cardiac Events (RESURFACE): A Randomized Pilot Intervention Study
   a. **Public Title:** RESURFACE

b. **Registration Data**:
   a. **Identifying Number:** IRB Number AAAR8497
   b. **Primary Sponsor:** NIH/NIA
   c. **Contact for Inquiries**:

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   d. **Sites of Recruitment:** Columbia University Medical Center
   e. **Health Condition(s) or Problem(s) Studied:** Psychological distress and poor sleep in surrogates of cardiac arrest (CA)
   f. **Key Inclusion and Exclusion Criteria**:
   Inclusion Criteria:

- 18 years of age or older
- Surrogate of an adult CA patient
- English- or Spanish-speaking
- Has a working smartphone, tablet, laptop, or other device with internet access

Exclusion Criteria:

- Any medical and/or psychiatric impairment precluding them from complying with the protocol
- Non-English and non-Spanish speaking
- Lack of internet/device access

- Surrogate of an adult CA patient who passed away
- Cannot be reached for initial contact (3 unsuccessful attempts made in ICU)
- Moved to the floor before initial contact can be established

g. **Study Type:** Unblinded two-arm pilot RCT of study intervention consisting of three online packages delivered in the ICU, inpatient floor, and at home for the intervention arm and care as usual for the control arm.
h. **Date of First Enrollment:** Pending
i. **Target Sample Size:** Up to 100 participants (recruiting 2:1 until at least 30 intervention arm participants conclude participation)
j. **Recruitment Status:** Not yet recruiting

c. **Roles and Responsibilities**:
Sachin Agarwal, MD, MPH sa2512@cumc.columbia.edu

Principal Investigator, Associate Professor of Neurology (Neurocritical Care) and Director of the NeuroCardiac Comprehensive Care Clinical & Research Program.

Dr. Agarwal has the requisite experience to lead this project as principal investigator. His research focuses on characterizing the cognitive, psychological, and health behavioral dimensions of CA survivorship for both survivors and their families, and its association with cardiovascular disease risk, functional outcomes, and quality of life. He developed the parent infrastructure for recruiting CA patients and families into a patient registry, and also developed the parent study which follows CA patients during ICU stay and post-discharge. This infrastructure will provide the recruitment pipeline for the proposed study. Dr. Agarwal will oversee study implementation, including recruitment and retention benchmarks, data integrity, preparing progress reports, and dissemination of study results.

Talea Cornelius, PhD, MSW, MA tmc2184@cumc.columbia.edu

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Jeffrey Birk, PhD, MS jlb2287@cumc.columbia.edu

Co-Investigator.

Isabella Tincher, BA imt2114@cumc.columbia.edu

Clinical Research Coordinator. Ms. Tincher will be responsible for participant recruitment and outreach, informed consent, survey administration, and payment coordination. She is also responsible for building and maintaining the Heartsight website, as well as contributing to study planning and design. She will also translate questionnaires from English to Spanish. She will report directly to Dr. Agarwal.

Danielle Rojas, MS dar2156@cumc.columbia.edu

Clinical Research Coordinator. Ms. Rojas will be responsible for the revision, finalization, and submission of all study materials that are to be submitted for IRB approval. Ms. Rojas will create the randomization allocation table, as well as contribute to study planning and oversight to ensure compliance with regulatory requirements. She will report directly to Dr. Agarwal.

Mina Yuan, BA my2798@cumc.columbia.edu

Medical Student. Ms. Yuan will contribute to creating the REDCap database, participant surveys, and MOP. She will also contribute to study planning, Heartsight development, and day-to-day interactions with study participants. She will report directly to Dr. Agarwal.

2. Introduction

a. Study Purpose and Rationale

The goal of this study is to test the feasibility and acceptability of Heartsight, an informational intervention, to reduce family members' uncertainty prevalent throughout the illness trajectory of their loved ones admitted with cardiac arrest (CA). CA is sudden and unexpected and carries substantial prognostic uncertainty during the early period of illness. Whereas patients are not conscious and often have little to no memory of the CA and the intensive care unit (ICU), immediate family members, who often act as ***surrogates***, bear the burden of uncertainty from the moment they witness the CA at home or participate in resuscitation, make life-and-death decisions during hospitalization, and/or go home with their loved ones with new physical, cognitive, and emotional needs. Not surprisingly, many fear recurrence. The prevalence of clinically significant levels of posttraumatic stress (PTSS) is higher for surrogates (35%-50%) than for CA patients (30%) at discharge. Nearly one in two surrogates reports persistent PTSS at 1 year.

