Consent

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

Title: Project UPLIFT to Reduce Anxiety and Depression in Cystic Fibrosis (CF) Patients

VCU IRB NO.: HM20002923

Principal Investigator: Michael S. Schechter, MD, MPH

If any information contained in this consent form is not clear, please call our research coordinator at (804) 628-4967 to explain any information that you do not fully understand. We can mail you a copy of this consent form to you so that you can discuss the study with family or friends before making your decision.

Introduction

You are being asked to take part in a research study because you are a cystic fibrosis patient 18 years of age or older who has screened positive for mild or elevated anxiety and/or depression. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study. The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

• Please carefully read this form or have it read to you

• Please listen to the study staff explain the study to you

• Please ask questions about anything that is not clear

You can keep a copy of this consent form. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

Study Overview

The purpose of this study is to find out if a program to manage depression and anxiety among people with CF using the internet can be done without major problems, if people with CF like taking part in the program, and if it is effective.

For this study, you may or may not be asked to volunteer to take part in a group that receives a program to manage depression and anxiety among people with CF. No matter if you are asked to do so or not, if you have symptoms of anxiety or depression that should be treated the CF care team will recommend that you get that treatment outside of the study. You are being asked to volunteer to take part in this study because you were identified by one of the CF team members at the VCU Cystic Fibrosis (CF) Center as someone who has CF and meets the other criteria to take part in the study. This is a multicenter study in which a total of about 70 people are being asked to volunteer for the study program. Other participating CF centers include Women's and Children's Hospital of Buffalo, Boston Children's/Brigham and Women's Hospital, the University of Michigan Cystic Fibrosis Center, Johns Hopkins Medical Institute, and Cincinnati Children's Hospital Medical Center..

Procedures

If you choose to take part in the study, you will be randomly assigned to an intervention group or a treatment-as-usual control group. The treatment-as-usual control group will be referred to a clinical social worker and/or psychologist with recommendations regarding the advisability of obtaining mental health services. The intervention group will participate in Web based group mental health counseling.

Assignment to a group will be done by chance, for example, by drawing a number out of a hat. Each study group will have 6-8 people in it.

If you are randomly selected to participate in the treatment group you will be asked to take part in a 1-hour group program session each week over the internet. Sessions may be monitored live or via audio or video recording by Dr. Robin Everhart, a Virginia-licensed psychologist. Recordings of sessions will be used for safety purposes only and will be destroyed after review. You will also have some on-your-own practice between sessions which will mainly be to do some reading. You should expect to spend around 2 total hours each week on the program.

At the start of the study, at the end of the 8-week program, 6 months later, and 12 months later, you will take surveys over the internet or on paper (4 total times). These surveys will ask questions about CF, depression, anxiety, and some questions about yourself. A member of the research team will contact you to let you know when and how to complete the survey. These surveys will take about 45 minutes, in total, to complete at each time point.

If you assigned to the treatment group, the groups will be led by another person with CF as well as a graduate student in psychology. The study groups will cover different topics including CF, depression, anxiety, self-esteem, goal-setting, and decision making.

In order to protect the privacy of group members, only participants enrolled in the program should be present in the room during intervention sessions. Speaking and writing in response to discussion and other parts of the intervention is restricted to participants only. Also, to maintain privacy, only one person per household can participate in the program.

Risks and Discomforts

A potential risk from participating in this study is that sometimes people feel sad or anxious when they talk about depression and anxiety. These feelings usually are not severe and do not last very long. If the problem does not go away, you will be referred for treatment. A potential risk of being in the group is that others in the group and the group leader will know that you have CF and some symptoms of depression and/or anxiety. If you do not want others to know that you have CF or symptoms of depression and/or anxiety, you should not take part in the study. At the beginning of a group, we will ask that people in the group not tell others outside the group the names or identifying information about people in the group. It is possible that some participants may experience stress from using the technology used for the groups.

New Information

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Use and Disclosure of Protected Health Information

Authority to Request Protected Health Information

The following people and/or groups may request my Protected Health Information:

• Principal Investigator and Research Staff • Study Sponsor

• Research Collaborators • Institutional Review Boards

• Data Safety Monitoring Boards • Government/Health Agencies

• Others as Required by Law

Authority to Release Protected Health Information

The VCU Medical Center (VCUMC) may release the information identified in this authorization from my medical records and provide this information to:

• Principal Investigator and Research Staff • Study Sponsor

• Research Collaborators • Institutional Review Boards

• Data Safety Monitoring Boards • Government/Health Agencies

• Others as Required by Law • Data Coordinators

• Health Care Providers at the VCUMC

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

Type of Information that may be Released

The following types of information may be used for the conduct of this research:

• Complete health record • Diagnosis & treatment

• History and physical exam • Laboratory test results

• Progress notes • Information about psychiatric care

• Information about drug or alcohol abuse

Uses of Your Protected Health Information

The purpose of this research study is to find out if a program to manage depression and anxiety among people with CF using the internet can be done without major problems, if people with CF like taking part in the program, and if it is effective Your health information as shown above will be used for the following reasons:

• To determine if you meet the requirements to be a participant in this study • To be able to conduct the study

• For safety monitoring

Expiration of This Authorization

This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

Right to Revoke Authorization and Re-disclosure

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator named above or in the Informed Consent document.

