Protocol for Proposed Pilot Study: Family-Authored ICU Diaries to Reduce Fear in Patients Experiencing a Cardiac Arrest (FAID Fear)

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1. Study Purpose and Rationale

A cardiac arrest (CA) is a terrifying experience for patients, but maybe even more so for their loved ones. Whereas patients are not conscious and often have little to no memory of the CA and associated stay in the hospital and the intensive care unit (ICU),[1,2] families witness all of these things, resulting in high levels of fear and psychological distress. Indeed, ~1/3 of family members of ICU patients report clinically significant posttraumatic stress symptoms (PTSS).[3] This phenomenon is so prevalent that it has been termed Post-Intensive Care Syndrome – Family (PICS – Family).[3-5]

Critically, emotions are socially transmitted,[6-8] memories are socially constructed,[9-13] and partner distress can undermine the provision of skilled social support that can buffer patient distress.[14,15] Prior research has suggested that patients experiencing CA will develop memories of the CA event over time[1,2] – potentially because they are trying to "fill in the gaps" in their memory.[16] As such, **partners or other close family members may play a critical role in creating and cementing fear-based memories and distress in patients experiencing a CA.** CA patients often report cardiac fear and preoccupation.[17] This is not without consequence: fear-based distress, particularly early anxiety related to symptoms (e.g., rapid heartbeat) and markers for PTSS in other patient populations predicts reduced engagement in behavior necessary for secondary prevention (e.g., reduced physical activity, medication avoidance) and increased morbidity and mortality.[18-24]

The present study will test the feasibility of a Family-Authored ICU-diary intervention to reduce fear of CA in patients' partners/family members, with the long-term goal of developing and implementing a large scale RCT to test whether fear reductions in family members improve patients' mental wellbeing, health behaviors, and, ultimately, health outcomes. Following the methods of a RCT published in 2020,[25,26] partners/family members will receive a bound diary from a trained research assistant and a brief explanation of how to use the diary, including recommended frequency for writing and tips on how to express themselves. This intervention found that family-authored diaries significantly reduced PTSS in family members (26.3% lower in intervention v. control conditions, 95% CI 4.8, 52.2) and trended towards a reduction in PTSS for patients (11.2% lower, 95% CI -15.7, 46.8).[25,26]

Aim 1: Enroll 31 partners/family members of CA patients to **(a)** pilot recruitment procedures, **(b)** estimate retention, and **(c)** assess acceptability of study procedures.

Partners/family members will be randomized to either complete an ICU diary[25,26] or to a control condition, and will complete surveys in the ICU or hospital floor, at patient end of hospital care (contingent upon discharge status), and 30 days post-end of hospital care.

Aim 2: Obtain an estimate of the association of intervention v. control with **(i)** partner/family member fear (operationalized as cardiac anxiety *about the patients' cardiac condition*) at hospital discharge and **(ii)** partner/family member PTSS 30 days post-discharge.

Exploratory Aims: Obtain an estimate of the association of intervention v. control with partner/family member aversive cognitions towards exercise at hospital discharge.

2. Study Design and Statistical Analysis

This is a randomized control study design using an intervention v. control condition. It is a pilot feasibility trial of up to 31 participants.

Participants will be drawn from caregiver participants enrolled in the CANOE study (AAAR8497), who have indicated they are willing to hear about additional research opportunities and who meet initial study criteria.

Eligibility

1) the primary partner or family member of a patient who has experienced a cardiac arrest,
2) age 18 years and over,
3) able to speak, read, and write in English or Spanish,
4) participating in the CANOE study and indicated they were willing to hear about future research opportunities,
5) willing to write in a journal about their experiences,
6) available for follow-up, and
7) does not have any medical or psychiatric impairment that would prevent them from complying with the research protocol.

Sample size and power estimates are based on Aim 1. Although some have used pilot studies to estimates effect sizes on primary outcomes, we agree with leaders in our field who argue that effect size estimates from small pilot studies are too imprecise to meaningfully inform effect size assumptions of power analyses for larger, later stage studies. Therefore, we do not provide power calculations for the effects of our intervention on fear-based mechanisms or behavioral outcomes. We will, however, use estimates from these studies (e.g., standard deviations, attrition rates) to help determine appropriate sample sizes for a subsequent study that is powered to detect meaningful reductions in measures of cardiac anxiety.

As this is a pilot study, our sample size was guided by the need to enroll enough participants – specifically, family members or partners of patients who recently survived CA – to examine the feasibility of conducting a larger stage II or III randomized clinical trial of our FAID-Fear intervention in this population. In particular, we will determine whether we are capable of recruiting, retaining, and assessing participants, and of implementing the proposed intervention with good compliance.

3. Study Procedures

IRB-approved personnel from the CANOE (AAAR8497) research team will identify participants enrolled in the CANOE study as part of the caregiver cohort who have indicated they are willing to hear about additional research opportunities and who meet initial study criteria. Members of the CANOE research team will generate a list that includes the CANOE caregiver participant

name, CANOE patient participant MRN, patient location, caregiver relationship to the patient, and caregiver contact information. The list will be sent to a member of the FAID Fear study team via encrypted email. Using the list, the FAID Fear study coordinator will either approach potentially eligible partners/family members in the ICU/hospital or contact them via telephone. A verbal information sheet that explains overall study participation will be used to complete the consent process.

