Protocol for non-CTIMPs

FINA (Financial INcentives to improve Asthma)

Financial incentives to improve adherence to inhaled asthma medications in children and young people with asthma.

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Protocol authorised by:

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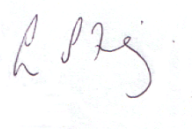
Dr Louise Fleming Chief Investigator	16/01/2023	

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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:

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Funder

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Asthma UK Centre of Applied Research (AUKCAR)
https://www.ed.ac.uk/usher/aukcar

This protocol describes the financial incentives to improve asthma study and provides information about procedures for entering 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 Chief Investigator.

This study will adhere to the principles outlined in the UK Policy Frame Work for Health and Social Care Research. It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

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GLOSSARY OF ABBREVIATIONS

AE	Adverse Event
ACT	Asthma Control Test
ATS	American Thoracic Society
B-IPQ	Brief Illness Perceptions Questionnaire
BMQ	Belief in Medicines Questionnaire
CI	Chief Investigator
CYP	Children and Young People
ED	Emergency Department
EMDs	Electronic Monitoring Device/s
ERS	European Respiratory Society
FENO	Fractional Exhaled Nitric Oxide
ICS	Inhaled Corticosteroids
MART	Maintenance and Reliever Therapy
MARS-A	Medication Adherence Report Scale for Asthma
OCS	Oral Corticosteroids
PAPA	Perceptions and Practicalities Approach
PIS	Participant Information Sheet
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAR	Serious Adverse Reaction
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
SRBAI	Self-report Behavioural Automaticity Index
TSRQ	Treatment Self-Regulation Questionnaire

KEYWORDS

Financial incentives
Electronic monitoring device (EMD)
Asthma
Adherence
Asthma control
Children and young people

STUDY SUMMARY

TITLE Financial incentives to improve adherence to inhaled asthma medications in children and young people (CYP) with asthma.

DESIGN Pilot randomised controlled trial (RCT)

AIMS To assess the effectiveness of a short-term financial incentives-based intervention at bringing about behaviour change, namely short-medium term improvements in inhaled corticosteroid (ICS) adherence and asthma control in children and young people (CYP) with asthma.

OUTCOME MEASURES

Primary outcome:

- Percentage ICS adherence (measured by EMD record of inhaler actuation%)

Secondary outcomes:

- Proportion of participants achieving good asthma adherence (≥80%)
- Time to next asthma exacerbation needing a course of oral corticosteroids (OCS)
- Total number of severe exacerbations
- Asthma control (Asthma Control Test, ACT)
- Exhaled nitric oxide (FENO)
- Belief in Medicine Questionnaire (BMQ)
- Brief Illness Perceptions Questionnaire (B-IPQ)
- Habit (self-report behavioural automaticity index, SRBAI)
- Autonomous/controlled motivation (adapted from the Treatment Self-Regulation Questionnaire, TSRQ, for the purpose of this study)
- Self-report adherence (Medication Adherence Report Scale for Asthma, MARS-A)

POPULATION CYP aged 11-17 years with an asthma diagnosis

ELIGIBILITY

- CYP aged between 11-17 years old
- A doctor diagnosis of asthma
- Presenting to an emergency department (ED) with a severe exacerbation of asthma (defined by ERS/ATS guidelines*)
- Own their own smartphone (running Android 8 or higher, or iOS 13 or higher)
- Prescribed maintenance inhaled corticosteroids (ICS) (which can include maintenance and reliever therapy (MART)) for at least 6-months.
- Prescribed one of the following inhalers: Clenil, Flixotide, Symbicort, Seretide.

DURATION Up to 24-weeks (participants will also be involved in a focus group at the end of the study period)

* Severe exacerbation of asthma: Asthma attack requiring a course of systemic corticosteroids (either prednisolone or dexamethasone), or hospital admission [1]

1. INTRODUCTION

1.1. BACKGROUND

Approximately 1.1 million United Kingdom (UK) children have asthma, making the disease one of the most common chronic conditions[2,3]. Asthma can be fatal if poorly managed or uncontrolled[4] and unfortunately, the UK has some of the worst outcomes for asthma[5]. Most children with asthma are prescribed low-dose inhaled corticosteroids (ICS), but not all have good control resulting in persistent and frequent exacerbations of symptoms and escalation of treatment[6]. Poor adherence to medication ICS significantly contributes to poor asthma control[7]. Good adherence is considered >80%[8,9] but children with asthma often have adherence rates of <50%[10]. Although in some cases ICS is wrongly or over-prescribed providing rational as to why adherence is low, the figures are still concerning and need addressing.

Electronic monitoring devices (EMDs) are not only seen as the 'gold standard' tool for measuring adherence as they electronically record inhaler actuation, but they have also been used as an intervention tool to improve medication adherence. EMDs can be programmed to deliver audio-visual reminders, which often result in improved short-term adherence, but no significant changes to clinical outcomes or sustained behaviour change[11,12].

The perceptions and practicalities approach[13] (PAPA) suggests medication adherence can be divided into two fundamental constructs: 1) unintentional adherence (practical factors such as capacity and resources) and 2) intentional adherence (perceptual factors such as motivations and beliefs). Previous EMD interventions have not targeted both unintentional and intentional adherence which could explain the lack of sustained change in adherence.

Additionally, adhering to medication regimes is heavily reliant upon developing a habit[14]. A habit usually forms through the consistent repetition of a desired behaviour until it is performed automatically, without the need for strong intentions to perform the behaviour[15]. Habitual behaviours are important as they are more likely to be sustained over the long term. Rewards may reinforce behaviours, and therefore strengthen habit formation. While there is evidence that autonomous motivation (compared with controlled)[16] is more effective at supporting habit formation, the exact nature of what counts as a reward to support habit formation is not well established. Autonomous motivation refers to being self-motivated compared to controlled motivation which refers to being motivated from external sources.

Therefore, to address the above, it is proposed that adding an additional behavioural strategy, alongside the electronic reminders, may be effective at bringing sustained long-term effects of adherence by successfully targeting the underlying motivations to adhere.

