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# Inhaler technology study

**Submission date**
16/01/2017

**Recruitment status**
No longer recruiting

**Registration date**
31/01/2017

**Overall study status**
Completed

**Last Edited**
29/03/2022

**Condition category**
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

## Plain English summary of protocol

Background and study aims
Asthma is a long-term condition which affects the airways. When a person is suffering from asthma, the airways are extremely sensitive (hyperresponsive) to both natural chemicals the body produces and irritants outside the body, such as dust or pollen. Coming into contact with these substances can cause an asthma attack (also known as an exacerbation), which involves feelings of tightness in the chest as the airways become inflamed, causing coughing, wheezing, chest tightness and difficulty breathing. The most common treatment for asthma is using an inhaler which delivers a medication to help expand the airways to make breathing easier. The development of inhaler monitoring technology has allowed information to be automatically captured, allowing researchers to explore patterns of inhaler use and to relate this to other important factors related with asthma control, rather than relying on questionnaires and prescription counting to determine asthma treatment and adherence. The aim of this study is to look at whether using this technology is patient friendly and cost effective in three main areas of asthma care: sticking to treatment (adherence), treatment decisions, and the prediction and prevention of asthma attacks.

Who can participate?
Asthmatic adults who use an inhaler to control their symptoms.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group have their inhaler usage monitored but have no feedback on this. Those in the second group have their inhaler usage monitored with specific feedback about usage patterns. Participants in both groups visit the study centre at the start of the study and the end (six months), as well as receiving telephone calls every four weeks in between these visits to find out how bad their asthma has been. At the first study visit, participants complete questionnaires about well they feel their asthma is controlled and how it affects their quality of life as well as completing some breathing tests. They are then given a special plastic casing to put on their inhaler which contains technology to feeds patterns of how participants use their inhalers back to investigators via participants' smartphones. At the end of the study, the initial assessments are repeated.

What are the possible benefits and risks of participating?
There are no direct benefits involved with participating in this study. There is a small risk that

the breathing tests used (spirometry) can sometimes make people feel a bit short of breath or dizzy, but the study centre is very experienced at carrying this test out and there will be a clinician on hand to help. There is a small cost when data is transmitted from participants' smartphones which the study team will reimburse.

Where is the study run from?
Nottingham Respiratory Research Unit (UK)

When is the study starting and how long is it expected to run for?
November 2015 to July 2019

Who is funding the study?
GlaxoSmithKline (UK)

Who is the main contact?
Dr Ireti Adejumo
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# Contact information

### Type(s)
Scientific

### Contact name
Dr Ireti Adejumo

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# Additional identifiers

### ClinicalTrials.gov (NCT)
NCT02977078

### Protocol serial number
31931

# Study information

### Scientific Title

Improving asthma treatment using inhaler technology

## Study objectives
The aim of this study is to investigate whether inhaler monitoring technology is patient friendly and cost effective in three main areas of asthma care: adherence, treatment decisions, and the prediction and prevention of asthma exacerbations.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
London – Central Research Ethics Committee, 13/09/2016, ref: 16/LO/1693

## Study design
Randomised; Interventional; Design type: Process of Care, Device, Active Monitoring

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Specialty: Respiratory disorders, Primary sub-specialty: Respiratory disorders; UKCRC code/ Disease: Respiratory/ Chronic lower respiratory diseases

## Interventions
Participants are randomised to one of two groups using a computer generated sequence.

Group A: Participants have their inhaler usage monitored but have no feedback on this.

Group B: Participants have their inhaler usage monitored with specific feedback about usage patterns.

All participants will be seen at visit 1 (week 0, baseline) and at visit 7 (week 24, end of study), giving a total of 2 visits to site per patient.
At Visit 1, participants will be assessed at the Nottingham Respiratory Research Unit. This involves having a brief clinical history taken, having their asthma control and quality of life assessed as well as undergoing spirometry. Baseline data on asthma phenotype will be collected from the patient's medical record where available (e.g. prior eosinophilia, skin prick test results, exhaled nitric oxide, IgE).

All participants will complete follow-up questionnaires (ACT and AQLQ) every 4 weeks i.e. Visit 2-6 (Weeks - 4, 8, 12, 16 and 20) by telephone call. Questions on changes to treatment will be asked.

At Visit 7 (Week 24), the follow-up questionnaires will be completed for a final time at the site visit and questions on changes to treatment will be asked. Spirometry with reversibility will be repeated. There will be a review of adherence data and debrief. Selected participants will also undergo an adherence questionnaire and a semi-structured qualitative interview.

GP letters will be sent for all participants at entry and exit and for selected participants after Visits 2-6.

