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Testing whether home sensors can predict flare-ups in chronic lung disease

Submission date 12/02/2026	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 25/03/2026	**Overall study status** Ongoing	
Last Edited 27/10/2026	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease (COPD) is a long-term lung condition. People with COPD can experience sudden worsenings of symptoms (exacerbations or flare-ups), which can reduce quality of life and sometimes lead to hospital admission. Earlier recognition of symptom worsening could help to improve self-management and care, but predicting flare-ups is difficult. This study will develop and test the feasibility of a remote monitoring platform that combines three types of information: a brief daily symptom score, passive information from a wrist-worn smartwatch (such as heart rate and activity), and indoor air quality information from a monitor in the home (such as particles in the air, temperature and humidity).
The study has two linked parts:
1. User needs and usability work to understand what people with COPD (and relevant clinicians) need from the platform, identify anything that could be confusing or unsafe to use, and improve the design through repeated testing and refinement.
2. A feasibility study in people with COPD to assess whether the platform can be used in everyday life, how acceptable it is, how consistently people engage with it, how complete the data are, and whether the study procedures work well enough to plan a future larger study. During this feasibility phase, the system will not provide automated alerts, clinical advice, or treatment recommendations. Any algorithm outputs will not be visible to participants or clinicians and will not be used to make clinical or self-management decisions. Usual clinical care will continue as normal.

Who can participate?
Adults aged 18 years and over with a clinician-confirmed diagnosis of COPD can take part. Participants will need to be able to give informed consent and take part in home/remote monitoring. Recruitment will aim to include people with a range of ages, backgrounds, digital confidence, and risk of COPD flare-ups to ensure the platform is assessed inclusively. Clinicians involved in COPD care (such as respiratory doctors, specialist nurses, and physiotherapists) may also be invited to take part in the user needs/usability work to understand practical implementation considerations (they will not use the system to manage patient care in this study).

What does the study involve?
Part 1: User needs and usability work
People with COPD will be invited to take part in:
1. A user-needs survey (around 60 people), completed online;
2. Interviews (around 16 people with COPD and around 4 clinicians), conducted remotely or in person; and
3. Task-based usability sessions (around 12 people with COPD), where participants try key tasks with the prototype platform (for example: onboarding, connecting devices, entering symptoms, and dealing with connectivity issues).
This work is designed to identify problems, reduce avoidable burden, and improve safety and ease of use before (or alongside) wider feasibility deployment.

Part 2: Feasibility study (single group)
Up to 60 adults with COPD will use the monitoring platform at home. The platform includes:
1. A smartwatch that passively records physiological information (for example, heart rate and activity-related measures)
2. An indoor air quality monitor that continuously measures the home environment (for example, airborne particles, temperature and humidity)
3. A brief daily symptom assessment completed through the FORESEE-COPD web interface. Participants will also be able to record suspected symptom worsenings or flare-ups and add details such as when symptoms started, whether they contacted healthcare services, and whether they started antibiotics and/or oral steroid tablets.
4. Brief smartphone-based vocal recordings collected through the FORESEE-COPD web interface, using simple guided voice tasks to capture vocal biomarker data.

At enrolment, a researcher will collect baseline information such as demographics and relevant COPD clinical history (for example, previous flare-ups, current treatments, and other health conditions), using standard clinical information where available.
To understand flare-ups during the study, we will use three sources of information:
1. Participant reports recorded in the platform at the time symptoms worsen
2. A short follow-up questionnaire to capture any flare-ups not logged at the time
3. With explicit consent, checking relevant parts of the participant's healthcare records to confirm flare-up-related contacts, treatments (such as antibiotics/oral steroids), and hospital admissions

At the end of the monitoring period, participants may be asked to complete short questionnaires about usability and acceptability. Some participants may also be invited to join focus groups or interviews about their experiences, including what worked well and what could be improved.

What are the possible benefits and risks of participating?
There may be no direct medical benefit from taking part. The main benefit is helping researchers design and test a monitoring platform that could support future studies aiming to recognise COPD flare-ups earlier and understand what changes happen before a flare-up.
Risks are expected to be low. Possible downsides include:
1. Inconvenience or time burden (for example, completing daily symptom check-ins)
2. Mild discomfort or skin irritation from wearing the smartwatch
3. Frustration if technology does not work smoothly (for example, connectivity problems)
4. Potential worries about privacy when sharing health-related information
The study will use secure processes to store and handle data, and access to healthcare records

will only occur with the participant's explicit consent. The platform will not replace medical care, and participants will be advised to follow their usual care plan and seek medical help as they normally would.

