Study Protocol:

My Lung Health Coach – A virtual COPD self - management support program integrated into the electronic patient record

Principal Investigator: Dr. Andrew Kouri

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Study Site(s):	Women's College Hospital
Funded By:	Women's College Hospital Foundation: Women's College Healthcare Breakthrough Challenge

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STATEMENT OF COMPLIANCE

This clinical trial will be carried out in accordance with the following:

- International Conference on Harmonisation Good Clinical Practice (ICH GCP)
- Tri-Council Policy Statement 2018 (TCPS 2)
- Personal Health Information Protection Act (PHIPA), 2004; Chapter 3 Schedule A (PHIPA) and applicable regulations
- Institutional and REB policies and procedures

_____ May 6th, 2024

Signature of PI _____ Date

LIST OF ABBREVIATIONS

Include a list of abbreviations used within the research protocol. A sample list is included below:

AE	Adverse Event
CRE	Certified Respiratory Educator
COPD	Chronic Obstructive Pulmonary Disease
CRF	Case report form(s)
DSMB	Data Safety & Monitoring Board
GCP	Good Clinical Practice
ICF	Informed consent form
MLHC	My Lung Health Coach
PHI	Personal Health Information
PHIPA	Personal Health Information Protection Act
PI	Principal Investigator
QI	Qualified Investigator
SAE	Serious Adverse Event
SUSAR	Suspected unexpected serious adverse reaction
TCPS 2	Tri-Council Policy Statement

CLINICAL TRIAL SUMMARY

Short Title	MLHC clinical study
Phase	Pilot study
Methodology	Single arm pilot study
Clinical trial Duration	12 months
Participating site(s)	Single site – *Women's College Hospital*
Objectives	To evaluate the feasibility and effectiveness of MLHC, a COPD self-management and education support program delivered virtually with an electronic patient-record integrated companion app
Number of Participants	50
Study Intervention Reference Therapy/Comparator	The intervention will be enrollment in the MLHC program (a COPD self-management and education support program delivered virtually), and access to the Epic Care Companion MLHC companion app. There will not be a control group for this pilot study.
Duration of Intervention	12 weeks intervention duration, 6 months total follow-up

Statistical Methodology	Feasibility outcomes (system use): ○ Number of patients who started program over total offered ○ Number of patients who completed program over total started ○ Number of providers who referred patients to the program over total ○ App use metrics over duration of study participation Effectiveness outcomes (clinical outcomes): These outcomes will be collected prior to program commencement, at program completion (3 month), and at 6-month follow-up. Outcomes will be collected by MLHC certified respiratory educators (CREs) using a standardized form in Salesforce, as well as a research assistant based on Epic electronic chart review. For continuous variables, difference in the mean (SD) will be calculated at 3 months and 6 months compared to baseline. For dichotomous variables, difference in proportions at 3 and 6 months compared to baseline will be calculated. ○ Healthcare system utilization: number of COPD-related outpatient visits, hospital admissions, ED visits, ICU admissions (at baseline will be over the previous 12 months) ○ COPD severity: CAT and mMRC scores, and number of COPD exacerbations ○ Health-related quality of life: CAT score ○ Medication, smoking, vaccination status: COPD controller medication use, oxygen therapy, oral corticosteroid use, antibiotic use, rescue inhaler use, packs per year smoking, smoking cessation attempts, routine vaccinations ○ Knowledge of COPD: Adapted COPD-Q score ○ Self-efficacy: Adapted COPD Self-Efficacy Scale (COPD SES) score ○ Self-management: Partners in Health Scale (PIHS) score ○ Referrals: pulmonary rehab, smoking cessation counseling, specialist care

1.0 INTRODUCTION

1.1 Background

Chronic Obstructive Pulmonary Disease (COPD) is a highly prevalent chronic airways disease that affects 1 in 9 adults in Ontario. COPD can cause significant symptoms of dyspnea, chronic cough, and wheezing, and lead to important reductions in health-related quality of life. People with COPD can also experience repeated acute exacerbations of their chronic disease, where symptoms worsen for days to weeks, leading to further loss of lung function and quality of life, increased healthcare resource utilization, and mortality. Up to 50% of people with COPD will have an exacerbation within the first year of follow-up, and among those who experience exacerbations, >50% have 2 or more each year. In Canada, COPD exacerbations are one of the leading causes of emergency room visits and hospitalizations nationally (~90,000 hospital admissions yearly, with >25,000 in Ontario alone), and COPD costs the healthcare system $1.5B annually. As COPD prevalence is increasing yearly, these numbers are unfortunately projected to further grow over time.

