Informed Consent Form for Participation in a Research Study

Study Title: A Program of Care in Chronic Obstructive Pulmonary Disease involving Virtual Pulmonary Rehabilitation, Integrated Care and Remote Clinical Monitoring after Discharge from a Recent Exacerbation: Mixed-Methods Study on Feasibility

Site Study Doctor: Dr. Robert Wu, Department of Medicine, Robert.Wu@uhn.ca, 416-340-4567

Site Study Contact: Alice Tu, Toronto General Hospital Research Institute, Alice.Tu2@uhn.ca, 416-340-4800 x5486

Sponsor/Funder(s): This study is partially funded by the AHSC AFP Innovation Fund at UHN and Sunnybrook. Some home oscillometers have been provided in-kind by Thorasys Thoracic Medical Systems Inc., and certain cough monitoring wearables provided in-kind by Hyfe Inc.

INTRODUCTION

You are being invited to participate in a research study. You are invited to participate in this study because you have Chronic Obstructive Pulmonary Disease (COPD), have been discharged from hospital with a recent exacerbation, and have been enrolled in outpatient care programs and/or referred to Toronto Grace Health Centre for Remote Clinical Monitoring and optionally Virtual Pulmonary Rehabilitation. This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study. You may find it helpful to discuss it with your friends and family.

Please take your time in making your decision.

The study staff will tell you about the study timelines for making your decision.

Taking part in this study is voluntary. You have the option to not participate at all or you may choose to leave the study at any time. Whatever you choose, it will not affect the usual medical care that you receive outside the study.

IS THERE A CONFLICT OF INTEREST?

The hospital is receiving financial payment from the funder to cover the cost of conducting this study.

WHAT IS THE BACKGROUND INFORMATION FOR THIS STUDY?

Patients with COPD commonly require hospitalized care, and some patients will be readmitted to hospital after an exacerbation. There is some evidence that shows that remote monitoring, including home visits, virtual visits with a respirologist and home monitoring through iPads and wearable devices can improve outcomes for patients and may prevent patients with COPD from needing to be re-hospitalized.

We are developing a program of care for people with COPD called CHARM-COPD (Connected, at-Home, Accessible Remote Monitoring for COPD) that includes Virtual Pulmonary Rehabilitation

(including education and exercises with a respirologist), Remote Clinical Monitoring (including devices such as a blood pressure cuff, smartwatches, or spirometers and reporting your symptoms daily), and/or outpatient care programs (including in-home and virtual follow-up appointments). The overall goal of this program is to improve health related quality of life, increase support for patients and reduce the likelihood people need to come back to the emergency department after discharge.

The standard of care after an admission for COPD may include pulmonary rehabilitation (either virtual or in-person), remote monitoring, and outpatient follow-up (including in-home or virtual follow ups).

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to determine how feasible, acceptable, and usable the CHARM-COPD program of care is for people with COPD, doctors, and nurses.

WHAT OTHER CHOICES ARE THERE?

You do not have to take part in this study in order to receive treatment or care.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is anticipated that about 120 participants will take part in this study, from research sites located in Ontario. This will include 100 patients and 20 clinicians.

This study should take 18 months to complete, and the results should be known in about two years.

WHAT WILL HAPPEN DURING THIS STUDY?

1. Day 1 visit – After consenting, you will have an in-person or virtual visit with a research coordinator so that we can show you how to use your optional devices and complete study questionnaires.
2. Monitoring – you will continue to be monitored remotely for 90 days, and will receive ongoing technical support from the research team.
3. Day 90 visit – After you have completed your monitoring period, you will have an in-person or virtual visit with a research coordinator to complete study questionnaires and a short interview.

WHAT IS THE STUDY INTERVENTION?