Financial incentives are a widely used behavioural strategy throughout health and research settings. They can help reinforce behaviours and are successful at improving health behaviours in adult populations such as smoking cessation, vaccination uptake and physical activity[17] and at improving medication adherence with for example anti-psychotics[18], statins[19], antihypertensive[20] and HIV medications[21].

Financial incentive studies are limited, but are increasing in children. A narrative review by Kenyon and colleagues[22] discusses design and effectiveness of randomized trials using

financial incentives to promote healthy behaviours specifically in children. Studies included focused on healthy eating (with interventions delivered within schools), preventing repeat adolescent pregnancies and diabetes management. All studies showed improvements in behaviour change but with mixed results at follow-up assessments.

The use of financial incentives to improve diabetes management is of particular interest because, as with asthma, outcomes are related to medication adherence. One non-randomised study found short-term financial incentives encouraged sustained behaviour change in adolescents with diabetes[23]. A randomised trial with a similar population conducted in 2017[24] showed improved adherence to self-monitoring compared to controls at 6-month follow-up, yet there was no significant difference in clinical outcomes (HbA1c) at both 3-month and 6-month follow-up. A second randomised trial conducted in 2019[25], similarly with an adolescent population again showed improved adherence to self-monitoring compared to control but with significantly improved clinical outcomes (HbA1c) at 3-month follow-up.

1.2. RATIONALE FOR CURRENT STUDY

In paediatric asthma, there are currently no randomised trials that explore the effectiveness of using financial incentives for improving medication adherence. A US proof-of-concept study that used electronic reminders coupled with financial incentives improved adherence to asthma medications in 12 African American adolescents[26]. Participants were provided with a smartphone and an EMD (with associated App) to provide visual reminders, positive reinforcement (e.g., shooting a basket game and positive text messages when dose is taken) plus rewards (short-term: accessories to decorate personal app avatar and long-term: 1$ per inhaler dose). Both adherence and asthma control (measured by the asthma control test ACT) improved across the 8-week period.

Similarly, a feasibility study conducted by ourselves found the use of financial incentives to be feasible and acceptable for improving adherence in paediatric asthma[27]. Adolescents diagnosed with asthma, who had poor medication adherence (<80%) and poor asthma control were recruited from an outpatient asthma clinic. Twelve adolescents were invited to take part and 10 were recruited (7 males, 3 females, 12-16 years) to a 24-week intervention that consisted of eight weeks of electronic reminders and financial incentives related to their adherence (£1 per morning dosage, £1 per evening dosage, capped at £2 per day). Eight out of 10 adolescents provided adherence measurements up to the final study visit. Three adolescents successfully paired their mobile app and EMD up to the final study visit which was associated with improved adherence. The 7 adolescents unable to pair their mobile app and EMD had no change in adherence. Overall, adherence did not significantly change. Exit interviews with adolescents revealed reminders and incentives were welcomed but issues with the technology was frustrating. Adolescents also commented that the intervention was useful by promoting self-monitoring and increasing motivation to take medication.

These findings within asthma warrant the further exploration of this intervention design using financial incentives with the inclusion of a larger sample size and randomisation. In addition, to explore the potential mediators of sustained behaviour change, motivation and the key feature of habit, automaticity, will be tracked in this study.

1.2.1 Hypothesis

The overarching hypothesis of this study is that a short-term intervention consisting of financial incentives will lead to behaviour change and improved ICS adherence and asthma control, in the short-medium term, in CYP with asthma.

2. STUDY AIMS AND OBJECTIVES

2.1 Aims

1. To assess the effectiveness of a short-term financial incentives-based intervention at bringing about behaviour change and improving ICS adherence and asthma control, in the short-medium term, in CYP with asthma.
2. To assess the feasibility of study processes, randomisation, and outcome assessments.
3. To generate pilot data that can be used to inform the power calculation and design of a definitive RCT of financial incentives in children with asthma.

