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A study to see if a digital app designed to support patients in self-managing their COPD and highlight when they need to have a medication review with their healthcare provider is safe and effective

Submission date
09/05/2025

Recruitment status
Recruiting

Registration date
10/06/2025

Overall study status
Ongoing

Last Edited
20/02/2026

Condition category
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic Obstructive Pulmonary Disease (COPD) is a common, globally important long-term lung condition that affects the lives of millions of people worldwide. Symptoms include breathlessness, cough and wheeze, often making it difficult to carry out everyday activities. In the UK, COPD is responsible for 130,000 annual hospital admissions, and approximately 30,000 people die each year, many prematurely due to fatal exacerbations (flare-ups). COPD cannot be cured, but it is treatable with inhaled medication.

Optimal medication management provides symptom control, slows disease progression, and aims to improve quality of life. However, despite the availability of national and international evidence-based guidelines, research has shown that COPD treatment is not always prescribed according to recommendations. Poor adherence to guidelines and underdiagnosis mean patients continue to experience symptoms regardless of the treatment they are taking. Furthermore, adherence to treatment or poor inhaler technique significantly impacts COPD health outcomes.

To address this, my mhealth Ltd and the University of Southampton created a digital tool to observe whether people using a digital self-management application (app) 'myCOPD' were receiving guideline-based inhaler treatment. This tool uses a treatment realignment algorithm to compare app user-reported inhaler use against COPD Assessment Test (CAT) scores, symptoms, and exacerbation history. The algorithm has been designed to follow the GOLD 2023 guidelines for COPD management. The algorithm has been tested using retrospective data (Proportionate Review Approval – IRAS: 320723; REC reference: 22/PR/1722). The algorithm will now be tested in a prospective randomised controlled trial called 'mySmartCOPD'.

This study is using two versions of an app called 'MMH-LAB1'. One version, called MMH-LAB_Control_1, is the control version and doesn't have the algorithm. The other, called MMH-

LAB_Test_1, is the test version and includes the algorithm. The app is only being used for the mySmartCOPD clinical study and is clearly labelled ‘Exclusively for Research Use only’. The goal is to see if the algorithm can spot when someone’s inhaler treatment doesn’t follow the GOLD 2023 guidelines, encourage them to speak to their healthcare team if they get a warning, and help them better understand their symptoms, history of flare-ups, and risk level based on their CAT score.

Who can participate?
Adult users of the myCOPD app who have opted in to be contacted for research purposes

What does the study involve?
The study involves participants downloading an additional app, ‘MMH-LAB1’, where they record their COPD symptoms and medications daily for 6 months. Participants will also complete a monthly questionnaire regarding their health, any issues and use of healthcare. They will also complete an additional ‘Feedback’ questionnaire at the end of the 6-month study. Participants who are randomised to the intervention arm will be informed if the information that they input relating to their COPD symptoms and medications identifies that they are out of guidance, and they will be notified that they should obtain a medication review with their GP/healthcare provider. The intervention participants will have access to the Patient Advocate, who will support them in their GP/healthcare interaction

What are the possible benefits and risks of participating?
Benefits - The data you provide as part of the study will help us understand the best ways of getting people with COPD onto the treatment that is right for them. We hope that this will improve the day-to-day symptoms of COPD patients and reduce the risk of hospitalisation due to COPD flare-ups.
Risks - The MMH-LAB1 algorithm has been fully tested prior to the study and will recommend the guideline-compliant medication for your symptoms. However, all medication decisions will be made between you and your healthcare team. The MMH-LAB1 app cannot make any changes to your medication on its own.

Where is the study run from?
Southampton General Hospital, UK

When is the study starting and how long is it expected to run for?
March 2023 to October 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR)

Who is the main contact?
mysmartCOPD Trial Manager, mysmartcopd@soton.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
355764

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 67335, AI_AWARD02200

Study information

Scientific Title
A randomised controlled trial to explore the safety and clinical efficacy of a treatment re-alignment algorithm using data from a digital self-management application for patients with COPD

Acronym
mySmartCOPD V1

Study objectives
Whether the mySmartCOPD treatment re-alignment algorithm as part of a digital self management application (app) in patients with COPD is safe and effective.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 26/06/2025, South Birmingham Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 1048211; Southbirmingham.rec@hra.nhs.uk), ref: 25/WM/0050

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
The safety and efficacy of a digital treatment guidance algorithm in patients with chronic obstructive pulmonary disease (COPD)

Interventions
Design
An open-labelled randomised controlled trial with a qualitative sub-study, designed to test a new approach to managing COPD inhaled treatment medication.

