Royal Brompton & Harefield NHS
NHS Foundation Trust

Imperial College London

A feasibility study to assess novel electronic monitoring devices for monitoring adherence in children with asthma

Protocol

Version 2

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STUDY COORDINATION CENTRE: Royal Brompton Hospital

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Investigators

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Protocol authorised by:

Name & Role	Date	Signature

Study Management Group

Principle Investigator: Dr Louise Fleming

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Study Management:

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Clinical Queries

Clinical queries should be directed to Sukeshi Makhecha who will direct the query to the appropriate person.

Sponsor

Imperial College London is the main research Sponsor for this study. For further information regarding the sponsorship conditions, please contact the Head of Regulatory Compliance at:

Joint Research Compliance Office
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This protocol describes the feasibility study to assess novel electronic monitoring devices (NEMD) for monitoring adherence in children with asthma and provides information about procedures for enrolling participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study. Problems relating to this study should be referred, in the first instance, to the Principle Investigator, Dr Louise Fleming.

This study will adhere to the principles outlined in the NHS Research Governance Framework for Health and Social Care (2nd edition). It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

Table of Contents

GLOSSARY OF ABBREVIATIONS

EMD	Electronic monitoring device
NEMD	Novel electronic monitoring device
ACT	Asthma Control Test
cACT	Childhood asthma control test
RBHT	Royal Brompton and Harefield NHS Foundation Trust
FeNO	Fractional exhaled nitric oxide
FEV_1	Forced expiratory volume in one second
BDR	Bronchodilator reversibility
QoL	Quality of Life
PAQLQ	Paediatric asthma quality of life questionnaire
mPAQLQ	Modified paediatric asthma quality of life questionnaire
rDOT	Remote directly observed therapy
NRAD	National review of asthma deaths
MARS-10	Medication adherence report scale - 10

KEYWORDS

Electronic monitoring device (EMD)
Novel electronic monitoring device (NEMD)
Compliance
Adherence
Children
Asthma

STUDY SUMMARY

TITLE	A feasibility study to assess novel electronic monitoring devices for monitoring adherence in children with asthma
DESIGN	A mixed method (quantitative and qualitative) open label, block randomised feasibility study
AIMS	1. To assess the feasibility of 4 novel electronic monitoring devices in children aged 6-16 years with asthma, in terms of usability and acceptability by patients/ guardians and healthcare professionals (qualitative study) 2. To evaluate the accuracy of these devices and assess whether they impact on asthma control (quantitative study)
OUTCOME MEASURES	**Primary outcome**: Acceptability and usability of devices to participants and healthcare professional at Royal Brompton and Harefield NHS foundation Trust (RBHT) **Secondary outcomes**: 1. Accuracy of the adherence data collected from the devices. 2. Effect on asthma control as measured by asthma control test (ACT) or childhood asthma control test (cACT) score; exhaled nitric oxide (FENO), spirometry (FEV1) and bronchodilator reversibility (BDR).
POPULATION	Children aged 6-16 years with asthma on inhaled corticosteroid therapy.
ELIGIBILITY	Children aged 6-16 years with a diagnosis of asthma on inhaled corticosteroids who are being treated or followed up by the paediatric respiratory difficult asthma clinic at Royal Brompton hospital.
DURATION	Up to 16 weeks

1. INTRODUCTION

1.1 BACKGROUND

Asthma affects 1.1 million children in the UK and is a significant economic burden to the NHS (NHS information centre). Despite advances in care, acute asthma attacks are one of the most common presentations to the Emergency Department. Persistent symptoms and frequent exacerbations can impact negatively on quality of life and sadly children still die from asthma. The National Review of Asthma Deaths (NRAD) included 28 deaths in young people under the age of 20 years. The report highlighted that poor adherence to medical treatment, especially in children is one of the most important reasons for apparent treatment failure and recommends that adherence should be continually monitored.

Suboptimal adherence has been linked to risk of exacerbations, hospital admissions, reduced quality of life and asthma related deaths (1)(2)(3). Once poor adherence has been identified, there is little evidence of benefit of adherence interventions(4).