During an NIH-funded workshop eliciting *"*on-the-ground" perspectives about the experiences and needs of surrogates of patients with CA, key cross-cutting themes emerged, including (1) the challenges of uncertainty and the desire for information about illness and prognosis for recovery, (2) gaps in the provision of logistical information and support, (3) the importance of communicating compassion, sharing uncertainty, and responding to emotional and physical needs, and (4) a desire among surrogates to participate in the discussion and development of practices to improve support for future families in similar situations. These findings have been confirmed by 44 other studies recently summarized in our scoping review on the experiences of 3,598 surrogates of patients of CA patients across 15 countries and 5 continents. We found similar guidance in our needs prioritization exercise among a national sample of 575 surrogates of CA patients. In preparation for this study, we conducted a feasibility observational pilot with a mixed-methods approach where surrogates enrolled in the ICU completed serial qualitative interviews and quantitative assessments during the ICU and 1 month after discharge. The feasibility of recruiting family members of CA patients in an intervention study has further been demonstrated via Roybal Pilot- FAID Fear (PI Cornelius).

Uncertainty is not equivalent to mere ignorance; rather, a subjective experience of ignorance is a promising target mechanism that may underlie the success of informational interventions for improving the surrogate's cardiac anxiety, PTSS, and sleep. Illness uncertainty contributes to greater psychological distress and poor quality of life outcomes in chronic illnesses, e.g., chronic liver, lung, and heart disease, cancer, and more recently, after COVID-19. Appraisal theories of emotion have specified a direct relationship between uncertainty and emotions. **Uncertainty is also modifiable.** Informational programs may limit uncertainty and improve psychological profiles in cancer survivorship. Despite the surrogate's clear desire for information and high

levels of uncertainty after CA, information-based interventions have never been tested in an acute care setting.

b. Objectives

We will test the feasibility and acceptability of Heartsight, an online informational intervention program developed by a multidisciplinary team of researchers and patient-surrogate stakeholders. It is a repository of bite-sized, simplified, information packages to be delivered at specific time points in the illness course: an **Understanding Cardiac Arrest** package in the ICU, a **Preparing for Discharge** package on the floor, and a **Focusing on You** package providing information on self-care and self-efficacy at 1 month post-discharge. Serial measurements of illness uncertainty and psychological distress (PTSS keyed to the cardiac event) will be performed at enrollment, discharge, and 3 months after discharge. We will objectively assess sleep duration via actigraphy for 1 week after hospital discharge.

Aim 1: Enroll up to 100 surrogates of CA patients to **(Aim 1a)** pilot recruitment and randomization (2:1) procedures, **(Aim 1b)** estimate retention rate at 3 months, and **(Aim 1c)** assess the engagement and utilization metrics through the website for frequency of access and time spent on each module of the packages.

Exploratory Aim 1a: Preliminary estimate of the association of intervention with the surrogate's uncertainty levels at 3 months post-discharge.

Exploratory Aim 1b: Preliminary estimate of the association of intervention with the surrogate's cardiac anxiety and posttraumatic stress at 3 months post-discharge.

Exploratory Aim 1c: Explore the lagged associations of uncertainty with cardiac anxiety and PTSS.

Exploratory Aim 2: Estimate the association of intervention with surrogates' sleep duration within the first week after hospital discharge.

