Pilot Evaluation of FAMCOPE-ICU (Family Coping and Emotion Regulation Tool in the ICU)

NCT05408468

January 11, 2022

Objectives

Aim 1: We will use probing qualitative questions and validated self-report scales to determine the acceptability of FAMCOPE-ICU. We hypothesize that family members of the critically ill will find FAMCOPE-ICU acceptable.

Aim 2: We will conduct a pilot, before-and-after clinical trial to generate evidence of FAMCOPE-ICU's preliminary efficacy. We hypothesize that recipients of FAMCOPE-ICU will report less severe psychological symptoms (i.e., post-traumatic stress disorder, anxiety, depression), higher satisfaction, and less sleep disturbance than non-recipients)

Background

Each year, more than 6 million American families will endure a loved one's admission to an intensive care unit (ICU).1 Consequently, most of these family members will report distressing psychological symptoms (stress, anxiety, and depression), which can compromise their involvement in surrogate decision-making, impair social functioning, and persist for months after the patient's ICU discharge.2 Over the last three decades, there have been varied attempts to support these family members; unfortunately, these supportive interventions have largely been ineffective in reducing the intensity of family member psychological symptoms. Notably, these interventions have largely focused on enhancing knowledge and improving communication, with little attention given to empowering family members with the skills needed to cope during these stressful, and often traumatic, circumstances.3 Consistent with models of family-centered critical care endorsed by numerous multidisciplinary professional societies, there is a significant need to develop novel and scalable interventions that mitigate distressing psychological symptoms reported by family members of the critically ill.4

Inclusion and Exclusion Criteria

	Patient Inclusion Criteria
1.	Age 18-89 years
2.	ICU length of stay between >= 48 hours
3.	No anticipated discharge for next 24 hours
4.	Unable to make healthcare decisions

	Patient Exclusion Criteria
1.	Less than 18 years or older than 89
2.	ICU LOS < 48 hours
3.	Anticipated ICU discharge within next 24 hours
4.	Able to make healthcare decisions

	Family Inclusion Criteria
1.	Identified by the critical care team as the LAR
2.	Able to speak or comprehend English.
3.	Age >= 18 years

	Family Exclusion Criteria
1.	Not identified by critical care team as the LAR
2.	Unable to speak or comprehend English
3.	*Age <= 18 years*

Number of Research Participants

We will recruit 60 participants (30/group).

Recruitment Methods

Each day, a research assistant (RA) will screen the admission orders and nursing admission flowsheet documentation within the electronic medical records (EMR) of patients in the CTICU, NSU, MICU, and TSICU (SICU patients only). Using this process, the RA will document the month, day of month, and time of the patient's ICU admission in our electronic screening log. They will use this information to identify patients on day 1 or 2 of their ICU stay who meet patient inclusion criteria #1 (age). It is possible that we will screen patients who have been in the ICU for more than two days (e.g., weekend admissions), in that case, we will follow the same procedures described below.

On ICU day 1 (0-24 hours). The RA will confer with the patient's nurse and/or provider to identify the patient's legally authorized representative. If there is uncertainty, the RA will examine the patient's bedside chart for a patient information sheet (i.e., face page), family information sheet (usually collected at admission), or signed consent document as means of identifying the patient's LAR.

- If the LAR is at the bedside, a RA will introduce the study (see "pre-recruitment script" document), emphasizing that they may be eligible for our study in two days. If interested in learning more about the study upon eligibility, the research assistant will collect the LAR's name and phone number, which will transferred directly into the screening log, and give them the recruitment letter. The RA will tell the LAR that if the patient eligibility criteria are met, our team will reach out to them to coordinate their possible enrollment in the study.
- If the LAR is NOT at the bedside, the RA will leave the recruitment letter at the patient's bedside or with the bedside nurse, who will be asked to give the letter to the LAR should they visit the patient.

On ICU day 2 (24-48 hours) of the patient's ICU stay, the RA will attempt the locate the LARs at the patient's bedside if they were unable to establish contact with them on day 1. They will also confer with the bedside RN about if the LAR has visited since we first tried to establish contact, and if the letter was given to the family member. (Family involvement is a key element of the ICU RN handoff; therefore, this information should be easy to obtain given there will only have been 1 RN (nightshift) that the RA would

not be in contact with since their last bedside visit). - If the letter was NOT given to the family member and is still at the bedside, the RA will once again ask the RN to give the letter to the family member should they visit.

- If the letter was NOT given to the family member and is NOT at the bedside, the RA will leave another letter, following the same process used on ICU day 1.
- If the family is at the bedside, the RA will give the family member the recruitment letter, following the process described for ICU day 1.

