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Developing and evaluating a mobile phone-based early alert system using high-resolution air quality forecast to improve asthma control in Malaysia

Submission date
05/04/2023

Recruitment status
Recruiting

Registration date
01/08/2023

Overall study status
Ongoing

Last Edited
12/12/2024

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
Outdoor air pollution, particularly haze, is common in Southeast Asia, including Malaysia. Haze has been associated with increased asthma exacerbations.
A prior feasibility study was funded by the UK NIHR Global Health Research Unit on Respiratory Health (RESPIRE) conducted in Klang Valley, Malaysia. The study showed that with every increase in inhalable airborne particulate matter with a diameter of 10 microns or less (PM10) there was an 8.7% increased risk of asthma exacerbation and the exacerbation was likely to occur 2 days after exposure. In the RESPIRE Klang Asthma Cohort study, 65.9% of the surveyed adult asthma patients reported having poor asthma control; 51% of the surveyed adult patients reported haze as a trigger for asthma exacerbation. Exposure to haze was found to be significantly associated with poorly controlled asthma. With these findings, the team propose to develop and evaluate a mobile-phone-based early warning system as an individual intervention to improve asthma control. Patients will be alerted of anticipated air pollution episodes so that they can take measures to prevent acute asthma exacerbation. The study aims to develop a high-resolution air quality model for a 2-day forecast for the local priority air pollutants in the Klang District, Malaysia; to adapt and refine the mobile health application; and, to undertake a pilot study to assess the feasibility of utilising a mobile health application with air quality indicators as an early warning system to support asthma self-management.

Who can participate?
Adult patients aged over 18 years old who live in the study location and have reported poor asthma control and exacerbation aggravated by haze

What does the study involve?
Participants will be allocated to either the control group or to the intervention group. All participants (intervention and control group) will receive asthma self-management education before the allocation of groups. For the control group, participants will be asked to follow their usual care for asthma at the clinic. The research staff of this study will carry out follow-up

assessments at 1, 3, 6 and 12 months to monitor your asthma status. For the intervention group, participants will be asked to install a mobile app on their phones. After installing the app, the research staff will explain on how to utilise it in the intervention group. To ensure participants' identity is non-identifiable when using the app, they will be given a code to log in before using the app. The research staff will demonstrate how to keep track of their asthma symptoms and how to use asthma action plans. Participants will learn about air quality, weather forecasts, and health-risk messages. Follow-up assessments will be carried out by research staff at 1, 3, 6 and 12 months.

What are the possible benefits and risks of participating?
There may or may not be any benefits to the participants. The results of this study will help to improve asthma control in adults with asthma compared to usual care, particularly during pollution using a mobile health app with a high-resolution air quality forecast as an early alert system to support asthma self-management to improve patient asthma control. Participants will be able to contribute significantly to the development of an intervention to improve asthma self-management during pollution. The researcher will also be able to contribute to the larger body of medical knowledge in the field of asthma self-management. There is no foreseeable risk involved in this study except the time to help with the interview.

Where is the study run from?
Department of Primary Care Medicine, Faculty of Medicine, Universiti Malaya (Malaysia)

When is the study starting and how long is it expected to run for?
December 2022 to December 2025

Who is funding the study?
NIHR Global Health Research Unit on Respiratory Health (RESPIRE) (UK)

Who is the main contact?
nhrita@um.edu.my (Malaysia)

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
AC23007, NIHR 132826

Study information

Scientific Title
Developing and evaluating a mobile phone-based early alert system using high-resolution air quality forecast to improve asthma control in Malaysia

Acronym
AQAapp

Study objectives
Is a mobile phone-based early alert system using high-resolution air quality forecast effective in improving asthma control during increased outdoor pollution?

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/05/2023, Edinburgh Medical Research Ethics Committee (None provided, Edinburgh, None provided, United Kingdom; None provided; emrec@ed.ac.uk), ref: EMREC-RESPIRE-23-05

Study design
Pilot randomized controlled trial

Primary study design
Interventional

Secondary study design
Pilot randomized controlled trial

Study setting(s)
Community, Other

Study type(s)
Prevention

Participant information sheet
Not available in web format

Health condition(s) or problem(s) studied
Improving asthma control among adult patients with asthma during increased outdoor pollution

Interventions
A mobile phone-based early alert system using high-resolution air quality forecast

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Mobile telephone-based healthcare application

Primary outcome measure
Asthma control measured using the Global Initiative for Asthma (GINA) Asthma Symptoms Control scoring at 1, 3, 6 and 12 months

Secondary outcome measures
Clinical endpoints assessed at baseline, 1, 3, 6 and 12 months:
1. Maximum speed of expiration measured using the peak expiratory flow rate (PEFR) value
2. Frequency of acute exacerbations (defined as episodes characterised by acute or subacute onset of progressively worsening symptoms, such as shortness of breath, cough, wheezing or chest tightness, which are worse than the patient's usual status and require a change in treatment) measured using patient questionnaire interviews and from patient medical record notes
3. Frequency of emergency visits due to asthma (emergency visit either to the health clinic and /or hospital emergency department) measured using patient questionnaire interviews and from patient medical record notes
4. Frequency of using an asthma action plan measured using patient questionnaire interviews
5. Frequency of using controller medications measured using patient questionnaire interviews and from patient medical record notes
6. Frequency of using reliever medications measured using patient questionnaire interviews and from patient medical record notes

Frequency of using reliever medications:
System endpoints assessed at 1, 3, 6 and 12 months:
1. Frequency of using the mobile health applications (app) (e.g., frequency of uploading daily symptoms and asthma diary) measured using data on users retrieved from the app
2. Frequency of reviewing the information (e.g., air pollution level) on the app measured using data on user retrieved from the app
3. System Usability Scale (ease of use, function integration, confidence in using) measured using the System Usability Scale questionnaire
4. Proportion of participant drop-out rates (not using the app) measured using patient questionnaire interviews and data on users retrieved from the app

Overall study start date

12/12/2022

Completion date
01/12/2025

Eligibility

Key inclusion criteria
1. Adult patients aged 18 years old and above with physician-diagnosed asthma and receiving asthma treatment in the previous year
2. Adult patients who live in Klang District for the duration of the study
3. Patients who had reported poor asthma control and exacerbation aggravated by haze (findings from baseline study in RESPIRE 1)
4. Patients who are on controller medication (e.g., an inhaled corticosteroid (ICS), inhaled combination ICS/long-acting beta-agonists (LABA), leukotriene receptor antagonist (LTRA))
5. Patients who own and are able to use a smartphone
6. Patients who are able to understand the Malay/English language
7. Patients who are willing and able to give consent to participate in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Patients below 18 years of age
2. Patients who have respiratory symptoms (e.g., cough, breathlessness, wheezing) due to other conditions for example established physician diagnoses of:
2.1. Respiratory infection e.g., pneumonia, tuberculosis (but not having underlying asthma)
2.2. Chronic obstructive pulmonary diseases
2.3. Congenital heart disease
2.4. Heart, liver or renal failure
2.5. Gastro-esophageal reflux
2.6. Active life-threatening malignancy and those receiving palliative care
3. Patients who have disabilities (physical/psychological) that may interfere with the completion of the study
4. Patients who are unwilling or unable to provide written informed consent (e.g. cognitive impairment)

Date of first enrolment

12/11/2024

Date of final enrolment
01/12/2025

Locations

Countries of recruitment
Malaysia

Study participating centre
Bandar Botanik Health Clinic
Bandar Botanic
Klang
Selangor
Malaysia
42000

Sponsor information

Organisation
Accord (United Kingdom)

Sponsor details
Academic and Clinical Central Office for Research and Development (ACCORD)
Royal Infirmary of Edinburgh Site:
Research & Development Management Suite
The Queen's Medical Research Institute
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Sponsor type
University/education

Website
https://accord.scot/about/staff-contacts/university-edinburgh-research-governance

ROR
https://ror.org/01x6s1m65

Funder(s)

Funder type
Research organisation

Funder Name
NIHR Global Health Research Unit on Respiratory Health (RESPIRE)

Results and Publications

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

Intention to publish date
12/12/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/analysed will be de-identified before publication.

IPD sharing plan summary
Available on request