STUDY TITLE: Effect of Bright Light Therapy on Depression Symptoms in Adult Inpatients with Cystic Fibrosis (CF) or Chronic Obstructive Pulmonary Disease (COPD)

Informed Consent Form

NCT Number: NCT04921332

12/28/2021

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Consent to Act as a Participant in a Research Study

STUDY TITLE: Effect of Bright Light Therapy on Depression Symptoms in Adult Inpatients with Cystic Fibrosis (CF) or Chronic Obstructive Pulmonary Disease (COPD)

PRINCIPAL INVESTIGATOR: [redacted]

CO-INVESTIGATORS: [redacted]

SOURCE OF SUPPORT: No sources of support to disclose.

QUESTIONS ABOUT THE STUDY:

- If you have any questions about your rights as a research subject or wish to talk to someone other than the research team, please call the University of Pittsburgh Human Subjects Protection Advocate toll-free at 866-212-2668.
- You can contact the study investigator if you have any questions about the study, concerns, or complaints. Contact Principal Investigator, Erica Osborn at 814-282-9793 or elo25@pitt.edu.

INTRODUCTION: This study is looking at the effect of light therapy on symptoms of depression in adults who have cystic fibrosis or chronic obstructive pulmonary disease. You are being asked to participate because you

1. are an adult (18 or older)
2. are diagnosed with cystic fibrosis or chronic obstructive pulmonary disease
3. have symptoms of depression according to a test called the "Beck Depression Inventory."
4. Are admitted to UPMC Presbyterian pulmonary unit.

The approximate number of subjects to be enrolled at UPMC Presbyterian is 30. The length of time will be from the time of enrollment up until discharge with a goal of at least seven days.

RESEARCH ACTIVITIES:
If you agree to be in this study, we will ask you to do the following things:

1. Provide answers to the 15-item "Mood Disorder Questionnaire" test.
2. Have a light therapy session every day for seven days while you are in the hospital. This involves using a device called a "Verilux" that looks like a computer tablet, about 7 by 9 inches. We will ask you to focus on having the device pointed towards you, but not looking directly at it for about 30 minutes. The device projects light that is similar to sunlight. The study team will provide you with the Verilux device. When you complete the study, you will be asked to return the device to the study team or your nurse.

The device is not approved by the United States Food and Drug Administration. It is available in stores without a prescription.

3. After seven days of therapy, we will ask you to repeat the Beck Depression Inventory test that you completed prior to signing this consent. If you are discharged prior to completing the repeat Beck Depression Inventory test, you may be contacted via phone by a study team member and administered the inventory verbally.

STUDY RISKS:

Using the Verilux light box can result in:

- Eyestrain
- Headache
- Nausea
- Irritability or agitation

There is a risk that someone could see your private information that is not authorized. This is called a "Breach of confidentiality." We try to prevent this from happening by the actions described below in the **Privacy and Confidentiality** section.

Note: if you, at any time during the study have feelings that you are very depressed, and have thoughts of hurting yourself, we ask that you tell the study team or your clinical care nurse immediately. We want to be sure you have the proper care.

STUDY BENEFITS:

There is a potential that light therapy could improve your mood and feelings of depression.

NEW INFORMATION: You will be promptly notified if any new information we learn during this research study may cause you to change your mind about continuing to participate in the study.

PRIVACY (Person) and CONFIDENTIALITY (Data):

All data collected will have your name or anything that identifies you removed. It will be replaced with a random ID code for each participant. The document that connects your name to your unique ID will be held securely by the study principal investigator.

Those who will have access to either research or medical records include:

- University of Pittsburgh Office of Research Protections
- UPMC hospitals or other affiliated health care providers

Data produced from this project may be shared with investigators conducting research on a similar topic within the University of Pittsburgh and outside. Shared information from this project will be de-identified.

Paper formatted data collection will be stored in a locked file in a locked office in the School of Nursing. These documents will only be accessible to those involved in the study.

- Per University of Pittsburgh policy, all research records must be maintained for at least 7 years following final reporting or publication of a project.

HIPAA Authorization

The study team is requesting your permission to collect and store information from your medical record for the purpose of confirming you are eligible and completing this study. This includes your name, CF diagnosis, and noting that you do not have any eye conditions, use of steroids, or other medical issues that would make you ineligible for the study. We will not enter anything in your medical record.

We will store this information for at least 7 years. Your permission does not expire. The data is available for as long as it takes to complete the study.

Other people who may view your medical record information, besides the study team, includes:

- University of Pittsburgh Office of Research Protections
- UPMC hospitals or other affiliated health care providers
- The United States Food and Drug Administration

If you do not give permission to use your medical records, you cannot be in the study.

WITHDRAWAL FROM STUDY PARTICIPATION:

- You can, at any time withdraw from this research study; you can also withdraw your authorization for us to use your identifiable medical information for the purposes described above. This means that you will also be withdrawn from further participation in this research study. Any identifiable research or medical information obtained as part of this study prior to the date that you withdraw your consent will continue to be used and disclosed by the investigators for the purposes described above.

1. To formally withdraw from this research study, you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form. Your decision to withdraw from this study will have no effect on your current or future relationship with the University of Pittsburgh.

2. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

The bright light lamp that is issued to you must be returned when you withdraw.

Investigator removes subject from study:

It is possible that you may be removed from the research study by the researchers if, for example, your primary doctor or medical team requests that bright light therapy be terminated for any reason.

If you are withdrawn from participation in this research study, no follow-up will be required for safety reasons; however, if your participation spanned greater than 48 hours, you may be asked to complete a post-bright light therapy depression inventory.

FDA CLINICAL TRIAL REGISTRY

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by US 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.

COSTS

There are no costs to you for participating in this study. The Verilux device will be provided to you while you are in the study.

PAYMENT

You will not be paid to participate in this study.

COMPENSATION FOR INJURY:

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not, however, waive any legal rights by signing this form.

VOLUNTARY PARTICIPATION:

Your participation in this research study is entirely voluntary. You may want to discuss this study with your family and friends and your personal physician before agreeing to participate. If there are any words you do not understand, feel free to ask us. The investigators will be available to answer your current and future questions.

Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

CONSENT TO PARTICIPATE:
The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given.

I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that occurred during my participation. By signing this form, I agree to participate in this research study and authorize the use and sharing of my medical records. A copy of this consent form will be given to me.

SUBJECT SIGNATURE

_____
Printed Name of Participant

_____ _____
Participant's Signature Date

INVESTIGATOR CERTIFICATION:
I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____
Printed Name of Person Obtaining Consent Role in Research Study

_____	_____
Signature of Person Obtaining Consent	Date