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Indoor air quality in respiratory disease

Submission date	**Recruitment status**	[X] Prospectively registered
05/05/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/06/2022	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
02/10/2023	Respiratory	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Air pollution causes 29,000 premature deaths and costs the economy £20 billion per year in the UK alone. The majority of these impacts are associated with Vulnerable Groups, who are most strongly affected by air pollution. People with pre-existing medical conditions, in particular those where the lung is affected (COPD/asthma), are of particular concern in terms of long-term health, and societal and economic impacts. Despite this, most of the efforts in air quality improvement focus on the general population and outdoor exposure.
Chronic obstructive pulmonary disease (COPD) is the name for a group of lung conditions that cause breathing difficulties.
Asthma is a common lung condition that causes occasional breathing difficulties.
This study has been designed to look at the perceptions and understanding of respiratory patients in relation to indoor air quality.
This trial aims to determine the sources and impact of indoor air pollution in patients with respiratory disease, specifically in relation to adults who have a COPD or asthma diagnosis.

Who can participate?
Adults aged 18 years or above, with either COPD or asthma

What does the study involve?
There are three parts to this study:
Part 1: Focus groups of up to 6 people, or individual interviews, according to patient preference, will be conducted, which will inquire about sources and impacts of indoor air pollutants, and about Indoor Outdoor Interfaces. The interviews will be conducted by a trained researcher, recorded and transcribed.

Part 2: An electronic questionnaire will be distributed using an online link. Participants can also request a paper equivalent, which will be sent by post thereafter. The questionnaire will take approximately five minutes to complete. Data will be stored in an anonymised manner. This will collect information based on the findings of Part 1.

Part 3: This part of the study involves participants completing a daily symptom questionnaire for a 2-week period. It also involves the installation of a Air Quality monitor in their homes.
COPD patients will be asked to complete a set of questions each day called the Bronkotest®. This will take around 2 minutes to complete each day. Asthma patients will be asked to complete

the ACT questionnaire and will be asked to provide a daily peak expiratory flow rate (PEFR) as part of their response. Both the ACT questions and PEFR will take around one minute to complete.
These symptom diaries will be provided in the form of an e-diary which is compatible with most electronic devices. If a paper version of the form is needed it can be provided.
A Plume Labs Flow 2 Device will also be installed in patients' homes during this part of the study. The Flow 2 collects data on air quality and pollutant concentrations within the environment it is placed.

What are the possible benefits and risks of participating?
There is no guarantee of this study benefitting participants personally, however, the main benefit of the study is to improve the understanding of how indoor air quality impacts those with respiratory conditions; and it may help in developing interventions to reduce the impact of poor indoor air quality on those with respiratory conditions. The results of this research could benefit other individuals with respiratory conditions in the future. We do not expect any harm to come to any participants as a result of taking part in any part of this study.

Where is the study run from?
This study is based at University Hospitals Birmingham, specifically the Queen Elizabeth Hospital, Birmingham. Work is also being conducted at the University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
June 2021 to October 2023

Who is funding the study?
1. Natural Environment Research Council (UK)
2. UK Research and Innovation

Who is the main contact?
Miss Eleanor Holt, cleanair4v@contacts.bham.ac.uk

Study website
https://www.birmingham.ac.uk/research/cleanair4v/cleanair4v.aspx

Contact information

Type(s)
Principal Investigator

Contact name
Prof Alice Turner

ORCID ID
http://orcid.org/0000-0002-5947-3254

Contact details
Institute for Applied Health Research
University of Birmingham
Birmingham
United Kingdom
B15 2TT

+44 (0)121 3713885
cleanair4v@contacts.bham.ac.uk

Type(s)
Scientific

Contact name
Miss Eleanor Holt

Contact details
School of Geography, Earth and Environmental Sciences
University of Birmingham
Birmingham
United Kingdom
B15 2TT
-
e.holt@bham.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
301897

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
RG_21-096, ERN_21-0821, IRAS 301897, CPMS 52509

Study information

Scientific Title
A mixed methods observational study to determine the sources and impact of indoor air pollution in patients with chronic airways disease

Acronym
IndoorAirVG

Study objectives
The study objectives are:
1. To identify the environments and/or locations that Vulnerable Groups considered to be important in their exposure to poor air quality indoors. This will be achieved by a combination of qualitative research and questionnaires.
2. To identify symptom based health outcomes driven by air quality based on symptoms and indoor air quality monitoring. This will be achieved using a daily symptom diary and an air quality monitor, used over a period of minimum 2 weeks, maximum 6 weeks.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/06/2022, Brighton and Sussex Research Ethics Committee (Health Research Authority, 2 Redman Place, E20 1JQ, UK; +44 (0) 207104 8202; brightonandsussex.rec@hra.nhs.uk), ref: 22/LO/0259

Study design
Mixed methods study qualitative research questionnaire study and observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
https://www.birmingham.ac.uk/research/cleanair4v/cleanair4v.aspx

Health condition(s) or problem(s) studied
The sources and impact of indoor air pollution in patients with respiratory disease

Interventions
Part 1: Understanding perceptions of Vulnerable Groups on indoor Air Quality
This part of the project will recruit 20-30 people. All will give informed consent.
Focus groups of up to 6 people, or individual interviews, according to patient preference, will be conducted, which will inquire about sources and impacts of indoor air pollutants, and about Indoor Outdoor Interfaces. The interviews will be conducted by a trained researcher, recorded and transcribed verbatim.

Part 2: Understanding Vulnerable Group's perceptions on indoor Air Quality and interventions to improve Air Quality
This part of the study will recruit a minimum of 100 patients. Consent will be taken remotely only, and the questionnaire distributed as a link to an electronic survey provided by Microsoft Forms. Participants can also request a paper equivalent, which will be sent by post thereafter. The questionnaire will take approximately five minutes to complete for each participant. Data will be stored in an anonymised manner electronically. Each question will use a binary yes/no response, or a numerical response (eg Likert scale) and data will be analysed using simple descriptive statistics only. Responses from those with asthma and those with COPD will also be sub-grouped and analysed separately.

Part 3: Quantifying indoor Air Quality and respiratory symptoms
This part of the study will recruit approximately 60 patients, aiming for an equal distribution of people with asthma and people with COPD.

At the first of two visits, an informed consent form will be signed and all available information will be collected according to a structured case record form (CRF). Baseline data will be collected including Date of Birth, Sex, Race and ethnicity, Height, Weight, Respiratory Diagnosis, Date of Diagnosis, Severity of disease (clinician defined), Exacerbations in last 12 months, Hospital admissions due to respiratory disease in last 12 months, smoking history, including years as a smoker, year of start and quitting and pack years, working status including relevant occupational exposures and type of agent. Current medication will also be recorded. Consent will be taken to extract from the medical record the latest values for lung function and any relevant radiological results.
A symptom questionnaire will be distributed to collect data, and patients with asthma will also receive a peak expiratory flow monitor (if they do not already have one) for conducting daily peak expiratory flow rate (PEFR). The questionnaire will be delivered in an electronic format compatible with all major phone operating systems, and will utilize validated questionnaires, namely the Bronkotest® questionnaire for patients with COPD and the asthma control test (ACT) for patients with asthma. Those with asthma will also enter their PEFR. The Bronkotest® questionnaire will take approximately two minutes to complete each day, while the ACT questionnaire will take around one minute to complete. Self-reported symptoms will be gathered every day over a minimum 2-week period. A paper version of the e-diary will be made available for those without a suitable device on which to collect data electronically.
The indoor air quality device; the same as or similar to a will be a Plume Labs Flow 2. The device will collect data on PM10 and PM2.5 mass concentrations and it will be installed in the location deemed most appropriate for gathering of data on exposure to indoor air, which we anticipate being their home. The Flow 2, is 12.5cm in height, 4 cm width, depth 3.5cm and a weight of 70g. The second of the visits will include collection of the monitor and questionnaire if it has been completed on paper.
Simple descriptive statistics will be used to delineate characteristics of the cohort, and the correlation between each pollutant measured by the indoor monitor and day to day symptoms, as determined by the total score on Bronkotest® or ACT. In addition daily puffs of inhaled short acting treatment (salbutamol) and (asthma only) PEFR will also be examined for relationship to indoor Air Quality, using a similar correlation analysis. Other factors relating to indoor AQ within collected demographic and medical history data will also be reported using simple comparative statistics.

Intervention Type
Other

Primary outcome measure
Part 1: Participant understanding and perception of Indoor Air Quality measured using focus group sessions. The questions will be informed by a literature review which has been conducted ahead of the trial commencement. These focus groups will be of around 6 participants and will last around one hour.
Part 2: Participant understanding and perception of Indoor Air Quality measured using an online questionnaire. These questions will be informed by the literature review and the information which is collected in part 1. Each questionnaire should take around 5 minutes to complete.
Part 3:
3.1. Air quality in participants' homes measured using an air quality monitor installed in participant's homes for a period of two-weeks.
3.2. Symptom diary completed by participants once per day for the same two week period. COPD patients will be asked to complete the Bronkotest e-diary, which will take around 2-

minutes each day, and asthma patients will be asked to complete the ACT questionnaire which will take around one-minute each day. Asthma patients will also be asked to submit a Peak Expiratory Flow Rate (PEFR) once a day as part of their diary.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/06/2021

Completion date
31/10/2023

Eligibility

Key inclusion criteria
Either COPD or asthma, as defined by their referring/usual care clinician in the medical record.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Around 200, however this could be lower as patients can participate in more than one part of the study.

Total final enrolment
334

Key exclusion criteria
Patients unwilling or unable to participate in the study, or those who do not have a COPD /asthma diagnosis.

Date of first enrolment
01/07/2022

Date of final enrolment
30/07/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals Birmingham
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Sponsor information

Organisation
University of Birmingham

Sponsor details
Edgbaston
Birmingham
England
United Kingdom
B15 2TT
+44 (0)121 414 3344
researchgovernance@contacts.bham.ac.uk

Sponsor type
University/education

Website
https://www.birmingham.ac.uk/index.aspx

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
Natural Environment Research Council

Alternative Name(s)
NERC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
29/02/2024

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 6.3	13/05/2022	17/06/2022	No	No
HRA research summary			28/06/2023	No	No