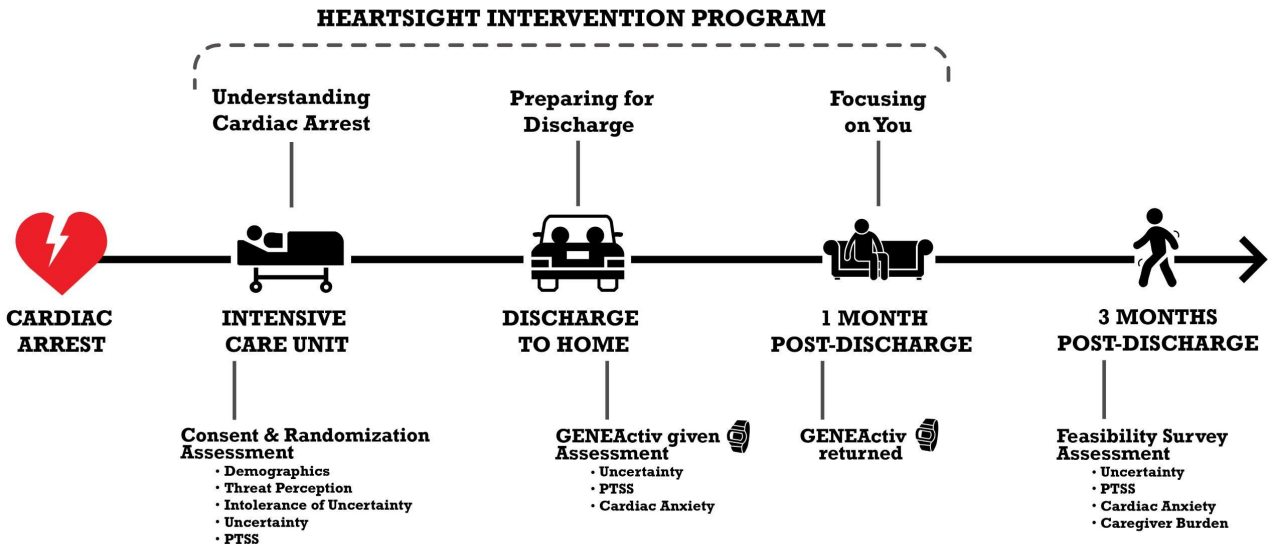
c. Study Design

This study is a two-arm unblinded RCT in which up to 100 adult CA surrogates will be enrolled over a 1-year period and randomized (using a 2:1 allocation until at least 30 intervention arm participants have completed their study participation) to either receive the Heartsight intervention or no additional information beyond usual treatment (control group). Data collection will occur at the initial approach in the ICU, on the floor, and at 3 months post-discharge. All participants will be English- and/or Spanish-speaking. If a CA patient dies at any point in the protocol, their surrogate is no longer eligible to continue in the study.

3. Methods

a. RESURFACE Study Overview

i. Study Flow



ii. Study Setting

This study will take place at Columbia University Irving Medical Center (CUIMC). The study will have the option of remote phone or email visits following initial enrollment.

iii. Sample Size

We plan to enroll up to 100 adult surrogates of CA patients in this study. All participants will be English and/or Spanish speakers. Participants will be enrolled and randomized (using a 2:1 allocation) to either the active informational intervention or the care as usual control group. Enrollment will end once 30 participants in the intervention arm have completed their participation in the study.

iv. Eligibility Criteria

Inclusion Criteria:

- 18 years of age or older
- Surrogate of an adult CA patient
- English- or Spanish-speaking
- Has a working smartphone, tablet, laptop, or other device with internet access

Exclusion Criteria:

- Any medical and/or psychiatric impairment precluding them from complying with the protocol
- Non-English and non-Spanish speaking
- Lack of internet/device access
- Surrogate of an adult CA patient who passed away
- Cannot be reached for initial contact (3 unsuccessful attempts made in ICU)
- Moved to the floor before initial contact can be established

v. Recruitment and Screening Procedures

Our recruitment strategy will include recruiting adult surrogates of CUMC patients who experienced cardiac arrest (CA) and are currently in the ICU. The study team will first confirm eligibility by reviewing the electronic medical record, then approach surrogates after admission in the ICU, if the patient is still living. An electronic screening log will be maintained by study coordinators in the CANOE-F spreadsheet under "ALL Eligibility RESURFACE."

