UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Pulmonary Specialist Health Coach Consultation (PuSHCon) Model: A Pilot Study of Health Coaching to help people with lung conditions receive and use recommendations from pulmonary specialists

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This is a research study about whether clinic health coaches supporting patients who have breathing conditions such as asthma or chronic obstructive pulmonary disease (COPD), improve the health and the quality of care that patients receive. I am from the study team, and I will explain the study to you.

This study is conducted by Rachel Willard-Grace from the Department of Family and Community Medicine and Dr. George Su from Zuckerberg San Francisco General Hospital Chest Asthma/COPD Clinic.

We are asking you to take part in this study because you have a breathing condition such as asthma or COPD.

Research studies include only people who choose to participate. Please take your time to decide whether or not you want to participate. If you wish, discuss your decision with your family or friends. If you have any questions, you may ask me, your physician, or the project directors in charge of the study.

Why is this study being done?

The purpose of this study is to see if people with breathing conditions such as asthma or COPD will receive better care related to their breathing conditions through the pulmonary specialist health coach consultation model.

What will happen if I take part in this research study?

If you are interested in taking part in this research study, the research assistant will ask you questions to make sure that you are eligible for the study. If you are, the research assistant will set up a time, either in person, by phone, or videoconference, to meet with you to conduct a survey. Answering these questions will take about 60 minutes. The research assistant will also ask how you wish to be contacted, such as whether you would like to receive text messages from the study team. If you wish to receive text messages, standard text messages rates will apply. The research assistant will ask a similar set of questions after 4 months. The survey will assess your breathing symptoms, how they affect your daily activities, how you work with your doctor, and cigarette or drug use.

After taking part in the survey, the research assistant will open an envelope to find out whether you are being randomly assigned to receive a health coach or usual care. If you are not up to date on breathing tests for your condition, the research assistant may work with your doctor or nurse to request updated tests in which you would be asked to breath into a machine to measure how hard you can breathe out and whether your airways are inflamed.

If you are assigned to receive usual care, you will receive care for your breathing condition from your primary care clinician. This can include referrals to a lung specialist, breathing tests, or classes.

If you are assigned to receive a health coach, you will still receive all of the care available through primary care. In addition, you will be assigned a health coach. The health coach will arrange a time to meet with you in person or through telephone or videoconference. During this meeting, the health coach will ask you questions about your medical history, symptoms, and smoking history. Your health coach may also observe how you take your inhalers. The health coach will share this information with your doctor and a pulmonary nurse practitioner to create a treatment plan for you. After this meeting, the health coach will follow up with you in the following months to review the treatment plan and support you in your health goals. If you wish to have an in person or virtual visit with a specialist instead of taking part in the health coach study, you may let the research assistant or your doctor know.

The research assistant and health coach will also review your medical record to get information about your asthma, COPD, or breathing condition, such as which medications you take, and any breathing symptoms that resulted in prescription of medications, an unscheduled emergency visit, or a hospitalization.

How long will I be in the study?

Participation in the study will be for 4 months.

If you are assigned to receive a health coach, the estimated total amount of time you will spend on the study will be about 9 hours, including 2 hour answering survey questions, four 1-hour visits with a health coach, four 30-minute follow ups with a health coach (either phone call, video conference, or in person), and 1 hour for a breathing test if requested by a specialist.

If you are assigned to receive usual care, you will spend a total of 2 hours answering survey questions with the research assistant. If you are not up to date on routine breathing tests for your condition, you may be scheduled for a breathing test, which may require an additional hour, for a total of 3 hours.

Can I stop being in the study?

You can decide to stop being in the study at any time. Just tell your health coach, the research assistant, or your physician that you want to stop being in the study. In addition, the study team or your physician may stop you from continuing in the study if they feel that it is not in your best interest, if you are not able to follow the study rules, or if the study is stopped. If you stop being in the study there will be no consequences – you will continue to receive care at the clinic with your physician.

What side effects or risks can I expect from being in the study?

Some of the survey questions may make you feel uncomfortable or upset, but you are free to choose not to answer any question that you do not wish to answer.

It might be uncomfortable working with a new person, your health coach, as part of your health care team in the clinic, over the phone, or by video conference. For more information on risks or side effects, you may talk with your physician or a study doctor.

Are there benefits to taking part in the study?

You will not receive direct benefit for taking part in the study.

For all patients who take part in the study, the information that you provide may help health professionals better understand whether using a health coach can benefit patients with breathing conditions such as asthma or COPD.

What other choices do I have if I do not take part in the study?

If you choose not to participate in the study, you will continue to receive your care as you have before at the clinic. You will still be cared for by your physician, who will see you and prescribe the medications you need. You will still receive access to specialty care. You may request an in person or virtual visit with the specialist instead of taking part in the health coaching model. You will not lose any benefits of your care at your clinic if you choose not to participate.

Will information about me be kept private?

The research team will do its best to keep personal information about you private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The study team and the University of California may look at or copy your research records for research, quality assurance and data analysis. No other individuals or organizations will have access to your personal identified information. If you communicate with the study team by text message, remember that messages you leave for us are secure, but messages we leave for you could been seen by someone else who has access to your phone. If you have concerns about your privacy related to receiving texts from the study, you can choose to stop receiving them at any time.

If you have a health coach and you and the coach have a discussion about feelings of depression or other concerning symptoms, the health coach will share that information with your primary care provider to discuss any follow up care.

What are the costs of taking part in this study?

You will not be charged for any of the study treatments or protocols. However, if you have co-pays for visits or medications, these will continue without any change from before. This includes visits to see the pulmonary specialist or receive a breathing test.

Will I be paid for taking part in this study?

You will receive a code for a $40 electronic gift card or $40 in cash for completing a survey at enrollment and 4 months. That means that during the 4 months, you may receive up to $80.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get your care from your provider and clinic the way you usually do.

What happens if I am injured because I took part in this study?

It is important that you tell the study director, Rachel Willard-Grace, if you feel that you have been injured because of taking part in this study. You can tell the study director in person or call her at 415-476-5245.

Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the UCSF Institutional Review Board at 415-476-1814.

Who can answer my questions about the study?

If you have questions, you can talk to your physician, or Rachel Willard-Grace, the director of the study, whose phone is 415-476-5245.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers, or if you wish to voice any problems or concerns you may have about the study, please call the UCSF Institutional Review Board at 415-476-1814.

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

You have been given a copy of this consent form to keep. You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, please sign below.

_____	_____
Date	Participant's signature for consent
_____	_____
Date	Person obtaining consent