On or After ICU Day 3 (48-72 Hours), The RA will identify patients who meet Patient Inclusion Criterion #2 by comparing admission information in the screening log to the EMR documentation screening process described on ICU day 1. Patient's meeting this criterion will be screen for Patient Inclusion Criterion #3.

If Patient Criterion #2 is met, the RA will confer with the nurse/provider to verify if the patient's current plan of care involves discharge within the next 24 hours by asking "To your knowledge, does the patient's plan of care involve discharging from the ICU by this time tomorrow?"

If the nurse/provider answers Yes, the patient does not meet Criterion #3. The RA will reevaluate on the next screening day if the patient is not discharged.

If the nurse/provider answers No, the patient meets Criterion #3. The RA will obtain permission from the RN/Provider to evaluate Patient Criterion #4.

Consistent with recommendations from the UH IRB Investigator Manual, a RA will conduct a global cognitive assessment by assessing the patient with the following questions:

1) Is the patient alert and able to communicate?
2) Is the patient comfortable enough to communicate?
3) Is the patient medically stable enough to have an informed consent discussion?

The RA will evaluate the potential patient participant for eligibility and will confer with the CWRU PI (Pignatiello) if there is a question. This conversation will be documented in the electronic screening log.

If the LAR is not at the bedside, the RA will confer with the screening logs and/or nurse to confer the delivery status of the opt out letter:

- If the letter has been delivered AND the opt out period has lapsed. The RA will call the LAR to ascertain interest (see phone script) and confirm eligibility criteria. If criteria are met, the RA will attempt to schedule a face-to-face meeting to discuss their participation (see recruitment script).
- If the letter has delivered, BUT the opt out period has NOT lapsed. The RA will make a note in the screening log about the date that we can call the LAR, assuming the patient remains eligible.
- If the letter has NOT been delivered and is at the bedside. The RA ask the nurse about their knowledge of the LAR's visiting habits and request that the RN deliver the letter should the family visit.

- If the letter has NOT been delivered and is NOT at the bedside. The RA will provide the RN with another letter to give to the LAR and update the screening log to reflect the new delivery attempt.

If the LAR is at the bedside, the RA will confirm the family inclusion criteria with the LAR face-toface. - If the family member is ineligible, the RA will thank the LAR for their time and document this finding in the screening log.

- If the family member is eligible, the RA will initiate the recruitment discussion (See attached "Recruitment Script").

Rationale for calling participants - Due to COVID-19 related delays with the US mail, mailing an opt out letter/flyer would likely reduce the opportunity the participant has to participate in this research study. Also, given our understanding of this population, it is very possible that participants may not be returning to home regularly to check their mail. Furthermore, it is very likely that, unless the LAR is the spouse/living with the patient, an address for the LAR will not available, further limiting the opportunity to participate in this study. In addition, due to the contextual nature of this study and work of our prior team, the need to contact family members early on the patient's ICU stay may potentiate the potential benefit of being in this study, as their psychological response to the first few days of their loved one's critical illness is a significant predictor of their well-being throughout the rest of the patient's hospital stay and post-discharge period. To reduce participant burden, we will only call participants during normal business hours (0900-1700), and will only call them a second time if they return our call or leave a voicemail expressing interest in the study.

Setting

1) We will be recruiting from UHCMC CTICU, NSU, and TSICU (SICU patients only)
2) Patient inclusion criteria will be partially verified in the private office of the CWRU PI using remote EMR capacity. The remaining criteria will be verified in person at the bedside, or over the phone.
3) We will conduct the interview in a private family conference room as designated by the respective medical directors of each ICU, a private location approved by the participant (including the patient's bedside), or the CWRU PI's Office (Nursing Research HRC 302E).

Consent Process

Once in a location with the LAR's desired privacy, the RA will formally initiate the informed consent process. The RA will provide a copy of the informed consent document to the LAR, giving them an option to review it independently first. Next, the RA will review each section of the informed consent document with the LAR. Consistent with the 2018 Common Rule, the RA will emphasize:

1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental
2) A description of any reasonably foreseeable risks or discomforts to the subject;
3) A description of any benefits to the subject or to others that may reasonably be expected from the research;

4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and
9) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility

After, the RA will give the LAR the opportunity to ask any additional questions about the study. Then, the RA will confirm their understanding with a post-consent quiz:

1) In a few sentences, tell me what you think the purpose of our study is?
2) Just to make sure you understand, can you tell me what we're asking you to do?
3) What are the risks of being a part of our study?
4) If you decide not to participate, what other options do you have?
5) What else would you like to know?