Where is the study run from?
The study will be run across two NHS sites in England: Bristol and Hull, including the Hull Virtual Ward, coordinated by the University of Bristol (UK)

When is the study starting and how long is it expected to run for?
September 2026 to February 2028

Who is funding the study?
NIHR Bristol Biomedical Research Centre (UK)

Who is the main contact?
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Additional identifiers

Integrated Research Application System (IRAS)
358273

Study information

Scientific Title
Feasibility study Of Remote Exacerbation Sensing & prEdiction in chronic obstructive pulmonary disease

Acronym
FORESEE-COPD

Study objectives
Current study objectives as of 21/04/2026:
User-needs/human factors:
1. Conduct a user-needs survey with approximately 60 people living with COPD to characterise desired features, acceptable burden, perceived risks, and preferences for feedback and alerts.
2. Undertake semi-structured interviews with ~16 people with COPD and ~4 clinicians (e.g. respiratory physicians, specialist nurses) to explore expectations, perceived value, and contextual factors influencing adoption and trust.
3. Conduct formative, task-based usability sessions with ~12 people with COPD to observe real-time interaction with the prototype (e.g. onboarding, wearing devices, symptom entry), identify usability issues and refine the design.
4. Synthesise user-needs and human factors findings into a structured set of functional, usability and safety requirements to guide refinement of the FORESEE-COPD platform.

Feasibility/multimodal monitoring:
5. Recruit 60 adults with COPD across two NHS sites and onboard them to the FORESEE-COPD platform for up to 12 months of remote monitoring.
6. Assess recruitment, onboarding and retention, including rates of consent, successful set-up and continued participation.
7. Quantify adherence and engagement with each component of the platform, including daily symptom reporting, vocal biomarker task completion, wearable use, and in-home air monitor operation.
8. Assess acceptability and usability using brief validated questionnaires and qualitative focus groups/interviews with participants.
9. Quantify data completeness and basic quality across each data stream (symptom, physiological, environmental, and vocal biomarker data), and identify technical issues affecting data capture.
10. Undertake exploratory machine learning analyses to investigate whether multimodal patterns precede patient-reported suspected exacerbation with treatment initiation, and use these results (alongside feasibility metrics) to inform sample size and design parameters for a future definitive study targeting clinically meaningful predictive performance.

Previous study objectives:
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3. Conduct formative, task-based usability sessions with ~12 people with COPD to observe real-time interaction with the prototype (e.g. onboarding, wearing devices, symptom entry), identify usability issues and refine the design.
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Ethics approval required
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Ethics approval(s)
Approved 07/04/2026, North West - Haydock Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)20 7104 8000; haydock.rec@hra.nhs.uk), ref: 26/NW/0064

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease (COPD)

Interventions
Data collection methods:
Component 1: User needs and formative HF/UE activities
Intended users, use environments and context of use (use specification)
The formative HF/UE work will define and document the intended context of use, including:
Intended users: people with COPD and, where relevant, clinicians involved in COPD care (e.g. respiratory physicians, specialist nurses, physiotherapists). Clinician involvement at this stage focuses on understanding implementation considerations and does not involve use of the system for patient management.
Use environment: predominantly home/remote settings (including periods of illness and

fatigue), with variable connectivity, competing demands, and differing levels of digital literacy and health literacy.
Operational context and training assumptions: onboarding and ongoing use with minimal training typical of remote monitoring deployments; any training materials or support processes used in the study will be documented as part of the "user interface" (including accompanying information).
Conducting formative HF/UE work will enable us to identify and mitigate use-related risks. This will allow us to develop FORESEE safely, effectively and ensure it is fit for its intended users and clinical context. This formative work will be essential for future regulation of the platform as a medical device, as it will directly enable robust summative usability validation and provide the HF /UE evidence required to demonstrate compliance with IEC 62366-1 during regulatory assessment.

Participants and recruitment:
People with COPD will be recruited from respiratory services at two NHS sites (e.g. Bristol and Hull, including Hull Virtual Ward).
Clinicians involved in COPD care will be invited via departmental networks.

