

Informed consent form / Duke University site

Addressing Psychological Distress Symptoms Among Serious Illness Survivors of a Viral
Pandemic With a Completely Self-directed, Symptom-responsive Mobile Mindfulness
Intervention: a Randomized Controlled Trial

ClinicalTrials.gov identifier: NCT04581200

Institutional Review Board identifier: Pro00106306, version 07/19/2021

A. Background, purpose, procedures

I just noticed that based on your survey responses, you're eligible for a new research study called Lift that is funded by the National Institutes of Health and being conducted by Duke University, the University of Colorado, Oregon Health & Sciences University, and the University of Michigan. Lift is a study for patients who have been hospitalized from COVID-19. The Lift study is testing a mobile app that's designed to address common problems related to COVID illness like high levels of stress and physical symptoms like pain, fatigue, and breathlessness—problems that make it harder to get back into the swing of family life, work, or school. Lift may help people use mindfulness to manage their reactions, emotions, and attitudes. Mindfulness is simply the practice of training the mind to be more aware of the negative ways we often react to thoughts and symptoms. Mindfulness has been used by professional athletes, the military, and even school aged children to improve well-being and quality of life.

This study is being conducted because although many people have been impacted by COVID, there are few easily accessible resources to help people after leaving the hospital. Your participation will help to determine if LIFT helps people to recover faster and more completely. If it does, Lift could represent a way for many hundreds of thousands of people across the country who are struggling with COVID. But first we have to do a research study to determine if this is the case.

If you agree to participate, you'll be randomly assigned (like flipping a coin) to either the LIFT program or traditional care.

- If you are in the LIFT group, you'll receive an email with a link to download the free Lift mobile app on your phone. You'll be asked to use the app for 1 month to practice mindfulness for 5 minutes a day. Once a week, you'll complete a single 2-minute survey.
- If you are in the traditional care group, you will have no required app activities. But when you finish the study, you'll receive an email that provides access to the LIFT mobile app.

You don't need to provide any medical information for the Lift study in addition to the BLUE CORAL telephone surveys that are already planned for 2 and 5 months from now. To see whether the Lift app or traditional care work better, the Lift team will analyze your BLUE CORAL survey data. These data will be transferred to Duke without identifiers from the BLUE CORAL teams at the Massachusetts General Hospital and at the University of Michigan through a secure password-protected data system located on a Duke University server. To access the Lift app and ensure that only you can access it, you need to provide your date of birth and phone number.

Would you be interested in hearing a little more about the Lift study?

No > Thanks for your time. If you change your mind, please check out Lift.duke.edu to learn more and see how to contact us.

Yes > Great!
[Continue]

B. Risks or discomforts

There are no known physical risks associated with this study. There is a very small chance that this study could increase emotional distress.

The mobile app used in this study was developed by Pattern Health (Durham, NC) 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. However, if you run a current operating system on your device, review the privacy/security settings often, and restrict any unnecessary access, this risk is very small.

We are not asking you to make any health decisions based on the use of this mobile app. Please use good judgment and follow prevailing laws. Do not perform study-related activities while you are driving, only in a safe environment.

C. Benefits

If you agree to take part in this study, there may be direct medical benefit to you such as improving physical and emotional symptoms—though this is not certain. We hope the information learned from this study will benefit other COVID patients.

D. Alternative procedures

You can choose to not participate and continue receiving your normal standard of care.

E. Confidentiality and data security / safety

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential as required by law and safeguarded by Federal Privacy Regulations, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals who are conducting, funding, or regulating the study. However, we will share only the minimum necessary information in order to conduct the research.

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) including during reporting of study results. The study results will be retained in your research record for at least six years and then either destroyed or have your identifying private information removed.

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.

F. Compensation

You will receive \$20 per survey you complete for the Lift study, up to \$60 to compensate you for your time. This is in addition to the compensation you receive for the BLUE CORAL study.

G. Whom to contact

For general questions about the study, contact Dr. Christopher Cox at 919-681-7232 during regular business hours and at 919-684-8111 after hours or email him at LiftCOVID@duke.edu.

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

H. Voluntary statement

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 by notifying the study team by phone or email (liftcovid@duke.edu). 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.

Do you have any questions about the study?

[Note FAQ section]

Do you agree to participate in this research study?

No > Thanks for your time. If you change your mind, please check out Lift.duke.edu/COVID to learn more and see how to contact us.

Maybe > Sounds like you might need a little time to think about it. What would be a good time and phone number where we could call you back in the next couple of days? Also, please check out the study informational video at Lift.duke.edu/COVID.

Yes > Great! We will send you an email today or tomorrow that describes what group you will be in and how to access any study activities you need to get started. Thanks so much.

Would you prefer if we email or mail you a copy of your informed consent document?

[Note choice]

FAQs

What is mindfulness?

Mindfulness is simply the practice of training the mind to be more aware in an open, non-judgmental way. It can help to change the negative ways we often react to thoughts and symptoms—and control our emotions and attitudes much better.

Is the mobile app secure?

The Lift mobile app meets all standards for digital security at Duke University. You can set up touch ID if you like. The Lift app was developed by researchers at Duke and mobile app developers (Pattern Health) located in Durham, NC.

Does the Lift study conflict with BLUE CORAL—and do the BLUE CORAL study teams approve it?

The National Institutes of Health fund both Lift and BLUE CORAL. Investigators work on both studies. It is perfectly fine to do both studies.