If the LAR is unsure or incorrect in their responses, the RA will re-review the relevant information in the consent document. The RA will then use a teach-back method to ensure understanding.

Next, the RA will ask the LAR to sign and date the written informed consent document. After which the RA will provide the LAR a copy of the consent document that they signed and dated. The RA will complete the attached "informed consent documentation" form and proceed with the T1 interview.

Reassessing the Patient for Decision-Making Capacity

Consistent with recommendations from the UH IRB, we will use the process described in the recruitment process to reassess the patient for decision-making capacity at the T4 interview (face-to-face) and T5 interviews (unless the patient died in the period between T1 and T4, or T4 and T5). For the reassessment process, the RA will ask the LAR the global assessment questions.

- If the LAR answers NO to any of the questions, the RA will NOT perform a telephone assent conversation with the patient.

- If the LAR's answers are a combination of Yes and/or Unsure, the RA will seek permission to perform their own global assessment. If there is still uncertainty, the RA will confer with the CWRU PI (Pignatiello) to determine the best course of action. This conversation and any firm determinations of patient capacity will be documented in the electronic enrollment log.
- If the LAR answers YES to any of the questions, the RA will perform a telephone assent conversation with the patient (see attached "Phone Assent")

When completing the assent (either on the phone or in person), the RA will perform their own global assessment. If the patient passes the RA's global assent, the RA will begin the formal assent process. At the end of the conversation, the RA will ask the following as a post-assent quiz:

1) In a few sentences, tell me what you think the purpose of our study is?
2) Just to make sure you understand, can you tell me what we're asking you to do?
3) What are the risks of being a part of our study?
4) If you decide not to participate, what other options do you have?
5) What else would you like to know?

Based on the answers to these questions, the RA will correct or expand upon information as needed using a teach-back method. If the RA:

- Thinks the patient is able to provide assent, the RA will ask the question at the bottom of the "Phone Assent" document: "Do we have your permission to use de-identified data from your medical record for our study?" The RA will thank the patient for their time, end the conversation, fill out the "Phone Assent" document, and document the outcome of the interview/assent conversation in the enrollment log.
- Thinks the patient is unable to provide assent, the RA will thank the patient for their time and request to speak to the LAR. They will then seek a verbal assent from the LAR on behalf of the patient.

If the patient participant regains capacity and refuses consent/assent to participation, no patient data will not be used for research

Sharing of Results with Research Participants

This study uses surveys to measure symptoms of anxiety, depression, and stress. As part of the FAMCOPE-ICU's design, individuals will be made aware of the severity of their symptoms based on their responses. We have a mitigation plan, see "Study Procedures" 2b below and attached "Suicide Screening Script".

Study Design

The study design is a pilot before and after clinical trial of FAMCOPE-ICU, a tablet-based coping and emotion regulation tool. The first 20 participants will be enrolled in the control group, and the next 40 participants will be included in the intervention group.

Study Procedures

These study procedures reflect the interview of the "family participant" (i.e., LAR).

1) This study has 5 interviews (T1-T5). The T1 (~35 minutes) will occur in person immediately after informed consent. The T2-T4 interviews will occur 24-48 hours after the completion of the preceding interview, depending on the participants availability. T2-T4 (~15-20 minutes) will occur in person for participants in the FAMCOPE condition; in the control condition (usual clinical care) will have the option of completing the study in person or on the phone. For all participants, the T5 interview will occur over the phone one month after their T1 interview. Following the T5 interview, an RA will complete the chart review instrument if they obtained assent. The first 20 participants will be enrolled in the control group (UC), and the next 40 participants will be included in the intervention group (FAMCOPE-ICU).

- Study groups:

o **FAMCOPE-ICU**: The FAMCOPE-ICU intervention design is grounded in Gross's Extended Process Model of Emotion Regulation. Consistent with this model, there are three distinct doses, which will be administered at T2, T3, and T4. via a tablet device (See "FAMCOPE Modules" attachment). The content of the intervention is tailored to participant responses to the T2-T4 surveys, which are built into the interventional interface. The informational content will be administered via pre-recorded audio with accompanying summary text and visuals. We anticipate each module will require 15-20 minutes to complete. Notably, its design interface is rooted in Cognitive Load Theory, which provides guidance on designing and delivering informational content in a way that reduces cognitive burden for the user.

o **Usual Care (UC)**: The UC condition represents the standard support afforded to all family members in the ICU. Idividuals in the UC group have the option of completing T2-T4 over the phone because they are not assigned to the interventional group.

- **In the case of the patient's death**:

o We will contact the family member on the day of their scheduled T5 offer our condolences and see if they would be willing to complete the T5 interview. We will remind them their continued participation is completely voluntary. We will then seek their verbal assent to perform our chart review. We will document the outcome of this conversation in our enrollment log and complete the chart-review if assent was obtained.