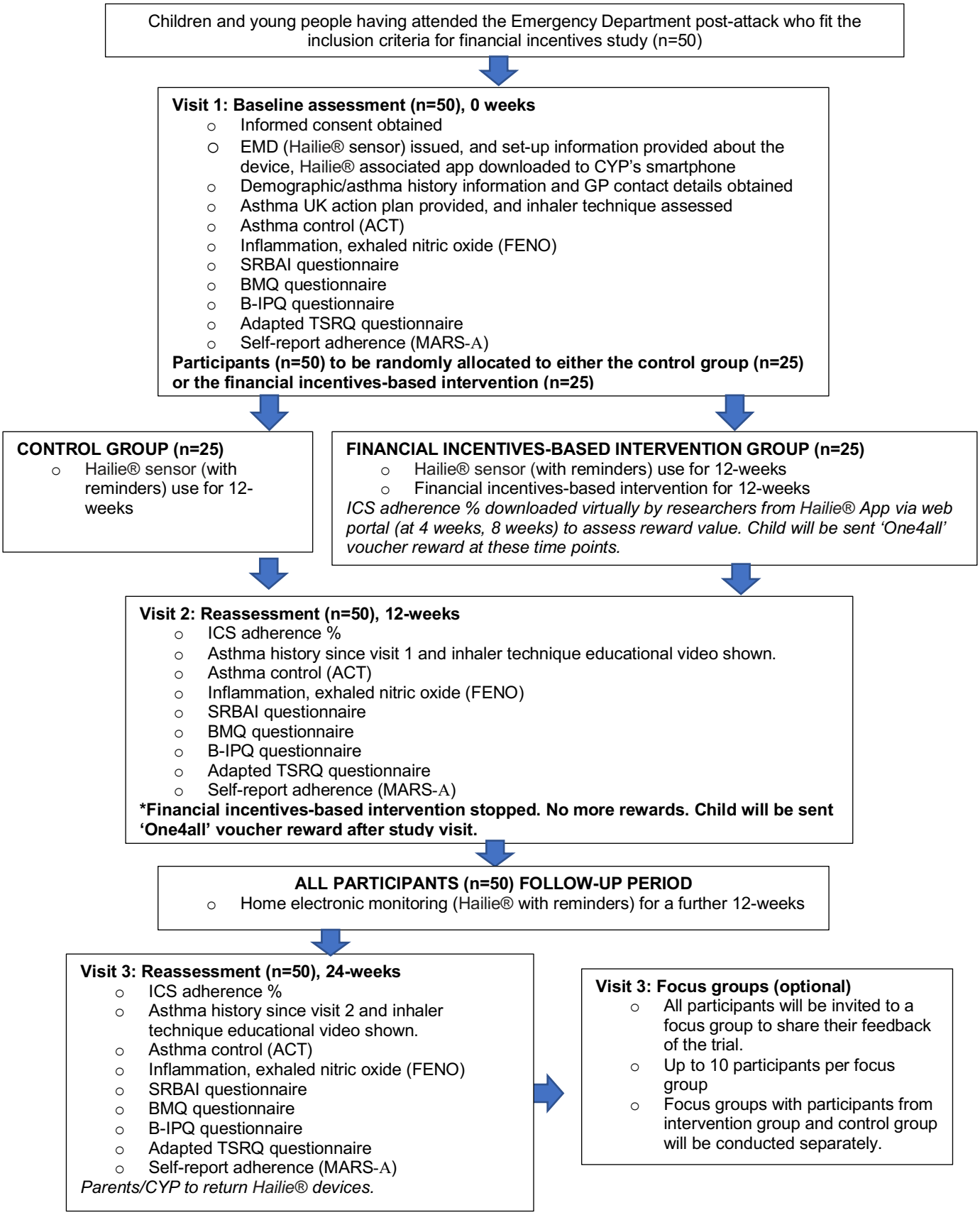
2.2 Objectives

1. To recruit children and young people aged between 11-17 years with asthma and measure adherence using EMDs (programmed with reminders) and a self-report measure (MARS-A) during a 12-week intervention period when financial incentives are given and compare to a group given an EMD (programmed with reminders) only, and to continue to measure adherence during a subsequent 12-week period (when no financial incentives are given) to assess whether financial incentives lead to continued better adherence in the short-medium term compared to the control group.
2. To measure asthma outcomes (number of severe exacerbations, time to exacerbation, asthma symptoms and if feasible given COVID-19 constraints, exhaled nitric oxide) at baseline, 12-weeks, and 24-weeks to assess whether financial incentives lead to short-medium term changes in a range of asthma control measures compared to the control group.
3. To measure habit (using the self-report behavioural automaticity index, SRBAI) and autonomous/controlled motivation (using a questionnaire adapted from the Treatment Self-Regulation Questionnaire (TSRQ)) at baseline, 12-weeks, and 24-weeks to

assess whether financial incentives lead to short-medium term changes in medication taking habits and motivations compared to the control group.

4. To measure beliefs in medicine (using Beliefs in Medicines Questionnaire, BMQ) and perceptions of illness (using the Brief-Illness Perceptions Questionnaire, B-IPQ) at baseline, 12-weeks, and 24-weeks to assess whether financial incentives lead to short-medium term changes in beliefs and perceptions regarding medication and illness and compared to the control group.
5. To conduct focus groups with participants from both the intervention and the control group and interviews with parents/guardians using a topic guide to obtain feedback of the trial and inform the design of a larger RCT.

3. STUDY DESIGN



This will be a pilot RCT of a financial incentives-based intervention. All CYP will be recruited from London Hospital Emergency Departments (EDs) including: St Mary's Hospital (Imperial College Healthcare NHS Trust); Chelsea and Westminster Hospital (Chelsea and Westminter Hospital NHS Foundation Trust); University College Hospital (University College London Hospital NHS Foundation Trust); Whittington Hospital (Whittington Health NHS Trust; The Royal London Hospital (Barts Health NHS Trust); The Hillingdon Hospital (Hillingdon Hospitals NHS Trust); Royal Brompton Hospital and Evelina Children's Hospital (Guy's and St Thomas' NHS Foundation Trust)

A list of ED attendees will be reviewed every week by the direct care team and those coded for acute asthma who fulfil the eligibility criteria will be identified and sent an automated WhatsApp/SMS message with a link to the study. If they are interested in participating, they will be asked to enter their contact details which will then be shared with the study coordinator. The study coordinator will then contact potential participants with further study information. The link to the study will also be provided on posters which will be displayed in the EDs and on leaflets which will be given to potential participants at the time of their attendance. For those CYP who have a post attack follow up review (either in person, via telephone or video platform) the study will be introduced by the clinician carrying out the review and if the CYP and their parent are interested permission will be obtained to share their contact details with the study coordinator.

No patient identifiable information will be accessed by the research team without prior consent.

If interested in the study, the study coordinator will provide parents with an information sheet as well as an age-appropriate version of the information sheet for CYP. Parents/CYP will have the opportunity to read the information and to ask any questions they have. The consent form, which will involve age-appropriate assent from the CYP, will be completed electronically via a Qualtrics link sent to parents (via email/SMS/WhatsApp). The first study visit will be arranged between 2-12 weeks post presentation to the department with asthma attack.

Fifty participants will be enrolled in the 24-week programme and will be randomly assigned to either the financial incentives-based intervention group or the control group using the online service Sealed Envelope™ which will allocate participants to each group on a 1:1

basis. Participants will be told which group they have been randomly assigned to during study visit 1.

For all participants, there will be a total of 3 study visits: at baseline (0-weeks), at 12-weeks and at 24-weeks. All study visits will take place at the Children's Clinical Research Facility (CCRF) at St Mary's Hospital, Imperial College Healthcare NHS Trust. Due to the continued COVID-19 restrictions, remote study visits will be offered to participants through Microsoft Teams (joining link will be sent to parents electronically) and an option for study visits to be conducted (by the study coordinator) at participant's homes will also be available, if necessary. However, due to financial constraints, we would not be able to perform FENO remotely, so it will be removed as a secondary outcome measure in this event. All study visits will include the collection of asthma-related clinical data, questionnaire data and adherence data which will be described in detail below.

All CYP's GP's will be informed of the CYP's involvement in the study and a summary of results from each study visit will be sent to the CYP's GP. Information shared in this summary will include ACT score, FENO and adherence data. This summary will also be sent to parents. It is important to note that the study team will not be managing the CYP's asthma or intervening if their adherence is poor – this will be made clear to parents/guardians and CYP and it will be suggested they contact their GP or asthma nurse if there are any concerns throughout the study.