Adherence to inhaled corticosteroids (ICS) in asthma ranges from 30-70% (5). Patient or parent report is inaccurate, over-estimating the treatment taken. and physician assessment little better than chance (2) (6).Objective measures of medication use, such as prescription refill rate are a little more accurate; however even if inhalers are picked up they are not necessarily taken.

Recently, there has been an increase in the use of electronic monitoring devices (EMD) which can be used to monitor adherence to inhaled treatments. The EMD's are available with or without reminders and provide important data on activation, timing of the activation and the number of doses activated. They have the potential to transform care for people with asthma (7) (8). EMDs have two key roles to play; enabling healthcare professionals to interpret control in the context of know adherence and inform decision making and as a tool for the patient to aid self-management and improve adherence. We have demonstrated the role of currently available EMDs in supporting the decision making process and identifying children with severe asthma (9).

The improvements across the range of asthma control measures suggested that adherence improved because the participants were aware they were being monitored. This supports the second role of EMDs as an intervention for adherence.

Studies which have compared EMDs with standard care have demonstrated significant improvements in adherence in the EMD arm (30% versus 85% and 49% versus 70%), however, they have shown only modest improvements in asthma control (8) (10). This may in

part be due to the limitations of current EMDs. Although they measure activation they give no information on whether the inhaler was used correctly, or even if inhaled at all. This would provide plausible explanation for limited clinical benefit despite large differences in adherence. Furthermore, in these studies adherence remained suboptimal (<80%) in the majority despite monitoring. This is unsurprising as EMDs only address some of the reasons for poor adherence.

Determinants of poor adherence

The practicalities and perceptions (PAPA) model (5) divides the numerous reasons for poor adherence into two broad themes. Practical barriers include poor technique and forgetfulness. This leads to unintentional non adherence: the patient wants to take the treatment but is limited by their capabilities. Perceptual barriers lead to intentional non adherence: the patient is not motivated to take medication because of their concerns. Thus, ongoing poor control despite documented good adherence (with current EMDs) may be a result poor technique (practical barrier) or deliberate manipulation because of concerns about treatment efficacy or side effects (perceptual barrier).

1.2 RATIONALE FOR CURRENT STUDY

A number of platforms are currently in development which will enable the clinician to monitor both activation and inhalation, thus ensuring more accurate estimates of adherence and better addressing practical barriers to adherence. Currently the utility and feasibility of these platforms and acceptability to children, their families and healthcare professionals is not known.

Often devices are formulated for adults then extrapolated to children (11),(12) , highlighted the need and benefits of user involvement in the design of EMDs in children, particularly adolescents with asthma and the need to consider all aspects of medical design including data, usability and aesthetics in future studies to maximise the chance of success.

The benefits of using user feedback in adherence monitoring have been highlighted in many studies some using focus groups other using one to one interviews(11), (13),(14). Other studies have recommended that robust technology support to troubleshoot technological issues arising during the intervention should also be taken into consideration into the feasibility of using EMD's for monitoring adherence (14).

We propose to conduct an open label, block randomised, mixed methods, feasibility study to assess the accuracy, usability and acceptance of four novel electronic monitoring devices

(NEMD) that monitor both activation and inhalation thereby providing information on dose taken and technique.

We will conduct face to face focus group or one to one interviews using semi-structured questions to evaluate user feedback and assess the accuracy of the NEMD's used. Additionally, asthma control will be assessed as part of routine clinical care using our difficult asthma protocol.

2. STUDY OBJECTIVES

Research question: Which novel electronic monitoring device (NEMD) (measuring both inhalation & activation) is the most feasible to use as a tool for monitoring adherence in children aged 6-16 years with asthma in terms of accuracy, usability and acceptability?

Aim: To conduct a feasibility study looking at four new electronic monitoring devices to monitor adherence in children with asthma aged 6-16 years prescribed inhaled corticosteroids.

Our primary objective is to assess which novel electronic monitoring device is the most feasible to use as a tool for monitoring adherence in children with asthma, in terms of its perceived accuracy, usability and acceptability by patients/guardians and healthcare professionals by using a face to face focus group discussion meeting or one to one interviews.