- **In the case of a missed**

o **T2-T4 Interview**, the RA will call the LAR to determine if the interview needs to be rescheduled. If the RA is unable to make contact, they will leave a brief voicemail stating the reason of the call and provide a call-back number. The next day, the RA will attempt to make contact in person with the family member and make one more phone call if unable to locate the LAR. If the LAR does not answer, the RA will not attempt to call the LAR again, until face to face contact is made or the T5 interview, whichever comes first. If

the LAR does not answer, the RA will leave a voicemail. No further contact efforts will be made.

o **T5 Interview**, the RA will leave a brief voicemail stating the purpose of the call and provide a call-back number. If the family member does not call back within one week, we will make a final attempt at phone contact and leave one final voicemail if they do not answer.

2) Procedures to monitor research participants for safety/minimize risk include:

a. Breach of Privacy/Confidentiality (Very Low Risk): Other than information used for screening and coordination of study interviews (Patient Name, MRN, bedspace; Participant name, address, and phone number), our study aims require no additional PHI. PHI will be stored with the other screening/enrollment/refusal tracking sheets in the REDCap server. Data collected for research purposes will be linked to a deidentified study ID # in REDCap. The REDCap mobile app will be used to collect baseline data for all T1 and T5 interviews, as well as the T2-T4 data for participants in the control group. T2-T4 research data (no PHI) will be collected by FAMCOPEICU for those in intervention condition. Upon completion of the indicated module, a RA will export data from FAMCOPE-ICU and upload it immediately to the REDCap server. To protect participant's privacy/confidentiality during the data collection process, we will give the participant the option of completing the T1-T4 interviews in a private conference room at the hospital. For any phone interviews (T2-T5 for control & T5 for intervention group), we will encourage participants to ensure they are in a location that they feel comfortable completing the interview, and will accommodate reasonable requests to reschedule interviews to a convenient time for the participant.

b. Psychological Well-Being (small risk): Given the population, we would expect the majority of participants to report mild or moderate symptoms of stress, anxiety, and/or depression. For participants who report severe levels of depression, anxiety, or stress (using previously validated and widely used PROMIS Instruments – see table below), The RA will follow the "Suicide Screening Script".

c. Risks from FAMCOPE-ICU (very low risk): While we anticipate the risks posed by delivery of FAMCOPE-ICU to be low, it is possible that the emotional focus of the intervention may in of itself be a subsequent trigger for psychological distress. However, the FAMCOPE-ICU intervention will screen for symptoms of stress, anxiety, and depression in each of the three modules, and will automatically provide resources discussed in 2b for those with severe symptoms. To this point, the purpose of the intervention is to empower users with evidence-based strategies they can use to cope with stress and regulate symptoms of anxiety and depression. Furthermore, to our knowledge of the extant literature in this population, supportive interventions have not been associated with deteriorations in psychological outcomes, except for the use proactive palliative care services in one isolated study which evaluated symptoms of PTSD over a six-month period. Furthermore, the intervention was designed to be succinct and contain necessary information consistent with the underlying theoretical framework and empirical evidence.

3) We will be using standard tablet devices to collect study data and deliver the FAMCOPE-ICU interventional components.

4) We will be collecting non-PHI source documentation from the EMR (See "Chart Review" instrument) that will be examined as potential covariates to include in the analysis for this study, as well as tailoring variables for future versions of FAMCOPE-ICU.

Study Timeline

	Pre-Screening	T1	T2	T3	T4	T5
Time (Minutes)	5	35-45	15-25*	15-25*	15-25*	20-30
*Those allocated to intervention increased time by ~10 minutes						

Data to be Collected for your study

Instrument	T1	T2	T3	T4	T5
Demographics	X				
Personality	X				
Values	X				
Need for Cognition	X				
Control Preferences Scale	X				
Emotional Support	X				
Emotional Beliefs Scale		X[a]			
Emotion Regulation Tendencies			X[a]		
Emotion Regulation Competency	X				
Resilience	X				X
Stress	X				X
Anxiety	X	X[a]	X[a]	X[a]	X
Depression	X	X[a]	X[a]	X[a]	X
Acceptability		X[a]	X[a]	X[a]	
Decision Fatigue				X[a]	
Decisional Conflict				X[a]	
PTSD	X				X
Sleep Disturbance	X				X
Sleep-Related Impairment	X				X
PSQI					X
Satisfaction				X[ab]	X
Chart Review					X

[a]Administered on FAMCOPE-ICU for those in FAMCOPE condition

[b]Only items 15-27 of FSICU-24R

Data Analysis Plan

Aim 1: We will use thematic analysis to code qualitative acceptability data, and interpret descriptive statistics for quantitative data

Aim 2: We will interpret associations between T1 data and T5 data to identify relevant covariates to include in our main analysis. For our main analysis, we will use analysis of covariance to determine if there are statistically significant differences in T5 variables between the control and intervention groups.

An a priori sensitivity analysis was conducted using G*Power. With a significance criterion (α) of .05 and power of .80, a sample of 120 will allow for statistical detection of medium effects (d = .52).

Risks to Research Participants

Breach of Confidentiality/Privacy: Low risk, low magnitude, potentially reversible

Physical Risks: n/a

Psychological: Low risk, mild to moderate magnitude, reversible, variable duration.

Social Risks: Low risk (e.g., conflict caused between family members via participating in study). Variable duration.

Legal: n/a

Economic: n/a

Provisions to Protect the Privacy Interests of Research Participants

1) All data (except for that selected by FAMCOPE-ICU will be collected and/or stored directly into UH REDCap. Data collected by FAMCOPE-ICU will be temporarily stored on the device (no PHI), and transferred to REDCap following the study interview.

2) We will have an available private space to conduct all in-person study procedures

3) We will provide individuals in the FAMCOPE-ICU study condition a headset to listen to the provided information

4) All data will be deidentified and referenced by only a study ID number 5) All phone interviews will be conducted in the CWRU PIs research office.

Potential Benefit to Research Participants

Consistent with our prior experience in this population, participants may experience catharsis by participating and sharing of their experiences through the study's course. Given the study's purpose, it is possible that those in the intervention group may benefit from the FAMCOPE-ICU Intervention, and

report improvements in psychological symptoms. Should this occur, it is possible that this may also promote psychological well-being in the long term.

Withdrawal of Research Participants

Subjects can choose to withdraw from the study at any time. We anticipate the most common cause of study withdrawal to be due to the discomfort of sharing their experiences serving as a surrogate decision maker or related, the inconvenience of the study procedures, or if the patient is unexpectedly discharge (e.g., dies). If a participant decides to withdraw from the study, we will use any data already collected for analysis, but will not attempt to collect more data nor contact the participant.

Alternatives to Participation

If an individual decides that they do not want to participate, their alternative is to not participate in this study.

Costs to Research Participants

All tablet devices that are used for FAMCOPE-ICU will be provided by the research team. We will not provide compensation for ensued costs related to transportation or telephone bills.

Research Participant Compensation

Participants who complete all five study interviews will be mailed a $25.00 Amazon gift card.

Provisions to Monitor the Data to Ensure the Safety of Research Participants

A data and safety monitoring plan will be put in place to ensure regulatory compliance of the research, address the fidelity of the procedures, and identify emerging issues associated with recruitment or concerns about the study. All safety-related risks will be monitored routinely by the PI. Informed consent forms and data collected during this study will be monitored for completeness and accuracy on a weekly basis by the PI. Adherence to the study protocol will be also assessed at every monthly team meeting and randomly monitored by the PI through direct observation of the RA. Emerging issues associated with screening and recruitment or study concerns will be regularly discussed with the study team. The security of confidential information will be monitored regularly by the PI and the RA will report any breaches of confidentiality to the PI. The PI will also evaluate the data for any negative outcomes that would require modification of the project or protocol. The PI will be responsible for regularly monitoring any adverse events or unanticipated problems. An adverse-event form will be developed detailing the incident, actions taken, supervisor notes, and follow-up steps. The PI will immediately report any serious or life-threatening incidents to the IRB. The research team will be also consulted as appropriate. The PI

will take appropriate action to stop the study, release a subject from the study, or modify procedures to reduce and/or eliminate the study-related risks if they occur.

References

1. Critical Care Statistics. Society of Critical Care Medicine. (https://www.sccm.org/Communications/Critical-Care-Statistics).

2. Johnson CC, Suchyta MR, Darowski ES, et al. Psychological sequelae in family caregivers of critically iIl intensive care unit patients. A systematic review. Annals of the American Thoracic Society 2019;16(7):894-909.

3. Bibas L, Peretz-Larochelle M, Adhikari NK, et al. Association of surrogate decision-making interventions for critically ill adults with patient, family, and resource use outcomes: a systematic review and meta-analysis. JAMA network open 2019;2(7):e197229-e197229.

4. Kon AA, Davidson JE, Morrison W, Danis M, White DB. Shared decision-making in intensive care units. Executive summary of the American College of Critical Care Medicine and American Thoracic Society policy statement. American Thoracic Society; 2016.