All CYP will be issued with an EMD (Hailie® sensor, Adherium, New Zealand) which attaches to their usual inhalers to electronically record inhaler actuation to provide % adherence data.

All CYP will be required to download the Hailie® associated app on their smartphones and to sync their Hailie® sensor with the associated app, via Bluetooth. The Hailie® sensor will detect medication usage from the attached preventer inhaler and send this to the Hailie® associated app on the CYP's smartphone, also via Bluetooth. The Hailie® associated app will then automatically upload (via WIFI/data connection) the medication usage data to the secure cloud-based Hailie® web portal where the research team will be able to view the data (see image below).

All CYP will regularly charge and sync their Hailie® device to ensure all data are collected accurately, they will be prompted to do this throughout the study through app notifications. Parents/guardians/CYP will be asked to inform a member of the study team if there are any issues with their EMDs so this can be sorted as soon as possible.

All CYP's Hailie® devices or smartphones will be programmed with both morning and evening audio-visual reminders across the 24-week period. CYP will choose the time of their reminders which will be recorded by the researcher.

There will be no covert adherence monitoring and CYP's adherence data will be downloaded and viewed by the study coordinator before/at each study visit (study visit 2, 12-weeks and study visit 3, 24-weeks). For those in the intervention group, adherence data will also be downloaded and viewed at 4-weeks, 8-weeks to calculate reward amount given only.

At the end of the 24-week programme, all participants will be invited to join a focus group discussion (which will either be in-person at the CCRF or virtually via Microsoft teams) with other CYP from the study. There will be up to 10 participants per focus group and numbers will be dependent upon participant availability. Focus groups with participants from the intervention group and with participants from the control group will be conducted separately. Focus groups will be optional for participants. Parents/guardians will also be invited to take part in an interview in person / via email or telephone to obtain their feedback about the programme. These interviews will be optional and will last approximately 45minutes.

Interviews will be conducted at study visit 3 and will be conducted in person or virtually (via telephone or via Microsoft Teams, dependent upon preference).

STUDY VISIT 1:

Prior to any tests, it will be ensured that all parents/CYP understand all the information provided and have electronically signed the informed consent form.

Participants will be given the Hailie® sensor and shown how to use this, as described above. Participants will be assessed and given guidance on their inhaler technique and will be provided with an Asthma UK children's asthma plan (unless already in receipt of an asthma plan, see appendix for plan) which will be conducted by a clinical research nurse.

The following information will be collected from all CYP; demographics, asthma history, asthma adherence (measured by self-report, MARS-A), asthma control (measured by ACT questionnaire, FENO – which will be measured by the child breathing out slowly though a mouthpiece where the nitric oxide from the breath will be measured the sensor and computer) and behavioural/psychological data (measured by BMQ, B-IPQ, SRBAI, TSRQ-adapted for this study).

Participants will be randomly assigned to either the 1) control group (n=25) or to the 2) financial incentives-based intervention group (n=25). Participants will be told which group they have been randomly assigned to during this visit.

1. *Control group (n=25):*

Participants will receive their usual care plus electronic reminders. Participants will not be required to do anything additional as part of this group.

2. *Financial incentives-based intervention (n=25):*

Participants will be provided with a summary information sheet regarding the intervention programme and will be given the time to read through this and to ask any questions.

Participants will receive gain-framed financial incentives based upon frequency of ICS adherence (£1 per morning dose and £1 per evening dose / maximum £2 per day regardless of prescription / £168 maximum per participant during the 12-week period). Participants will not be able to earn more money by taking their inhaler more than

prescribed. Participants will be able to see how much money they have earned in real-time by an in-app totaliser which increases by £1 every time the EMD recognises the morning or evening dose has been taken when the Hailie® sensor and the app are synced. Participants will receive their money (in form of an 'One4all' voucher) in 4-weekly instalments (at 4-weeks, 8-weeks, and 12-weeks / total £56 per each 4-week period). The 'One4all' voucher will be sent to the child's smartphone via text message. Participants will receive regular messages updating them on their progress in terms of financial incentives. Messages will be delivered as notifications via the app and will be seen on participants' smartphones. Participants will also be able to monitor their adherence in an in-app calendar that follows a traffic-light coding system to display daily adherence (e.g., red if no doses taken, orange if some taken and green if all inhaler puffs are taken per day).

During this intervention period, participant's Hailie® adherence data will also be downloaded and viewed via the Hailie® web portal virtually by the study coordinator at 4-weeks and 8-weeks (in addition to being downloaded at 12-weeks, study visit 2 and 24-weeks, study visit 3) to assess reward amount given.

STUDY VISIT 2:

The following information will be collected from all participants; asthma history, asthma control (ACT questionnaire, FENO), asthma adherence (self-report, MARS-A and electronically from Hailie®) and behavioural/psychological data (BMQ, B-IPQ, SRBAI, TSRQ-adapted). All participant's Hailie® adherence data will also be downloaded.

1. *Control group (n=25):*

Participants will continue to receive their usual care plus the electronic reminders. Participants will not be required to do anything additional.

2. *Financial incentives-based intervention (n=25):*

Participants will receive their final instalment of financial incentives and the financial incentives-based intervention will stop. Participants will no longer receive any financial incentives/rewards and will no longer have access to the in-app totaliser, the weekly messages, and the in-app traffic light calendar. Participants will continue to use their Hailie® device (with the programmed reminders) for the remaining 12-weeks of the study.

STUDY VISIT 3:

The following information will be collected from all participants; asthma history, asthma control (ACT questionnaire, FENO) asthma adherence (self-report, MARS and electronic from Hailie) and behavioural/psychological data (BMQ, B-IPQ, SRBAI, TSRQ-adapted). All participant's Hailie® adherence data will also be downloaded.

Participants will be asked to return their Hailie® device and will no longer be required to monitor their adherence.

Participants will be invited to take part in a focus group discussion (which will either be in-person at the CCRF or virtually via Microsoft teams) to discuss their perceptions of the trial and to obtain feedback. Focus groups will be optional for participants. Parents/guardians will also be invited to an optional interview to their feedback of the trial.