For the purposes of this study feasibility is the overarching term used to assess if the devices are capable of being used in clinical practice to monitor adherence.
Accuracy of the device will be assessed by capturing usable data from the devices.
Usability of the device will be assessed from the focus group or one to one interviews encompassing ease of use, time taken, problems encountered, easy to learn to use the device.
Acceptability will also be assessed from the focus group discussions or one to one interviews in terms of aesthetically pleasing, liked the device, fits in with day to day living.

Our secondary objective is to evaluate the effect on asthma control as measured by asthma control test (ACT) or childhood asthma control test (CACT) score; exhaled nitric oxide (FENO), spirometry (FEV1) and bronchodilator reversibility (BDR)

3. STUDY DESIGN

This is an open label, block randomised (10 in each block), mixed method (quantitative and qualitative) study to be conducted for a period of up to 16 weeks

Children aged between 6-16 years with asthma attending the paediatric respiratory difficult asthma clinic will be recruited into the study and randomly allocated to one of three arms using block randomisation matched for age and size of group. Children will be assigned to trial one of the following four NEMD's to be tested:

1. Block 1 (10): Smartinhaler Plus™ (Adherium, New Zealand)
   - This measures inhalation usually flow sensors and is the next generation of a currently commercially available EMD

2. Block 2a (5) : Flo-Tone (Clement Clarke, UK) plus Rafi-tone, acoustic enabled Smartphone App (clin-e-cal, UK) for children aged 6 – 11 years
   - The Flo-Tone attaches to an MDI and makes a sound when the inhaler is used correctly. Rafi-tone is a Smartphone App that detects the sound and activates a game The game is aimed at younger children and therefore children aged 6 – 11 years will be randomised to this block.

   Block 2b (5) : Inhaler Compliance Assessment (INCA™) device (INCA, Ireland)
   - This is an audio recording device which attaches to a Diskus dry powder inhaler. Analysis of the digital audio recordings enables objective assessment of inhaler use and technique. As it can only be used with a Diskus only children ≥ 12 years will be randomised to this block

3. Block 3: Video and Remote Directly Observed treatment (rDOT)
   - Children are filmed on a Smartphone using their inhaler. The clip is then automatically uploaded via a Smartphone App (Continga, UK) and reviewed by a Clinical Nurse Specialist to ensure inhaler technique is correct.

Recruitment

30 children will be recruited into the study; 10 per block (5 per block aged 6-11 years and 5 aged 12-16 years)

Visit 1:Novel electronic monitoring device (NEMD) issued

Routine clinical care assessments will be carried out at the end of the study period as below, including asthma control test (ACT) or the childhood asthma control test (cACT), exhaled nitric oxide (FeNO) and spirometry (FEV1 and BDR) .

Patient/parent/Carer will be invited to take part in the study.
Information regarding the study and its objectives will be communicated to the Patient/parent/carer in both oral and written form using patient information leaflets.

All children will be issued with a novel electronic monitoring device which will be attached to the child's usual inhaler or require an app on their mobile phone as described above. Parents and children will be provided information and advice on the use of the novel electronic monitoring device and asked to conduct up to 16 weeks of home monitoring using their allocated NEMD on their first visit.
Information on how to contact the team in case of any problems will be related to the participant in both oral and written form.

The data will be stored electronically and downloaded at the next clinic visit.
Contact by telephone will be made at day 7-14 to ensure that the device is working and to answer any other queries then at week 6-7 to determine if the device is being used appropriately and to answer any related questions.

Week 1 - for the rDOT arm, adherence data will be downloaded to check for consistencies in inhaler technique. If inhaler technique is inaccurate, the participants will be called by the respiratory nurse specialists to advise on correct technique. This will be documented as part of the data collection.
Week 4 – All devices, adherence data will be downloaded and checked to ensure that the devices are working correctly.

Visit 2: up to 16 weeks of adherence data collection
Routine clinical care assessments will be carried out at the end of the study period as below, including asthma control test (ACT) or the childhood asthma control test (cACT), exhaled nitric oxide and spirometry (FEV1 and BDR) .
Adherence data will downloaded at the end of the study period and stored electronically.

Visit 3: Focus group or one to one interviews

The participants and their carers will be invited to a face to face focus group interview, or a one to one interview, depending on their availability at the end of the study period. The focus group and one to one interviews will utilise a semi structured questionnaire, to provide qualitative feedback on the acceptability and usability of the devices.

A separate focus group meeting will also be conducted with the peadiatric respiratory nurses who are part of the MDT to assess their views on the devices used as they routinely provided all asthma devices and are also involved in downloading data from other devices that we would use as part of routine care (smart-inhaler). They will also be consented to take part in the study

Where possible a second researcher from University College London (UCL), Christina Pearce will sit in the focus groups discussion and interviews to ensure there is no bias.

The conversations from the focus group and one to one interviews will be transcribed and coded into themes. We will utilise an external company for transcribing the conversations called 1st Class. https://www.1stclass.uk.com/

Analysis

Qualitative:

The focus group and one to one interviews will be audio recorded, transcribed and put into themes to conduct an inductive thematic analysis. 25% of the transcripts (8) will be double coded by an independent researcher from UCL, Dr Amy Chan, experienced in qualitative research to ensure that the correct themes have been used and to ensure that there is no bias.

The focus group and one to one interviews will be used to assess the usability and acceptability of the devices

Quantitative:

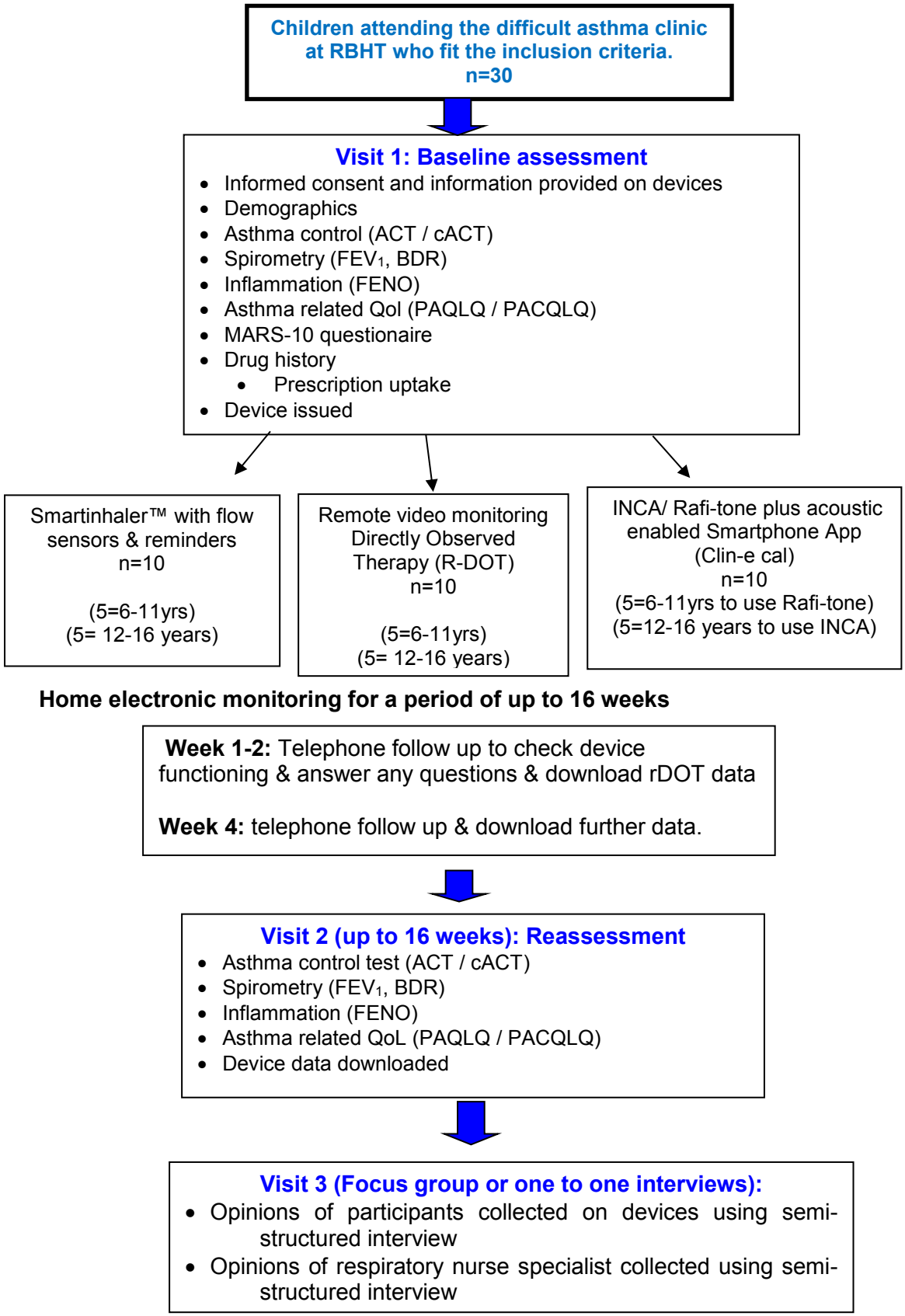
The amount of usable data from each device will be quantified and compared.

This will provide data on the perceived accuracy of the device.

The quantitative and qualitative results will be amalgamated and an evidence report prepared to assess the feasibility of each device.

An expert panel will be convened to select the most appropriate device to take forward to a larger randomised controlled trial to assess the impact of the device on adherence in children with asthma.

REFERENCE DIAGRAM



4. PARTICIPANT ENTRY

4.1 PRE-REGISTRATION EVALUATIONS

Children will be recruited from the outpatient clinics at the Royal Brompton Hospital

Written information regarding the study (the patient information sheet) and contact details of the study team will be given to parents

Written, informed consent from the parent / guardian and consent (if appropriate) or assent from the child will be obtained by a member of the study team prior to undertaking any study procedures. “Informed consent” requires individual discussion with the child and their parent / guardian about the study and the nature of the procedures to be conducted in a language that is easy to comprehend. The child and their parent /guardian will be given adequate time to decide whether or not they wish to participate. The child and their parent / guardian should understand that his / her refusal to participate in the study will not affect their subsequent medical care and if they do consent they may withdraw at any point without affecting their care.

The participant consent form must be signed by a member of the study team to confirm that informed consent was obtained. The original of the signed declaration of consent will be stored in the case notes. A copy will be given to the parent / guardian

Information sharing

Consent will be sought to inform the child’s GP and usual hospital consultant of their enrolment in the study. If clinically important information is found as a result of the study this will be discussed with the participant and their parent / guardian and their consent sought to share this information with their GP and / or other relevant medical professionals.

Follow up of participants after study completion

At the end of the study (as a result of study completion or withdrawal) participants will continue to receive their usual clinical care.

4.2 INCLUSION CRITERIA

A child will be included in the study if the following criteria applies:

- Informed consent obtained from parents/guardian/adolescents and/or assent from the child.
- Children aged between 6-16 years with a diagnosis of asthma attending the Royal Brompton and Harefield Difficult asthma clinic.
- Children on inhaled corticosteroids
- Parents/ young person has a mobile phone which can download apps
- Paediatric respiratory nurses working in the difficult asthma team at Royal Brompton Hospital.

4.3 EXCLUSION CRITERIA

A child will not be eligible for the study if the following applies:

- Unable to provide consent
- As a result of medical interview, physical examination or screening investigation the physician responsible considers the child unfit for the study.
- Those who, in the opinion of the investigator, have a risk of non-compliance with study procedures
- Children under the age of 6 years.
- Children not on inhaled corticosteroid
- It is not anticipated that any children will be pregnant, however, if they are they will not be included in the study

4.4 WITHDRAWAL CRITERIA

Children/parents/carers may withdraw any time without affecting their treatment or care.
If adherence data has been collected for > 8 weeks of treatment then permission will be requested to use this data from parents/carers. If data has not been collected for > 8 weeks then this will not be used.

5. ASSESSMENT AND FOLLOW-UP

No study assessments will take place until written informed consent and age appropriate assent is obtained.

Routine clinical care data will be collected at the baseline visit and at the end of the study as follows:

Routine clinical care monitoring tests

Routine clinical care test to assess	Test	Visit 1: Study entry	Visit 2: completion of study
Asthma control	ACT/cACT	√	√
Spirometry	FEV_1/FVC/BDR	√	√
Inflammation	FeNO	√	√
Asthma related quality of life questionnaire	PAQLQ/PACQLQ	√	√
Prescription uptake		√	√
Drug history		√	
Data downloaded from device: Routine clinical care would be to download from smartinhaler	Data downloaded from new device		√

The main difference between data collection in this study and routine clinical care monitoring is that data will be downloaded from the new devices (NEMD) in comparison to the current smartinhaler device

6. ADVERSE EVENTS

6.1 DEFINITIONS

Adverse Event (AE): any untoward medical occurrence in a patient or clinical study subject.

Serious Adverse Event (SAE): any untoward and unexpected medical occurrence or effect that:

- **Results in death**

- **Is life-threatening** – *refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe*

- **Requires hospitalisation, or prolongation of existing inpatients' hospitalisation**
- **Results in persistent or significant disability or incapacity**
- **Is a congenital anomaly or birth defect**

Medical judgement will be exercised in deciding whether an AE is serious in other situations. Important AEs that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious.

6.2 REPORTING PROCEDURES

All adverse events will be reported. Depending on the nature of the event the reporting procedures below will be followed. Any questions concerning adverse event reporting should be directed to the Chief Investigator in the first instance.

6.2.1 Non serious AEs

All such events, whether expected or not, will be recorded.

6.2.2 Serious AEs

An SAE form will be completed and faxed to the Chief Investigator within 24 hours. However, relapse and death due to asthma and hospitalisations for elective treatment of a pre-existing condition do not need reporting as SAEs.

All SAEs should be reported to Sukeshi Makhecha where in the opinion of the Chief Investigator, the event was:

- 'related', ie resulted from the administration of any of the research procedures; and
- 'unexpected', ie an event that is not listed in the protocol as an expected occurrence

Reports of related and unexpected SAEs will be submitted within 15 days of the Chief Investigator becoming aware of the event, using the NRES SAE form for non-IMP studies. The Chief Investigator will also notify the Sponsor of all SAEs.

Any SAEs will be reported as required by the Local Research Ethics Committee, Sponsor and/or Research & Development Office.

There are no know SAEs from the use of these devices

It is not anticipated that there will be any SAE's with the use of the devices, however, should anything occur as a result of the device then the child will be followed up daily in the first instance then weekly for the next four week.

A period of four weeks of follow up care will occur after the last treatment for any adverse events to be recorded and reported.

Contact details for reporting SAEs
Fax: xxx, attention xxx
Please send SAE forms to: Sukeshi Makhecha, Pharmacy Department, Royal Brompton Hospital.
Tel: 0207-352-8121 Bleep 7403 (Mon to Fri 09.00 – 17.00)

7. STATISTICS AND DATA ANALYSIS

Sample Size

This is largely a qualitative study, focusing on the views of the participants on the usability and acceptability aspect of the devices, though there is a component of quantitative analyses in the perceived accuracy of the device.

Qualitative studies are different from quantitative studies in that they attempt to identify themes rather than quantify results. Therefore power analyses to calculate sample size are difficult to conduct and based largely on thematic saturation (where no further themes can be found).

It has been argued that the main goal is to ensure that the sample size is small enough to manage the material and large enough to provide new and rich data (15).

Braun and Clark, 2013 offer a guide on sample size based on the size of the project (small, medium, large). They suggest that for small projects, 6-10 participants for individual

interviews, 2-4 for focus groups, 10-50 participants for individual interviews in medium projects and up to 100 or over for larger projects.

Fugard and Potts, 2015 (16), offer a tool to quantify sample sizes for thematic analyses in qualitative studies to help support choices and decision making. They feel that the concept of theoretical saturation, whereby collecting more data does not add further themes is problematic for prospective study planning. They recommend that for adjusted prevalence of 10%, 2 instances and 80%, 29 participants would be required.

Though our sample size of 30 participants, randomised into blocks of 10 per each platform roughly fits into this model, it is nonetheless subjective, as this is largely an exploratory study.

Data management

The data entry will be collected by the study investigator (Sukeshi. Makhecha).The data analysis will be conducted by the study investigator (Sukeshi Makhecha) and the chief Investigator (Dr Louise Fleming).

Additionally, an independent researcher will aid with the analysis of the themes for the qualitative aspect of the study to ensure there is no bias.

All data will be entered on a paper clinical report form (CRF) and all data entered on a database (Excel or Access) held on the secure RBH server.

Data analysis.

- **Qualitative data**

  The focus group interviews will be audio recorded, transcribed and put into themes to conduct an inductive thematic analysis.
  25% of the transcripts will be double coded by an independent researcher from UCL, Dr Amy Chan, experienced in qualitative research.
  The focus group interviews will be used to assess the usability and acceptability of the devices

- **Quantitative data**

  The amount of usable data from each device will be quantified and compared.
  This will provide data on the perceived accuracy of the device.
  Additionally, data on asthma control and quality of life will be assessed.

These will be analysed quantitatively statically using the Statistical Package for the Social Services (SPSS). Data will be tested for normality using visual inspection, histograms and Kolmogorov-Smirnov testing. Parametric tests will be used if the data is normally distributed. If the data is not normally distributed or there are only small numbers non parametric tests will be used or the data will be logarithmically transformed. The significance levels for all tests will be set at <0.5.

Comparative analysis of variance between 2 groups for continuous data will be performed using the student's t test for normally distributed data and the Mann Whitney U tests for non normally distributed data and for more than 2 groups the ANOVA or Kruskal Wallis respectively. A comparison of the proportions between groups will be performed using the Pearson Chi 2 tests.

The quantitative and qualitative results will be amalgamated and an evidence report prepared to assess the feasibility of each device.
An expert panel will be convened to select the most appropriate device to take forward to a larger randomised controlled trial to assess the impact of the device on adherence in children with asthma.

Data and all appropriate documentation will be stored for a minimum of 10 years after the completion of the study, including the follow-up period.

8. REGULATORY ISSUES

8.1 ETHICS APPROVAL

The Study Coordination Centre has obtained approval from the xxx Research Ethics Committee (REC) and Health Regulator Authority (HRA). The study must also receive confirmation of capacity and capability from each participating NHS Trust before accepting participants into the study or any research activity is carried out. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

8.2 CONSENT

Consent to enter the study will be sought from each participant only after a full explanation has been given, an information leaflet offered and time allowed for consideration. Signed participant consent will be obtained. The right of the participant to refuse to participate without

giving reasons must be respected. After the participant has entered the study the clinician will remain free to give alternative treatment to that specified in the protocol at any stage if he/she feels it is in the participant's best interest, but the reasons for doing so will be recorded. In these cases the participants will remain within the study for the purposes of follow-up and data analysis. All participants are free to withdraw at any time from the protocol treatment without giving reasons and without prejudicing further treatment.

8.3 CONFIDENTIALITY

The Chief Investigator will preserve the confidentiality of participants taking part in the study and is registered under the Data Protection Act.

8.4 INDEMNITY

Imperial College London holds negligent harm and non-negligent harm insurance policies which apply to this study.,

8.5 SPONSOR

Imperial College London will act as the main Sponsor for this study. Delegated responsibilities will be assigned to the NHS trusts taking part in this study.

8.6 FUNDING

Asthma UK are funding this study.
Participants will receive reimbursements costs for travel and for refreshments when attending the focus group meeting.

8.7 AUDITS

The study may be subject to inspection and audit by Imperial College London under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the NHS Research Governance Framework for Health and Social Care (2nd edition).

9. STUDY MANAGEMENT

The day-to-day management of the study will be co-ordinated through Sukeshi Makhecha.

10. PUBLICATION POLICY

The study results will be submitted in abstract to National and international conferences and submitted for publication in appropriate peer reviewed journals.

10. REFERENCES

[List of useful and relevant references for the study]

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Appendix 1. Summary of investigations, treatment and assessments

Study Procedures	**Screening**	**During treatment: Visits**		**Follow up** *(7 days)*	**Follow up** *(4 weeks)*	**Follow up** *(up to 16 weeks)*	**Follow up** (up to *6mnths*)
		1	**2**				
Informed consent	√						
Inclusion/exclusion criteria	√						
Medical history		√	√				
Demographies	√						
Rotuine clinical care monitoring: Spirometry FeNO Asthma control test		√	√				
Quality of Life Questionaires		√	√				
Prescription uptake		√	√				
Adherence monitoring				√	√	√	
End of visit							√
Telephone call				√	√		
Provision of novel electronic monitoring device		√					
Data download				√	√	√	
Focus group or one to one interviews							√