Assessing Adherence to Home Telemedicine in Individuals with COPD

Informed Consent

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Telephone Consent

IRB Study #___20-0107_____

Hello, my name is_____. I am a (research coordinator/investigator) from the University of North Carolina at Chapel Hill.

We are working on a research study of home devices that can monitor your breathing and symptoms. The purpose of this study is to see if the device would be used by patients with COPD. We are contacting you because you either you have responded to one of our recruitment postings or your lung doctor thinks you may be eligible. Your participation in this phone call and research study are completely voluntary.

Here is a summary of the study to see if you wish to hear more about the study. This study involves a set of home electronic devices that measure lung function, oxygen levels (using a device on your fingertip), ask questions, and send reminders to you. The purpose of this research study is to see if patients with COPD are able to use these devices at home.

If you are eligible, the total study lasts ~15 weeks. You will first undergo a one-hour screening visit where you will answer questions and do breathing tests (spirometry) to see if you can participate. If you are eligible, there is a 90-minute enrollment visit (which can be done on the same day as screening) where you will be shown how to use the device. You will then take the devices home for three months. During those three months you will perform daily breathing tests, measure your oxygen level and heart rate on your finger, answer some questions about your breathing, and get reminders to take your inhaled medicines. This information will be automatically sent to the research team, who can call you if there are signs of changes. You will also have three 30-minute phone visits during the study, and one final in-person visit.

The greatest risk of this study is related to dizziness or chest soreness due to spirometry, and loss of confidentiality. The benefits to you from being in this study may be improvement in your COPD care as the research team will be able to call you if breathing or symptoms change.

Would it be OK if we ask you some questions to see if you qualify for the study?

(If person says “No”- thank the person for his/her time and politely end the call).

If the person says “Yes”-

We will be collecting information about you during this phone call. Your taking part in this phone call is completely voluntary. Your information will only be seen by researchers at University of North Carolina. We try to make sure that the information we collect from you is kept private and used only for the research study we are discussing. If you do not agree to continue the phone call, it will not affect your care at UNC. We will not keep your information if you choose not to enroll in the study or if you do not qualify to be in the study.

We have a list of questions to determine if you may be eligible for the study:

1. Are you between the age of 40 and 80? (NO= INELIGIBLE)
2. Do you have COPD, emphysema, or chronic bronchitis? (NO= INELIGIBLE)
3. In the last year, have you had a flare or worsening of your breathing called an exacerbation of your COPD? (NO= INELIGIBLE)
4. In the last year, have you had at least two flares of your breathing (exacerbation) requiring antibiotics and/or steroids, or one flare that required a hospital stay? (NO= INELIGIBLE)

(If answer to any question leads to ineligibility: "Based on your answers, you are not eligible for this study. We thank you for time in answering these questions.")

(Otherwise):

Based on your answers, you may be eligible for this study. Would it be OK if I explain the study details including the study procedures, number of visits and length of study? (If "No"- stop).

You are being asked to take part in a research study. To join the study is voluntary.
You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Here are the details about this study. It is important that you understand this information so that you can make an informed choice about being in this research study.

The purpose of this research study is to see if a set of home devices can be used by COPD patients, and get your opinion on the device after the study is completed. Each day these electronic devices (see picture below) will measure lung function, oxygen levels (using a device on your fingertip), ask questions, and send reminders to you. Information from your tests and answers to questions are sent immediately to the study team over a private website for review. We are also interested in seeing if these devices can decrease your chance of breathing flares (exacerbations) or improve your symptoms. These devices are FDA approved and are being used according to their approved labeling.

You should be aware that the devices in this study do not replace your usual doctor. If you are having an emergency, you should call your doctor or 911. You should not wait for a response through the system in this study. Similar monitoring with these devices is not available outside of this study.

You should not be in this study if you do not have COPD. Other reasons to not be in the study are if you have other illnesses that are not controlled or do not wish to participate.

We plan to enroll approximately 12 people with COPD into the study.

This study does not require any visits to the research clinic, and can be done entirely over the phone. The time period that you would participate in this study is up to 15 weeks. There are six phone call interviews will be less than 1 hour each.

If interested in the study, we would first ask you to answer questions to make sure you are eligible. If eligible, we would then ship a set of devices out to your home.

The devices include a small monitor, breathing device to measure lung function, and a pulse oximeter (that measures oxygen levels on your fingertip). You would be asked to do breathing tests at home every day, and answer questions about your breathing daily. The device screen will also send you daily reminders to take your medications, and other information about COPD. When you receive your devices, we will call you to set up the devices and teach you how to use them. If we can't get the devices set up or you decide you don't want to do the study, you don't have to be in the study and we can help get the devices shipped back to us.

While at home during the 12-week study, you will be asked to perform daily breathing tests with the home device. This should be done in the morning within 15 minutes of taking your regular breathing medicines. You will do different types of tests on different days.

