Official Title:

Optimizing a Self-directed Mobile Mindfulness Intervention for Improving Cardiorespiratory Failure Survivors' Psychological Distress

Brief Title:

Optimizing a Mobile Mindfulness Intervention for ICU Survivors (LIFT2)

NCT: NCT04038567

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DUKE UNIVERSITY HEALTH SYSTEM

Consent To Participate In A Research Study
Mobile Mindfulness After Critical Illness (LIFT2 Study)

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 determine which version of a mobile mindfulness program is most helpful in improving these symptoms. Involvement in this study requires that a person use a mobile app daily to watch videos and to complete three surveys over the course of three months. Participants will be randomized into one of eight groups. Each group will receive a slightly different version of the mobile app that is accessible from any smart device, such as your phone or tablet. Total study participation is 3 months.

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 ICU 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 an intensive care unit (ICU). 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.

Why is this study being done?
The purpose of this study is to find a better way to help people who have experienced an ICU admission cope with physical and emotional difficulties that can occur following discharge from the hospital.

How many people will take part in this study?
Approximately 320 people will take part in this study at 3 different hospitals and medical facilities, and approximately 125 people will take part at Duke.

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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. After signing and dating this consent form, you will be asked to download the Pattern Health app on your mobile phone and complete a brief series of questions about yourself, your home, and how you were doing prior to your hospital admission. After the completion of this survey, your study coordinator will monitor your progress via your electronic medical record in anticipation of your discharge date.

Once you are discharged from the hospital, you will receive a notification on your mobile phone informing you that you to take a survey. You will take a brief survey that will take about 10-15 minutes to complete. When taking this survey, you will be asked to think about how you have felt over the last week. The purpose of this survey is to determine if you are eligible to continue participation in the study.

If you are not eligible to continue in the study, your participation will at that time and you will not be asked to do anything additional.

However, if you are eligible to continue in the study, you will receive a notification informing you that you have been randomized (like a flip of a coin) to 1 of 8 groups.

Each possible group is defined below; ask your study coordinator to navigate to the URL to review a full description of each group:

- Group 1 Team Introduction, High Dose and Team Help (lift.duke.edu/group1)
- Group 2 App Introduction, High Dose and Team Help (lift.duke.edu/group2)
- Group 3 Team Introduction, High Dose and App Help (lift.duke.edu/group3)
- Group 4 App Introduction, High Dose and App Help (lift.duke.edu/group4)
- Group 5 Team Introduction, Regular Dose and Team Help (lift.duke.edu/group5)
- Group 6 App Introduction, Regular Dose, and Team Help (lift.duke.edu/group6)
- Group 7 Team Introduction, Regular Dose and App Help (lift.duke.edu/group7)
- Group 8 App Introduction, Regular Dose and App Help (lift.duke.edu/group8)

You will then be asked to do the following for the next 4 weeks:

- Watch a weekly video introducing you to that week's mobile mindfulness practice - this takes 10 minutes (Day 1)
- Practice mindfulness by watching a daily video – this takes 6 minutes (Days 2-7)
- Complete 1 weekly survey once a week – this takes 5-10 minutes

After you have completed the daily activities for 4 weeks, you will asked to take one last survey after 3 months. This survey will take about 10-15 minutes to complete.

Depending on the group you are randomly assigned to, you may receive a "Welcome" phone call from our study therapist at the time of the completion of your first survey once you are discharged. Our study

therapist will provide you with information about mindfulness and why it's important to practice it. You can ask any questions you may have of the study therapist, at that time.

Additionally, we want to make sure you stay well and safe during your study participation. As a result, if you begin to feel worse (i.e., more anxious) while participating, our study therapist may call you and talk with you to see if they can help.

Also, some patients after an ICU admission, often experience great ups and downs that lead them to have thoughts of harming themselves. If you begin to feel this way, the study therapist or your study doctor may contact you and talk with you about how you are feeling and provide you with resources to help during this time.

Last, participation in this study requires that you allow the study team (the study doctor and the research coordinators) have access to your electronic medical record (EMR). They would like to document health information related to your ICU admission. Examples of the information they would like to know are listed below:

- Date of ICU admission and date of discharge
- Primary and secondary diagnoses related to the ICU admission
- Additional conditions and problems that may develop as a result of your ICU admission
- Laboratory value results from your standard of care tests
- Medications you are currently taking or may be prescribed as a result of your ICU admission

How long will I be in this study?
Your participation in the study will last approximately 3 months from the time you sign the consent form. You will be asked to complete surveys within the app at three different time points.

- Survey 1: approximately 1 week after returning home.
- Survey 2: approximately 1 month after returning home.
- Survey 3: approximately 3 months after returning home.

Participation in this study is voluntary. If you refuse to participate you will involve no penalty or loss of benefits to which the subject is 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 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.

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We may text or email 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 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 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 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 is not certain. Additionally, we hope the information learned from this study will benefit other ICU 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 secure database behind Duke's firewall.

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.

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.

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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 Cox at 919-681-7232 during regular business hours and at 919-684-8111 after hours, weekends, and holidays and ask that the study doctor be paged.

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.

Additionally, you may be withdrawn from this study without your consent. Reasons for why you may be withdrawn are listed below:

a) At the time of discharge from the hospital you are required to continue in-patient rehabilitation for your illness or injury at the same hospital in which you are currently receiving care or at a different location.
b) At the time of discharge home, but prior to completing your first survey, you are re-admitted to the hospital.
c) At the time of discharge home and after completing the first survey, you are re-admitted to the hospital.

In the last two scenarios, you will have the option to choose to participate in the study again, should you want to.

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.

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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 Cox at 919-681-7232 during regular business hours and at 919-684-8111 after hours, weekends, and holidays and ask that the study doctor be paged.

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.

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		