Data collection:
1. User-needs survey (approximately 60 people with COPD)
Topics: current self-management practices; experience with digital/monitoring tools; preferences for monitoring frequency and format; acceptable burden; attitudes to feedback /alerts; concerns about privacy, safety and trust; perceived barriers (e.g. digital access and literacy).
Mode: online or telephone, according to participant preference.
2. Semi-structured interviews (approximately 16 people with COPD; approximately 4 clinicians)
Topics: expectations and perceived benefits/risks; trust and transparency; equity and accessibility; interaction with existing care pathways; perceived burden and long-term willingness to use; training/support needs; foreseeable circumstances that could lead to misunderstanding, non-use or incorrect use.
Conducted remotely (e.g. Microsoft Teams/telephone) or in person as appropriate; audio-recorded with consent.
3. Task-based formative usability sessions (approximately 12 people with COPD)
Participants will complete key representative tasks with the prototype in a structured, task-based session reflecting anticipated home use as far as practicable (simulated use where required).
Tasks will be selected to cover safety-relevant and operationally critical activities (e.g. onboarding; pairing/connecting devices; donning/wearing devices; entering symptoms; recognising and responding to device/app prompts; understanding data displays; managing connectivity/data transmission issues).
Use errors, close calls, use difficulties and workarounds will be observed and documented, alongside task completion and perceived burden/difficulty.
Short post-task questionnaires may be used to capture immediate impressions.
Formative intent: These sessions are intended to identify and mitigate use problems and do not constitute summative (validation) usability testing.

Analysis and outputs (Component 1):
Survey data will be summarised using descriptive statistics (frequencies, percentages, means /medians as appropriate).
Interview and usability session data will be analysed using thematic analysis to identify user needs, barriers and facilitators, trust and safety concerns, and requirements for training/support.
Usability findings will be documented as a structured log of use problems/use errors and their

contributing factors, and prioritised to inform iterative design changes (e.g. changes to interface elements, workflows, instructions, onboarding, and support procedures). Where relevant, findings will be mapped to reasonably foreseeable use errors and the context of use.
Outputs will include a documented set of user, functional, usability and safety requirements for the FORESEE-COPD platform to inform prototype refinement before, or in parallel with, wider feasibility deployment.
These outputs will contribute to the Usability Engineering File and Risk Management File for the FORESEE-COPD system as it progresses towards potential classification as Software as a Medical Device.

Component 2: Feasibility and multimodal monitoring
Participants and setting:
Up to 60 adults with clinician-confirmed COPD will be recruited from respiratory services at two NHS sites (e.g. Bristol and Hull, including the Hull Virtual Ward).
Sampling will aim to capture diversity in age, sex, ethnicity, socioeconomic background, digital confidence, and exacerbation risk, to support inclusive assessment of feasibility and acceptability.

Baseline assessment:
At enrolment, a research nurse or trained researcher will collect:
Demographic data: age; sex/gender; ethnicity; smoking status (including pack-years); body mass index (BMI); education; employment status; postcode (for Index of Multiple Deprivation).
Clinical characteristics: mMRC dyspnoea score; GOLD stage; spirometry (where available); number of exacerbations and hospitalisations in the preceding 12 months; comorbidities (including Charlson Comorbidity Index); current medications and oxygen use; vaccination status (influenza, pneumococcal, COVID-19); eosinophil count.

Remote monitoring procedures and exacerbation capture:
Participants will use a home-based, multimodal monitoring platform comprising:
Wearable device: Participants will be provided with a wrist-worn smartwatch that passively records physiological data (e.g. heart rate, heart rate variability, activity proxies, and other manufacturer-derived metrics where available). Data will be transmitted via a web-based platform to a secure Amazon Web Services (AWS) server.
Indoor air quality monitor: A home-based sensor will continuously collect indoor environmental data (e.g. particulate matter, temperature, humidity), transmitted via secure application programming interfaces (APIs). These APIs act as structured digital pathways that allow the monitor to automatically and safely send data to the study's central data platform in real time. The APIs standardise data format, enable reliable data transfer, and ensure that only authorised systems can access the incoming sensor data.
Symptom reporting: Participants will complete a brief daily symptom assessment (e.g. CAT /CAAT) via the FORESEE-COPD web interface. Participants will also be asked to record suspected symptom worsening or exacerbation events in the interface, including key event details (e.g. date of onset, symptom pattern, healthcare contact, and whether they commenced antibiotics and/or oral corticosteroids).

Added 21/04/2026: Vocal biomarker recordings: Participants will also complete brief guided voice recordings via the FORESEE-COPD web interface using a smartphone or other compatible device. These recordings will involve simple vocal tasks designed to capture vocal biomarker data for later analysis.

