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Title: Mobile Coping Skills Training to Improve Cardiorespiratory Failure Survivors' Psychological Distress (Blueprint)

Identifier: NCT04329702

DUKE UNIVERSITY HEALTH SYSTEM

Consent To Participate In A Research Study
Optimizing Outcomes after the ICU _ Aim 2 (BluePrint Study)
Pro00101848

CONCISE SUMMARY
Many people who receive treatment for a critical illness have physical and emotional symptoms that can last for months to years. The purpose of this study is to optimize a mobile app that addresses these symptoms. Involvement in this study requires only that a person use a mobile app at their own pace and complete three short surveys. Participants will be randomized into one of three groups. Two groups will receive a mobile app that can be used on a smartphone, computer, or tablet and one group will receive usual care. Participants will be asked to use the app for one month and then complete a final survey 2 months later, for a total of 3 months of study participation.

There are no known physical risks of participating in this study. There is a very small chance that this study will increase emotional distress. There is the potential risk of loss of confidentiality. There may be no direct benefit to you. We anticipate that the study may improve physical and emotional symptoms, though this is not certain. Additionally, we hope the information learned from this study will benefit other hospitalized patients in the future.

If you are interested in learning more about this study, please continue reading below.

You are being asked to take part in this research study because you received treatment in a hospitalized setting. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. Please tell the study doctor or study staff if you are taking part in another research study.

A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Dr. Christopher Cox's and his research team's salaries will be paid by this grant.

Who will be my doctor on this study?
If you decide to participate, Dr. Christopher Cox will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

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Why is this study being done?
The purpose of this study is to find better ways to help people who have been patients in a hospitalized setting deal with stress and both physical and emotional difficulties that occur following discharge from the hospital.

How many people will take part in this study?
Approximately 80 people will take part in this study at Duke Regional Hospital and Duke University Hospital.

What is involved in the study?
If you agree to be in this study, you will be asked to sign and date this consent form. You will need to complete the baseline study visit which includes the following procedures:

- App Registration
- Baseline Survey Completion

At the time of your discharge, you will be asked to complete an additional survey. This survey will take approximately 10-15 minutes to complete and will be done on the app. This survey will determine if you are eligible to be randomized (like flipping a coin) to one of three groups. If you are not eligible, your study participation will end after the completion of the first survey. If you are eligible to continue, you will complete daily coping skills training for one month. Additionally, during the one month, you will be asked to complete four weekly check-ins which take approximately 2-5 minutes to assess how you are coping. A member of the study team may contact you if you seem to be having a hard time.

At the end of the first month, you will be asked to complete a second survey (lasting 10-15 minutes). You will be given the option to continue using daily coping skills using the app for an additional two months. At the end of two months, you will be asked to take a final third survey, lasting 10-15 minutes.

How long will I be in this study?
Your participation in the study will last approximately 3 months from the time you sign and date the consent form. We will interview you at three different time points:

- Interview 1: approximately 1 week after returning home, either by phone or electronically
- Interview 2: approximately 1 month after returning home, either by phone or electronically
- Interview 3: approximately 3 months after returning home, either by phone or electronically

Participation in this study is voluntary. If you refuse to participate you will involve no penalty or loss of benefits to which you are otherwise entitled. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in

the study, we encourage you to talk to your doctor first. If you do not sign and date this consent form, you will continue to receive care, but not as a part of this study.

What are the risks of the study?
There are no known physical risks associated with this study. There is a very small chance that this study will increase emotional distress. There is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study.

We will be texting or emailing you reminders to complete surveys. Texting may be convenient but does not provide a completely secure and confidential means of communication. Please initial on the line below if you wish to keep your reminders private and we will communicate with you through regular channels like the telephone or email:

_____ I choose to OPT OUT of text reminders

The mobile web app used in this study is developed by an outside party specifically for use in this study. As with any website you view or software that you download, there may be potential security risks and Duke cannot guarantee that the website/software is free of risk. In general, it is recommended that you run a current operating system (OS) on your computer, review the privacy/security settings on your web browsers, run antivirus software, make sure that your connection is encrypted (look for the lock icon when you connect), and log off of websites when you are done. When viewing the website on a mobile device or tablet, it is recommended that you run a current operating system (OS) on your device, review the privacy/security settings often, and restrict any unnecessary access. If you do not have an unlimited data/text plan, you may incur additional charges.

We are not asking you to make any health decisions based on the use of this mobile web app. You should discuss health decisions directly with your healthcare provider. As with all technology, we ask you to wait until you are in a safe environment, use good judgment and follow prevailing laws. Do not perform study-related activities while you are driving.

Are there benefits to taking part in the study?
If you agree to take part in this study, there may be direct medical benefit to you. We anticipate that the study may improve physical and emotional symptoms—though this cannot be guaranteed. We hope the information learned from this study will benefit other patients.

Will my information be kept confidential?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal

information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Duke University Health System (DUHS). For records disclosed outside of DUHS, you will be assigned a unique code number. The key to the code will be kept in a locked file in Dr. Cox's office.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives of the DUHS Institutional Review Board. The study results will be retained in your research record for at least six years after the study is completed. At that time, either the research information will be destroyed or information identifying you will be removed from such study results at DUHS. While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations. Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name are removed. If your identifying information is removed from your data, we will no longer be able to identify and destroy them.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1. There is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2. You have consented to the disclosure, including for your medical treatment; or
3. The research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

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Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).
You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

What are the costs to you?
There will be no additional costs to you as a result of being in this study.

What about compensation?
You will be reimbursed $20 per completed survey for your time, up to a possible total of $60.

What about research related injuries?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury. For questions about the study or research-related injury, contact Dr. Christopher Cox at 919- 681-7232during regular business hours or contact the Duke operator at 919-684-8111 and ask to have Dr. Cox paged after hours, or on weekends and holidays.

What about my rights to decline participation or withdraw from the study?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. All data that have already been collected for study purposes will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. Nonparticipation or withdrawal from this study will not affect your job status if you are a Duke employee. If you do decide to withdraw, we ask that you contact Dr. Christopher Cox in writing and let him know that you are withdrawing from the study. His mailing address is Duke University, Box 102043, Durham, NC 27707.

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We will tell you about new information that may affect your health, welfare, or willingness to stay in this study. The sponsor or regulatory agencies may stop this study at any time without your consent. The investigators also have the right to stop your participation at any time. If this occurs, you will be notified.

A description of this clinical trial will be available on https://clinicaltrials.gov/ as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Whom do I call if I have questions or problems?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Christopher Cox at 919- 681-7232during regular business hours or contact the Duke operator at 919-684-8111 and ask to have Dr. Cox paged after hours, or on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at 919-668-5111.

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Statement of consent
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____ _____ _____
Signature of Subject Date Time

_____
Printed Name of Subject

_____ _____ _____
Signature of Person Obtaining Consent Date Time

_____
Printed Name of Person Obtaining Consent