The study coordinator will pitch RESURFACE to the surrogate using this script. Surrogates who are interested will complete the informed consent process with a study coordinator. The informed consent process includes explaining risks and benefits of the study, payment structure, voluntary nature of participation, procedures for termination, strategies for maintaining confidentiality, and contact information for the study. If surrogates are ready to consent now, they will provide their written consent by signing the consent form. Participants will also indicate to the study coordinator their preferred form of payment at this time (TruCentive e-gift card). Completed consent forms will be filed in the NeuroCardiac Care office, and a paper copy will be provided to participants.

If not interested in RESURFACE, surrogates will have the option to refer study coordinators to another family member who may be more interested in participating, and/or to participate in the CANOE-F parent study instead, which only requires one survey. Surrogates may also ask study coordinators to reapproach later if they would like more time to consider RESURFACE.

After 3 unsuccessful attempts to reach an eligible participant in the ICU for recruitment, they will be marked ineligible for participation in this study.

vi. Participant Retention

Every effort will be made by the PI and study team to ensure eligible participants complete each study visit and survey. We will use the following strategies to minimize loss to follow-up:

- Enhancing participant's understanding of the study's objectives and the protocol by reminding the participant of the study aim during study visits and leaving time for participants to ask questions about the study, if needed
- Building participant relations and participant satisfaction, with the study coordinator taking a central role on this effort (e.g., the study coordinator checking how family members are doing when approaching at baseline)

- Identifying low-use or no-use intervention arm participants at discharge and 3 months post-discharge and eliciting targeted user feedback via surveys
- Providing technical support, if requested, for intervention arm participants who are struggling to use Heartsight

If a participant does not return for study visits, study coordinators will make several contacts using all the contact information provided by the participant. This may include phone calls, emails, and/or asking the cardiac arrest survivor when their surrogate might next visit the hospital.

vii. Study Intervention

The study intervention for RESURFACE is Heartsight, an online repository of bite-sized, lay-friendly informational articles developed by CA stakeholders for CA surrogates. Heartsight contains three packages of articles developed for specific timepoints in this study. The first two packages aim to reduce illness uncertainty among participants, whereas the third package aims to promote self-care and reduce caregiver burnout:

1. Understanding Cardiac Arrest (15 articles) - articles relevant to understanding CA and the ICU experience; delivered when participants are in the ICU
2. Preparing for Discharge (7 articles) - articles relevant to understanding post-hospitalization life, such as rehab options; delivered when participants are on the floor
3. Focusing on You (12 articles) - articles relevant to practicing self-care after returning home; delivered 3 months after hospital discharge

Study participants will receive unique login and password information for their Heartsight account, created for them by study staff, which will allow the study team to track intervention utilization through User Insights. User Insights enables the study team to track the articles read and time spent per article for each intervention arm participant.

Heartsight is accessible via any device with an internet connection.

viii. Randomization

Ms. Rojas will be responsible for generating the randomization allocation table for the REDCap randomization module, which will assign participants to arms.

Method:

1. Before study launch, Ms. Rojas will build a master randomization allocation table using Excel. This allocation table will yield arm assignments for 100 study participants (67 in the intervention arm, 33 in the control arm).
2. Ms. Rojas will upload the allocation table to the REDCap randomization module.
3. Once the study launches, REDCap will switch to production mode, and the randomization module will be locked. Randomization assignments cannot be changed going forward.

4. When a new participant is recruited, study coordinators will click "Randomize" for a new record in REDCap. This will yield the arm assignment for the new participant, as determined by the pre-made allocation table.

ix. Study Measurements and Protocol

Visit 1 (Baseline):

Survey 1 (Baseline, 20 min):

Once written consent has been obtained, a study coordinator will use the REDCap randomization module to assign the participant to a study arm. All participants, regardless of randomization, will receive a baseline survey that they can complete asynchronously in-person (on paper) or via REDCap (an online, HIPAA-compliant data collection tool that can be sent via email). The baseline survey will contain questions about participant demographics (22 questions), threat perception (Threat Perception Survey, 7 questions), uncertainty intolerance (Intolerance of Uncertainty Scale, 27 questions), illness uncertainty (Mishel Uncertainty in Illness Scale for Family Members, 31 questions), PTSS (PCL-5, 20 questions), and the surrogate's presence during their loved one's cardiac arrest (4 questions).

