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

NCT05408468

04/04/2023

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IRB EXPIRATION DATE: 4/3/2024

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES
(v. 09.2021)

Project Title: A Pilot Evaluation of FAMCOPE-ICU

Principal Investigators: Grant Pignatiello, PhD, RN & Seth Alan Hoffer, MD

Key Information: The following is a short summary of this study to help you decide whether to be a part of this study. More detailed information is listed later in this form.

Why am I being invited to take part in a research study?

You are being invited to be a part of this study because while you are a patient in the ICU and unable to make your healthcare decisions, your decision-maker signed up for a study. This study focused on supporting family members and loved ones of ICU patients.

Things I should know about a research study

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Introduction/Purpose

Having a family member or loved one in the ICU can be a very stressful experience. We have created a tablet-based tool (FAMCOPE-ICU) that is designed to help people cope with this experience. In this study, we will be recruiting 60 health proxies from the ICUs to see if FAMCOPE-ICU is helpful.

Key Study Procedures

This study requires no additional effort or time, other than this conversation. We are seeking permission to take medical information from your medical record so we can understand how you recovered after leaving the ICU. More detailed information about the study procedures can be found under “Detailed Study Procedures”.

Key Risks

There is no physical risk to being in this study. There is a minor risk that your privacy and/or confidentiality may be breached. More detailed information about the risks of this study can be found under “Detailed Risks”

Benefits
We do not anticipate any direct benefit to you by being a part of this study.

Alternatives to Study Participation
Participation in this study is voluntary. Your only alternative is not to participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Detailed Study Procedures

- Your healthcare proxy recently enrolled in our clinical trial. The first 20 participants were assigned to the usual care condition and the remaining 40 participants were given the study intervention, FAMCOPE-ICU.
- Once you sign the document, a research assistant will use your name and medical record number to track your recovery while you are in the hospital.
- Once you are discharged, we will collect the following anonymized data: age (years), gender, race, admission diagnosis, type of Doctors who took care of you in the IC, how long you stayed in the ICU/Hospital (days), and the kind of care you needed when you left the hospital.

Detailed Risks

- There is a small risk that your privacy and confidentiality will be breached. However, we expect the risk is very low.

Consequences of Withdrawing or Being Discontinued from the Research
Participation in this study is voluntary. So, you can withdraw from the study at any time. Withdrawing from the study will not impact your care or your relationship with the healthcare team. If you decide to not participate in the study, we will keep the information that we collected about your healthcare proxy but will not collect any information about you from your medical record.

Financial Information

There are no costs for you to participate in this research study and you will not be compensated for your participation.

Student/Employee Rights

Choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor will the results be shared with your supervisor.

Termination of Participation

You may be withdrawn from the study if there is any negative effect on your health, which we do not expect.

Confidentiality

We will keep all information in a safe and secure place that can only be seen by our study staff. Your name will not be assigned to any of the information we collect about you. Instead, we will assign you a study number that will be used to organize the information we collect about you to protect your identity and maintain your confidentiality. All paper records (including this form) will be kept in a locked file cabinet in a secure location. None of the information collected about you will be shared with your doctor, family, or any other hospital staff. When we publish our findings, you will not be personally identified, and your name will not appear in the publication. However, if the study personnel find evidence that suggest you have been physically or sexually abused, they are required by law to report this to local authorities.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Privacy of Protected Health Information (HIPAA)

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The Health Insurance Portability & Accountability Act (HIPAA) is a federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled "A Pilot Test of FAMCOPE-ICU" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Seth Alan Hoffer, MD, and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally, the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect following PHI: Your name, medical record number, admission/discharge dates, and location in the hospital. This PHI will be used to contact you about this/future studies and collect de-identified information about the patient's hospitalization. access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research:

- National Institutes of Health, its study monitors, and representatives
- The Food and Drug Administration
- The Department of Health and Human Services
- The National Cancer Institute (NCI)
- Other Institutional Review Boards
- Data Safety and Monitoring Boards
- Other staff from the Principal Investigator's medical practice group that are involved in the research

- University Hospitals, including the Center for Clinical Research and the Law Department; any UH or CWRU employee required to process information for research, finance, compliance, or hospital operation, and Government representatives or Federal agencies, when required by law.

It is possible, that in the future, additional research sites may be added. In this event, your PHI that was collected during this research project may be shared with research personnel at these additional sites.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to: **Seth Alan Hoffer, MD c/o Grant Pignatiello, PhD, RN Neurological Surgery; Nursing, CWRU 2120 Cornell Rd, Cleveland, OH 44106-4904**

If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

Summary of Your Rights as a Participant in a Research Study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. De-identified data from this study may be published, presented, or otherwise made publically available. If this happens, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of Your Study Records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact Information

_____ has described to you what is going to be done, the risks, hazards, and benefits involved. The UH Principal Investigator, Seth Alan Hoffer, MD can be contacted at 216 844 5744. The CWRU Principal Investigator, Grant Pignatiello, PhD, RN can also be contacted at 216 844 4480. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Associate Chief Scientific Officer, The Center for Clinical

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Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

x		
Signature of Patient	Date	Time
x		
Printed Name of Patient		

x		
Signature of person obtaining informed consent	Date	Time
x		
Printed name of person obtaining informed consent		

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(Needed for illiterate individuals or those unable to physically sign)

x			
Signature of Witness to Consent Process		Date	Time
x			
Printed Name of Person Witnessing Consent Process			

x			
Signature of Legally Authorized Representative		Date	Time
x			
Printed name of Legally Authorized Representative (LAR)			

Indicate the relationship from the list below (Note: These are listed in descending order of priority):

- ☐ Court appointed Guardian for Healthcare
- ☐ Durable Power of Attorney for Healthcare
- ☐ Spouse
- ☐ Majority Adult Child
- ☐ Custodial Parent
- ☐ Majority Adult Sibling
- ☐ Adult relative (related by blood or adoption)