3.1. STUDY OUTCOME MEASURES

Primary outcome:

- ICS adherence (measured by EMD record of inhaler actuation%)

Secondary outcome:

- Proportion of participants achieving good asthma adherence (≥80%)
- Time to next asthma exacerbation needing a course of oral corticosteroids (OCS)
- Total number of severe exacerbations (incident rate ratio)
- Asthma control (measured by asthma control test (ACT))
- FENO
- Habit (measured by Self-Report Behavioural Automaticity Index, SRBAI)
- Belief in Medicines Questionnaire (BMQ)
- Brief Illness Perception Questionnaire (B-IPQ)
- Autonomous/controlled motivation (adapted from the Treatment Self-Regulation Questionnaire, TSRQ)
- Self-report adherence (Medication Adherence Report Scale for Asthma, MARS-A)

4. PARTICIPANT ENTRY

4.1. PRE-REGISTRATION EVALUATIONS

Participants must be contactable by telephone/email and able to receive written information. No pre-registration tests are required.

Prior to any study procedures, informed consent from the parent/guardian and assent from the child or young person will be obtained. 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 their 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. For parents and guardians participating in the subsequent interviews, they are free to withdraw at any time and without giving a reason before the interview. Otherwise, all data will be kept once collected as it will be anonymous.

4.2. INCLUSION CRITERIA

Inclusion criteria are:

- Informed consent obtained from parent/guardian and assent from the child.
- Children or young person with doctor diagnosed asthma presenting to Emergency Departments (ED) with a severe asthma exacerbation (as defined by ERS/ATS guidelines).
- Aged between 11 and 17 years old
- Prescribed maintenance inhaled corticosteroids (ICS) (which can include maintenance and reliever therapy (MART)) for at least 6-months.
- Own their own mobile smartphone (running Android 8 or higher, or iOS 13 or higher)
- Prescribed the following inhalers:
    - Clenil
    - Flixotide
    - Symbicort
    - Seretide

4.3. EXCLUSION CRITERIA

Exclusion criteria are:

- Parent/guardian unable to provide consent / CYP unable to provide assent
- CYP with other, co-existing respiratory conditions
- Parent/guardian/CYP who are not fluent or able to understand the information provided in English
- CYP who are involved in other intervention research studies (including CTIMPs)

4.4. WITHDRAWAL CRITERIA

CYP will be withdrawn from the study if CYP/parent/guardian refuse or withdraw their consent to participate in the study. Parent/guardian/CYP can refuse intervention, adherence monitoring or any study tests/questionnaires at any time without any negative consequences. Participation or withdrawal in the study will not affect the patient's clinical care and participants will not be prevented from receiving any treatment that may be required without participating in the study.

We don't anticipate any reason to stop the trial or other research early.

Any data already collected from a participant who decides to withdraw from the study will be kept. If a participant decides to withdraw from the study, data already collected until that point in the study will be used.

5. ADVERSE EVENTS

5.1. 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 should 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.

5.2. REPORTING PROCEDURES

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

5.3.1 Non serious AEs

All such events, whether expected or not, should be recorded- it should be specified if only some non-serious AEs will be recorded, any reporting should be consistent with the purpose of the trial end points.

Potential AEs and known complications:

Procedure	Known complications
n/a	n/a

5.3.2 Serious AEs

An SAE form should be completed and emailed 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 the London-Bloomsbury REC 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 should 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 must also notify the Sponsor of all related and unexpected SAEs.

Local investigators should report any SAEs as required by their Local Research Ethics Committee, Sponsor and/or Research & Development Office.

Contact details for reporting SAEs
RGIT@imperial.ac.uk
CI email (and contact details below)
Please send SAE forms to: Dr Louise Fleming
Tel: +44 (0)20 7352 8121 ext 2938 / Email: l.fleming@imperial.ac.uk
(Mon to Fri 09.00 – 17.00)

6. ASSESSMENT AND FOLLOW-UP

The following data will be collected at each study visit.

	Study visit 1 (0wks)	Study visit 2 (12wks)	Study visit 3 (24wks)
Study enrolment			
(1) Participant informed consent (and assent from CYP) (n=50)	X		
(2) Information and provision of Hailie® device (n=50)	X		
(3) Randomisation to intervention (n=25) or to control group (n=25)	X		
Inhaler technique	X	X	X
Asthma UK Action plan	X		
Demographic information	X		
Asthma characteristics/history	X	X	X
Control group (n=25) *Electronic monitoring device* (programmed with morning and evening reminders)	→	→	→

Financial incentives-based group (n=25) *Electronic monitoring device* (programmed with morning and evening reminders) *Financial incentives* (with in-app totaliser, in-app messages recording progress and in-app traffic light calendar)	→	→	→
Asthma measures			
(1) ICS adherence %	-	X	X
(2) Asthma control (ACT)	X	X	X
(3) Exhaled nitric oxide (FENO)	X	X	X
(4) Self-report adherence (MARS)	X	X	X
Behavioural/psychological measures			
(1) Habit (SRBAI)	X	X	X
(2) Belief in Medicines Questionnaire (BMQ)	X	X	X
(3) Brief illness Perceptions Questionnaire (B-IPQ)	X	X	X
(4) Autonomous/Controlled motivation (adapted from TSRQ)	X	X	X

Incidental findings

We don't anticipate there to be any incidental findings within this study. However, in the event of any incidental findings, the research team will inform the participant (and their parent/guardian) and will encourage them to inform and discuss findings with their GP. The summary of results from each study visit will also be sent to the GP after each study visit.

Study completion

Study end is defined as once all contactable participants have had their third and final research visit (the last research visit of the last subject recruited) and completion of the final focus groups for those involved.

All data will be stored for 10 years following completion of the study. At study completion, participants will continue to receive their usual care.

Follow-up contact

No further contact from the research team directly related to this study is anticipated following completion. Participants will continue to receive their routine care as per prior to enrollment in this project.

7. STATISTICS AND DATA ANALYSIS

7.1 Data management

Data entry will be collected by the study coordinator (Jasmine Hine) and the data analysis will be conducted by the study coordinator with assistance from the chief Investigator (Dr Louise Fleming).

All collected data will be entered onto an electronic database (REDCap/Excel) held on a secure Imperial College London server.