Between Visits 1 and 2:

Heartsight Intervention Package 1 (Understanding Cardiac Arrest):

After completion of the baseline survey, participants assigned to the intervention arm will be emailed login and access details for their Heartsight account. These participants will be instructed to view the Understanding Cardiac Arrest package of articles, which provides information about cardiac arrest and the ICU, and provide article-specific feedback by leaving comments on the website. Participant utilization of Heartsight will be tracked using User Insights. Intervention arm participants who do not access Heartsight within 4 days of receiving access details will be sent a reminder email.

Participants assigned to the control arm will not receive any materials.

Heartsight Intervention Package 2 (Preparing for Discharge):

Study coordinators will monitor EPIC to determine when intervention arm participants have moved to the floor. At this time, intervention arm participants will be emailed access details for the Preparing for Discharge package of Heartsight articles, which provides information about getting ready to leave the hospital. They will also be asked to leave article-specific feedback by leaving comments on the website. Participant utilization of Heartsight will be tracked using User Insights. Intervention arm participants who do not access Heartsight within 4 days of receiving Preparing for Discharge access details will be sent a reminder email.

Participants assigned to the control arm will not receive any materials.

Visit 2 (Discharge):

Survey 2 (Discharge, 15 min):

Study coordinators will monitor the electronic medical record to determine when participants will be discharged from the hospital. Approximately one day before discharge, study coordinators will approach participants to deliver the second survey. This survey, taken by participants in both arms, can be completed asynchronously in-person (on paper) or via REDCap (online). The discharge survey will contain questions about subjective perception of uncertainty (3 questions), illness uncertainty (Mishel Uncertainty in Illness Scale for Family Members, 31 questions), PTSS (PCL-5, 20 questions), cardiac anxiety (Cardiac Anxiety Questionnaire fear subscale, 8 questions), and social support (Enriched Social Support Instrument, 6 questions). Intervention arm participants who have been identified as viewing less than 25% of the Preparing for Discharge articles will receive two additional questions asking for user feedback.

Upon completion of the discharge survey, study coordinators will process the first $50 payment to the participant. At this time, study coordinators will also provide all participants with a GENEActiv device, study log, stamped envelope for return, and instructions for proper use and return in 1 week.

Between Visits 2 and 3:

At 1 week post-discharge, study coordinators will call participants to remind them to return the GENEActiv. The second payment of $25 will be processed once a participant's GENEActiv has been returned to the PACE team.

Heartsight Intervention Package 3 (Focusing on You):

One month after hospital discharge, intervention arm participants will be emailed access details for the Focusing on You package of Heartsight articles, which provides information about getting ready to leave the hospital. They will also be asked to leave article-specific feedback by leaving comments on the website. Participant utilization of Heartsight will be tracked using User Insights. Intervention arm participants who do not access Heartsight within one month of receiving Focusing on You access details will be sent a reminder email.

Participants assigned to the control arm will not receive any materials.

Visit 3 (Final):

Survey 3 (Final, 20 min):

Three months after hospital discharge, study coordinators will call participants to schedule the final survey. This survey, taken by all study participants, can be completed via REDCap (online) or over the phone. The final survey will contain

questions about subjective perception of uncertainty (3 questions), illness uncertainty (Mishel Uncertainty in Illness Scale for Family Members, 31 questions), PTSS (PCL-5, 20 questions), cardiac anxiety (Cardiac Anxiety Questionnaire fear subscale, 8 questions), and caregiver burden (Zarit Burden Interview, 12 questions). Intervention arm participants who have been identified as viewing less than 25% of the Focusing on You articles will receive two additional questions asking for user feedback. All intervention arm participants will also receive a Heartsight feedback survey (23 questions).

Upon completion of the final survey, study coordinators will process the final $50 payment to the participant. At this point, surrogates' participation in the study is considered complete.

x. Visit Procedures

Visit 1 (Baseline):

Survey 1 (Baseline, 20 min):

Once written consent has been obtained, the study coordinator should leave a baseline survey in the correct language (English or Spanish) with the participant to complete. Schedule a time to pick up the completed baseline survey and explain to the participant that a copy of their completed consent form will be provided to them at that time.