Phase 1 (Pilot): An interim futility analysis to determine if the trial should continue based on whether participants follow the advice provided by the app. The focus is on adherence to the intervention guidelines.

Phase 2 (Efficacy): We will evaluate the safety, acceptability, and effectiveness of the intervention.

Qualitative Sub-study: Semi-structured interviews to understand how acceptable and practical the treatment approach is for participants and their healthcare providers.

Consent
Consent to participate in the trial will be captured through a dedicated trial website using an electronic consent (eConsent) system. Potential participants will be invited to visit the website, where they will read a brief description of the trial. If interested, they can then read the ethically approved Patient Information Sheet with a full explanation of the trial. A telephone number to contact the trial team will also be provided should the patient have any questions about the trial or the consent process. If the patient is willing to take part in the trial, the eConsent system will guide them through the eConsent process, using an ethically approved eConsent form. Once consent has been provided by the patient, an email will be sent to the participant with a copy of the PIS.

Following consent, a letter informing the patient's GP of the trial and the patient's involvement will be sent. This letter will contain further information about the possibility of COPD treatment change requests by the participant whilst the patient is on the trial.

Participants who agree to be contacted regarding the qualitative sub-study interviews will also give consent for their contact details to be shared with the qualitative researcher. The contact details will be accessed securely by the researcher, who will contact these patients directly by telephone. If patients agree to be interviewed, recorded verbal consent will be taken by the researcher before starting the interview. All patient advocates will be invited by email to be interviewed. They will also be asked to provide verbal consent before starting interviews.

Recruitment
Trial recruitment will be performed using data contained within the myCOPD app from the pool of existing myCOPD app users who have agreed via the app to be contacted for research purposes.

Participant Identification
Potential participants will be identified through the myCOPD database. Existing agreements, where myCOPD users have agreed to participate in research via the app, allow the My MHealth team to perform a pre-screening check on existing user data. Data that the users have entered into the app over the last 12 months will be used to pre-screen them against the eligibility criteria.

Only users who have opted into the My MHealth research community, which allows My MHealth to contact patients about clinical trials, under consent as a lawful basis, will be eligible for this trial. A randomly ordered list of up to 1000 top app users will be generated, with trial invitations sent to them via email, phone and/or SMS. The number of users approached each week will be altered depending on the recruitment rate. If the trial sample size is not reached following the first 1000 invites, the process will be replicated with the next 1000 users with the highest app engagement. This process will be replicated as many times as necessary to reach the trial recruitment target.

Eligible, potential participants will be informed about the trial via telephone, SMS, and/or email by My MHealth. They will be signposted to the trial website hosted by the University of Southampton. Those who do not respond to the initial invite may be re-invited to the trial 2 months after the initial invite was sent.

Screening Procedures
A participant identification number will be allocated at screening, which will be used throughout the trial should the participant consent and fulfil the eligibility criteria.

Screening Post Consent
Following informed consent but prior to randomisation, the participant will be registered to the MMH-LAB1 app, where the My MHealth team will make a one-off transfer of study-relevant participant myCOPD data. This data will be reviewed by the trial-centred, medically qualified doctor for screening to ensure that the patient still fulfils all eligibility criteria at the point of randomisation. Based on this data transfer, MMH-LAB1 will allocate a GOLD group and App COPD Classification (note: this is required to ensure eligibility).

Registration and Randomisation Procedures
Patients who are pre-screened within the myCOPD app will be provided with a unique ID, with a prefix, e.g. msc_uos_followed by a randomly generated, unique personal identification number, allocated on invitation to the trial. This number will act as the patient's ID for the entire trial and will be used to identify the patient between the eConsent, the Randomisation system, the app, and any external database.

Patients who provide electronic consent and are confirmed eligible for the trial will be registered to the MMH-LAB1 app, randomised and their involvement in the trial will commence. On registration to MMH-LAB1, participants must agree to the standard app Terms and Conditions and Privacy Policy.