If you agree to take part in this study, you may continue to participate in outpatient care at the hospital if you are currently receiving it, Remote Clinical Monitoring through Toronto Grace Health Centre (TGHC), and optional Virtual Pulmonary Rehabilitation through Toronto Grace Health Centre. These are all part of standard of care. At the end of 90 days, we will ask you to complete an interview to discuss your experience using the program. We will also ask you to complete a short questionnaire on your first and last day of the program.

WHAT ARE THE STUDY PROCEDURES?

Day 1 visit:

On the first day of the study, we will instruct you on how to use the research study-specific remote clinical monitoring devices you have chosen:

- Hyfe cough monitoring wearable
- FitBit smartwatch
- Home Oscillometer or Spirometer
- CHARM-COPD mobile app
- Audio Recordings on your TGHC tablet as applicable

We will then ask you to complete a short survey asking some demographic information and information on your medical history, alcohol and drug history, social history and use of technology. We will also ask you to complete 3 short questionnaires about your health. This visit should take 20-30 minutes and will typically be conducted virtually. The visit may be conducted in-person at the hospital, a clinic, or in your home, if study setup is unable to be completed virtually. For setup in the home, the research team will ask for your permission to visit and set up a meeting time with you. During the home visit, we will complete the questionnaires and set up the devices, including connecting the devices to home Wi-Fi if you have it. If not, a researcher-provided internet connection will be used. If you have a phone which supports Fitbit, this will be used to communicate with the Fitbit smartwatch (if applicable). The Fitbit app will be downloaded onto your phone, and you will be logged into a researcher-created account. Bluetooth connectivity for your phone will also be turned on, if not already on. If you choose to use the CHARM-COPD mobile app, it will be downloaded to your phone, and you will need to enter your phone number for user verification to log in. The app will also be linked to your Fitbit account (if applicable). If you don't have a usable phone, the research team will provide a clean smartphone with a data plan (if necessary), and the Fitbit app will be installed on the device. We will guide you through each step, and any questions you have will be answered.

The study team will also review your hospital medical records after your first visit to collect additional demographic information and medical history (Medical Status).

Throughout the study:

As part of standard of care, you may have been enrolled in outpatient care from the hospital and Remote Clinical Monitoring at Toronto Grace Health Centre. The University Health Network (UHN) research team will collect the data from all of the Remote Clinical Monitoring devices you use, and will regularly review this information during your study participation so that we can see how much each was used. Some of this data will be sent to us and clinicians at TGHC through the GRTHealth platform installed on a blue tablet (GRTHealth Platform is the platform TGHC uses to remotely follow patients). You will use the tablet to complete surveys and upload the vitals you measure from the Remote Clinical Monitoring devices to the GRTHealth dashboard. Note: no personal identifying information will be entered or stored on the tablet, and your information will be identified by a unique identifier assigned by TGHC. We, the UHN study team, will also access your hospital health records to see how often you had follow up visits, in person or virtually, with Integrated Care/ outpatient care program. You may also have been enrolled in Virtual Pulmonary Rehabilitation from Toronto Grace Health Centre. If you are enrolled in Virtual Pulmonary Rehabilitation, we will access your TGHC health records to see how many Virtual Pulmonary Rehabilitation sessions you completed, and how long you used the program for.

The standard of care for your post-discharge follow-up will not be altered in any way if you choose to participate in this research study.

When you were referred to Remote Clinical Monitoring at Toronto Grace Health Centre, you consented to the use of various devices. In the case that you are unable to use a tablet for symptom and vitals reporting, we will provide paper diaries for you to use that will be collected at the end of the program. You may also use these diaries to report any other information you find may be important for the researchers to know.

