RESP-FIT: Technology-Enhanced Self-Management in COPD
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Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

RESP-FIT: Technology-Enhanced Self-Management in COPD

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask them to explain any words or information that you do not clearly understand.

A. PURPOSE OF THE RESEARCH

The purpose of this study is to test whether a 6-week respiratory exercise program, using a breathing device with a mobile application (app), helps people with Chronic Obstructive Pulmonary Disease (COPD) improve lung functioning and manage symptoms, such as fatigue and difficulty in breathing. The study will take place in your home, but you will be asked to come to the clinic three times over the study period to complete some brief surveys and have your lung functioning measured. You are being asked to participate in this study because you are over 40-years old, have COPD, and are a patient at MUSC. The investigator in charge of this study is Dr. Sarah Miller, a nurse researcher at MUSC College of Nursing. The study is being done at MUSC and approximately 30 volunteers will take part in it. The study is sponsored by the National Institute of Nursing Research, which is part of the National Institutes of Health. Portions of Dr. Miller's and her research team's salaries will be paid for by this grant.

B. PROCEDURES

If you agree to participate, the following will happen:

Visit One, Part 1: Screening
At this visit, you will be asked some basic questions about your demographics and your health history, complete a brief survey about your COPD and, if you have not had one done in the past 6 months, have a Pulmonary Functioning Test (PFT) performed. If you have had a PFT in the past 6-months, then the results from this test will be gathered from your medical record. Your answers to these questions and the results from your PFT will be used by the researchers to see if you are eligible to enroll in the study (~35mins).

Visit One, Part 2: Measures
If you are eligible, and agree to take part in this research study, you will then be asked to complete nine (9) short surveys about your general health and quality of life with COPD (~25mins).

Visit One, Part 3: Enrollment
After these measures are completed, you will then be enrolled into the study and randomized by computer into one of two study groups (Group A or Group B). You will have a 50/50 chance (like a coin toss) of being put in Group A or B.

If you are enrolled in Group A, you will be asked to wear a Fitbit physical activity tracking device on your wrist for 6-weeks at all times of the day and night, except when bathing or charging the device. You will also be a given respiratory training device. These devices are to be returned to the researchers at the end of the study. You will be asked to use the training device to perform a set of five breathing exercises five days a week over 6-weeks, and to record the exercises you perform in the mobile application. These five exercises will take about 20 minutes a day to do. You will download the Fitbit app and the SAMS app on your smartphone, which you will use to track your symptoms and how you are feeling during the study. Additionally, once a week, you will be asked to record a 30-second video of yourself doing one breathing exercise. This video clip will be used by the researchers to provide you with breathing exercise technique feedback.

If you are put in Group B, you will be asked to wear a Fitbit physical activity tracking device on your wrist for 6-weeks at all times of the day and night, except when bathing. You will download the Fitbit app and SAMS app, which you will use to track your symptoms and how you are feeling during the study.

You will receive study instructions based upon which group you are put in.

Visit Two: Week 6
After 6-weeks, you will be asked to come back to MUSC to repeat those surveys that you did at Visit One, and to have another lung functioning test performed. Additionally, if you are in Group A, you will be asked to complete a satisfaction survey about how useful you found the app in completing the exercises and managing your COPD symptoms. If you are in Group B, you will be asked to complete a satisfaction survey about how useful you found the app in managing your COPD symptoms. All study materials given to you by the researchers are to be returned at this visit. (~1 hour)

Visit Three: 2 months after study completion
Two months after you have completed Visit Two, you will be asked to come back for a final follow-up visit via telephone or at MUSC. At this visit, you will be asked to complete the same surveys that you did in Visit One. (~1 hour)

C. DURATION

Depending on whether you have had a previous pulmonary functioning test (PFT) performed in the past 3 months and on record, Visit One will take about 1 hour to 1.5

hours. The lung exercise portion of the study will last 6 weeks and involves about 20 minutes a day. Visits Two and Three will also take approximately 1 hour.

