



DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study

Mobile Mindfulness to Improve Psychological Distress after Critical Illness (LIFT Study)

You are being asked to take part in this research study because you suffered a critical illness and were 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 Center for Complimentary and Integrative Health (NCCIH) will sponsor this study. Portions of **Dr. Christopher Cox's** and his research team's salaries will be paid by this grant. We will recruit participants from Duke University Medical Center (DUMC) over approximately twelve months from the time of study initiation.

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 better ways to help people who have been patients in an ICU 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 200 people will take part in this study at different hospitals and medical facilities. We will recruit approximately 90 participants from Duke University Medical Center (DUMC) over approximately twelve months from the time of study initiation.

What is involved in this study?

If you agree to be in this study, you will be asked to sign and date this consent form. You will be randomly assigned (like drawing straws) to one of three groups. Of the 90 people enrolled, 35 people will be in Group 1, 35 people in group 2, and 20 people in Group 3. You will be told to which group you are assigned. If you are in **Group 1**, you will receive the mindfulness-based training telephone program. This program is a series of 4 short (30 minutes) telephone calls that will be scheduled weekly according to your convenience. During these calls, a trained professional will provide training in mindfulness techniques for stress and symptom management such as relaxation, activity pacing, and communication. If you are in **Group 2**, you will receive the mobile mindfulness training program (mMBT), which is delivered via a website designed for mobile devices. This program will be self-directed via a website accessible from a computer, tablet, or phone. This program will provide training in mindfulness techniques for stress and symptom management such as relaxation, activity pacing, and communication. You will also receive brief weekly surveys to fill out within the website so that we can measure your progress. You will be contacted by our trained interventionists by phone for an initial session and then only as needed depending on your progress or if you request an additional session. If you are in **Group 3**, you will participate in a critical illness education program. You will receive educational handouts and access to videos that provide information about acute respiratory failure. You will also receive 2 brief, check-in calls from a member of our study team to provide additional support and answer any questions.

Those in **all groups** will participate in three telephone interviews and one in-person interview identical in content and timing. In these interviews you will complete questionnaires asking about your mood, anxiety level, and your



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understanding about your medical care. These interviews will take no more than thirty minutes to complete. The interviews will be conducted at enrollment in the hospital and then within 1 week of your arrival home, 6 weeks, and 3 months after you return home from the hospital.

If you are willing, we will audio record certain telephone calls: 1) during the final telephone interview to ask about your impression of the telephone program and its usefulness and 2) during periodic mindfulness training telephone sessions for quality assurance purposes. We will not audio record you if you do not want us to do so.

This recording is purely for research purposes and your identity will be kept completely confidential. No one other than the research team will have access to these recordings. The recordings will be labeled with a unique number. Any link to your name will be kept in a secured file. All personal identifiers will be removed from the audio-recordings at the time of transcription. All recordings will be stored securely (on a password protected computer file on a secure server to which only the researchers associated with the study will have access to). The audio-recordings will be destroyed at the completion of the study. The option to allow this audio recording is completely voluntary and will not affect eligibility to participate in the study. To indicate whether or not you permit these select phone calls to be audio recorded, please initial on the line that best matches your choice:

_____ I agree to be audio recorded during the final telephone interview and during telephone mindfulness training sessions

_____ I DO NOT agree to be audio recorded during the final telephone interview or during telephone mindfulness training sessions.

If you are in **Group 2**, we will be texting you reminders to complete mindfulness sessions or weekly 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

How long will I be in this study?

Your participation in the study will last approximately 6 months from the time you sign the consent form. We will interview you at four different time points:

- Hospital Interview: within 24 hours of enrollment
- Interview 1: approximately 1 week after returning home, either by phone or electronically
- Interview 2: approximately 6 weeks after returning home, either by phone or electronically
- Interview 3: approximately 3 months after returning home, either by phone or electronically

Your participation is voluntary; 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 the study doctor (Dr. Christopher Cox) first.

We will record information from your medical chart such as demographic information, insurance, laboratory test results, and other information relevant to your sickness and treatment. By signing this consent document, you agree to our collection of this information. No travel or additional blood tests or x-rays are required of you. If you do not want to participate in this study, there will be no penalty or loss of benefits to which you are entitled.



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What are the risks of this study?

There are no known physical risks associated with this study. There is, however, 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 or cause emotional distress. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

Because e-mail and text messages do not provide a completely secure and confidential means of communication, please do not use email or text messages if you wish to keep your communication private. Instead, please let us know and we will communicate with you only through regular channels like the telephone.

The website used in this study is developed by an outside party specifically for use in this study. As with any website that you visit 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 website. 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 this study?

If you agree to take part in this study, there may be no direct medical benefit to you. Your responses to the surveys and interviews will not affect the clinical care you receive. If you are in any Group, we anticipate that the study may reduce distress and improve your satisfaction with your ICU care, the communication you have with doctors, and possibly the process of recovery after critical illness—though this is not certain. We hope the information learned from this study will benefit other persons who receive care in an ICU in the future.

Are there alternatives to taking part in this study?

You are free to choose not to participate in this study. You will continue to receive regular clinical care regardless of whether or not you choose to participate.

Will my information be kept confidential?

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 or for your care, 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 securely at DUHS.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives of the DUHS Institutional Review Board. If this group reviews your research record, they may



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also need to review your entire medical record. The study results will be retained in your research record for at least six years after the study is completed, with the exception of the audio recordings, which will be destroyed at the completion of the study. At that time either the research information not already in your medical record will be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

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. This information may be further disclosed by the sponsor of this study, the National Center for Complimentary and Integrative Health (NCCIH). If disclosed by the sponsor, the information is no longer covered by the federal privacy regulations. 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.

What are the costs?

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

What about compensation?

If you are in **Group 1**, you will receive \$25 for each post-discharge interview completed and \$75 for completing all mindfulness sessions for a total of \$150.

If you are in **Group 2**, you will receive \$25 for each post-discharge interview completed and \$50 for completing the mindfulness sessions and \$25 for completing the weekly surveys for a total of \$150.

If you are in **Group 3**, you will receive \$25 for each post-discharge interview completed and \$25 for completing all education telephone sessions for a total of \$100.

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. Cox at 919-681-7232 during regular business hours and at 919-358-6451 after hours, 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. 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.

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 address is DUMC, Division of Pulmonary and Critical Care Medicine, Box 102043, Durham, NC 27710. We will tell you about new information that may affect your health, welfare, or willingness to stay in this study. Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. Reasons why



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this might occur include significant emotional distress or anxiety caused by the study procedures. If this occurs, you will be notified and your study doctor will discuss other options with you.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website 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 919-681-7232 during regular business hours and at 919-358-6451 after hours, 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