7.2 Statistical methods and sample size

As this is a pilot study, a formal sample size calculation is not required. However, the estimated sample size of 50 participants in total is based upon a calculation from un-published adherence data obtained from Royal Brompton Hospital from 400 children. Mean adherence in the sample was 65% (SD 22%). A Cochrane review[28] of adherence interventions to ICS for asthma found that electronic trackers or reminders led to better adherence of 19% (95% CI 14.47 to 25.26). Based upon this information, to give 80% power to achieve a 19% difference between the intervention group and controls, 21 participants are required per group. The target of 25 per group accounts for participant drop-out. This is supported by evidence that as a pilot study, 25 participants per group, with a total of 50 participants is sufficient[29].

Data analysis will be conducted using the Statistical Package for the Social Services (SPSS). Statistical analysis of quantitative, normally distributed data will be reported with means ± standard deviations (SD) and non-parametric data will be reported as medians with interquartile range. Data will be tested for normality using visual inspection, histograms, and Kolmogorov-Smirnov testing. Parametric tests will be used where possible for normally distributed data and logarithmically transformed data, otherwise appropriate non-parametric tests shall be used. The significance levels for all tests will be set at <0.5.

Categorical data will be reported as proportions. 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. Within group analysis the ANOVA test will also be used.

Questionnaire data will be used alongside group comparisons to observe any notable changes or differences between groups.

Qualitative data obtained from the focus groups will be thematically analysed. An independent researcher will aid with the facilitation/analysis of qualitative aspect of the study to ensure there is no bias.

8. REGULATORY ISSUES

8.1. ETHICS APPROVAL

The Study Coordination Centre has obtained approval from the London-Bloomsbury Research Ethics Committee (REC) and Health Research 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.

For participants involved in the financial incentives-based intervention, the financial incentives are gain-framed so participants will be rewarded dependent upon adherence behaviour, the reward will not be removed.

The clinical tests (FENO) may be familiar to participants. It is often used as routine care in many clinics. The test is very basic and will be fully described to the child.

The behavioural/psychological questionnaires (including SRBAI, BMQ, B-IPQ and adapted TSRQ), the self-report adherence questionnaire (MARS-A) and the focus group discussion will involve simple questions that should not be distressing.

Participants can refuse to answer any questions at any point.

All questionnaires are included in the appendix.

8.2. CONSENT

Consent to enter the study must be sought from both parent/guardian and assent obtained from the CYP. Consent/assent must be sought only after a full explanation has been given, an information leaflet offered and time allowed for consideration. Signed participant consent/assent should be obtained. The right of the participant to refuse to participate without giving reasons must be respected. All participants are free to withdraw at any time from the protocol treatment without giving reasons and without prejudicing further treatment.

Consent will also be obtained separately from parents/guardians who will be taking part in the interviews.

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.

Data will be pseudonymised.

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

Imperial College London and AUKCAR are funding this study.

Finances:

- Awaiting quote from Adherium, New Zealand (regarding the Hailie sensors)
- Up to £168/participant (n=25) in financial incentives-based intervention group = £4,200
- Reimbursement costs for travel and for refreshments will be provided to parents/guardians/CYP who attend any study visits in person at the CCRF, St Mary's Hospital.

8.7. AUDITS

The study may be subject to audit by Imperial College London under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Frame Work for Health and Social Care Research.

9. STUDY MANAGEMENT

The day-to-day management of the study will be co-ordinated through Jasmine Hine (CCRF, St Mary's Hospital, Imperial College London Healthcare Trust).

10. PUBLICATION POLICY

The results of this study will be presented at national and international scientific meetings to audiences of both paediatric and adult respiratory, allergy and general physicians. All results will be submitted for publication in peer-reviewed medical journals using open access policies where applicable. We will also use appropriate patient facing social media and channels via Imperial College Public Relations team and AUKCAR communications team to disseminate results. Results will also be included in a submitted PhD thesis submission to Imperial College London and will be detailed on the AUKCAR website/newsletters.

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APPENDIX:

1. Questionnaires to be used in this study
    a. Asthma Control Test (ACT)
    b. Brief Illness Perceptions Questionnaire (B-IPQ)
    c. Belief in Medicines Questionnaire (BMQ)
    d. Self-Report Behavioural Automaticity Index (SRBAI)
    e. Medication Adherence Report Scale for Asthma (MARS-A)
    f. Autonomous/Controlled Motivation questionnaire (Adapted from the Treatment Self-Regulation Questionnaire for the purpose of this study)

2. Asthma UK Children's asthma plan

1.Questionnaires to be used in this study

a. Asthma control test (ACT)

1. In the past *4 weeks,* how much of the time did your *asthma* keep you from getting as much done at work, school or home?					
All of the time (1) ☐	Most of the time (2) ☐	Some of the time (3) ☐	A little of the time (4) ☐	None of the time (5) ☐	SCORE
2. During the past *4 weeks,* how often have you had shortness of breath?					
More than once a day ☐	Once a day ☐	3 to 6 times a week ☐	Once or twice a week ☐	Not at all ☐	SCORE
3. During the past *4 weeks*, how often did your *asthma* symptoms (wheezing, coughing, shortness of breath, chest tightness or pain) wake you up at night or earlier than usual in the morning?					
4 or more nights a week ☐	2 or 3 nights a week ☐	Once a week ☐	Once or twice in the past 4 weeks ☐	Not at all ☐	SCORE
4. During the past *4 weeks,* how often did you have to use your rescue (blue) inhaler or nebuliser medication?					
3 or more times a day ☐	1 or 2 times a day ☐	2 or 3 times per week ☐	Once a week or less ☐	Not at all ☐	SCORE
5. How would you rate your *asthma* control over the past *4 weeks?*					
Not controlled at all ☐	Poorly controlled ☐	Somewhat controlled ☐	Well controlled ☐	Completely controlled ☐	SCORE
				TOTAL SCORE	
				Completed by (circle): child / parent / both	

b. Brief Illness Perceptions Questionnaire (B-IPQ)

Appendix A. The Brief Illness Perception Questionnaire

For the following questions, please circle the number that best corresponds to your views:

How much does your illness affect your life?