D. RISKS AND DISCOMFORTS

Use of Surveys: Some of the questions the researchers ask you may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you can skip it and go to the next question.

Breathing device: The lung exercise breathing device used is called Respironics Pflex (model#HS553). Risks involved while performing breathing exercises may include dizziness, feeling short of breath, or coughing during deep inhalation. If you have difficulty breathing or become dizzy or light headed while performing the breathing exercises, you should immediately stop doing the exercise. If you have any unusual feelings you should go to the nearest emergency department.

Pulmonary Functioning Test: Pulmonary functioning tests (PFT) are non-invasive tests that show how well the lungs are working. It is a safe and quick procedure for most people. However, as with all procedures, depending on your general health, there are potential risks involved. The risks of this procedure may include: dizziness during the tests, feeling short of breath, and coughing brought on by deep inhalation. If you have any unusual feelings you should immediately notify the technician performing the test.

Loss of Privacy: Your privacy is very important to us, and the researchers will make every effort to protect it. However, as with any process that collects personal information about you (such as your name, address, and date of birth), there are risks associated for the loss of privacy and confidentiality. Information obtained about you for this study will be kept confidential to the extent allowed by law. Research information that identifies you may be shared with the MUSC Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to conducting research.

The results of all surveys and tests that you complete will be shared by the MUSC researchers with the National Institutes of Nursing Research (NINR) and stored electronically on a password protected secure server. The purpose of sharing this information is to build a large repository of data for future research purposes among the general scientific community and for public health benefit. Only de-identified data (that is information which does not include anything that might directly identify you) will be shared.

The information from the research may be published for scientific purposes; however, your identity will not be given out.

Randomization: You are being assigned to a study group and treatment program by chance. Group A's breathing exercise program may prove to be less or more effective or have more or less or unknown side effects than Group B or other available treatments. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

E. CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation for Federally funded projects or for information that must be disclosed in order to meet the requirements of the Federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Exceptions: A Certificate of Confidentiality does not prevent the researchers from voluntarily disclosing information about you, without your consent in incidents such as child abuse, and intent to harm yourself or others.

F. BENEFITS

There will be no direct benefit to you from participating in this study. However, it is hoped that the information gained from the study will help researchers learn more about developing lung exercise technology and mobile apps for patients with COPD.

G. COSTS

There will be no cost to you as a result of participation in this study. If needed, you will be given access to all the materials needed to participate in the study. These materials are to be returned at the end of the study to the researchers. If you chose to use your own smartphone or tablet device, your cellular provider's normal data and usage fees will apply.

H. PAYMENT TO PARTICIPANTS

In return for your time and efforts, you will receive $25 for completion of the screening portion of the study. If you are eligible and enrolled into the study you will receive $50. You will receive $50 for successfully completing Visit 2 at Week 6, and another $50 for completing Visit 3 at your two-month follow-up.

Additionally, you may receive up to $75 as an incentive for logging into the app to answer questions, and wearing your Fitbit throughout the study. You may earn up to a total of $225 for full participation and completion of the study.

Compensation will be paid in the form of check that will be mailed to you. If you need to come to MUSC to get enrolled in the study or attend a study visit, we will validate your MUSC parking garage ticket.

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

I. ALTERNATIVES

You do not have to take part in this study, your alternative is to not participate. In this case, you will be provided with information on the benefits of performing breathing exercises for individuals with COPD.

J. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please initial by your choice below:

____Yes, I agree to be contacted.

____No, I do not agree to be contacted.

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled. The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteer's Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Dr. Sarah Miller at (843) 792-1692. I may contact the Medical University of SC Hospital Medical Director (843) 792-9537 concerning medical treatment. If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148.
This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records. If you wish to participate, you should sign below.

_____	_____
Signature of Person Obtaining Consent	Date
_____	_____
Signature of Participant	Date