## Intervention Type
Device

## Primary outcome(s)
1. Preventer use: The mean percentage of prescribed doses taken daily over the study period is assessed using electronic monitoring device data at Week 24
2. Reliever Use: The number of days with >16 actuations/day of Salbutamol taken in a 24-hour period is assessed using electronic monitoring device data at Week 24

## Key secondary outcome(s))
Medication use (Categorised by preventer and reliever medication):
1. Number of days of preventer non-adherence (0 actuations per 24 hours), expressed as a rate: number of days/days of treatment, is measured by electronic monitoring device at Week 24
2. Number of days of 100% preventer adherence (when all prescribed doses taken) is measured by electronic monitoring device Week 24
3. Mean % of prescribed preventer dose taken daily is assessed by electronic monitoring device every month for 6 months
4. Number of days of overuse of preventer treatment (when more than daily prescribed doses taken i.e. >2 or >4/day) is measured by electronic monitoring device at Week 24
5. Mean daily ICS (preventer) dose is assessed by dividing the total number of actuations over study period multiplied by dose per actuation by the number of days of treatment exposure, at Week 24
6. Overuse of SABA (reliever): Number of days of >24 and >32 actuations of salbutamol in a 24 hour period, is measured by electronic monitoring device at Week 24
7. Number of days of zero SABA use (reliever) is measured by electronic monitoring device at Week 24

Clinical control:
1. Number of exacerbations (treatment with systemic corticosteroids for asthma or antibiotics) is measured by electronic monitoring device at weeks 4, 8, 12, 16, 20 and 24 (final visit)
2. FEV1 is measured using spirometry at baseline (Week 0) and final visit (Week 24)
3. Subjective asthma control is measured using the Asthma Control Test (ACT) at baseline (week 0), weeks 4, 8, 12, 16, 20 and 24 (final visit)

Secondary outcomes: treatment decisions:
1. Patient views/attitudes to monitoring/ feedback are assessed using patient interviews at the final study visit
2. Understand patient factors around using devices are assessed using patient interviews at the final study visit
3. Ease of use/patient acceptability are assessed using patient interviews at the final study visit
4. Utility of differing thresholds for feedback (e.g. ICS adherence of <75% or <80%; salbutamol thresholds based on number of days of at least one salbutamol actuation or maximal daily number of actuations) are assessed from electronic monitoring device data at Week 24
5. Study practicality of data feedback processes is assessed by investigator feedback at study end
6. Episodes where advice provided to seek GP/clinical review based on monitoring data; and, episodes when participants actually sought review subsequently is assessed by participant interview at weeks 8, 12, 16, 20 and 24 (6 months)

### Completion date
31/12/2019

# Eligibility

### Key inclusion criteria
1. Age 18-65 inclusive
2. Use of systemic corticosteroids for worsening asthma (or an increase from baseline dose in patients on long-term oral corticosteroids) in the prior 12 months (i.e. at least one asthma exacerbation requiring additional systemic corticosteroid in the prior 12 months) patient reported
3. Doctor’s diagnosis of asthma for at least 12 months
4. On BTS step 2-5 treatment via MDI
5. Use of own internet-enabled and compatible mobile phone
6. Participant is willing and able to give informed consent for participation in the clinical investigation
7. Able (in the Investigators opinion) and willing to comply with all clinical investigation requirements
8. Willing to allow his or her General Practitioner and consultant, if appropriate, to be notified of participation in the clinical investigation

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Upper age limit
65 years

### Sex
All

### Total final enrolment
36

### Key exclusion criteria
1. Diagnosis of COPD or onset of symptoms after the age of 40 in patients with ≥10 PYH of smoking
2. Other clinically significant coexisting respiratory disease e.g. fibrosis, bronchiectasis
3. No personal mobile smartphone
4. Patients on maintenance and reliever therapy (Symbicort ‘SMART’ or Fostair 'MART’)
5. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the clinical investigation, or may influence

the result of the clinical investigation, or the participant's ability to participate in the clinical investigation

### Date of first enrolment
06/12/2016

### Date of final enrolment
31/12/2018

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Nottingham Respiratory Research Unit**
Clinical Sciences Building
University of Nottingham
City Hospital Campus
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

## Sponsor information

### Organisation
Nottingham University Hospitals NHS Trust

### ROR
https://ror.org/05y3qh794

## Funder(s)

### Funder type
Industry

### Funder Name
GlaxoSmithKline

### Alternative Name(s)
GlaxoSmithKline plc., GSK plc., GlaxoSmithKline plc, GSK

### Funding Body Type
Government organisation

### Funding Body Subtype
For-profit companies (industry)

### Location
United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Ireti Adejumo (ireti.adejumo@nottingham.ac.uk) in the form of de-identified individual participant data until June 2025 for the purpose of secondary analysis. This will be for investigators who provide a methodologically sound proposal for secondary analysis.

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 04/03/2022 | 28/03/2022 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Participant information sheet | version V2 | 24/11/2016 | 31/01/2017 | No | Yes |