0	1	2	3	4	5	6	7	8	9	10
no affect at all										severely affects my life

How long do you think your illness will continue?

0	1	2	3	4	5	6	7	8	9	10
a very short time										forever

How much control do you feel you have over your illness?

0	1	2	3	4	5	6	7	8	9	10
absolutely no control										extreme amount of control

How much do you think your treatment can help your illness?

0	1	2	3	4	5	6	7	8	9	10
not at all										extremely helpful

How much do you experience symptoms from your illness?

0	1	2	3	4	5	6	7	8	9	10
no symptoms at all										many severe symptoms

How concerned are you about your illness?

0	1	2	3	4	5	6	7	8	9	10
not at all concerned										extremely concerned

How well do you feel you understand your illness?

0	1	2	3	4	5	6	7	8	9	10
don't understand at all										understand very clearly

How much does your illness affect you emotionally? (e.g. does it make you angry, scared, upset or depressed?)

0	1	2	3	4	5	6	7	8	9	10
not at all affected emotionally										extremely affected emotionally

Please list in rank-order the three most important factors that you believe caused your illness.
The most important causes for me:-

1. _____
2. _____
3. _____

c. Beliefs about Medicines Questionnaire (BMQ)

(©R Horne)

Beliefs about medicines questionnaire (BMQ) Horne, Weinman, Hankins, (1999)
***Psychology and Health,* 14, 1-24**

BMQ –Specific

Your views about medicines prescribed to you.

- I would like to ask you about your personal views about medicines prescribed for your asthma.
- These are statements other people have made about their asthma medication.
- Please indicate the extent to which you agree or disagree with them by placing a cross in the appropriate box.
- There are no right or wrong answers. I am interested in your personal views.
- Please only cross one box per question.

1) My health at present depends on my asthma medicines

Strongly agree ☐ agree ☐ uncertain ☐ disagree ☐ strongly disagree ☐

2) Having to take asthma medication worries me

Strongly agree ☐ agree ☐ uncertain ☐ disagree ☐ strongly disagree ☐

3) My life would be impossible without my asthma medication

Strongly agree ☐ agree ☐ uncertain ☐ disagree ☐ strongly disagree ☐

4) Without my asthma medication I would be very ill

Strongly agree ☐ agree ☐ uncertain ☐ disagree ☐ strongly disagree ☐

5) I sometimes worry about the long term effects of my asthma medication

Strongly agree ☐ agree ☐ uncertain ☐ disagree ☐ strongly disagree ☐

6) My asthma medication is mystery to me

Strongly agree ☐ agree ☐ uncertain ☐ disagree ☐ strongly disagree ☐

7) My health in the future will depend on my asthma medication

Strongly agree	agree	uncertain	disagree	strongly disagree
☐	☐	☐	☐	☐

8) My asthma medication disrupts my life

Strongly agree	agree	uncertain	disagree	strongly disagree
☐	☐	☐	☐	☐

9) I sometimes worry about becoming too dependent on my asthma medication

Strongly agree	agree	uncertain	disagree	strongly disagree
☐	☐	☐	☐	☐

10) My asthma medication protects me from becoming worse.

Strongly agree	agree	uncertain	disagree	strongly disagree
☐	☐	☐	☐	☐

BMQ-General

- I would like to ask you about your personal views about medicines in general.
- These are statements other people have made about medicines in general.
- Please indicate the extent to which you agree or disagree with them by ticking the appropriate box.
- There are no right or wrong answers. I am interested in your personal views.
- Please only tick one box per question.

11) Doctors use to many medicines

Strongly agree	agree	uncertain	disagree	strongly disagree
☐	☐	☐	☐	☐

12) People who take medicines should stop their treatment for a while every now and again.

Strongly agree	agree	uncertain	disagree	strongly disagree
☐	☐	☐	☐	☐

13) Most medicines are addictive.

Strongly agree ☐ agree ☐ uncertain ☐ disagree ☐ strongly disagree ☐

14) Natural remedies are safer than medicines

Strongly agree ☐ agree ☐ uncertain ☐ disagree ☐ strongly disagree ☐

15) Medicines do more harm than good.

Strongly agree ☐ agree ☐ uncertain ☐ disagree ☐ strongly disagree ☐

16) All medicines are poisons

Strongly agree ☐ agree ☐ uncertain ☐ disagree ☐ strongly disagree ☐

17) Doctors place too much trust on medicines

Strongly agree ☐ agree ☐ uncertain ☐ disagree ☐ strongly disagree ☐

18) If doctors had more time with patients they would prescribe fewer medicines.

Strongly agree ☐ agree ☐ uncertain ☐ disagree ☐ strongly disagree ☐

d. Self-report Behavioural Automaticity Index (SRBAI)

Habit questionnaire – Self-report Behavioural Automaticity Index (SRBAI)

These questions are all about your taking of your preventer inhaler on a regular basis.

1. Taking my preventer inhaler in the morning and in the evening is something I do automatically

☐ Strongly agree ☐ Agree ☐ Uncertain ☐ Disagree ☐ Strongly disagree

2. Taking my preventer inhaler in the morning and in the evening is something I do without having to consciously remember

☐ Strongly agree ☐ Agree ☐ Uncertain ☐ Disagree ☐ Strongly disagree

3. Taking my preventer inhaler in the morning and in the evening is something I do without thinking

☐ Strongly agree ☐ Agree ☐ Uncertain ☐ Disagree ☐ Strongly disagree

4. Taking my preventer inhaler in the morning and in the evening is something I start doing before I realise I'm doing it

☐ Strongly agree ☐ Agree ☐ Uncertain ☐ Disagree ☐ Strongly disagree

Gardner, B., Abraham, C., Lally, P., & de Bruijn, G. J. (2012). Towards parsimony in habit measurement: Testing the convergent and predictive validity of an automaticity subscale of the Self-Report Habit Index. *International Journal of Behavioral Nutrition and Physical Activity*, *9*(1), 1-12

e. Medication Adherence Report Scale for Asthma (MARS-A)

Medication Adherence Report Scale for Asthma (MARS-A)

Many people find a way of using their medication which suits them

This may differ from the instructions on the label or from what their doctor has said

We would like you to answer a few questions about how you use your medicines

Here are some of the ways people have said that they use their medicines.

