Title: Capnography-Assisted Learned Monitored (CALM) Breathing Therapy for COPD

Investigator: Annamaria Norweg, PhD

NCT04786184

Unique Protocol ID: AAAT8556

ICF (Approved November 11, 2022)

Columbia University Consent Form

Protocol Information

Attached to Protocol: IRB-AAAT8556
Principal Investigator: Annamaria Norweg (amn2212)
IRB Protocol Title: Capnography-Assisted Learned, Monitored (CALM) Breathing Therapy for COPD

General Information

Consent Number: CF-AACP8650
Participation Duration: 4 months
Anticipated Number of Subjects: 65

Key Information:

CALM Breathing is a mind-body intervention that uses breathing biofeedback (of ETCO2, RR, and breath flow) and tailored breathing exercises targeting dyspnea and anxiety symptom relief, increased physical activity levels, and improved PR use. CALM Breathing was developed to provide a bridge and help patients transition to pulmonary rehabilitation. The 4-week (1-hour, twice weekly) CALM Breathing is implemented by rehabilitation clinicians before pulmonary rehabilitation.

Contacts

Contact	Title	Contact Information
Annamaria Norweg	Principal Investigator	Phone: 212-305-1651 Email: amn2212@cumc.columbia.edu

Detailed Information on Research

INTRODUCTION

The purpose of this form is to give you information to help you decide if you want to take part in a research study. This consent and HIPAA authorization form includes information about:

- why the study is being done;
- the things that you will be asked to do if you are in the study;
- any known risks involved;
- any potential benefit;
- options, other than taking part in this study, that you have; and
- the way your health information will be used and shared for research purposes.

The principal investigator (the lead researcher for this project) or a research assistant will discuss the study with you. If at any time you have questions about the study, please ask a member of the study team. Take all the time you need to decide whether you want to take part in this research study.

The purpose of this research is described below.

WHAT INFORMATION IS ON THIS FORM?

This consent and HIPAA authorization form is written to address a research subject. We are asking you to take part in a research study. This form explains why we are doing this study and what you will be asked to do if you choose to be in this study. It also describes the way we (Researchers) would like to use and share information about you.

Please take the time to read this form. We will talk to you about taking part in this research study. You should ask us any questions you have about this form and about this research study. You do not have to participate if you don't want to.

WHY IS THIS STUDY BEING DONE?

We are doing this research study to find out if a new, experimental breathing therapy, called Capnography-Assisted Learned, Monitored (CALM) Breathing, is feasible and acceptable for adults with chronic obstructive pulmonary disease (COPD). We also want to find out if CALM Breathing can relieve shortness of breath and other symptoms such as stress, improve quality of life, and improve participation in pulmonary rehabilitation.

We are asking you to participate in this research because you have chronic obstructive pulmonary disease and have been referred for pulmonary rehabilitation.

Before agreeing to participate in this study, it is important that you read this form and talk with the research staff. You should only take part in this study if you want to. This form will explain why we are doing the research and what will happen to you if you are in this research study. We would like to discuss the study and review this form with you. You can ask questions at any time before, during or after our discussion. You will also have time to read this form and ask any questions about the research study. At the end, we will ask you to sign this form if you agree to participate.

It is okay to ask questions about what we are telling you. If you do not understand something, just ask us. We want you to ask any time you think of a question.

In this research study, we want to learn more about chronic obstructive pulmonary disease and the benefit of a new breathing therapy and rehabilitation approach.

There will be about 65 people participants in this study in total at this site.

WHAT WILL I BE ASKED TO DO IF I CHOOSE TO BE IN THIS STUDY?