During the 90 days you are taking part in this study you have the option to additionally use the following devices. Optional means you can decide not to use any of the following devices and still take part in the study. Using the additional devices may take between 20 and 30 minutes per day:

- Spirometer to assess lung function at home; you will be asked to complete a home spirometry reading once daily. This will involve forced exhalations into the spirometry device, which we will train you to use.
- Speech recording on the tablet: you will be asked to record several sentences spoken aloud once per day, which will be stored on the GRTHealth platform used by Toronto Grace Health Centre. We will be analyzing these spoken sentences to detect subtle changes in your breathing and health.
- The Hyfe cough monitoring wearable used in this study may be one of two watch models: one of which will continually record sound and monitor for explosive (cough-like) sounds. When these sounds are detected, they will be time-stamped and the device will upload a 0.5-1 second audio clip, which it uses to determine whether the sound was a cough. The other model does not record or store audio; instead, when cough-like events are detected, they will only be time-stamped and the data will be synced via the Hyfe app installed on your smartphone. In both cases, these data (including short audio clips, if applicable) will be uploaded to the Hyfe server, and shared with the UHN study team. You will not be asked to enter any personal identifying information into the app. We will regularly review this information during your study participation and use these data to determine how much the device is being used, as well as how many times you cough daily and hourly. De-identified cough data collected for the study will be stored by the research team for 10 years after study completion and then destroyed; however, Hyfe may retain the data on its secure servers and does not currently specify a fixed end date for retention. You will be asked to wear your Hyfe watch during the day and charge it at your bedside overnight.
- A FitBit smartwatch that continuously monitors your heart rate, temperature, respiratory rate, oxygen saturation, activity and sleep (vital signs); you will be asked to wear your FitBit during the day, keep it charged, and use it as much as you like to monitor your vital signs. The site study team will regularly review your Fitbit data during your study participation to identify any potential device-use or technical issues. If you choose to use a Fitbit device as part of the study, Fitbit (owned by Google) will collect and store your device and health data (such as your heart rate, activity, and sleep information) on its own secure servers in accordance with its Terms of Use and Privacy Policy. Data collected using the Fitbit device and app that reside on Google servers are subject to their own Terms of Use and Privacy Policy, and no assurance can be made about their confidentiality or that they will only be used for research purposes.
- Home oscillometer to assess lung function at home: you will be asked to complete a home oscillometry reading once per day. You will be trained on how to use the device. Data collected, including oscillometry readings, age, sex, height and weight, and other relevant

clinical information, will be stored on a local computer or tablet at your home (that we will provide) throughout the study and then exported to the secured server at UHN. The oscillometer includes a tag that allow the device to be located if needed. The research team will not routinely monitor the device location and will only access this information if the device is lost or stolen.

- CHARM-COPD App: a mobile app that integrates clinical self-monitoring and smartwatch data (if applicable), such as Fitbit, for individuals with COPD. You will be asked to enter your symptoms and vital signs into daily diaries, and will be able to view your smartwatch data and reach out to the UHN research team and your healthcare providers at UHN or TGHC for COPD-related questions through the platform.

  You will need to agree to the app's Terms and Conditions (or End User License Agreement) and privacy policy to use this app. The collected data (including your diary entries, vital signs, smartwatch data, if applicable, and certain personal health information that may be entered into the clinician-facing dashboard, such as your name, sex, age, and other identifiers needed for your clinicians to identify you) will be stored on a secure AWS server at UHN in Toronto, Canada, for 10 years after study completion. If you choose to connect a Fitbit device to the CHARM-COPD App, the app will import your steps, heart rate, blood oxygen, breathing rate, and sleep metrics from your Fitbit account into the study database. For app maintenance and troubleshooting purposes, personnel from MindSea Development Inc. (the app developer) may have limited, secure access to the study data stored on the AWS server, including the data described above and app usage analytics.

  If you have clinicians involved in your COPD care at UHN, they will have the option to monitor and receive reports and alerts based on the input data through an associated clinician-facing dashboard, which may or may not become part of your hospital medical record at the discretion of your healthcare providers.

  Please note that this app is NOT meant to be used as a replacement for urgent care. If you have a medical emergency, please call 911 or visit your nearest emergency room.