After scheduling the pick-up time, the study coordinator should obtain a patient sticker from the binders near the nursing station. Apply the patient sticker to the consent form, photocopy the consent form, and file the original copy of the consent form in the NeuroCardiac Care office.

The study coordinator should also create a new REDCap record in Arm 3: Randomization. Open "Demographics," enter the CANOE-F ID, then click the "Randomize" button. If randomized to Heartsight, create a new record with the participant's CANOE-F ID in Arm 1. If randomized to control, create a new record with the corresponding CANOE-F ID in Arm 2. At this time, also navigate to the "Subjective Discharge" and "Subjective 3-Month" surveys and select "No" for "Ready to send?". This prevents the discharge and 3-month surveys from automatically joining the survey queue at earlier time points.

At the scheduled time, the study coordinator should return to the ICU, pick up the completed baseline survey, and give the participant the copy of their completed consent form. Enter the completed baseline survey into REDCap and file the paper copy in the NeuroCardiac Care office.

If the participant has indicated they would prefer to complete the survey on REDCap instead, the study coordinator should obtain their email address. Then click into the "Demographics" instrument in their REDCap record, click "Survey

Options," and open "Survey Access Code + QR Code." Copy and paste the survey link and code into an email from neurocardiac@cumc.columbia.edu. Confirm verbally with the participant that they have received the email (if not, ask them to check their spam inbox).

The study coordinator should add the participant to the CANOE-F spreadsheet under the "CURRENT Participants RESURFACE" tab and log date of baseline completion under "ALL Participants RESURFACE."

Between Visits 1 and 2:

Heartsight Intervention Package 1 (Understanding Cardiac Arrest):

After completion of the baseline survey, participants assigned to the intervention arm will be emailed login and access details for their Heartsight account using this email script. Intervention arm participants who do not access Heartsight within 4 days of receiving access details will be sent a reminder email (also included in email script). Log the date the package is issued and when the reminder email is sent, if needed, under "ALL Participants RESURFACE."

Participants assigned to the control arm will not receive any materials.

Heartsight Intervention Package 2 (Preparing for Discharge):

Study coordinators will monitor EPIC to determine when intervention arm participants have moved to the floor. At this time, intervention arm participants will be emailed access details for the Preparing for Discharge package of Heartsight articles using this email script. Intervention arm participants who do not access Heartsight within 4 days of receiving Preparing for Discharge access details will be sent a reminder email. Log the date the package is issued and when the reminder email is sent, if needed, under "ALL Participants RESURFACE."

Participants assigned to the control arm will not receive any materials.

Visit 2 (Discharge):

Survey 2 (Discharge, 15 min):

Study coordinators should check EPIC each morning to determine when participants will be discharged from the hospital. Approximately one day before discharge, study coordinators should approach participants on the floor.

Before approaching, check User Insights to see whether the participant is a low- or no-use participant (accessed <25% of previous Heartsight package). If so, include the low- or no-use questions in addition to the discharge survey in the packet of materials for the participant.

Leave the discharge survey in the correct language (English or Spanish) with the participant to complete. Schedule a time to pick up the completed discharge

survey. At the scheduled time, return to pick up the survey, enter the responses into REDCap, and file the paper survey in the NeuroCardiac Care office.

If the participant has indicated they would prefer to complete the survey on REDCap instead, the study coordinator should click into the "Subjective Discharge" instrument in their REDCap record. If the participant is a low- or no-use participant, click the corresponding radio button, and save. Then click back into the record and switch "Ready to send?" to yes. Save, exit, click back into the record, navigate to "Survey Options," and open "Survey Access Code + QR Code." Copy and paste the survey link and code into an email from neurocardiac@cumc.columbia.edu. Confirm verbally with the participant that they have received the email (if not, ask them to check their spam inbox).

The study coordinator should also leave a GENEActiv device, study log, stamped envelope for return, and instructions for proper use and return in 1 week with the participant. Remind the participant that the study team can be reached at neurocardiac@cumc.columbia.edu or (212) 305-4234 if any questions about using or returning the GENEActiv come up.

Once the discharge survey has been completed, study coordinators should also process the first $50 payment to the participant through TruCentive.

Log dates of discharge survey completion and first payment under "ALL Participants RESURFACE."

Between Visits 2 and 3:

At 1 week post-discharge, study coordinators will call participants to remind them to return the GENEActiv, following this phone script. Log date of call under "ALL Participants RESURFACE."

The study coordinator should check in with the PACE team whenever a GENEActiv is expected to be returned. Only when the PACE team has confirmed that a participant's GENEActiv has been returned should the second payment of $25 be processed. Log dates of GENEActiv return and second payment under "ALL Participants RESURFACE."

Heartsight Intervention Package 3 (Focusing on You):

One month after hospital discharge, intervention arm participants will be emailed access details for the Focusing on You package of Heartsight articles using this email script. Participant utilization of Heartsight will be tracked using User Insights. Intervention arm participants who do not access Heartsight within one month of receiving Focusing on You access details will be sent a reminder email, also following the email script linked above. Log the date the package is issued and when the reminder email is sent, if needed, under "ALL Participants RESURFACE."

Participants assigned to the control arm will not receive any materials.

Visit 3 (Final):

Survey 3 (Final, 20 min):

Three months after hospital discharge, study coordinators will call participants to schedule the final survey using this phone script. Be sure to check which arm the participant is in to obtain the correct version of the survey.

If the participant prefers REDCap, the study coordinator should click into the "Subjective 3-Month" instrument in their REDCap record. If the participant is a low- or no-use participant, click the corresponding radio button and save. Then re-open the instrument, switch "Ready to send?" to yes, save, and exit. Re-open the instrument, click "Survey Options," and open "Survey Access Code + QR Code." Copy and paste the survey link and code into an email from neurocardiac@cumc.columbia.edu. Confirm with the participant that they have received the email (if not, ask them to check their spam inbox).

If the participant prefers a phone call, the study coordinator should either fill out the REDCap directly while on the call or fill out the paper survey, enter responses into REDCap, and file the paper survey in the NeuroCardiac Care office.

Once the 3-month survey has been completed, study coordinators should process the final $50 payment to the participant through TruCentive.

Log dates of final survey completion and final payment under "ALL Participants RESURFACE." At this point, surrogates' participation in the study is considered complete. Remove them from the "CURRENT Participants RESURFACE" tab and mark them as complete under "ALL Participants RESURFACE > Study Status."

b. Data Collection, Management, and Analysis

i. Data Collection Methods

Study coordinators will conduct surveys via paper copies, phone, or REDCap, depending on the participant's preferences. All survey responses will be entered into REDCap, and any paper copies will be filed in the NeuroCardiac Care office.

Survey 1 (Baseline):

a. Demographics
b. Threat Perception Survey (TPS)
c. Intolerance of Uncertainty Scale (IUS)
d. Mishel Uncertainty in Illness Scale - Family Member (MUI/PPUS-FM)
e. PTSD Checklist (PCL-5)
f. Presence at cardiac arrest

Survey 2 (Discharge):

a. (If no-/low-use) No- or low-use questionnaire
b. Subjective perception of uncertainty
c. Mishel Uncertainty in Illness Scale - Family Member (MUI/PPUS-FM)
d. PTSD Checklist (PCL-5)
e. Cardiac Anxiety Questionnaire (CAQ)
f. Enriched Social Support Instrument (ESSI)

Survey 3 (3 Months Post-Discharge):

g. (If no-/low-use) No- or low-use questionnaire
h. Subjective perception of uncertainty
i. Mishel Uncertainty in Illness Scale - Family Member (MUI/PPUS-FM)
j. PTSD Checklist (PCL-5)
k. Cardiac Anxiety Questionnaire (CAQ)
l. Zarit Burden Interview – 12-item short form
m. (If intervention arm) Heartsight feedback

GENEActiv Data: bin files and csv files.

ii. Data Management

Statistical analyses will be led by Sachin Agarwal, MD, MPH. He has been involved from the earliest stage of pilot study planning to ensure that rigorous statistical analyses are planned.

Data management will be led by the CBCH Data Team. They use proven tools that have been successful in other trials conducted by CBCH, all of which integrate with REDCap.