Study Visits at Week 0, ~Week 5 - 6, ~ Week 17 (2-hours): We will ask you to come to the Georgian Building, 617 W. 168th St, 3rd Floor, New York, NY 10032. We will ask you to complete questionnaires to evaluate shortness of breath, symptoms, mood, daily physical activity levels, awareness of internal bodily sensations, and quality of life. We will ask you to provide some personal information, such as your age, gender, marital status, and education. A six-minute walk test (6MWT) will evaluate how far you can walk back and forth in a hallway while your vital signs and symptoms are closely monitored. We will also measure your lung function as well as carbon dioxide levels and the respiratory rate of your exhaled breath. We will get information from your medical records such as past medical history (e.g. smoking status and medications). We will also ask you to participate in approximately a 30-minute in-person or remote interview with a psychologist on our research team. We will ask you to wear a wrist-worn sleep/physical activity monitor for 7 consecutive days and nights, and a night pulse oximeter for 1 additional night to objectively measure sleep. We will provide a sleep diary as well.

Study Evaluation Visits 2 and 3: ~ Week 5 and ~ Week 17 (2-hours): Questionnaires will again be used to re-evaluate shortness of breath, symptoms, mood, daily physical activity levels, awareness of internal bodily sensations, quality of life, treatment satisfaction, demographic information, and medical history (e.g. smoking status and medication). A 6MWT will evaluate how far you can walk back and forth in a hallway for 6 minutes while your vital signs and symptoms are closely monitored. We will measure your lung function, as well as carbon dioxide levels and the respiratory rate of your exhaled breath. We will ask you to wear a wrist-worn sleep/physical activity monitor for 7 consecutive days and nights, and a night pulse oximeter for 1 additional night to objectively measure sleep. We will provide a sleep diary as well. You will also participate in a 20 – 30 minute interview about your experience participating in CALM Breathing and/or pulmonary rehabilitation.

CALM Breathing Intervention: If you are assigned by chance to receive CALM Breathing, you will receive this intervention before you begin pulmonary rehabilitation. CALM Breathing consists of a total of eight therapy sessions, which are each 1-hour long and implemented twice per week for a total of 4 weeks. These sessions will be conducted in the PACE Lab in the Georgian Building, 617 W. 168th St, 3rd Floor, New York, NY 10032. The first session will introduce the CALM Breathing therapy program and involve evaluating your breathing using a capnograph monitor. At the first visit, we will also conduct an initial interview and manual assessment of your breathing muscle function. CALM Breathing sessions involve 10 tailored breathing exercises, a computer feedback display of your breathing pattern, and homework exercises. At home, you will use a small respiratory rate monitor, audio exercises, and a paper log to assist you with your home breathing exercises. You will also use a breathing app on your mobile phone to record your breathing exercises and monitor your breathing rate.

If you are not assigned to receive CALM Breathing, you will wait as usual approximately 4 – 6 weeks for your pulmonary rehabilitation program (as part of standard care) to begin.

Pulmonary Rehabilitation: At approximately 6 weeks after enrolling in this study, all participants will participate in the standard, outpatient pulmonary rehabilitation program at New-York Presbyterian Hospital.

Permission for future contact: The researchers may want to contact you in the future to invite you to participate in other research. Please initial below to show whether or not you give permission for future contact.

_____ (initial) I give permission to be contacted in the future for research purposes.

_____ (initial) I give permission to be contacted in the future for information relating to this study.

AUDIO/VIDEO RECORDING OR PHOTOGRAPHY

We are asking for you to allow recording procedures such us to audiotape (voice recording) and videotape (video recording) you during CALM Breathing sessions as part of the research study. The recording(s) will be used for analysis by the research team, as well as possible use as a teaching tool to those who are not members of the research staff (i.e., for educational purposes). The recordings may include full facial pictures. The recording(s) will be stored in a password protected database. The recordings will be retained indefinitely.

Risks

There is a small risk that questions about your shortness of breath or mood may cause you to feel uncomfortable or nervous. You may refuse to answer any question that makes you feel uncomfortable. There is also a small risk that the breathing exercises may cause you some discomfort, shortness of breath, or nervousness. Walking during six-minute walk tests may make you feel uncomfortable or tired. There is also a risk of falling, developing joint pain, chest pressure, or shortness of breath during the walk tests. The research may also involve risks that are currently unforeseeable.

Other Risks
There is also a chance that people not connected with this study may learn your identity or personal information.

