Document finalized: 8/20/2024

Pilot Development and Biomarker Engagement of a Singing Intervention for Chronic Obstructive Pulmonary Disease (COPD)

Protocol # 00160422

NCT # Pending

Sponsor: KUMC Department of Internal Medicine

Investigator: Rebecca Lepping, PhD
3805 Eaton Street
University of Kansas Medical Center
913-588-0287

RESEARCH CONSENT FORM

Pilot Development and Biomarker Engagement of a Singing Intervention for Chronic Obstructive Pulmonary Disease (COPD)

Protocol # 00160422

Sponsor: KUMC Department of Internal Medicine

Investigator: Rebecca Lepping, PhD
3805 Eaton Street
University of Kansas Medical Center
913-588-0287

Key Information: You are being invited to consider a research study. Research studies are always voluntary. The first section of this form is a short summary of the study. Please also read the Detailed Information that follows this summary before you make your decision.

Why are people interested in joining your study?
• To learn if singing/vocalizing can help improve lung function for people with COPD
• Free monitoring of lung health with CT imaging and pulmonary function testing
• Singing is fun

How does this study differ from their other options?
• This study will use singing/vocalizing with music as a potential therapy for COPD to improve breathing. Usually, pulmonary rehabilitation uses exercise on a stationary bike or treadmill or breathing exercises.

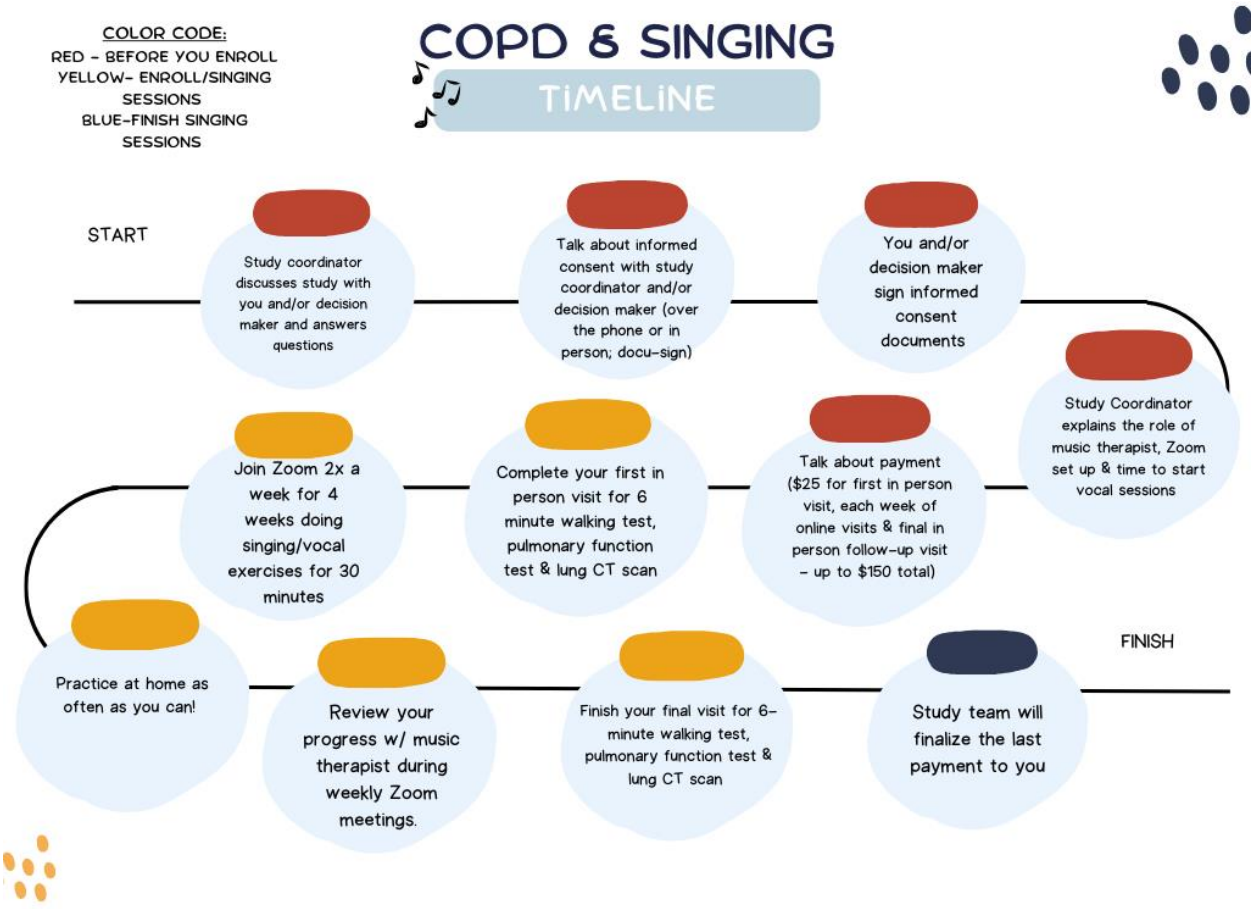
What extra procedures will occur solely because of the research?
• Research is different from standard care. We will use some of the same tests as standard care, including Pulmonary Function Tests and CT imaging.
• The research will use singing/vocalizing instead of traditional pulmonary rehabilitation exercises that use cycling or treadmill walking. The research will repeat the pulmonary function and CT testing before and after the vocal respiratory program, which is more frequently than during standard care.

