

Inhaler technology study

Submission date 16/01/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 31/01/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/03/2022	Condition category Respiratory	<input type="checkbox"/> 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

msxia6@nottingham.ac.uk

Contact information

Type(s)

Scientific

Contact name

Dr Ireti Adejumo

ORCID ID

<https://orcid.org/0000-0002-0181-5856>

Contact details

Clinical Sciences Building

Nottingham City Hospital

Hucknall Road

Nottingham

United Kingdom

NG5 1PB

+44 115 823 1935

msxia6@nottingham.ac.uk

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

Primary study design

Interventional

Study design

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

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 Irete Adejumo (irete.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