Benefits

CALM Breathing is an experimental therapy. For this reason, we do not know if it will help your COPD. However, there is a chance the techniques may help relieve shortness of breath and other symptoms, improve chest mobility, reduce fear, anxiety, and stress, and improve quality of life and your participation in your pulmonary rehabilitation program.

Future patients may also benefit from the information we learn from this study.

Alternative Procedures

You may choose not to take part in this research study.

Confidentiality

Any information collected during this study that can identify you by name will be kept confidential. We will do everything we can to keep your data secure, however, complete confidentiality cannot be promised. Despite all of our efforts, unanticipated problems, such as a stolen computer may occur, although it is highly unlikely.

Your data, questionnaire responses, and health information will be assigned a code number, and separated from your name or any other information that could identify you. The research file that links your name to the code number will be kept in a locked file cabinet and in a password-protected computer, and only the investigator and study staff will have access to the file.

The following individuals and/or agencies will be able to look at and copy your research records:
- The investigator, Columbia University Medical Center and NewYork-Presbyterian Hospital study staff and other medical professionals who may be evaluating the study;
- Authorities from Columbia University and NewYork-Presbyterian Hospita, including the Institutional Review Board ('IRB');
- Researchers on our study team from New York University - coded, electronic data will be shared via secure Columbia email for study tracking and data analyses;
- The Office of Human Research Protections ('OHRP'); and
- National Institutes of Health, including persons or organizations working with or owned by the sponsor.

Any research information that is shared with people outside of Columbia University Medical Center and NewYork-Presbyterian Hospital will not include your name, address, telephone number or any other direct identifier unless disclosure of the information is required by law or you have authorized the disclosure.

Your authorization to use and share your health information expires at the end of your study participation.

You may change your mind and revoke (take back) this consent and authorization at any time and for any reason. To revoke this consent and authorization, you must contact the Principal Investigator, Anna Norweg at amn2212@cumc.columbia.edu. However, if you revoke your consent and authorization, you will not be allowed to continue taking part in the Research. Also, even if you revoke this consent and authorization, the Researchers and the Sponsor may continue to use and disclose the information they have already collected.

If you choose to take part in this study, you are giving us the authorization (i.e. your permission) to use the protected health information and information collected during the research that can identify you. The health information that we

may collect and use for this research may include medical information that may be considered sensitive.

To help us protect your privacy, we received a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, we cannot be forced to provide information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. We will use the Certificate to resist any demands for information that would identify you, except as explained below.

Identifiers might be removed from the identifiable private information and, after such removal, the information could be used for future research studies for future research studies without additional informed consent.

Compensation

You will receive $50 at each evaluation visit. If you choose to leave or are withdrawn from the study for any reason before finishing the entire study, you will be paid for the evaluation visit that you complete. If you complete all study evaluation visits, you will receive $150 for being in this study.

In addition, if you are assigned by chance to receive CALM Breathing therapy, we will reimburse you up to $30 per visit for reasonable travel and parking expenses (for up to $240 for eight therapy sessions).

Additional Costs

TTaking part in this study will not involve additional costs to you. You and/or your insurance company will have to pay for any costs that are part of your regular medical care.

Voluntary Participation

Voluntary participation

Taking part in this study is your choice. You can decide not to take part in or stop being in the study at any time. Your choice will not affect the treatment you receive from doctors and staff at Columbia University Medical Center and NewYork-Presbyterian Hospital.

Termination of participation by investigator

You should know that we will not let you participate in the study any more if you have not followed study instructions, or the principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision. In addition, your participation will end if the investigator or study sponsor stops the study earlier than expected.

Additional Information

ClinicalTrials.gov Website

A description of this clinical trial will be available on http://www.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.

Statement of Consent

Statement of consent and HIPAA authorization

I have read this consent form and HIPAA authorization. The research study has been explained to me. I agree to be in the research study described above. A copy of this consent form will be provided to me after I sign it. By signing this consent and HIPAA authorization form, I have not given up any of the legal rights that I would have if I were not a participant in the study.

Signatures

Participant Signature Lines

Study Participant

Print Name _____ Signature _____

Date & Time _____

Research Signature Lines

Person Obtaining Consent

Print Name _____ Signature _____

Date & Time _____