Benefits

Taking part in this study may not benefit you personally, but the researchers may learn new things that will help other people with CF. If the program is effective, you may benefit by learning new skills and having your mood improve. Society will benefit through the development of an effective program to manage depression and anxiety among people with CF. Your symptoms of depression and/or anxiety may improve while you are in this study but they may not, and they may even get worse. The study results may be used to help others in the future.

Costs

There will be no costs to you for participating in this study. You will not be charged for any of the research activities.

Compensation

You will receive $25 for each program session you take part in and an additional $100 if you attend at least 7 out of the 8 weekly sessions (if you are randomly assigned to the UPLIFT program group), and $25 for each group of assessments you complete (regardless of what group

you are assigned into), in the form of checks. The checks will be mailed to you approximately two weeks after we receive completed payment forms from you. Attendance for each program session is defined as logging in during the weekly group video conferences. If you complete the surveys at all four time points, you will receive $100 in total. Additionally, if you are assigned to the UPLIFT program group and complete all eight sessions you will receive $300. We will need to obtain your address and social security number in order to send you checks.

Other Treatment outside this Study

You do not have to be in this study to be treated for symptoms of depression or anxiety. If you decide not to enter this study, there is care available to you outside of this research. We can make sure you are referred to a mental health professional for treatment. The study staff will discuss this with you.

Confidentiality of Data

Each time you complete one of our surveys, we are collecting data from you. Although no questions are expected to be particularly sensitive or intrusive, your individual answers will not be shared with anyone or recorded in a manner so your answers can be attributed back to you.

Your data will be identified by ID numbers, not names, and stored separately from your contact information in a password-protected electronic document. All personal identifying information will be kept in password-protected files and these files will be deleted approximately one year after the study ends. De-identified data will be kept indefinitely. Access to all data will be limited to study personnel; though de-identified data may be made available to other researchers in the future if requested. A data and safety monitoring plan is established.

Group video conferencing sessions may be audio taped for the purposes of safety monitoring. These recordings will only be available to select members of the study team, and the recordings will be destroyed at the end of the 8-week program. At the beginning of the session, all members will be reminded that they are not required to share their names.

We will not tell anyone the answers you give us; however, information from the study and information from your medical record and the consent form submitted by you may be looked at or copied for research or legal purposes by the sponsor of the research, the Cystic Fibrosis Foundation, or by Virginia Commonwealth University. Personal information about you might be shared with or copied by authorized officials of the Department of Health and Human Services or other federal regulatory bodies.

If, as part of this research, we learn about real or suspected child or elder abuse, the law says that we have to let people in authority know so they can protect the person(s) at risk. Additionally, if something we learn through this research indicates that you may intend to harm yourself or others, we are obligated to report that to the appropriate authorities, and you will be contacted by the supervising clinical psychologist.

What we find from this study may be presented at meetings or published in papers, but your name will not ever be used in these presentations or papers.

In general, we will not give you any individual results from the study. If we find something of medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

In the future, identifiers might be removed from the information you provide in this study, and after that removal, the information could be used for other research studies by this study team or another researcher without asking you for additional consent.

Withdrawal from the Study

You have the right to leave a study at any time without penalty. Your participation is completely voluntary and you have the right to refuse to be in this study. This decision will not affect in any way your current or future medical care or any other benefits to which you are otherwise entitled.

The researchers and VCU also have the right to stop your participation in this study without your consent if:

• They believe it is in your best interest;

• You were to object to any future changes that may be made in the study plan; or if you do not follow study instructions.

Should you choose to withdraw from the study, the researchers will remove your contact information and data from the study databases. However, data that has already been included in analyses cannot be withdrawn.

Contact Information

Contact Michael S. Schechter at 804-828-9960 or Andrea Molzhon at 804-628-4967, or by mail to 1000 East Broad Street, P.O. Box 980270, Richmond, VA 23298-0270:

• if you have any questions about this study or your part in it,

• if you feel you have had a research-related mental health concerns,

• if you have questions, concerns, or complaints about the research.

Contact the VCU Office of Research at 804-827-2157.

• if you have questions about your rights as a research participant.

• if you have questions, concerns, or complaints about the research.

If you are a patient receiving care at Virginia Commonwealth University and have a question about your rights, please contact:

Office of Research, Virginia Commonwealth University

800 East Leigh Street, Suite 3000

P.O. Box 980568

Richmond, VA 23298

Telephone: (804) 827-2157

Contact this number for general questions, concerns or complaints about research. You may also call this number if you cannot reach the research team or if you wish to talk with someone else. General information about participation in research studies can also be found at http://www.research.vcu.edu/irb/volunteers.htm.

* must provide value

1) I have been given the chance to read this consent form. I understand the information about this study. Questions that I wanted to ask about the study have been answered. I certify that I am willing to participate in this study.

* must provide value

2) Please type the information into the space provided if you agreed above:

Your Full Name

Agree

Disagree, I do not wish to participate in the study.

reset

3) Date:

* must provide value

XX-XX-20XX M-D-Y

Today

4) Are you 18 years of age or older?

* must provide value

I am 18 or older.

I am younger than 18.

Submit

Save & Return Later