Exacerbation capture, classification, and verification:
Exacerbations are the primary clinical events of interest. In this study, exacerbations will be

captured using a triangulated approach:
1. Prospective participant self-report (index capture): Participants will log suspected exacerbations in real time via the platform. Where possible, the platform will prompt for structured information including treatment initiation (antibiotics and/or oral corticosteroids), healthcare utilisation (GP/out-of-hours/ED attendance), and perceived recovery date.
2. Structured case report form (recall capture): At scheduled follow-up (or study completion), participants will complete a brief exacerbation questionnaire/case report form to capture any events not logged contemporaneously, including dates, management, and healthcare contacts. This will support ascertainment of unreported events and clarify uncertainty in timing or severity.
3. Electronic health record linkage (objective verification): With explicit participant consent, the research team will access relevant sections of participants' electronic health records (e.g. GP and /or hospital records as applicable) to identify exacerbation-related healthcare contacts, prescriptions for antibiotics/oral corticosteroids for acute worsening, and hospital admissions with COPD exacerbation. These data will be used to corroborate and classify events recorded by participants and to identify severe events that may not have been self-reported.

Exacerbation severity will be classified as follows (operational definitions):
Moderate exacerbation: acute worsening of respiratory symptoms consistent with an exacerbation, requiring treatment with antibiotics and/or oral corticosteroids, with or without contact with primary/community care, and not resulting in hospital admission.
Severe exacerbation: exacerbation resulting in emergency department attendance or hospital admission (including admissions identified via EHR linkage), regardless of whether antibiotics /oral corticosteroids were prescribed.
Discrepancies between self-report, recall CRF, and EHR-derived data (e.g. differing onset dates or treatment details) will be resolved using a pre-specified adjudication approach (e.g. prioritising dated healthcare records for treatment/admission where available, while retaining participant-reported symptom onset where clinically plausible).

Clinical responsibility and platform outputs:
The platform will not provide automated alerts, clinical advice, or treatment recommendations. All clinical care will continue as usual, and participants will be instructed to follow their usual care plan and seek medical advice according to standard practice.

Engagement and participant support:
The platform will automatically record interaction metrics, including log-ins, symptom submissions, device connectivity, and data transmission status.
The research team will review a monitoring dashboard to assess data completeness and technical functioning. Participants may be contacted if prolonged gaps in data collection occur (e.g. >7 consecutive days for any data stream), to troubleshoot technical issues and explore barriers to engagement.
Any planned pauses in participation (e.g. due to illness, travel, or participant preference) will be logged as planned breaks, and their impact will be explored analytically.

Acceptability, usability, and real-world use:
Quantitative assessment:
At the end of the monitoring period, participants will be invited to complete brief, validated questionnaires, including:
1. The System Usability Scale (SUS) to assess perceived usability
2. The Acceptability of Intervention Measure (AIM) to assess overall acceptability of the

monitoring approach
These measures will provide a concise quantitative assessment of usability and acceptability with minimal participant burden.

Qualitative assessment:
Up to four focus groups (approximately six participants each) will be conducted at different time points to explore experiences of using the system in the home context, including perceived burden, trust, acceptability, usability, and perceived impact on self-management. The number of focus groups will be flexible and guided by thematic saturation and practical considerations.
A subset of participants will be invited to take part in end-of-study semi-structured interviews to explore experiences in greater depth, including reasons for sustained engagement or disengagement and suggestions for improvement.
Where relevant, identified use problems will be mapped to foreseeable use errors, potential hazards, and preliminary risk control measures, informing iterative system refinement.

Data analysis methods:
Quantitative analysis:
Feasibility outcomes will be summarised using descriptive statistics (means, medians, standard deviations, interquartile ranges, frequencies, and percentages).
Adherence will be calculated per participant and per data modality as the proportion of expected data captured over the monitoring period:
Symptom reporting: proportion of expected symptom reports completed.
Wearable data: proportion of days meeting a pre-defined minimum wear-time threshold, estimated using availability of heart rate data.
Air quality data: proportion of days with sufficient data completeness (e.g. ≥80% of expected readings).

Added 21/04/2026: Vocal biomarker data: proportion of expected guided voice recordings completed.

Engagement will be assessed using measures of continuity and consistency of data contribution, including the number and duration of gaps in data streams and trajectories of engagement over time. Time-series plots and heat maps may be used to visualise patterns of engagement.
Retention will be described as the proportion of participants remaining in the study at key time points. Where informative, Kaplan–Meier plots will be used to describe time to last contributed data, with subgroup comparisons treated as hypothesis-generating only.
Exploratory machine learning analyses will be conducted offline only. After data quality checks and pre-processing, models will be developed to explore associations between multimodal data streams and patient-reported suspected exacerbation events with treatment initiation (antibiotics and/or oral corticosteroids). Missing data handling (e.g. multiple imputation for continuous variables with <20% missingness) and exclusions will be reported transparently. Model performance metrics (e.g. sensitivity, specificity, positive predictive value) will be interpreted cautiously given the feasibility aims and sample size.

Qualitative analysis:
Audio recordings from interviews and focus groups will be transcribed verbatim and anonymised. Data will be analysed using thematic analysis, identifying themes related to usability, acceptability, burden, trust, accessibility, and factors influencing engagement and retention. NVivo (or similar qualitative software) will be used to support coding and data organisation.

Mixed-methods integration:
Quantitative and qualitative findings will be integrated to develop a comprehensive

understanding of feasibility and acceptability (e.g. qualitative explanations for disengagement considered alongside adherence trajectories; usability issues identified in interviews mapped to observed data gaps or technical issues).
Integrated findings will inform:
1. Refinement of the FORESEE-COPD platform and study procedures
2. The design and powering of a future definitive model-development and clinical evaluation study
3. A preliminary regulatory and implementation roadmap for the system as a potential future Software as a Medical Device (SaMD).

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
FORESEE

Primary outcome(s)
1. Participant engagement with the remote monitoring platform, measured using percentage adherence over the monitoring period using the proportion of days participants complete daily symptom reports, complete vocal biomarker recordings, and wear the wrist-worn device, at over 12 months following enrolment

Previous primary outcome:
1. Participant engagement with the remote monitoring system measured using the proportion of days participants complete daily symptom reports and wear the wrist-worn device (percentage adherence over the monitoring period), at over 12 months following enrolment

Key secondary outcome(s)

Completion date
14/02/2028

Eligibility

Key inclusion criteria
1. Age: ≥18 years.
2. Diagnosis: Clinician-confirmed COPD, defined according to GOLD (Global Initiative for Chronic Obstructive Lung Disease) criteria.
3. Exacerbation history: Between 1 and 3 COPD exacerbations in the past 12 months requiring treatment with antibiotics, systemic corticosteroids and/or hospitalisation.
4. Consent: Able to provide written informed consent after full explanation of the study. Proxy consent is not permitted.
5. Digital participation: Willing and able, either independently or with support from a carer /family member, to:
5.1. Enter symptom data via a web or app-based platform
5.2. Wear a smartwatch for prolonged periods

5.3. Host and tolerate an in-home environmental monitoring device
6. Access to technology: Access to a compatible smartphone, tablet or computer (own or carer's) and home internet/4G connection sufficient to support data transfer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
90 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Consent capacity: Significant cognitive impairment or other condition judged by the investigator to preclude informed consent.
2. Confounding respiratory diagnoses: A primary diagnosis of another chronic respiratory disease such as asthma, idiopathic pulmonary fibrosis, non-COPD bronchiectasis or other interstitial lung disease where COPD is not the predominant condition.
3. Significant comorbidities or instability:
3.1. Major cardiovascular event (e.g. myocardial infarction, stroke) within the past 3 months;
3.2. Unstable or decompensated cardiac, renal or hepatic disease where participation is considered unsafe by the investigator;
3.3. Active malignancy requiring systemic treatment (excluding localised non-melanoma skin cancer); or
3.4. Any other serious medical or psychiatric condition that, in the opinion of the investigator, would significantly interfere with participation or completion of the study.
4. Digital/device-related barriers:
4.1. Persistent inability or unwillingness to use the required digital devices despite training and support;
4.2. Known allergy or significant skin intolerance to materials used in the smartwatch strap or casing.
5. Other practical barriers:
5.1. Severe psychiatric or neurological conditions likely to impair protocol adherence;
5.2. Markedly unstable housing or lifestyle circumstances (e.g. no fixed abode) that would make device use or follow-up impracticable over 12 months.

Date of first enrolment
14/09/2026

Date of final enrolment
14/03/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
North Bristol NHS Trust
Southmead Hospital
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Study participating centre
Hull University Teaching Hospitals NHS Trust
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Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type

Funder Name
NIHR Bristol Biomedical Research Centre

Alternative Name(s)
NIHR Biomedical Research Centre Bristol, National Institute for Health Research Bristol Biomedical Research Centre, NIHR Bristol BRC, Bristol BRC, Bristol Biomedical Research Centre

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Funder Name
Engineering and Physical Sciences Research Council

Alternative Name(s)
UKRI Engineering and Physical Sciences Research Council, Engineering and Physical Sciences Research Council - UKRI, Engineering & Physical Sciences Research Council, Science Research Council, Science and Engineering Research Council, EPSRC, SRC, SERC

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
Not expected to be made available