What must they be willing to do if they decide to join?
• Attend frequent study visits: 2 in-person visits, Zoom online sessions 2X/week for four weeks, daily at home practice
• Not participate in another music-based program during the study

Why might some people decide not to join?
- Time commitment could be too high
- Zoom online sessions can be challenging
- Singing might not be effective for improving lung health
- Radiation exposure from CT
- Inconveniences such as the daily at home practice and weekly diary
- Lifestyle changes such as finding space and time to practice

Are there rare but serious side effects you will be closely watching for?
- We will be monitoring for COPD exacerbations

Will participants get individual results?
- Yes – participants will get results of the Pulmonary Function Tests and CT imaging



Please review the rest of this document for details about these topics and important things you should know if you decide to join. Before you sign up for the study, please ask the study team to answer all your questions.

DETAILED INFORMATION

This research study will take place at the University of Kansas Medical Center (KUMC) with Dr. Lepping as the researcher. Researchers at the University of Kansas in Lawrence and the University of Oregon will provide the online vocal respiratory program. The study will take place in-person at KUMC's Pulmonary Function Lab and online through Zoom. About 15 people will be in the study at KUMC.

Why is this study being done?
Chronic Obstructive Pulmonary Disease (COPD) causes airflow blockage creating breathing issues, distress, and lower well-being. COPD also causes hyperinflation of the lungs. We are doing the study to learn more about improving lung function for patients with COPD by using voice-based experiences.

What is being tested in this study?
If singing/vocalizing can improve lung function.

How long will I be in the study?
The study will last 4 weeks and involve 2 in-person visits to KUMC with virtual vocal sessions two times a week over Zoom.

What will I be asked to do?

Once enrolled in the study, researchers will ask your permission to perform a spirometry pulmonary function test. The spirometry test is being done to assess your lung function using standard clinical tests. Spirometry is done to check how your lungs work and involves blowing forcefully into a tube connected to a machine called a spirometer. The procedure will last approximately 30 minutes. If you have done spirometry testing within 14 days of the study visit, you will not need to repeat this test.

You will be asked to perform a six-minute walk test. This test requires you to walk for 6 minutes. At the beginning and end of your test, your study doctor will test your oxygen level by putting a sensor on your finger and check your blood pressure with a blood pressure cuff. If you have had a 6-minute walk test within 14 days of the study visit, you will not need to repeat this test.

The pulmonary team will perform a test diffusing capacity of the lungs for carbon dioxide (DLCO). DLCO is done to assess your lungs' ability to transfer gas from air to your bloodstream. The test will require you to hold your breath for 10 seconds and exhale completely.

The study team will ask your permission to perform two lung CT scans: one at the beginning of the study and the final test occurring toward the end. This scan can be useful in detecting blockage in the small airways of your lungs. During this scan, you will be asked to lie on your back and asked to breathe in deeply, and then breathe out 3 times. You will then be asked to hold your breath two different ways, with your lungs full of air, and with all the air out of your lungs. The study team or CT technician will review the breathing methods with you before you begin the scan, and you can ask questions at this time. The procedure will last approximately 2 minutes.

The music therapist will ask you to participate in 20–40-minute vocal and singing sessions two times a week over Zoom for four weeks. The interventionist will measure your breathing by asking you to chant, sing, read a passage or recite song lyrics, whichever comes naturally, one or two times.