A posting on clinicaltrials.gov will be made to summarize the details of the study protocol. At the end of the study procedures, the publicly available clinicaltrials.gov posting will be updated with a summary of enrollment data and key results at the end of the trial.

iii. Statistical Methods

Statistical approach for Aim 1: *Enroll up to 100 (until 30 in the intervention arm) surrogates of CA patients to* ***(Aim 1a)*** *pilot recruitment and randomization procedures,* ***(Aim 1b)*** *estimate retention rate at 3 months, and* ***(Aim 1c)*** *assess the engagement and utilization metrics through the app for frequency of access and time spent on packages.*

Aim 1a. Based on our prior studies with surrogates of CA patients who survive to hospital discharge, 8 surrogates/month will be eligible to participate in the proposed study and <5 participants/month will be considered not meeting the outcome. **Aim 1b.** Based on our prior successes, we expect retention rates of ~90%. Since this is an

interventional study, the proportion of participants who complete the 3-month assessments <80% will be considered as not meeting the outcome. A sample size of N = 30 surrogates results in a 95% confidence interval of this estimate equal to 79% – 100%,[61] providing sufficient precision for study planning. **Aim 1c.** Acceptability will be assessed by recording reasons for dropout, reasons for noncompliance, and querying participants about burden at 3 months. We will consider scale completion >90% acceptable. The application can track the utilization of the content, time spent on each module of the packages, and participants' review and content feedback.

Statistical approach for Exploratory Aims 1a-c. *Estimate the association of intervention v. control with the surrogate's uncertainty levels at 3 months post-discharge* ***(Exploratory Aim 1a)****, cardiac anxiety, and PTSS at 3 months post- discharge* ***(Exploratory Aim 1b)****, and explore the lagged associations of uncertainty with cardiac anxiety and PTSS* ***(Exploratory Aim 1c)****.* We will compute 95% bootstrap confidence intervals around the mean difference in **(1a)** uncertainty in illness total scores; **(1b)** total scores on the cardiac anxiety questionnaire and PCL-5 between intervention and control conditions and (**1c**) the associations between surrogates' uncertainty scores and cardiac anxiety as well as PTSS accounting for enrollment, discharge, and 3 month scores. The lower bounds of these correlations will be used for sample size calculations when planning the larger study to account for uncertainty in small samples. N = 30 has been recommended as sufficient for pilot studies.[62]

Statistical approach for Exploratory Aim 2: *Obtain a preliminary estimate of the association of intervention v. control with surrogates' sleep duration within the first one week after hospital discharge.* We will compute 95% bootstrap confidence intervals around the mean difference in duration of sleep over the one week post-discharge, between intervention and control participants.

b. Monitoring

i. Data Monitoring

The Study Principal Investigator (PI), Sachin Agarwal, MD, MPH, will be responsible for ensuring participants' safety. He will be assisted in this responsibility by Jeffrey Birk, Ph.D., a board-certified experimental psychologist, and Talea Cornelius, Ph.D., MSW, both are co-Is of the Pilot Core. This pilot study is an unblinded clinical trial with two arms (i.e., the web-based educational platform and control group) evaluating a low-risk intervention. Therefore, a Data Safety and Monitoring Board (DSMB) will not be formed to oversee the activities of this pilot study unless required by the NIA. Entities responsible for monitoring activities for this study will include the study PI (Dr. Agarwal) and the CUIMC IRB.

ii. Risks

Questionnaires: The proposed questionnaires have been extensively used in clinical research and during routine clinical practice and pose no risk to the subjects. The questions asked and thoughts evoked during this research study pose minimal risk of psychological discomfort. Participants will be made aware of these risks and assured they can terminate their participation in the study at any time without penalty.

Wrist-accelerometry: The GENEActiv monitors are the size of a wristwatch and come with a strap so that they are worn on the wrist and pose no risk other than the potential for mild skin irritation from the wrist strap. These accelerometers are routinely used in clinical, commercial and research practice.

Confidentiality: A potential risk from this study is the violation of the participant's privacy, since patient medical information will be used as a source of data. Special protections against this risk be provided.

There are no known long-term risks from any study activities.