- On Sundays, Mondays, Wednesdays, Fridays and Saturdays you will do a slow breathing test
- On Tuesdays and Thursdays you will do a breathing test with full effort
- The device will automatically remind you to do your testing each day
- The device will coach you through your breathing test each day using on-screen instructions.
- You will also be asked to measure the oxygen level (oxygen saturation) of your blood and heart rate each day with a finger probe called a Pulse Oximetry that works with your study device. A clip-like device called a probe is placed on the finger. The measurement is then sent to the device.
- Each day you will get reminder messages to take your inhaled medicines.
- Each Friday you will answer questions on the device about your inhaled medicine use.
- You will also get messages throughout the week about your breathing.

The information from your breathing tests and answers to questions will be sent to the study team doctor (Dr. Drummond) through a secure website. He can review this information each day. If there are changes in your breathing or symptoms, he may call you to see if you are feeling OK.

You will be called once per month for two times after enrollment. The purpose of these phone calls is to collect information about your breathing, medication use, and any worsening of breathing symptoms or general health. Each phone call will take around 30 minutes.

During each phone call, we will ask about:
- Medication use
- Breathing symptoms
- Details about any recent COPD flares
- Answer any questions you may have

We will call you for one last phone visit. The reason for this visit is to complete your study procedures. This visit will last about thirty minutes.

During this visit, you will:
- Complete a questionnaire about your current COPD symptoms and treatment
- Measure your oxygen level with the home device
- Answer questions about any worsening of breathing symptoms or general health
- Complete a questionnaire about your opinions on the device you used at home

After the last phone call, we will have you ship the devices back to us. We would ask you to keep the box you received it in, and we will provide you a shipping label and we will arrange pick-up of the device by FedEx or another company.

During the entire study, you will receive your regular care. The study does not provide routine medical care for other medical problems. No medications will be changed or stopped because you are in this study.

If eligible, there are no costs to you. You will not be compensated for this study.

There is no direct benefit to you from being in this study. Research is designed to benefit society by gaining new knowledge. The benefits to you from being in this study may be improvement in your COPD care as the research team will be able to call you if breathing or symptoms change.

Here are the risks of being in the study:

We will ask you to do lung function tests (spirometry) at home. During this test, you will wear a clip on your nose and blow air forcefully from your lungs. We will measure how much air comes out and how fast the air comes out. Rarely, patients may become dizzy during the test. The test is done while you are sitting to decrease this risk. You should let the study team know if you do get dizzy. Their phone number will be included in the box with the devices.

There are no physical risks related to filling out questionnaires. There is a chance of distress if answers to these questions are not kept private. To minimize this chance, all information is kept in locked files, locked rooms or secure computer servers. Any electronic information transmitted from your home does not identify who you are, is protected by passwords and can only be seen by doctors or nurses who are part of the study. You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

There may be uncommon or previously unknown risks. You should report any problems to the researcher using the phone number that will be included in the box with the devices.

Here is how we will protect your information. You will be assigned a study number, and that is the number that will be used on all study records and data, and this number is all that will be entered into the study databases. Information obtained from these studies will be kept in

confidential research records, and all electronic in maintained in a secure database. The worksheets that the study coordinators use will have your name and study number, but this information will stay in the study file which will be kept in the study coordinators office or other locked storage area in the Meadowmont building. Only the study physicians, research technicians and coordinators will have access to the paper records. The information from your questionnaires will be uploaded to a secure database which is password protected.

The answers you complete on the electronic device are sent to a secure computer server using a random study number. There is no information that can identify you directly sent across the internet. Only study team members can get access to the electronic data.

The companies supporting the devices will not have access to your personal information. However, if you were to call the company for technical support, they could potentially know your name and other information about you. To avoid this, we want you to call the study team number on the first page of this form for any problems or questions about your device. If you decide to call the companies directly, you acknowledge that the company may know your name and other private information about you.

Participants will not be identified in any report or publication about this study. We may use de-identified data and/or specimens from this study in future research without additional consent.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

We will go over a separate form ("HIPAA Authorization") to allow researchers to review your medical records.

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care.

Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

If you think you have been injured from taking part in this study, call the Principal Investigator Dr. Drummond. His phone number will be in the information we ship to you. They will let you know what you should do.

By agreeing to be in this study, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

This research is funded by Midmark Corporation. This means that the research team is being paid by the sponsor for doing the study. In addition, Brad Drummond, Principal Investigator on this study, has received money from Midmark Corporation for work that is not a part of this study. These activities may include consulting, service on advisory boards, giving speeches, or writing reports.

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. 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.

Do you have any questions?

You can also call Dr. Drummond at 410-963-2322 with questions about the research study. All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Do you agree to be in this study?

Participant Name:

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Coordinator Documentation:

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Coordinator Name: _____

Date: _____