During the treatment, the music therapist will ask you to participate in short vocal warm-ups and vocal exercises that include reciting short and long song phrases. You may be asked to complete guided at-home practice sessions for 15-20 minutes a day and document each practice session you complete at the end of each week. We will also ask for updates on how you are using the vocal activities at each session.

What are the possible risks or discomforts?
There are no physical risks involved in collecting information about you. There is a small risk of breach of confidentiality. For that reason, your information will be protected as described in the Privacy section below. You may feel nervous at chanting and singing with the music therapist and sometimes it may feel hard to do, but we will work with you so you feel comfortable in the vocal and singing activities. Sessions will be between you and the music therapist.

COPD Exacerbations
The vocal and singing sessions will require 20-40-minute vocal and singing sessions two times a week and at home practice sessions as often as you can for 15-20 minutes. The increased use of your lungs could flare up your COPD symptoms, creating more shortness of breath than usual. For this reason, contact the study team or music therapist if you experience an increase in coughing, wheezing or if other symptoms worsen.

Radiation Risks - CT Scans
In addition to any scans you may have as a part of your normal medical care, you will have two additional CT scans as part of this research. These scans are not needed for your medical care. You are exposed to radiation every day. This radiation comes from the sun and the earth. It is called background radiation. The amount of radiation from this study could be up to 16 months of what you are exposed to from background radiation. Radiation exposure at this level may be associated with a very low increased risk of cancer. Most cancers caused by radiation develop 20 or more years after the exposure to radiation. There are many factors that contribute to an individual's personal risk, and your increased risk may be higher or lower than the average person. You may wish to discuss radiation risk further with your Study Doctor or radiologist.

Pregnancy Risks
The CT scans might hurt an unborn child . You cannot be in this study if you are pregnant . There may be pregnancy risks that are not known yet. For this reason, you must tell the researchers right away if you get pregnant during the study.

Are there benefits to being in this study?
Researchers hope that the vocal sessions will help improve your breathing, lung capacity, shortness of breath, and other COPD related symptoms. Researchers hope that the information from this research study may be useful in the treatment of other

patients with COPD.

Will it cost anything to be in the study?
The study will cover all study-related items and services provided during this study. These services include the study drug, study visits, and study related tests and procedures such as the physical exams, laboratory tests, and CT scans as listed in this consent form.

Any other medical visits and procedures you have that are unrelated to the study will be billed to your insurance through normal hospital billing practices. Your insurance may not cover some or all the services if you are part of a research study. Pre-Certification is not a guarantee of payment. You may want to talk to your insurance company and review your specific benefits and coverage before deciding to participate. You will be responsible for normal co-pays, deductibles and non-covered services that are not the responsibility of the study.

You can still be in the study even if your insurance denies coverage for your routine medical treatment or if you are uninsured. The hospital has a financial assistance program which it makes available to all patients who qualify. If you do not qualify for financial assistance you will be responsible for all bills that are not payable by the study. The study staff will be able to provide more information to you.

Will I receive payments for being in the study?
You will receive $25 for each study visit. If you complete all regularly scheduled visits, you may receive up to $150. If you leave the study early, you will be paid only for the visits you complete.

You will be given a ClinCard, which works like a debit card. After a study visit, payment will be added onto your card by computer. The money will be available within 1 business day. You can use the ClinCard at an ATM or at a store. No one at KUMC will know where you spent the money. You will be given one card during the study. If your card is lost or stolen, please call (866) 952-3795.

The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to set you up in the ClinCard system. Study payments are taxable income. A Form 1099 will be sent to you and the Internal Revenue Service if your payments are $600 or more in a calendar year. If you do not provide a valid social security number or tax identification number, 30% of your payments will be set aside by KUMC and sent to the IRS for withholding on your behalf.

Your personal information will be kept on a secure computer. It will be removed from the computer after the study is over and the money on the card has been used. Your information will not be shared with other businesses. It will be kept completely confidential.

What are the financial arrangements for this study?
The institution (KUMC Research Institute, Inc.) will receive payments from the sponsor, the Division of Pulmonary Medicine in the KUMC Department of Internal Medicine for conducting this study. Payments will be used for research purposes only.

What happens if I get hurt or sick during the study?
If you have a serious side effect or other problem during this study, you should immediately contact Dr. Lepping at 913-588-0287. If it is after 5:00 p.m., a holiday or a weekend, you should call 913-588-5000 and ask for the Pulmonology attending physician on call. Please tell the physician that you are in this research study. A member of the research team will decide what type of treatment, if any, is best for you at that time.