During your 90 days on this study, TGHC and the UHN study team, will continuously monitor data collected by the sensors and remote clinical monitoring devices you have selected. If there are any issues with the additional devices, we offer technical support for the duration of the study. This may be conducted over the phone or through in-person visits. Verbal consent will be obtained before any home visits are scheduled. Please note that data is not being monitored constantly and you should reach out to your health care team or visit the emergency room if needed.

Day 90 visit:

We will meet virtually or in-person after 90 days or at withdrawal if you choose to withdraw from the study intervention sooner. We will ask you to complete a short survey asking about your experience with the program. We will then conduct an interview through a video conferencing service that will take up to one hour. The interview will be audio recorded so the responses to the questions can be transcribed and reviewed at a later date. The audio recording may be sent to a transcription service. Any personal identifying information on the audio recordings will be removed prior to the recordings being sent. Once the audio recordings have been transcribed and information confirmed to be correct the transcription service and the researcher team will permanently delete the audio recordings.

Questionnaires

You will be provided with questionnaires when you begin the study and then after your 90 days of monitoring are complete. The purpose of the questionnaires is to collect some basic demographic information about you, understand your current disease and quality of life and to record your impressions of the study interventions. Each questionnaire will take about 15 minutes to complete.

The information you provide is for research purposes only. Some of the questions are personal. You can choose not to answer questions if you wish.

Interviews:

You will be asked to participate in one interview after you have completed your 90 days of monitoring. During this interview, you will speak with a member of the research team. The interview will be about 30 minutes in length and will take place virtually on video conference or in-person at the hospital/clinic or your home. You will be asked to provide information about your experiences using the study interventions.

Summary of Schedule

Visit	**Procedures**
Consent	Phone call to review study procedures
Visit 1 (30 min – 1 hour)	Questionnaires, set up devices
Ongoing	Daily use of Toronto Grace Remote Monitoring tablet; use of wearable devices, speech recording, and CHARM app (optional)
Visit 2 (1 hour)	Questionnaires, interview

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

If you choose to participate in this study, you will be expected to:

- Let the researchers know about any technical issues with study devices, or if devices are lost or stolen
- Return study devices at the end of the study period
- Return paper diaries at the end of the study period, if applicable

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

The study intervention will last for about 90 days.

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. If you choose to withdraw from the study, you are encouraged to contact the study doctor or study staff.

You may be asked questions about your experience with the study intervention.

If you decide to leave the study, you can ask that the information that was collected about you not be used for the study. Let the study doctor know if you choose this option. Otherwise, information that was recorded before you withdrew will still be used by the researchers for the purposes of the study, but no information will be collected after you withdraw from the study.

CAN PARTICIPATION IN THIS STUDY END EARLY?

The study doctor may stop your participation in the study early, and without your consent, for reasons such as:

- You are unable to complete all required study procedures
- The study doctor no longer feels this is the best option for you
- The Research Ethics Board withdraw permission for this study to continue

If this happens, it may mean that you would not receive the study intervention for the full period described in this consent form.

If you are removed from this study, the study doctor will discuss the reasons with you and plans will be made for your continued care outside of the study.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

There is a possibility of risks that we do not know about and have not been seen in humans to date. Please call the study doctor if you have any side effects even if you do not think it has anything to do with this study.

The risks we know of are:

There is always a low risk of breach of confidentiality of recorded or collected information. We will take all possible measures to keep your personal health information secure. Information will be stored on and transmitted through secure servers.

Feedback received from your devices may not always be accurate. Devices such as FitBit and Hyfe are not currently Health Canada approved and should not be used as a replacement for usual medical care.

The Hyfe device will upload 0.5-1 second audio clips when an explosive sound such as a cough is detected. There is a low risk that this audio may contain comprehensible speech which will be transferred to Hyfe.

It may be uncomfortable to answer survey or interview questions, or to receive feedback about your vital signs. It may also be uncomfortable to have your data monitored by others.