Managing COPD and preventing exacerbations can be extremely challenging, as disease progression is often heterogeneous, and symptoms can fluctuate significantly over time. There are also several important patient-level barriers to reducing COPD exacerbations, including lack of medication adherence, limited participation in smoking cessation counseling, low health literacy levels, and poor COPD action plan use. Many of these barriers are related to a lack of effective self-management, a crucial part of holistic COPD care. Self-management refers to the skills and behaviours required for people with COPD to cope with their disease and preserve their quality of life and function. This can include knowledge and skills related to medication adherence and inhaler technique, smoking cessation, physical activity and exercise, managing symptoms and self-recognition of exacerbations, healthy diet, and stress management.[18,20]

Interventions to improve COPD self-management are an essential part of COPD care. However, many patients with COPD do not have access to self-management interventions, and poor self-management behaviour (including low adherence to medications and action plans, lack of exercise maintenance, and low health literacy levels) remains an important care gap in COPD. In Ontario, there is currently no uniformly available pathway for patients with COPD to access evidence-based self-management interventions, and individual providers lack the time and resources necessary to provide effective self-management support to all of their patients.

1.2 Study Intervention

My Lung Health Coach (MLHC) is a freely available evidence-based and person-centered COPD self-management program that connects people virtually with experienced certified respiratory educators (CREs) to provide structured COPD education and self-management support. MLHC was jointly developed by the Lung Health Foundation (a charitable organization focused on lung health advocacy) and academic Respirologist Dr. Andrew Kouri, with input from community members living

with COPD. MLHC links community members living with COPD with certified respiratory health educators, using a person-centered approach to provide COPD education and self-management support. It is delivered virtually through one-on-one meetings offered over multiple sessions over 12 weeks. The topics covered in the program include: general COPD knowledge, smoking cessation, COPD medications (inhalers, oxygen), physical activity counseling, mental health and wellness, vaccinations, symptom self-management skills (breathing, energy management, symptom monitoring), nutrition, travel, and long-term planning (including end-of-life care).

In order to improve the patient experience using MLHC, we have integrated the MLHC program into the Epic Care Companion app at Women's College Hospital, an interactive patient facing app designed as an extension of the Epic electronic health record system. Using Care Companion, patients will be able to track their progress through MLHC, accomplish session specific educational and self-management tasks, and share their progress with their Women's College healthcare teams.

1.3 Preclinical Data to Date

We are currently testing the MLHC Care Companion app through a rapid cycle design process, to optimize app usability and acceptability. This is being accomplished using an iterative end-user testing process with patient focus groups and qualitative and quantitative assessments. This process is approved as a quality improvement project (APQIP # 2024-0015-P)

1.4 Clinical Data to Date

n/a

1.5 Risks/Benefits

The intervention being offered is patient education and self-management support program, developed in line with international COPD guidelines. A recent Cochrane review of COPD self-management and support programs (Schrijver et al. 2022) reported that these types of interventions are unlikely to cause harm. However, potential harms that may occur could include poor management of care by CREs (however this is unlikely as the CRE is a licensed and regulated clinical professional), risk of data breach through the use of the Care Companion smartphone app (again this is unlikely given the app is operated through high security protocols within Women's College), and risk of embarrassment if personal health information is inappropriately released.

The virtual format of this program is unlikely to confer any additional risk, as the format of self-management and education support is not specified in international and national guidelines, only the content delivered.

In terms of benefits, the same review found that these types of interventions were associated with improved health-related quality of life and a reduction in respiratory-related hospital admissions in COPD. These types of interventions also reduced anxiety and depression levels.

2.0 CLINICAL TRIAL OBJECTIVES

2.1 Primary Objective

The primary objective is to evaluate the feasibility of delivering the MLHC program accompanied by the Epic Care Companion application. This will be evaluated by assessing system use over the study period, including the number of patients who start the program (over total number referred/offered), the number of patients who complete the program over the total number started, and the number of providers who refer patients to the program over the total number of eligible providers. We will also evaluate app use metrics by patients (number of interactions with the app, number of tasks completed, app features activated, time spent using the app)

2.2 Secondary Objective

The secondary objective is to assess for potential clinical benefits of participating in the MLHC program accompanied by the Epic Care Companion application. To assess this we will evaluate healthcare system utilization, COPD severity, health related quality of life, COPD medication use, smoking status, vaccination status, COPD knowledge, self-efficacy scores, self-management scores, and healthcare provider referrals prior to using the program vs. after program completion.

3.0 CLINICAL TRIAL DESIGN

3.1 Overall Design

This pilot study will be a single center, single arm, pilot trial. There will not be a control group. Each participant will complete the 12-week MLHC virtual program, during which time they will also interact with the Care Companion app. Clinical outcomes will then be reassessed at 6 months after study initiation. The trial is expected to last 12 months.

3.2 Primary Endpoints

Feasibility endpoints:

- MLHC program participation
    - Number of patients who started program over total offered
    - Number of patients who completed program over total started
    - Number of providers who referred patients to the program over total
- MLCH Care Companion app use
    - Number of times app opened
    - Number of sessions accessed within the app
    - Number of session tasks marked completed
    - Use of other app features (ex: medication reminder notifications)
    - Time spent using the app each time used

3.3 Secondary Endpoints

Clinical endpoints:

- Assessed prior to study start, at 3 months (end of MLHC program) and at 6 months (follow-up after program completion). Outcomes will be collected by MLHC CREs using a standardized form in Salesforce, as well as a research assistant based on Epic electronic chart review. For continuous variables, difference in the mean (SD) will be calculated at 3 months and 6 months compared to baseline. For dichotomous variables, difference in proportions at 3 and 6 months compared to baseline will be calculated.

  - Healthcare system utilization (number of COPD-related outpatient visits, hospital admissions, ED visits, ICU admissions (at baseline will be over the previous 12 months)
  - COPD severity (CAT and mMRC scores, and number of COPD exacerbations)
  - Health related quality of life (CAT score)
  - COPD medication use (COPD controller medication use, oxygen therapy, oral corticosteroid use, antibiotic use, rescue inhaler use)
  - Smoking status (packs per year, quit attempts)
  - Vaccination status (routine guidelines recommended vaccines received)
  - COPD knowledge (Adapted COPD-Q score)
  - Self-efficacy score (Adaptd COPD Self-efficacy scale score)
  - Self-management score (Partners in Health Scale score)
  - Healthcare provider referrals prior to using the program (pulmonary rehab, smoking cessation counseling referrals

4.0 PARTICIPANT SELECTION AND WITHDRAWAL

4.1 Target Population

Patients with physician diagnosed COPD will be the target patient population.

4.2 Participant Recruitment and Screening

We will target a recruitment of 50 patients with physician diagnosed COPD. The patients will be recruited from the WCH Respirology Program clinics (as patients must be followed at WCH in order to use the Epic Care Companion app component). Recruitment will be accomplished through: advertisement posters in the Respirology clinic directing patients to discuss participation with their WCH Respirologist, and referrals from clinicians/circle of care. The potential participant's respirolgist will be the one to determine interest/consent in the participant being contacted for the study.

Participants who have expressed interest in the study will be contacted by study personnel (for example, a research assistant) to discuss potential participation in the study. Patients will not be compensated for their participation.

4.3 Equity, Diversity and Inclusion Considerations

We will consider patient gender during study recruitment, and collect this information on study enrollment. As this is a small pilot study, it will likely not be possible to meaningfully analyze study results in a disaggregated manner based on gender.

4.4 Eligibility Criteria

4.4.1 Inclusion Criteria

The participant must meet all of the inclusion criteria to eligible for this clinical trial:

1. Must be deemed to have capacity to provide informed consent;
2. Must sign and date the informed consent form;
3. Stated willingness to comply with all study procedures;
4. Be diagnosed with COPD as per a WCH Respirologist
5. Be 40 years or older
6. Be a current or ex-smoker
7. Have a history of at least 1 COPD exacerbation (requiring prednisone or antibiotic use, or an urgent healthcare visit of any kind) in the previous 12 months

4.4.2 Exclusion Criteria

An individual who meets any of the following criteria will be excluded from participation in this clinical trial:

1. Experienced a COPD exacerbation in the 4 previous weeks to study enrollment
2. Co-diagnosis of asthma by a WCH Respirologist
3. Significant co-morbidities that could interfere with program participation, or terminal illness
4. Willing to download and use the Epic Care Companion app and has a suitable mobile device to do this
5. Pregnancy

4.5 Lifestyle Considerations

None

4.6 Screen Failures

We will collect screen failures demography, screen failure details, eligibility criteria, and any serious adverse events (SAE).

4.7 Participant Withdrawal Criteria

4.7.1 When and How to Withdraw Participants

Participants are free to withdraw from participation in the clinical trial at any time.
An investigator may discontinue or withdraw a participant from the clinical trial for the following reasons:

- Pregnancy;
- If any adverse event (AE), laboratory abnormality, or other medical condition or situation occurs such that continued participation in the clinical trial would not be in the best interest of the participant;
- Disease progression which requires discontinuation of the study intervention;
- If the participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation

The reason for participant discontinuation or withdrawal from the study will be recorded within the participant's research record, and/or legal health record.

4.7.2 Follow -up for Withdrawn Participants

If a participant withdraws consent, they can also request the withdrawal of their data and/or biological specimens subject to any research-specific restrictions, if applicable. Once withdrawn from the clinical trial, no further research procedures or evaluations will be performed, or additional research-specific data collected on the participant. Reasonable effort will be made to obtain permission to document the reason for withdrawal.

4.7.3 Early Termination Visit

If a participant withdraws from the clinical trial, an Early Termination Visit will be arranged if possible with study staff. This will include:

- Assessment of new and ongoing AEs;
- Assessment of any complications following the study intervention;
- Performance of other relevant study-related procedures.

The PI and/or QI will ensure the participant is appropriately transitioned/followed for any additional care as required.

4.7.4 Participants who are Lost to Follow -up

A participant will be considered lost to follow-up if they fail to return for 2 scheduled visits and is unable to be contacted by the research team.

The following actions will be taken if a participant fails to attend a required study visit:

- The research team will attempt to contact the participant and reschedule the missed visit within 2 weeks, counsel the participant on the importance of maintaining the assigned visit schedule, and reconfirm whether the participant wishes to and/or should continue in the clinical trial.
- Before a participant is deemed lost to follow-up, the research team will make every effort to regain contact with the participant (where possible, three telephone calls and, if necessary, a certified letter to the participant's last known mailing address or local equivalent methods). These contact attempts should be documented in the participant's research record and/or legal health record.
- Should the participant continue to be unreachable, they will be considered to have withdrawn from the clinical trial with a primary reason of lost to follow-up.

5.0 STUDY INTERVENTION

5.1 Description

MLHC is delivered virtually through one-on-one meetings with the CRE offered over multiple sessions. The full program consists of 6 sessions across 12 weeks, covering all topics (geared towards new COPD diagnosis). The topics covered in the program include: general COPD knowledge, smoking cessation, COPD medications (inhalers, oxygen), physical activity, mental health and wellness, vaccinations, symptom self-management skills (breathing, energy management, symptom monitoring), nutrition, travel, and long-term planning (including end-of-life care). As participants complete their virtual MLHC program with CREs, they will also have access to the Epic Care Companion app developed as a companion app to MLHC. This app will display a section for each MLHC program session completed, along with session-specific educational and self-management tasks for the patient to complete after the session. These will mostly consist of links to session-specific educational content, but there will also be medication reminder notifications, and reminders to discuss specific topics with their respiratory healthcare providers. This app may also contain individualized tasks created between the CRE and MLHC participant during their sessions. A final report of all completed tasks will be generated on program completion and available in the participant's Epic electronic health record, which can be reviewed by their respiratory healthcare providers.

5.2 Treatment Regimen

MLHC will be delivered virtually through secure videoconferencing software (Zoom) by CREs. Participants will be contact by the CREs to organize an acceptable program schedule. Ideally, participants will have 1 session every 2 weeks, for a total of 6 sessions over 12 weeks. They will be free to engage with the MLHC Care Companion app at their own leisure throughout this period and after program completion.

5.3 Method for Assigning Participants to Treatment Groups

N/A – single arm study

5.4 Administration of Study Intervention

MLHC will be delivered virtually through secure videoconferencing software (Zoom) by CREs as detailed above. All onboarding for the virtual program will be completed by the CREs. Upon study consent, patients will also be oriented to the use of the MLHC Care Companion app by study staff virtually or in-person. They will be shown how to download and login to the Epic Care Companion app, and how to navigate through the MLHC materials. Any tech support needed throughout the study will also be provided by study staff at WCH.

5.5 Participant Compliance Monitoring

Participation in the virtual MLHC program will be tracked by the CREs using standardized forms (using the Lung Health Foundation's Salesforce architecture developed for MLHC administration). This information will be securely sent to WCH and

integrated into Epic in collaboration with the Womens' Virtual Care Research Laboratory. Use of the Epic Care Companion MLHC companion app will be tracked internally at WCH.

5.6 Concomitant Therapy

COPD medication use/treatments (inhalers, antibiotics, prednisone, and oxygen) will be recorded at baseline, at 3 months follow-up, and at 6 months follow-up.

5.7 Packaging

N/A

5.8 Blinding of Study Intervention

N/A

5.9 Receiving, Storage, Dispensing and Return

5.9.1 Receipt of Study Intervention Supplies

N/A

5.9.2 Storage

N/A

5.9.3 Dispensing of Study Intervention

N/A

5.9.4 Return or Destruction of Study Intervention

N/A

6.0 RESEARCH PROCEDURES

6.1 Research Visits

- Pre-Screening Visit / Screening Visit (virtual or in-person)
  - Informed consent
  - Review of eligibility criteria
  - Orientation to the Epic Care Companion MLHC companion app
  - This visit will be performed by study staff (research assistant, or study investigators)

- Baseline Visit (virtual)
  - Collection of baseline outcome data
  - This visit will be performed by CREs as part of the MLHC program, study staff (research assistant, or study investigators) will confirm data collection and if needed supplement data collection using Epic or by contacting the participant

- Delivery of MLHC program – 6 virtual sessions over 12 weeks, delivered by CREs, no outcome collection during this phase of the study

- Follow-up Visit at 3 months post baseline (virtual)
  - Collection of follow-up outcome data
  - This visit will be performed by CREs as part of the MLHC program, study staff (research assistant, or study investigators) will confirm data collection and if needed supplement data collection using Epic or by contacting the participant

- Follow-Up Visit at 6 months post baseline (virtual)
  - Collection of follow-up outcome data
  - This visit will be performed by CREs as part of the MLHC program, study staff (research assistant, or study investigators) will confirm data collection and if needed supplement data collection using Epic or by contacting the participant

6.2 Schedule of Events

Procedures	Screening Day -7 to -1	Baseline Visit 1, Day 1	Study Visit 2, 3 months	Study Visit 3, 6 months
Informed consent	X			
Confirming eligibility	X			
MLHC companion app orientation	X			
Demographic information	X			
Health system utilization		X	X	X
COPD severity (CAT and mMRC scores)		X	X	X
Health-related quality of life (CAT score)		X	X	X
Mediation review		X	X	X
Smoking status review		X	X	X
Vaccination status review		X	X	X
Adapted COPD-Q score (knowledge of COPD)		X	X	X
Adapted COPD Self-Efficacy score		X	X	X
Partners in Health Scale score (self-management)		X	X	X
COPD referrals review (rehab, smoking cessation)		X	X	X
Adverse event review and evaluation		X	X	X
Complete Case Report Forms (CRFs)	X	X	X	X

7.0 STATISTICAL CONSIDERATIONS

7.1 Statistical Hypotheses

This is a pilot study of feasibility, so there are no a priori null hypotheses to test

7.2 Sample Size Determination

As this is a pilot study, a sample size of 50 participants was chosen in order to adequately evaluate system feasibility first and foremost. The clinical outcomes of interest will be collected and analyzed, but the study will not be powered to capture a specific predicted difference at this stage. The results we do obtain will help inform the sample size calculations for a future larger clinical trial with control group.

7.3 Populations for Analyses

Feasibility outcomes will be assessed for all patients referred to study enrolment
Clinical outcomes will be assessed for all patients who complete the MLHC program and provide follow-up information. Essentially a Per-Protocol Analysis format.

7.4 Statistical Analyses

7.4.1 General Approach

7.4.2 Analysis of the Primary Endpoint(s)

Feasibility endpoints:

- MLHC program participation
    - Number of patients who started program over total offered
    - Number of patients who completed program over total started
    - Number of providers who referred patients to the program over total
- MLCH Care Companion app use
    - Number of times app opened
    - Number of sessions accessed within the app
    - Number of session tasks marked completed
    - Use of other app features (ex: medication reminder notifications)
    - Time spent using the app each time used

7.4.3 Analysis of the Secondary Endpoint(s)

Clinical endpoints:

- Assessed prior to study start, at 3 months (end of MLHC program) and at 6 months (follow-up after program completion). Outcomes will be collected by MLHC CREs using a standardized form in Salesforce, as well as a research assistant based on Epic electronic chart review. For continuous variables, difference in the mean (SD) will be calculated at 3 months and 6 months compared to baseline. For dichotomous variables, difference in proportions at 3 and 6 months compared to baseline will be calculated.

- Healthcare system utilization (number of COPD-related outpatient visits, hospital admissions, ED visits, ICU admissions (at baseline will be over the previous 12 months)
- COPD severity (CAT and mMRC scores, and number of COPD exacerbations)
- Health related quality of life (CAT score)
- COPD medication use (COPD controller medication use, oxygen therapy, oral corticosteroid use, antibiotic use, rescue inhaler use)
- Smoking status (packs per year, quit attempts)
- Vaccination status (routine guidelines recommended vaccines received)
- COPD knowledge (Adapted COPD-Q score)
- Self-efficacy score (Adapted COPD Self-efficacy scale score)
- Self-management score (Partners in Health Scale score)
- Healthcare provider referrals prior to using the program (pulmonary rehab, smoking cessation counseling referrals

7.4.4 Safety Analyses

CRE will liaise with clinical team during delivery of MLHC session if any safety concerns arise

At 3- and 6-month follow-up periods, clinical outcomes detailed above will be assessed by study investigators to determine if there are any concerning safety signals (for example, increased exacerbation rates or health service use, COPD severity scores).

7.4.5 Baseline Descriptive Statistics

Gender, age in years, education (highest level completed), race/ethnicity, type of smartphone used, smartphone use frequency, baseline clinical outcomes listed above

7.4.6 Planned Interim Analyses

N/A

7.4.7 Sub Group Analyses

N/A

7.4.8 Tabulation of Individual Participant Data

N/A

7.4.9 Exploratory Analyses

N/A

8.0 SAFETY AND ADVERSE EVENTS

8.1 Definitions

Adverse Event
An adverse event (AE) is any untoward medical occurrence in a research participant administered an investigational product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the investigational product.

Serious Adverse Event
A serious adverse event (SAE) is any AE that is:

- Fatal;
- Life-threatening;
- Requires or prolongs hospital stay;
- Results in persistent or significant disability or incapacity;
- A congenital anomaly or birth defect; or
- An important medical event (events that may not be life threatening but are of major clinical significance, such as a drug overdose or seizure that did not result in in-patient hospitalization).

Adverse Event Collection Period
The period during which adverse events must be collected is normally defined as the period from the initiation of any research procedures to the end of the study treatment follow-up. For this clinical trial, the study treatment follow-up is defined as 30 days following the last administration of the study intervention.

Post-study Adverse Event
At the last scheduled visit, the PI and/or QI will instruct each participant to report any subsequent event(s) that the participant believes might reasonably be related to participation in this clinical trial. The PI and/or QI will notify the study sponsor of any death or adverse event occurring at any time after a participant has discontinued or terminated participation that may reasonably be related to this clinical trial. The sponsor will also be notified if the PI and/or QI should become aware of the development of cancer or of a congenital anomaly in a subsequently conceived offspring of a participant that was involved in this clinical trial.

Abnormal Laboratory Values
N/A

8.2 Recording of Adverse Events

All adverse events occurring during the study period will be recorded. At each contact with the research participant, the research team will seek information on adverse events by specific questioning. Information on all adverse events will be recorded immediately

in the participant's research record and/or legal health record, and transcribed into the adverse event log.

8.3 Reporting of Serious Adverse Events

8.3.1 Investigator Reporting: Notifying the Sponsor

SAEs will be reported to the sponsor within 24 hours of becoming aware of the event.

8.3.2 Investigator Reporting: Notifying the REB

The process for notification to the REB for applicable serious adverse events (SAEs) will be completed as per REB reporting requirements. SAEs and unanticipated events will be recorded and reported to the REB in accordance with the REB's reporting requirements and timelines. Copies of each report and documentation of REB notification and REB receipt/acknowledgement will be kept in the Investigator Study Binder.

8.3.3 Sponsor Reporting of SUADRs: Notifying Health Canada

N/A

8.3.4 Sponsor Reporting of SUADRs: Notifying Sites

N/A

8.4 Reporting of Device Deficiencies

N/A

8.5 Safety Management Plan

Participants will be followed bi-weekly by CREs during their participation in the MLHC virtual program. Should any safety concerns arise during this period of the study in relation to COPD severity, exacerbations, or increased healthcare visits, CREs will contact the study team and cases will be discussed on an individual basis. The study team will then liaise with the participant's regular health care team to arrange any necessary follow-up. Following completion of the program, participants will be assessed for clinical outcomes at 3 months and 6 months post-study initiation, at which time safety concerns will also be evaluated, and communicated with the study PI as needed. The study team will then liaise with the participant's regular health care team to arrange any necessary follow-up. As the intervention being delivered represents guideline-based self-management and education support, there is unlikely to be any harm associated with it (this is supported by recent systematic review and meta-analysis data of self-management interventions in COPD). However, though the study is not powered to detect clinical effectiveness, if there are any safety concerns related to study participation at follow-up visits in terms of increased health service use and COPD severity (ED visits, hospitalizations, COPD exacerbations), these will be communicated to the study team, REB and the next appropriate steps will be considered, including but not limited to study termination.

8.6 Unblinding Procedures

N/A

8.7 Data and Safety Monitoring Board

N/A

9.0 CLINICAL TRIAL DISCONTINUATION AND CLOSURE

9.1 Clinical Trial Discontinuation

This clinical trial may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause (i.e. closure based on PI decision, sponsor/funder decision, REB or other oversight bodies' decision; review of serious, unexpected and related AEs; noncompliance; futility). Notification, which includes the reason for study suspension or termination, will be provided by the suspending or terminating party to research participants, the PI, funding agency, WCH, and regulatory authorities. If the clinical trial is prematurely terminated or suspended, the PI will promptly inform research participants, the REB, and the sponsor, and will provide the reason(s) for the termination or suspension. All communication with participants for this purpose will go through REB review and approval. Research participants will then be contacted, as applicable, and be informed of changes to the study visit schedule.

10.0 DATA HANDLING AND RECORD KEEPING

10.1 Source Documents & Case Report Forms

Please reference this study's Data Management Plan (DMP).

Data for this clinical trial will be managed using REDCap electronic case report forms. This system is maintained on central WCH servers with data backed up daily, and is supported by the WCH REDCap Administrator.

This study will involve the collection of system use and clinical data by study staff (which may include PI, co-investigators, or research assistants) from securely transferred data collection from CREs, medical records from EPIC, and/or REDCap questionnaires in order to evaluate system feasibility and effectiveness. CRE notes from participation in the MLHC program will be kept in LHF servers and transferred securely to WCH servers.

The personal health information (PHI) required for this study is described in the Patient Data collection form. PHI is required for this study because we are evaluating measures of clinical effectiveness in order to inform future larger trials.

10.2 Protocol Deviations

No deviations from or changes to the protocol will be implemented without prior agreement from the sponsor as required, and approval from the REB, unless to eliminate an immediate hazard to a participant.

10.3 Record Retention

Records will be maintained for a duration of 7 years following study completion on internal WCH servers.

10.4 Clinical Trial Registration

The trial will be registered on ClinicanTrials.gov prior to study initiation.

11.0 STUDY MONITORING, AUDITING, AND INSPECTING

11.1 Study Monitoring Plan

Site monitoring is conducted to ensure that the rights and well-being of research participants are protected, the reported trial data are accurate, complete, and verifiable, and the conduct of the clinical trial is in compliance with the currently approved protocol/amendment(s), ICH GCP, and applicable regulatory requirement(s).

- An on site monitoring plan will be developed with the Quality Assurance Office at WCH. N2 SOP will be used for all study operating procedures.

11.2 Auditing and Inspecting

The PI and site will permit study-related audits, and inspections by the REB, WCH, sponsor, and applicable granting agencies or regulatory bodies, including access to all study-related documents (e.g. source documents, regulatory documents, data collection instruments, study data, etc.). The PI will ensure the capability for audits/inspections of applicable study-related facilities (e.g. research pharmacy, clinical laboratory, imaging facility, etc.).

12.0 ETHICAL CONSIDERATIONS

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12.1 Research Ethics Board (REB) Approval

Research Ethics Board (REB) approval will be obtained prior to beginning any research-specific procedures. Following initial ethics approval, ongoing ethical approval will be maintained and the clinical trial will undergo REB review at least annually, in accordance with regulatory and REB requirements. The clinical trial will be conducted in accordance with the REB-approved study documents and the determinations (including any limitations) of the REB, and in compliance with REB requirements.
Whenever new information becomes available that may be relevant to participant consent, a consent form and/or consent for addendum will be presented to the REB for

review and approval prior to its use. Any revised written information will receive REB approval prior to use.

12.2 Informed Consent Process & Documentation

Prior to the consent discussion, research personnel will contact participants/SDMs using a verbal consent script. Research personnel will obtain consent to send a copy of the ICF to the participant prior to the consent discussion, which may occur via REDCap or email according to participant/SDM preference.

The consent discussion will occur by telephone or Micorsoft Teams/Zoom, at the participant's preference. The consent discussion will be conducted by research personnel who are not the PI and do not have a clinical relationship with participants.

Informed consent will be documented through REDCap e-Consent.

After informed consent has been obtained, a complete (fully signed) copy of the ICF will be provided to participants by email or mail, according to their preference.

13.0 PRIVACY AND CONFIDENTIALITY

All clinical trial-related documents and data will be held in strict confidence and stored at WCH or on WCH servers, and will follow WCH policies and procedures to ensure participant privacy and confidentiality. Data in the Epic Care Companion app will be used to assess feasibility of using this app as a companion to the MLHC program. The app is managed by WCH and participant data is stored locally. Data is accessible by the research team only. Data is encrypted and data is protected in the tool via standard PHIPA EHR protocols while traveling in and out of the app and while stored in it. Participants may continue to access the data at the end of the clinical trial. The participant will have to agree to a Terms of Use and Privacy Policy to use the app prior to data collection. No information concerning the clinical trial or the data will be released to any unauthorized third party without prior written approval of the sponsor, and the consent of the participant (where applicable).

All research activities will be conducted in as private a setting as possible. The study monitor, other authorized representatives of the sponsor, representatives of the REB, regulatory agencies may inspect all documents and records required to be maintained by the PI, including but not limited to, medical records and pharmacy records for the participants in this clinical trial. The participant's contact information will be securely stored at WCH for internal use during the clinical trial. At the end of the clinical trial, all records will continue to be kept in a secure location in accordance with applicable institutional and regulatory requirements.

14.0 CLINICAL TRIAL FINANCES

14.1 Funding Source

This study is funded through a grant from the Women's College Hospital Foundation.

14.2 Conflict of Interest

No conflicts of interest present.

15.0 PUBLICATION POLICY/DATA SHARING

16.0 REFERENCES