If you have a physical injury as a result of participating in this study, treatment will be provided for you at the usual charge. Treatment may include first aid, emergency care and follow-up care, as needed. Claims will be submitted to your health insurance policy, your government program, or other third party. You will be billed for the costs that are not covered by the insurance. You do not give up any legal rights by signing this form.

What other choices do I have?
You can choose not to be in the study. Instead of being in this study, you can receive treatment that is already available, such as pulmonary rehabilitation. You can decide to leave the study at any time. Leaving will not affect the treatment or services you get at KUMC.

How will my information be protected?
The researchers will keep your identity confidential, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

Your study information will be labeled with your research ID number. The study team will keep a separate list that matches your name to the research ID number. These steps will lessen the risk that your personal identity and information will be seen by others who shouldn't have it.

If you sign this form, the research team will collect, use and share your private health information as described below. If you decide not to sign this form, you cannot be in the research study.

Study data includes information from your study activities and from your medical record. Your health care providers may release your private health information to Dr. Lepping and the research team. The team may use any and all of your information needed for the study. Your medical records may contain your name, address, phone, date of birth, social security number, or other identifiers. Others at KUMC might need to look at your research records. They include KUMC Research Institute, the Institutional Review Board or other committees and offices that review and monitor research studies.

Your participation in this study and your study information may be put into the University of Kansas Health System electronic medical record and combined with your health

information from your clinical care. The health system may use and share this information for other purposes described in the Notice of Privacy Practices.

You may not be able to see your records relating to the study until after the study is over and the results are known. Any research information that is put in your medical record will be kept indefinitely.

The research team will share your study data with people outside KUMC. These groups or agencies may make copies of study data for audit purposes. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may not protect it. These groups may include:

- Federal agencies that oversee human research (if a study audit is performed)
- Study partners, including researchers at the University of Kansas in Lawrence and the University of Oregon
- Experts who inspect the study information to see if the study is being done correctly and if it is still safe to continue
- Other groups that help manage or provide services to support the study
- Ethics committees that review the study for other locations

Your permission to use and share your health information will not expire unless you cancel it. To cancel your permission, please write to Dr. Lepping. The mailing address is Dr. Rebecca Lepping, University of Kansas Medical Center, 3901 Rainbow Boulevard, Kansas City, KS 66160. If you cancel your permission, you will be withdrawn from the study. The researchers will stop collecting any additional information about you about you unless they need information about a side effect of the treatment. They are permitted to use and share information that was gathered before they received your cancellation.

The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

<u>(Optional) Authorization for Release of Confidentiality</u>
The University of Kansas Medical Center (“KUMC”) publicizes and promotes its activities in various media formats for general educational use and for the general public in the areas of research, patient care, and service. To accomplish this goal, KUMC requests persons to authorize KUMC to record and to use their name, likeness, voice, and/or performance by any means of recording, including, without limitation, photography, video recording, and/or quoted statements.

We will be recording the Zoom vocal sessions as part of your participation in the study for the purposes of the research. These audio and video recordings will not be shared with anyone outside the research team or the groups listed above unless you sign a separate form (the Multimedia Authorization and Release Form). You do not have to sign the Multimedia Authorization and Release Form to participate in the study. If you choose not to sign that form, your name, likeness, voice, or recordings will not be shared.

Certificate of Confidentiality
This research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). This protects the researchers from being forced to give out personal information about you for legal proceedings. This does not stop you from voluntarily releasing information about yourself or your participation in this research.

One exception to the Certificate is if you agree that we can give out research information that identifies you. Your information will be shared for the purposes listed in this consent form. Other exceptions are information we must report if we learn about child abuse or neglect or if we think you might harm yourself or others.

Information about your research participation may be included in your medical record. The Certificate of Confidentiality does not prevent releases of information in your medical record for routine purposes such as treatment or billing purposes. Any research information in your medical record might be included when copies are sent for routine purposes.

Will I be told about research results?
You will be told about any study results that directly affect your personal medical care, including the results of the pulmonary function tests and chest CT imaging. These results will not be added to your medical record. During the vocal activity sessions, you may also be given informal feedback on progress and changes to the vocal and singing exercises. At the end of the study, we will send you a letter with a summary of the results.

How will my research information and specimens be used in the future?
In the future, researchers at KUMC and at other locations might re-use the information from this study for other research. If that happens, information that could identify you will be removed first. You will not be asked if you agree to the future research that has identifiers removed.

The future research may be about similar diseases or conditions to this study. However, research could also be about unrelated diseases, conditions, or other aspects of health. These studies may be done by researchers at KUMC, at other institutions, or by commercial entities.

Your data will be combined with others who participate in this study and uploaded into a public available database. Once uploaded, it may not be possible to remove your information.

The place where your data will be stored may not be controlled by or owned by KUMC or by the Principal Investigator for this study. The decision on how and with whom your data is shared is made by individuals who own the database.

As recommended by the National Institutes of Health, we plan to share the data from this study in a public available database called the Open Science Framework (https://OSF.io). Your data will be deidentified, meaning that any information that could be used to identify you has been removed, and shared publicly in a web-based database called the Open Science Framework OSF). The OSF is a website for sharing

data and other information about the research, such as detailed descriptions of the methods that were used, who the study team members were, and publications.

Can I stop being in the study?
You may stop being in the study at any time. Stopping will not prevent you from getting treatment or services at KUMC. You might be asked to come back for a final study visit.

Could my participation be stopped early? This study might be stopped, without your consent, by the investigator or the sponsor . Your participation also might be stopped by the investigator or by the sponsor if it is no longer safe for you or if you do not follow the study requirements.

The University of Kansas Medical Center, the sponsor, and the investigator are not obligated to provide you with any treatment if the study is stopped early. Your physician will decide about future treatment, if it is needed.

Who can I talk to about the study?
Dr. Lepping or other members of the study team should answer all your questions before you sign this form. They will also tell you if they learn anything new that might affect your decision to stay in the study. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints. If you have questions about your rights as a research participant, or if you want to talk with someone who is not involved in the study, you may call the KUMC Institutional Review Board at (913) 588-1240. You may also write the Institutional Review Board at Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160 or IRBhelp@kumc.edu

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.

CONSENT

Dr. Lepping or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

By signing this form, you say that you freely and voluntarily agree to be in this research study. You have read the information and had your questions answered.
You will be given a signed copy of the consent form to keep for your records.

_____
Print Participant's Name

_____ _____ _____
Signature of Participant Time Date

_____
Print Name of Person Explaining Consent

_____ _____ _____
Signature of Person Explaining Consent Time Date

CONSENT BY A SURROGATE DECISION-MAKER

You are a relative or other individual who is making decisions on behalf of a person with COPD. You are being asked to approve his or her participation in the research study described in this consent form.

By signing this form, you agree that Dr. Lepping or the study team have given you the information you need to make your decision. The study team has explained what will happen in the research. They explained any inconvenience, discomfort or risks that should be considered. You have had a chance to get your questions answered. At this time, you agree to have the participant enroll in the study.

If the participant becomes able to consent to research during the course of the study, the information in this form will be presented again so they can provide their own consent.

You will be given a signed copy of the consent form to keep for your records.

As legal guardian or representative, I, _____,
Print Name of Guardian/Representative

authorize the participation of _____ in this research study.
Print Name of Participant

I understand that I may not authorize participation in this study if the individual has previously expressed wishes to the contrary, either orally or in writing.

I am (please initial one of the following categories):

_____ *Legal guardian or Durable Power of Attorney for Healthcare Decisions*

_____ *Adult or emancipated minor's spouse (unless legally separated)*

_____ *Adult child*

_____ *Parent*

_____ *Adult relative by blood or marriage*

_____ _____ _____
Signature of Legal Guardian/ Representative Time Date

_____
Print Name of Person Explaining Consent

_____ _____ _____
Signature of Person Explaining Consent Time Date

ASSENT

I am being asked to be in a research study because I have COPD. The investigator or the study team has explained the study to me and the person who is making decisions for me.

If I join this study, I will have 2 in-person visits at KUMC I will have some medical tests that test my breathing and lung capacity. I will also have music sessions online over Zoom. I will have to participate in singing exercises and songs and practice on the days in between the Zoom sessions.

The person who is making decisions for me has read the consent form. He or she has agreed for me to do this research study. If I sign my name, I am saying that I want to be in the study. I know that I don't have to do it even if someone else has given their permission. I know that I can stop being in this study even if I signed my name. If I want to stop at any time, all I have to do is tell the study team.

_____
Print Participant's Name

_____ _____
Signature of Participant Date