Partners/family members who undergo informed consent and agree to participate will be randomized 2:1 to either the ICU diary (intervention) or the control condition. Randomization will occur using opaque sealed envelopes to be opened by the study coordinator after consent is provided/documented. The partner/family member participant will be informed of the randomization assignment and a baseline assessment will also occur.

Randomized to ICU Diary Condition

These partners/family members will receive standard contact and communication from ICU/hospital doctors.

Following the design of Nielsen et al.,[25] partners/family members will be provided with a hard-cover diary containing written instructions (diary instructions included in RASCAL attachments) and a pen. If consent and randomization occur in person, the diary will be handed to the participant. If consent and randomization occur by phone, the diary will either be mailed to the participant or the coordinator will arrange for a time to meet the participant in the hospital or at the CBCH offices to provide the diary. A trained research assistant will explain how to use the diary, and instructions will include recommended frequency for writing and tips on how to express themselves. The hard copy of the diary will remain with the partner/family member participant and they will be asked to continue writing in the diary until patient end of hospital care (e.g. ICU). The diary will not be collected at the conclusion of the study. Research assistants will check in with participants via weekly telephone calls to provide support, as needed, if the partner/family member reports difficulty in writing diary entries (e.g., suggesting the partner/family member write at home rather than in the hospital, encouraging use of key words or focusing on the present if events are hard to summarize).

We confirm that the hard-copy diary that is provided to subjects will not reference any identifiers or codes and the diary will NOT be collected back from participants as part of the study (once the blank diary is given to the participant, it is theirs to keep).

Randomized to Control Condition

These partners/family members will receive standard contact and communication from ICU/hospital doctors.

The CANOE patient MRN will be used to access the patient EHR to view/document the date of discharge or death. All FAID Fear study participants (both intervention and control) will complete 1) a survey upon end of hospital care (contingent upon discharge status; specifically, if a patient dies, then we will not contact family members at this time but will wait to contact them until one month has passed in accordance with the procedures of the CANOE-F team in

order to be respectful of, and sensitive to, the needs of participants for space and time), and 2) a final survey at 30 days post-end of hospital care (participants randomized to the control condition will not be asked questions about intervention appropriateness, feasibility, and acceptability, but will be asked if they kept a diary. If yes, they will be asked questions about diary usage). Upon completion of the 30-day survey, study participation is complete.

For analysis purposes, the data collected as part of this study will be shared with CANOE study (AAAR8497) researchers. The patient MRN number will be used to link partner/family member participant data from this study with data from the CANOE study.

In addition, identifiable data from the PACE study (AAAT4053) will be accessed and used as part of our analysis.

Compensation: Participants will be provided with compensation to acknowledge the time and effort put into study participation as follows:

- Payment for randomization - $25.
- Payment for survey completion at baseline - $25
- Payment for survey completion at 30-days post-end of hospital care - $50

Total compensation for the completion of all study activity is $100. Payments will be distributed in the form of Bank of America PayCards.

4. Risks

Study procedures (i.e., completing questionnaires and, as applicable, writing in an ICU diary) present minimal risk. The questions asked and the thoughts evoked during the course of this research study pose minimal risk of psychological discomfort, and participants may wish to skip any question or questionnaire that they choose. Participants will be made aware of these risks and will be assured they can terminate their participation in the study at any time without penalty. A mental health referral plan is outlined in the Data Safety and Monitoring section of this protocol.

Study participation also involves the possibility of a loss of confidentiality. The study team has outlined plans to protect participant confidentiality in the Privacy and Data Security section of RASCAL.

5. Benefits

There is no direct benefit to subjects who participate in this study. Results may be used to design future adequately powered RCTs to refine and develop ICU-based diary interventions. The information obtained as a result of this study may thus help future family members cope with the distressing experience of a loved one experiencing a cardiac arrest, and surviving patients may also benefit.

6. Alternatives

The alternative is not to participate.

7. Data and Safety Monitoring

As this study presents minimal risk to participants, data and safety monitoring will be conducted by the study staff as directed by the principal investigator. Thus, there is no plan for a Data Safety and Monitoring Board (DSMB).

Mental Health Referral Plan: To support subject well-being, all subjects will be asked if they would like to be provided with a mental health resource sheet (which reflects referral to General Psychiatry at Columbia University Irving Medical Center) at the 30-day contact.

If a participant expresses immediate risk of self-harm during study participation, we will follow mandated reporting requirements, which may include emergency room evaluation and/or psychiatric services. These safety procedures will be overseen by Dr. Talea Cornelius, who also holds a master's degree in Clinical Social Work, and has previous experience with counseling, care coordination, patient referrals, and client services.

Study Team Meetings: Investigators and research assistants will meet weekly to discuss any issues or concerns with the study, in particular, whether there were any unexpected complaints about the study procedures or questionnaires, or whether there were any breaches in data confidentiality (which will be reported to the IRB as required by policy). If unexpected complaints about the study tasks or questionnaires are generated, then the study may be stopped or altered prior to recruiting the full sample.

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