For each statement please tick the box which best applies to you:

Your own way of using your medicines	Always	Often	Sometimes	Rarely	Never
	1	2	3	4	5
I only use my steroid (preventer) inhaler when I need it					
I only use it when I feel breathless					
I decide to miss out a dose					
I try to avoid using it					
I forget to take it					
I alter the dose					
I stop taking it for a while					
I use it as a reserve, if my other treatment doesn't work					
I use it before doing something which might make me breathless					
I take less than instructed					

(©R Horne)

Cohen JL, Mann DM, Wisnivesky JP, Home R, Leventhal H, Musumeci-Szabó TJ, Halm EA. Assessing the validity of self-reported medication adherence among inner-city asthmatic adults: the Medication Adherence Report Scale for Asthma. Ann Allergy Asthma Immunol. 2009 Oct;103(4):325-31. doi: 10.1016/s1081-1206(10)60532-7.

f. Autonomous/Controlled Motivation questionnaire (Adapted from the Treatment Self-Regulation Questionnaire (TSRQ) for the purpose of this study)

Autonomous/controlled motivation (adapted from the Treatment Self-Regulation Questionnaire, TSRQ, for the purpose of this study)

The following question relates to the reasons **why you would take your asthma preventer inhaler.**

Different people have different reasons for doing that, and we want to know how true each of the following reasons is for you. All 8 response are to the same question.

Please indicate the extent to which each reason is true for you, using the following 7-point scale:

1	2	3	4	5	6	7
not at all true			somewhat true			very true

I take my asthma preventer inhaler because…

1. I would feel in the wrong if I did not take my inhaler

1	2	3	4	5	6	7
not at all true			somewhat true			very true

2. I personally believe it is the best thing for my health.

1	2	3	4	5	6	7
not at all true			somewhat true			very true

3. Others would be upset with me if I did not take my inhaler

1	2	3	4	5	6	7
not at all true			somewhat true			very true

4. I believe it is very important for many aspects of my life.

1	2	3	4	5	6	7
not at all true			somewhat true			very true

5. I would feel bad about myself if I did not take my inhaler

1	2	3	4	5	6	7
not at all true			somewhat true			very true

6. It is an important choice I really want to make.

1	2	3	4	5	6	7
not at all true			somewhat true			very true

7. It is very important for being as healthy as possible.

1	2	3	4	5	6	7
not at all true			somewhat true			very true

8. I want others to see I can do it.

1	2	3	4	5	6	7
not at all true			somewhat true			very true

INTERVENTION GROUP ONLY

1. I take my asthma preventer inhaler to get the incentive

1	2	3	4	5	6	7
not at all true			somewhat true			very true

2. The reason why I take my asthma preventer inhaler is to get the reward

1	2	3	4	5	6	7
not at all true			somewhat true			very true

Adapted for this study from TSRQ, accessed from: https://selfdeterminationtheory.org/, Healthcare, Self-determination theory packet (Geoffrey C. Williams, Richard M. Ryan, & Edward L. Deci), first used for "behaving in a healthy way" by Williams, Grow, Freedman, Ryan & Deci (1996).

2.Asthma UK Children's asthma plan

My asthma plan

1 My usual asthma medicines

- I need to take my preventer inhaler every day. It is called:

  and its colour is:

- I take ____ puff/s of my preventer inhaler in the morning and ____ puff/s at night. I do this every day even if my asthma's OK.
- Other asthma medicines I take every day:
- My reliever inhaler helps when I have symptoms. It is called:

  and its colour is:

- I take ____ puff/s of my reliever inhaler when I wheeze or cough, my chest hurts or it's hard to breathe.

If I need my reliever inhaler (usually blue) when I do sports or activity, I need to see my doctor or asthma nurse.

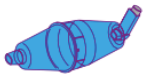
2 My asthma is getting worse if...

- I wheeze, cough, my chest hurts, or it's hard to breathe **or**
- I need my reliever inhaler (usually blue) three or more times a week **or**
- I'm waking up at night because of my asthma (this is an important sign and I will book a next day appointment).

If my asthma gets worse, I will:

- Take my preventer medicines as normal
- And also take ____ puff/s of my reliever inhaler (usually blue) every four hours if needed
- See my doctor or nurse within 24 hours if I don't feel better.

URGENT! If your reliever inhaler isn't lasting four hours, you need to take emergency action now (**see section 3**)



Remember to use my spacer with my inhaler if I have one.

(If I don't have one, I'll check with my doctor or nurse if it would help me.)

Other things my doctor or nurse says I need to do if my asthma is getting worse (e.g. check my peak flow)

3 I'm having an asthma attack if...

- My reliever inhaler isn't helping or I need it more than every four hours **or**
- I can't talk, walk or eat easily **or**
- I'm finding it hard to breathe **or**
- I'm coughing or wheezing a lot or my chest is tight/hurts.

If I have an asthma attack, I will:

Call for help.

Sit up – don't lie down. Try to be calm.

Take one puff of my reliever inhaler (with my spacer if I have it) **every 30 to 60 seconds** up to a total of 10 puffs.

If I don't have my reliever inhaler, or it's not helping, I need to **call 999** straightaway.

While I wait for an ambulance I can use my blue reliever again, every 30 to 60 seconds (up to 10 puffs) if I need to.

Even if I start to feel better, I don't want this to happen again, so I need to see my doctor or asthma nurse **today**.

My asthma triggers

List the things that make your asthma worse so you can try to avoid or treat them

I will see my doctor or asthma nurse **at least** once a year (but **more** if I need to)

Date my asthma plan was updated:

Date of my next asthma review:

Doctor/asthma nurse contact details:

Parents – get the most from your child's action plan

- **Take a photo** and keep it on your mobile (and your child's mobile if they have one)
- **Stick a copy** on your fridge door
- **Share** your child's action plan with their school

Learn more about what to do during an asthma attack
www.asthma.org.uk/child-asthma-attacks

If you have any questions, your parents can talk to our respiratory nurse specialists by **calling 0300 222 5800** or **messaging on WhatsApp on 07378 606 728** (Monday-Friday, 9am-5pm over 16 only).

My asthma plan

Name: