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Study Title: Evaluation of the Paramedic Evaluation for Acute COPD Exacerbation (PEACE) Intervention.

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NCT Number: TBD

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UMASS CHAN MEDICAL SCHOOL

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title: Evaluation of the Paramedic Evaluation for Acute COPD Exacerbation (PEACE) Intervention.

Protocol No.: Sponsor's protocol number [TBD]

Sponsor: National Institute of Heart, Lung, and Blood Institute, National Institute of Health

Investigator: Laurel O'Connor

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Worcester, Massachusetts, 01655

Daytime Phone Number: 508-421-1400

Consent Version: January 30, 2025

You are being invited to take part in a research study. Someone will explain this research to you. This form helps to sum up their explanation.

KEY INFORMATION

You are being invited to participate in a research study because you have chronic obstructive pulmonary disease (COPD).

If you have questions or don't understand something, please ask.

Taking part in this research is voluntary and completely up to you. You are free to say no or to leave the research at any time. There will be no penalties or changes in the quality of the health care you receive, and you will not lose any benefits to which you are otherwise entitled.

The main question this study is trying to answer is whether a program called mobile integrated health improves how patients with COPD feel and decreases the number of times they need to seek emergency care. Mobile integrated health programs send specially trained paramedics, called community paramedics, to perform home visits to check on patients at home when they need extra help or aren't feeling well. Working as a team with doctors, the paramedics will examine you and provide treatment for your COPD symptoms.

If you join this research, you will be eligible for up to several home visits from the mobile integrated health program if your doctors or another member of your healthcare team think you would benefit from a visit.

As part of the study, you will need to complete several surveys over the next year. You will also be asked to participate in interviews with study staff during the study period. You may also be asked to participate in a focus group with other patients and clinicians. You can complete the

surveys and interviews from home. We will continue to collect information from your medical record for as long as a year after you stop participating in the study.

You may not want to be in this study if you are uncomfortable with:

- Having paramedics come to your home to provide treatment
- Receiving some care from a team that is different from your usual physician
- Waiting a little longer for urgent care
- Sharing your private information with researchers
- Sharing information related to your COPD diagnosis and how it affects your life with other patients who are subjects in this study and clinicians

We will take steps to protect your personal information. However, there is a risk of breach of confidentiality.

There may also be risks that we do not know yet.

Benefits:

- Your participation will help us to gain knowledge that may help design and implement mobile integrated health programs in the future that will help patients receive care at home and stay out of the emergency room.
- We cannot promise any benefits to you if you take part in this research. You may benefit from the frequent evaluation and treatment through the mobile integrated home visits, which may make managing your COPD easier and help you avoid going to the emergency room when you are not feeling well.

Alternatives: If you choose not to participate in the study, you will still have access to pulmonary rehabilitation if your doctor orders it, and the usual care from your primary care and specialist doctors. You do not have to be in this study to receive care for your COPD.

If you think you might like to participate in this research, please continue reading to learn more about the details of this study.

STUDY DETAILS

How many people will take part in this research?

About 30 people will take part here at UMass Chan Medical School.

How long will I be in this research?

You will actively participate in this research for about one year. We may review your health records for up to a year after you complete the study.

What happens if I say yes, I want to be in this research?

- First, we will make sure you understand the project and answer all of your questions.
- Once you have decided to participate and sign the consent form, we will ask you some baseline questions about yourself and your health history. This will take about 5 minutes.

- We will also ask you to complete a survey about how your COPD affects your life. This is called the COPD Assessment Test (CAT). This should take you about 10 minutes.
- After you enroll, you will become eligible for mobile integrated health home visits. This means that your doctor or your pulmonary rehabilitation team (The Wellinks Team) may recommend a home visit at any time while you are in the study. Someone may recommend a home visit if you aren't feeling well and need to be examined, if you are having trouble using your medications, or if you need an exam and/or treatment but are having a hard time getting an appointment in the clinic.
- If a home visit is recommended for you, you can decline it at any time
- If you have a home visit, a uniformed paramedic will come to your home. This could happen at any time, day or night, or on weekends depending on when you need help. If you have one or more home visits, they will take 1-2 hours to complete.
- The paramedic will speak with you and examine you. He or she may also perform blood tests or recommend an X-ray depending on how you are feeling.
- You and the paramedic will then speak to an emergency room doctor using telehealth.
- If you are not feeling well, the paramedic may give you medication, such as a breathing treatment, depending on the recommendations from the doctor.
- The paramedic and doctor who take care of you at home will make sure your primary care doctor and/or lung doctor know about the visit and what happened.
- Within about 7 days of each home visit, the study team will ask you to fill out an online survey about your experience with the home visit. They may also call you to talk about your opinions about your home visit. This will take 10-15 minutes to complete.
- At two times during the study- once about six months after you start the study, and once at the end of the study, you will be asked to participate in an interview about your experiences with the mobile integrated health program. These will take place using a teleconferencing platform (like Zoom) so you can do them from home. You will be asked to participate whether or not you have had any home visits. Each interview will take about an hour to complete.
- You may also be asked to participate in a focus group with other patients and clinicians. If you participate in the focus group, you will be asked questions about your COPD and how it affects you in a group setting with other patients and clinical staff.
- At the end of the study, you will be asked to complete the COPD Assessment Test (CAT) again. This will take 10 minutes to complete.
- After you stop participating in the study, the study team will continue to review your records for an additional year to get information about your health. You will not be contacted during this time.
- Once the study is completed, you will stop receiving home visits from the mobile integrated health program.

Could being in this research hurt me?

- Risks of participating in this study include psychological distress that might be triggered by filling out surveys related to COPD and the negative effects it can have on your life.
- There is a risk that if you are feeling sick and the paramedics take some time to get to your home, there could be a delay in starting urgent treatment you need to address your illness.
- There is a risk that someone could get access to the data we have stored about you. If those data suggest something serious about your health, it could be misused. For example, it could make it harder for you to get or to keep a job or insurance. We believe the chance these things will happen is very small, but we cannot make guarantees.

In addition to these risks, taking part in this research may harm you in unknown ways.

Will it cost me any money to take part in this research?

- You will not be billed for the mobile integrated health home visits or any of the medications you receive during them. All treatments or medications provided by the MIH team during the home visits will be paid for by the research study.
- However, you or your insurance will be billed for all routine medical and diagnostic costs that are part of the standard of care for treating your COPD. This may include the cost of tests, procedures, or prescribed medicines to manage any side effects. You will be responsible for any deductibles, co-payments, or co-insurance payments that your coverage normally requires.

Will I be given any money or other compensation for being in this study?

You may be paid up to a total of $150. Your compensation will be broken down as follows:

- You will be paid $50.00 after you enroll and fill out your first set of surveys
- You will be paid $50.00 after you participate in your first interview with the study team, about six months into the study
- You will be paid $50.00 after you participate in your second interview with the study team and complete some exit surveys, about one year after you enroll in the study.
- If you drop out of the study, you will not receive any further payments

In order to receive a stipend for study participation, you will need to give us private information like your name, address and phone number. We will then share this information with the business offices and companies that need it to process the payment. You will need to provide your social security number and complete a W-9 (tax form) if you receive:

- $300 or more from a single study within a single calendar year at UMass Chan, or
- $600 or more in a calendar year across multiple research studies at UMass Chan.

The Medical School may report the payment to the IRS and send you a 1099 form for tax purposes. The business offices and companies will keep the information as part of their financial

records. The research team will destroy this information [insert when you will destroy this data – must be no later than six years after study closure].

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

If you are injured while in the study, seek treatment and contact the study doctor as soon as you are able.

The UMass Chan Medical School does not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available.

You do not give up any of your legal rights by signing this form.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to: Describe the responsibilities of the participant.

- Tell your usual doctor if you are feeling at all unwell or think that you are having a COPD exacerbation
- Follow the directions of the study doctor and research staff.
- Tell your study doctor and staff about all prescriptions, over the counter medications, and vitamins or herbal supplements you are taking, and about all of your health issues.
- Tell your other health care providers that you are in a research study.

What happens if I say yes, but I change my mind later?

If you decide to leave this research, contact the research team so that the investigator can tell your medical team. If you decide to stop, we may ask if we can contact you for safety reasons or to follow your health. We may also ask you if we can collect data from your medical records and your routine medical care.

Can I be removed from the research without my approval?

The person in charge of this research study can remove you even if you want to continue. This may happen if:

- You move away from Worcester County or move into a long-term care facility like a nursing home
- It becomes unsafe for the mobile integrated health team to perform home visits at your house

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

How will my information be stored and when will it be destroyed?

We will remove your name and any other information that could directly identify you from your data. We will replace this information with a code number. We will create a master list linking your code number to your name. We will keep this list separate from your data.

We will keep paper documents under lock and key. We will keep electronic health information and research data on secure computer networks. These computer networks have many levels of protection.

There is no limit on the length of time we will store your data. We will destroy the master list of identifiers when the research project is complete.

It is possible that we might use the research data in other future research. We may also share data with researchers and companies that are not part of UMass Chan. In these cases, we will not share your name or other information that identifies you directly, and we will not come back to you to ask you for your consent.

Who has access to my information?

Signing this document means you allow us, the researchers in this study, and others working with us to use some protected health information for this research study.

As part of the research, UMass Memorial Medical Center or any other healthcare facility where you are treated may disclose the following information:

- Demographic and identifying information like your name, date of birth, address, telephone number, and your email address
- Related medical information like family medical history, and current and past medications or therapies
- Information from physical examinations, such as blood pressure reading, heart rate, temperature, height/weight, and lab results
- All tests and procedures that will be done in the study

Your health information and research records will be shared with the study team and with individuals and organizations that conduct or watch over this research, in order to conduct the study and to make sure it is conducted as described in this form. Information and records may be shared with:

- Federal and state government agencies, such as state auditors
- The UMass Chan Medical School and UMass Memorial Health, including their Institutional Review Board (IRB) and research, billing, and compliance offices
- Health care providers who provide services in connection with this study
- People and companies who work with UMass Chan and UMMH on activities related to the research
- We will protect your identifiable information from disclosure to others to the extent required by law, but we cannot promise complete secrecy.
- We are legally required to disclose information about child abuse, abuse of the elderly or disabled, you potentially harming yourself or others, and certain reportable diseases.
- Any disclosure carries the potential for re-disclosure. Once your protected health information is disclosed, it may no longer be protected by federal privacy laws.

Your authorization does not have an expiration date. If you change your mind, you have the right to revoke your authorization in writing or using the contact information at the beginning of this form. If you revoke your authorization, you will not be allowed to continue to participate in the study. We will not collect any new information about you. However, information that we have already collected will stay in the study database and cannot be removed in order to maintain the integrity of the research. Your information may still be used and disclosed if you have an adverse event.

You do not have sign this authorization. If you choose not to sign, it will not affect your treatment, payment, or enrollment in any health plans, or affect your eligibility for benefits. You will not be allowed to participate in the research study.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Because the National Institutes of Health (NIH) funds this research, this study has a Certificate of Confidentiality. The Certificate keeps us from sharing your identifiable sensitive information collected for the research unless you allow us to do so. It also keeps us from being forced to release information that may identify you, as part of a court, legislative, administrative, or other proceeding.

There are times when the Certificate cannot be used. For example, we cannot refuse to give information to government agencies that oversee or fund research, such as the NIH or Food and Drug Administration (FDA). The Certificate also does not stop us from giving information to local government agencies, law enforcement personnel, or others if we suspect you or someone else is in danger or if we are required to do so by law.

The Certificate does not stop you from giving out information about yourself or your participation in the research. If you give an insurer, employer, or someone else your permission for us to release information, we will do so.

Will you share any results with me?

It may be several years before the results of the research are available. If you would like us to try to reach you at that time, please let us know. We will ask for your contact information.

We can share your individual results with you if you ask.

Who can I talk to?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed on the first page.

This research is being overseen by an Institutional Review Board. An IRB is a group of people who perform independent review of research studies. You may talk to them at (508) 856-4261 or irb@umassmed.edu for any of the following:

Your questions, concerns, or complaints are not being answered by the research team.

You cannot reach the research team.

You want to talk to someone besides the research team.

You have questions about your rights as a research participant.

You want to get information or provide input about this research.

Signature Block for Capable Adults

Your signature documents your consent to take part in this research.

Signature of adult research participant	Date
Printed name of adult research participant	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	