In/Out of Guidance pre-Randomisation
Prior to randomisation, the trial clinician will assess whether the patient is in or out of guidance

as per the inclusion criteria and GOLD group. Following this assessment, the patient will be randomised to either the control or intervention arm of the trial MMH-LAB1 app.

Randomisation
Patients who have provided consent for the trial and are confirmed as fully eligible will be randomised by the central trial team using the web-based TENALEA randomisation service.

The patient will be randomised to the intervention (MMH-LAB_Test_1) or control (MMH-LAB_Control_1) arm using a 1:1 block allocation. Data used to confirm the patient's eligibility will be used to stratify the patients between the arms. The stratification criteria will be the patient's App COPD classification (a, b or c) and whether the patient is GOLD 2023 guideline-adherent.

The randomisation result will be emailed directly to the central trial team from TENALEA. The central trial team will then relay the result to the My MHealth team, who will assign the patient to the intervention (MMH-LAB_Test_1) or control (MMH-LAB_Control_1) arms as applicable. The participant will be informed of the randomisation result and will automatically enter the correct Arm when they log in to the MMH-LAB1 app. Coach cards will be provided to give instructions on what is expected. At this point, the patient will formally start on the trial.

Data Transfer
Following randomisation, specific retrospective user data for each participant will be copied from my COPD to MMH-LAB1.

Data collected via myCOPD, MMH-LAB1, case report forms and the patient advocate will be transferred directly to the University of Southampton via SafeSend.

Definitions of procedures
The following data will be collected via the intervention (MMH-LAB_Test_1) and control (MMH-LAB_Control_1) apps or the trial-specific Qualtrics surveys over the participants' 6-month involvement in the trial, depending on the timepoints the data is required:

Demographic data, exacerbation of COPD details, COPD treatment details, healthcare usage, COPD symptom score, safety data, smoking data, COPD Assessment Test (CAT) questionnaire, EuroQol Five Dimensions Five Level (EQ-5D-5L) questionnaire, adverse event (AE) / serious adverse event (SAE) reporting and feedback questionnaires.

Patient Advocates
Patient advocates are non-clinical employees of my mhealth who will be employed to support participants on the intervention arm on how to navigate the app and understand messages regarding the algorithm that they receive. They will guide participants on how to discuss the app's recommendations with their healthcare providers. Participants do not have to use the Patient Advocate option.

Qualitative Sub-Study
During consent to the main trial, patients and patient advocates will be given the option to participate in the qualitative sub-study. The qualitative researcher (at the University of Southampton, who is also part of the trial team) will contact the participants who consented to their contact details being shared and patient advocates, to discuss any potential questions and to arrange a time to speak with them by telephone or video call. All participants and patient advocates will be given a copy of the qualitative sub-study participant information sheet about these interviews. They will also be sent an email, a text, or an invitation letter prior to their qualitative sub-study interview to remind them of their appointment. The interviews will last up

to 60 minutes and will take place 3-12 months after randomisation to the main trial. Patients will receive reimbursement for their time.

Follow Up
Participants are expected to use the MMH-LAB1 app for the full trial duration of 6 months. Participants who have not provided key 6-month trial data may be contacted up to one month after their scheduled 6-month questionnaires to collect this data. There is no planned follow-up or continued provision of the intervention following the completion of the 6-month trial duration. At the end of the 6-month follow-up, participants will no longer have access to the MMH-LAB1 app. No further data can be collected outside of the trial app environment. Participants will continue to use myCOPD as usual.

Withdrawal
Following withdrawal, participants will no longer have access to MMH-LAB1. This will not affect them using the myCOPD app. No further data can be collected outside the trial app environment.

Definition of End of Trial
The definition for End of Trial will be once all participants have reached 6 months post-randomisation; all data has been collected via the trial apps and Qualtrics databases to answer the primary trial objective; and the data has been centrally reviewed, cleaned and locked ready for analysis.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
MMH-LAB1 app

Primary outcome(s)
Patients (frequency and %) receiving guideline adherent treatment measured using data that will be collected via the intervention (MMH-LAB_Test_1) and control (MMH-LAB_Control_1) apps at baseline and trial completion (month 6)

Key secondary outcome(s))
The following secondary outcome measures are assessed using data collected via the intervention (MMH-LAB_Test_1) and control (MMH-LAB_Control_1) and the methods stated:
1. The effect of the intervention on patients' adherence to guideline-mandated treatment measured using the following methods by frequency and % of daily:
1.1. Rate of algorithm indication to change treatment
1.2. Response to treatment change indication
1.3. Nature of treatment change

2. The effect of the intervention on exacerbation frequency and patient wellness scores measured using the following methods by mean, SD, median and range, frequency and % for exacerbations at baseline and 6 months:
2.1. Change in COPD Assessment Test (CAT) score
2.2. Exacerbation frequency
2.3. Change in quality of life ratings measured using the EQ-5D questionnaire

3. The feasibility of the intervention pathway in the pilot phase and to identify additional patient support mechanisms for the efficacy phase to maximise healthcare equality, measured using the following methods by frequency and percentage or description at baseline and month 6, unless mentioned below in brackets:
3.1. % Patients receiving guideline-adherent treatment
3.2. Rate of app indication to change treatment
3.3. Response to treatment change indication (measured intermittently, depending on when the participant goes out of guidance)
3.4. Nature of treatment change (Measured intermittently – depending on when a participant goes out of guidance)

4. The level of the app with algorithm usage and engagement measured using the following methods by frequency and percentage. Measurement timepoint – see below in brackets:
4.1 Frequency of app engagement (daily)
4.2. Rate of completion of endpoint data (6 months)
4.3. Resource requirement to allow patients to act on intervention information (intermittently, depending on when the participant goes out of guidance)

5. The understanding of the participants' and PAs' experiences of using the app will be measured using the following methods:
5.1. Patient Satisfaction Rating using the Patient Feedback questionnaire at month 6
5.2. Interviews completed 3-12 months during the trial, with a qualitative analysis of interviews

6. The safety of the algorithm if clinicians do not act on the recommendations and if participants do not act on notifications measured using data collected daily via the MMH-LAB1 app by frequency, percentage, means and standard deviations; data collected through qualitative interviews at between 3-12 months of the trial and measured by qualitative analysis:
6.1. That the algorithm behaves as expected in delivering the appropriate message. That if clinicians do act on the recommendations that they do so appropriately.

Completion date
20/10/2026

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 20/02/2026:
1. Adult patients over 18 years of age and able to give informed consent
2. A clinical diagnosis of COPD (all patients registered on the app have a confirmed diagnosis of COPD confirmed by their clinician before being prescribed the app).
3. A registered and activated user of the myCOPD app
4. One or more CAT questionnaires completed on the myCOPD app in the last 12 months
5. One or more exacerbation forms completed on the myCOPD app in the last 12 months
6. Classified appropriately into 3 groups:
6.1. Few symptoms (CAT < 10, 0 or 1 moderate exacerbations within the last 12 months)
6.2. Many symptoms (CAT > = 10, > = 0 or 1 moderate exacerbations within the last 12 months)
6.3. Exacerbators (> = 2 moderate or > = 1 severe exacerbation independent of CAT within the last 12 months)
7. Existing opt-in to research agreement to be completed by the patient

Previous key inclusion criteria:
1. Adult patients over 18 years of age and able to give informed consent
2. A clinical diagnosis of COPD (all patients registered on the app have a confirmed diagnosis of COPD confirmed by their clinician before being prescribed the app).
3. A registered and activated user of the myCOPD app
4. One or more CAT questionnaires completed on the myCOPD app in the last 12 months
5. One or more exacerbation forms completed on the myCOPD app in the last 12 months
6. One or more COPD medication diaries completed on the myCOPD app in the last 12 months
7. Classified appropriately into 3 groups:
7.1. Few symptoms (CAT < 10, 0 or 1 moderate exacerbations within the last 12 months)
7.2. Many symptoms (CAT > = 10, > = 0 or 1 moderate exacerbations within the last 12 months)
7.3. Exacerbators (> = 2 moderate or > = 1 severe exacerbation independent of CAT within the last 12 months)
8. Existing opt-in to research agreement to be completed by patient

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
110 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Cannot read or write in English as required to understand the trial materials and provide the trial data.
2. Has not opted in to the research agreement via myCOPD

Date of first enrolment
22/07/2025

Date of final enrolment
18/04/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
England
SO16 6YD

Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes