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Investigation of a digital inhaler monitor and smartphone app providing real-time information on inhaler use

Submission date
24/09/2024

Recruitment status
Recruiting

Registration date
16/06/2025

Overall study status
Ongoing

Last Edited
07/11/2025

Condition category
Respiratory

[ ] 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
Steroid inhalers reduce swelling and sensitivity in the lungs in asthma and using them every day lowers the risk of an asthma attack. Despite this, half of asthma patients don't take their inhaler as prescribed by their doctor, this is called non-adherence and can cause poorly controlled asthma, damage to the lungs, time off work, hospitalisation, and death. Digital inhaler monitors record the use of inhalers through a smartphone app, provide patients with reminders and feedback on their inhaler use and give healthcare professionals information on patient inhaler use. They have been shown to improve asthma control but is not known which patient groups would benefit the most (e.g. reduced exacerbations, or hospital attendances) and whether they are cost-effective. This is a feasibility study (a practice run for a larger study). We would like to see if the digital inhaler monitor can lead to better asthma control. In this study we will look at how best to measure this and how acceptable the trial is for people with asthma.

Who can participate?
People aged 18 years or above who:
1. Have had a confirmed diagnosis of mild to moderate asthma for at least a year
2. Are prescribed an inhaler containing an inhaled steroid that is compatible with the Find Air inhaler sensors
3. Have had at least one exacerbation of their asthma that required oral steroid treatment in the last 12 months
4. Are non-smokers and do not have any other respiratory conditions
5. Have evidence of variable lung function

What does the study involve?
Patients will be randomly allocated to receive digital inhaler monitors on their preventer and reliever inhalers and a smartphone app and usual asthma care, or to receive usual asthma care without monitors. Patients will be followed for one year with assessments at 2, 6 and 12 months to check for differences between the groups in asthma control (i.e. number of exacerbations and hospital admissions). At each visit patients will complete questionnaires on asthma control, quality of life, adherence to inhalers and the impact of their asthma on their daily life and

perform breathing tests to check for inflammation in their lungs and reviews of their adherence to inhalers. Once the study is finished participants will be invited to a semi-structured interview to examine their opinion of the digital monitors.

What are the potential benefits and risks of participating?
1. Patients with asthma may benefit from the intervention through improved adherence to their preventer inhaler and potentially improved asthma control.
2. Medical professionals working with asthma may benefit from learning more about adherence, how it can be monitored and how it can be approached with patients as well as how to support and educate patients.
3. A better understanding of which patients could benefit from inhaler monitors and potential cost benefits which will hopefully begin to provide the evidence required to enable digital inhalers to be adopted into clinical practice.
Participating in the study is not likely to cause discomfort or any additional risks.
Participants will continue to use their medication as usual. Those in the intervention group will be asked to use the Find Air system as often as they can when they take their inhaler as prescribed.

Where is the study run from?
Wythenshawe Hospital (UK)

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

Who is funding the study?
North West Lung Centre Charity (UK)

Who is the main contact?
Lynn Elsey, lynn.elsey@manchester.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
340464

Protocol serial number
NHS002179

Study information

Scientific Title
Improving Adherence in Asthma (IAA) through the use of digital inhaler monitors and mobile health technology: a randomised controlled feasibility study

Acronym
IAA

Study objectives
To assess the feasibility and acceptability of a future definitive randomised controlled trial (RCT) evaluating the clinical and cost effectiveness of a digital inhaler monitor (FindAir One) and a smartphone app to improve asthma control and inhaler adherence in adult asthma patients.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 16/12/2024, NHS Health Research Authority- North West Greater Manchester South Research Ethics Committee (Virtual meetings, Manchester, Zip/postal code not provided, United Kingdom; +44 (0)208 104 8051; gmsouth.rec@hra.nhs.uk), ref: 24/NW/0345

Study design
Single-site interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Asthma

Interventions
The main aim of the study is to assess the feasibility and acceptability of a future study evaluating the clinical and cost-effectiveness of the Find Air One add-on inhaler devices and smartphone app in adult asthma patients. Other aims include:
1. Whether the use of the Find Air One add-on inhaler device and the smartphone app leads to improved asthma control in asthmatic patients over a 12-month period compared with those receiving "usual care" alone.

2. When compared to usual asthma care, do digital inhaler monitors affect adherence to preventer inhalers and clinical measures, including airway inflammation (FeNO test) and patient-reported outcomes, including mini asthma quality of life questionnaire and test of adherence to inhalers.
3. Are digital inhaler monitors cost-effective? This will be analysed utilising health economic questionnaires (EQ5D5L, WPAI), resource utilisation and a patient diary of the impact of asthma on life.
4. Behaviour change and medication-taking behaviour over the 12 months will be assessed utilising the test of adherence to inhalers questionnaire and differences between the digital inhaler group and the usual care group will be examined.

The Find Air One Inhaler System technology consists of two parts:
1. Find Air add-on inhaler sensors - a CE-marked device available in four variants that fit on the majority of inhaler devices (pMDI, Ellipta, Turbohaler, Easyhaler). These capture each activation of the inhaler device and transfer this through Bluetooth to the Find Air app.
2. Find Air App - class I medical device accessory (CE marked), available on Apple and Google app stores.

The researchers will recruit adult patients (≥18 years of age) admitted to A&E or the respiratory wards or referred by their GP to the asthma outpatient clinics at Wythenshawe Hospital. Patients will be randomised to the digital inhaler group or usual care utilising Graph Pad randomisation software (Graph Pad ©2024 Boston, USA). Due to the nature of the study, patients cannot be blinded to allocation and therefore the study will be open-labelled.

At the baseline visit patients' eligibility will be assessed and consent form signed. Data will be collected on their prescriptions for inhaled corticosteroids (ICS) and oral steroid tablets over the previous 12 months from their GP and hospital records, which we will access through the Greater Manchester Care Record, to assess adherence and steroid courses for asthma exacerbations to assess asthma control.

Information will be collected on their demographics (i.e. age, education status, employment status), medical and medication history, smoking status, BMI, co-morbidities and their asthma history.

At a baseline visit the digital inhaler group patients will be provided with FindAir digital inhaler sensors (https://www.findair.eu) for their preventer and reliever inhalers and will be asked to download the FindAir app on their smartphone. The sensors will then be synced to their account on their app.

Objective measurements will be taken in both groups as per usual care, including forced expiratory nitric oxide (FeNO), a measure of airway inflammation that responds to inhaled corticosteroids, blood eosinophils, an indicator of inflammation and the phenotype of asthma the patient may have, lung function and patient-reported test of adherence to inhalers (TAI), asthma control questionnaire (ACQ6) and mini asthma quality of life questionnaire (mAQLQ) and the questionnaires identified for the health economic analysis, EQ-5D-5L and work productivity and activity impairment (WPAI) questionnaire. Blood samples will be taken by a phlebotomy-trained member of the clinic staff and transferred via hospital porters to the Manchester University NHS Foundation Trust Haematology laboratory. In the lab they will be analysed by trained clinical scientist staff following the Trust procedures for blood sample analysis to obtain a full blood count, which will include the blood eosinophil count. The sample will be retained for a maximum of 72 hours within the lab after which time it will be destroyed in line with the Trust policies and procedures. A test to check for reversibility of lung function obstruction will be

carried out at the first visit to help confirm the patient's diagnosis of asthma. The patients will also be supplied with a peak flow meter and a diary to record their peak flow measurements for 1 to 2 months. At 1 to 2 months they will have a follow-up appointment to create a personalised asthma action plan to support their self-management of their asthma throughout the study and to help identify their asthma control and when they are exacerbating. The researchers will review their inhaler technique and their response to any changes in treatment made at the baseline visit. They will also confirm that the patients in the digital inhaler group have been able to change their inhaler sensor to their next inhaler and that their app and sensors are working properly. A FeNO, ACQ6, mAQLQ and TAI will be completed.

The clinical measurements carried out at visit 1 plus prescriptions data on inhaled corticosteroids (ICS) and steroid courses will be reassessed at 6 and 12 months in both groups in line with the standard asthma clinic visits, to identify the impact the digital sensors and app have on the patient’s adherence and asthma control. Clinical outcomes and adherence data will be carried out. The health economic model will be trialed within this study to assess its effectiveness for a larger RCT and to begin to gather data on the health economic impact of the digital inhaler monitors versus usual care.

At the end of the final visit at 12 months participants will be invited to take part in a semi-structured interview to assess usability and acceptability of the digital inhaler monitors and app.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Find Air One System and Find Air App

Primary outcome(s)
The feasibility of a future definitive trial:
1. The effect size for future larger studies, calculated using the between-group difference in asthma control on completion of the study
2. The estimated recruitment rate for future larger multisite studies, calculated using the recruitment rate of this study at the completion of the study

Key secondary outcome(s))
Between-group differences in:
1. Asthma control measured using:
1.1. The Asthma Control Questionnaire 6 (ACQ6) score
1.2. Asthma exacerbations requiring oral steroids (reported by the participant and confirmed by GP records)
1.3. Healthcare utilisation for asthma (reported by the participant and confirmed by GP records)
1.4. Reliever inhaler use (reported by participant and confirmed by GP records)
Measured at baseline, 6 and 12 months
2. Adherence (Medicines Possession Ratio [MPR]) to preventer inhaler measured using prescription collection data from GP records at baseline, 6 and 12 months
3. Lung function measured using spirometry results (FEV1 and FVC) at baseline, 6 and 12 months
4. Airway inflammation measured using forces exhaled nitric oxide (FeNO) at baseline, 6 and 12 months

5. Health-related quality of life scores measured using mini asthma quality of life questionnaire (mAQLQ) and EQ-5D-5L questionnaire at baseline, 6 and 12 months
6. Behaviour change as measured by self-reported adherence using the test of adherence to inhalers (TAI) at baseline, 6 and 12 months
7. Healthcare resource use and cost measured through EQ-5D-5L, WPAI and study-specific health economic questionnaire and healthcare records at baseline, 6 and 12 months

Digital inhaler group only:
8. The use, acceptability, and satisfaction of use of the FindAir system to patients and their families/carers, measured using the number of patients accepting the offer of digital inhaler continued use, feasibility questionnaire and interviews at baseline, 6 and 12 months
9. The feasibility for FindAir to be incorporated into routine standard care as part of the asthma clinical pathway, measured through the support needs of the patient and appointment times at 6 and 12 months

Completion date
30/11/2026

Eligibility

Key inclusion criteria
1. Identified at admission to Wythenshawe Hospital A&E, respiratory wards, or referral to general asthma clinic
2. Male and female patients ≥18 years
3. A physician diagnosis of mild to moderate asthma for at least one year prior to screening
4. Prescribed an ICS or ICS/LABA which is compatible with the FindAIR digital inhaler monitors
5. ≥1 asthma exacerbation requiring oral steroids in the past 12 months
6. Non-smoker or ex-smoker, defined as someone who completely stopped smoking cigarettes (including e-cigarettes) for at least 12 months prior to screening and with a smoking history of less than 5-pack years
7. Confirmed diagnosis of asthma as documented evidence of one of the following:
7.1 Blood eosinophils above the laboratory reference range.
7.2 Forced exhaled nitric oxide (FeNO) above 50 parts per billion (ppb)
7.3 Bronchial hyperresponsiveness assessed as documented evidence of variable expiratory airflow limitation at screening or in the past 2 years prior to screening, defined as one of the following:
7.3.1.≥12% or ≥200 ml improvement in FEV1 in a bronchodilator reversibility test
7.3.2. Provocative dose or concentration of methacholine resulting in a ≥20% drop in FEV1 (PD20 or PC20, respectively) of ≤1 mg or ≤16 mg/ml, respectively

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Inability to comply with study procedures, required restrictions, study treatment intake or any other reason that the Investigator considers makes the subject unsuitable to participate
2. Requires oxygen therapy, even on an occasional basis
3. Known respiratory disorders other than asthma according to the investigator’s judgement.
4. A diagnosis of severe asthma.
5. Participation in another clinical trial and received investigational drug within 30 days (or 5 half-lives whichever is longer) prior to screening. N.B.: For biologic products with slow elimination a washout of at least 6 months needs to be met prior to screening.

Date of first enrolment
01/06/2025

Date of final enrolment
30/09/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Wythenshawe Hospital
Southmoor Road
Wythenshawe
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Charity

Funder Name
North West Lung Centre Charity

Results and Publications

Individual participant data (IPD) sharing plan
The dataset generated during and/or analysed during the current study will be stored in a publicly available repository, Figshare, at the University of Manchester.

IPD sharing plan summary
Stored in publicly available repository