This study may use video conferencing for the end of study virtual visit. If you agree, the study staff may use e-mail to communicate with you about your participation in this study. The study staff will discuss this with you. We are using a virtual platform to conduct interviews. You will receive an email with the appointment link and information to join your interview. Please note, all electronic communication carries some risks. There are security risks related to using video conferencing. In order to use video conferencing, you will receive an email from the research

coordinator with the appointment link and information to join the video conference. If you receive a link or email regarding a virtual visit and are not sure it is coming from the research team, please call them at 416-340-4800 ext.5486 to check before clicking on any links. Electronic messages are easy to forge, find, copy, and forward to others. Electronic messages may exist indefinitely (forever). The hospital is not responsible for the security of your internet service providers, email domains, personal devices, personal computers, applications on those devices, etc. We suggest that you use your personal email when communicating with research staff. Use a secure internet connection. Do not use a public internet connection where it may be easier to "hack" into your email account and access your personal information. In-person interviews can be accommodated if virtual conferencing is not an option.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

You may not directly benefit from being in this study. Information learned from this study may help people with COPD in the future.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

If you decide to participate in this study, the study doctors and study staff will only collect the information they need for this study.

Records identifying you at this centre, UHN, will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organization(s) may look at your original (identifiable) medical/clinical study records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines.

- Representatives of UHN and its affiliated sites, including the UHN Research Ethics Board, who oversees the ethical conduct of this study in Ontario

Information that is collected about you for the study (called study data) may also be sent to the organizations listed above. Representatives of Clinical Trials Ontario, a not-for-profit organization, may see study data that is sent to the research ethics board for this study. Your name, address, email, or other information that may directly identify you will not be used. The records received by these organizations may contain your participant code.

The following organizations may also receive study data:

- Sunnybrook Health Sciences Centre, which is a participating site for this study. A deidentified dataset will be provided to Sunnybrook. Deidentified means that your personal information will be removed and replaced with a code.
- University of Toronto, who is conducting statistical analysis and machine learning using deidentified study data. A full deidentified dataset will be provided to University of Toronto.
- Hyfe Inc., who is providing the Coughwatches used in the study. Participants who opt in to using the coughwatch may have the following deidentified data provided to Hyfe:
    - Age
    - Sex
    - Approximate year of COPD diagnosis date

- Study feedback given to the research team

Studies involving humans sometimes collect information on race and ethnicity as well as other characteristics of individuals because these characteristics may influence how people respond to different interventions. Providing information on your race or ethnic origin is voluntary.

Communication via e-mail is not absolutely secure. We do not recommend that you communicate sensitive personal information via e-mail.

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during this study will be used in analyses and will be published/ presented to the scientific community at meetings and in journals.

Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

Your participation in this study will also be recorded in your medical record at this hospital. This is for clinical safety purposes.

Any information sent outside of Canadian borders may increase the risk of disclosure of information because the laws in other countries dealing with protection of information may not be as strict as in Canada. However, all study data that are transferred outside of Canada will be coded (this means they will not contain your personal identifying information such as your name, address, medical health number or contact information). Any information will be transferred in compliance with all relevant Canadian privacy laws. By signing this consent form, you are consenting to the disclosure of your coded information to organizations located outside of Canada.

Data collected using the FitBit, Toronto Grace tablet, Hyfe cough monitoring wearables, and CHARM-COPD platform reside on the FitBit, GRTHealth, Hyfe, and hospital-based AWS servers, respectively, and no assurance can be made about its confidentiality or that it will only be used for research purposes.

We recommend that you remove the study app (e.g. CHARM app) from your personal devices once participation has ended. We will remind you to do this with your study completion.

Other future research

Your coded study data may be used or shared with other researchers (inside and outside of Canada) for future studies. “Coded” means that directly identifying information (such as your name and date of birth) will be replaced by a number, which will be applied to the study data. The code matching your study data and samples with your name and other directly identifying study data will be kept by the study team.

Future study topics may include correlation of data to COPD exacerbations for predictive analysis.

This may include storing the coded study data in

- Secure, restricted-access databases. Anonymized study data may be placed in such databases. The goal of sharing is to make more research possible. Potential future

research will be to use demographic data, vital signs, audio cough data, wearable data, and other device data to help predict exacerbations early.

You will not be asked if you agree to take part in future research studies using your study data. You or your study doctor will not be told what type of research will be done. You will not be given reports or other information about any research that is done with your study data.

Interview:

During the discussions, participants will be encouraged to refrain from using names. If names or other identifying information is shared during the discussion, it will not be included in the written records.

The video/audio recordings will be stored in a secure location and viewed only by members of the research team. The recordings will be kept until they have been transcribed (turned into written records), and then they will be destroyed.

WILL FAMILY DOCTORS/HEALTH CARE PROVIDERS KNOW WHO IS PARTICIPATING IN THIS STUDY?

Your family doctor/health care provider will not be informed by the study team that you are taking part in the study. You can choose to let your family doctor/health care provider know if you like.

WILL INFORMATION ABOUT THIS STUDY BE AVAILABLE?

A description of this clinical trial will be available on http://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.

You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of the results of this study, please contact Dr. Robert Wu and indicate your preferred communication methods. Study results will be shared with you if/when they become available after the entire study is completed. It is expected that this may take a number of years. Please talk to the UHN research team if you have any questions about the results.

WHAT IS THE COST TO PARTICIPANTS?

The research devices (FitBit, cough monitoring wearable, tablet, oscillometer, and others) will be supplied at no charge while you take part in this study.

Potential mobile data charges: participation in this study may require the use of the app (e.g. CHARM-COPD app) on your mobile device, which could result in mobile data charges depending on your mobile plan. We recommend checking with your mobile service provider for details on data costs associated with using the app if there are any concerns.

Participation in this study will not involve any additional costs to you or your private health care insurance.

ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?

If you decide to participate in this study, you will receive a $50 gift card at the end of the study.

If you decide to participate in this study, you will be reimbursed up to a total of $200 for all visits for study related expenses such as transportation and parking of in-person study visits.

You will need to provide your receipts for taxis, Uber rides, public transportation and parking to the research staff in order to be reimbursed.

COMMERCIALISATION

It is possible that the research conducted using your samples and/or study data may eventually lead to the development of new diagnostic tests, new drugs or devices, or other commercial products.

There are no plans to provide payment to you if this happens.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of the results of this study, please contact the study doctor.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By signing this form you do not give up any of your legal rights against the study doctor or involved institutions for compensation, nor does this form relieve the study doctor or their agents of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to participating in this study.

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, or if you suffer a research-related injury, you can talk to your study doctor, or the doctor who is in charge of the study at this institution. That person is:

Dr. Robert Wu, 416-340-4567

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. Please contact:

University Health Network Research Ethics Board, 416-581-7849

Title: A Program of Care in Chronic Obstructive Pulmonary Disease involving Virtual Pulmonary Rehabilitation, Integrated Care and Remote Clinical Monitoring after Discharge from a Recent Exacerbation: Mixed-Methods Study on Feasibility

CONSENT

- All of my questions have been answered.
- I allow access to medical records and related personal health information as explained in this consent form.
- I do not give up any legal rights by signing this consent form.
- I agree to take part in this study.

Printed Name of Participant	Signature	Date
Printed Name & Role of Person Conducting the Consent Discussion	Signature	Date

If the participant is assisted during the consent process, please check the relevant box and complete the signature space below:

The following attestation must be provided if the participant is unable to read or requires an oral translation.

☐ The person signing below acted as an interpreter, and attests that the study as set out in the consent form was accurately sight translated and/or interpreted, and that interpretation was provided on questions, responses and additional discussion arising from this process.

Printed Name of Interpreter	Signature	Date

Language

☐ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to the participant, and any questions have been answered.

Printed Name of Witness	Signature	Date

Relationship to Participant