**PARTICIPANT INFORMATION SHEET: AAMOS-00 Phase 2**

“Mobile device monitoring to inform prediction of

asthma attacks: an observational study (AAMOS-00) Phase 2”

We’re inviting you to take part in our study. Before you make a decision, you need to take the time to understand why we’re doing this research and what it involves. Please read the following information carefully – you may want to discuss it with friends and relatives. Thank you for taking your time to consider this invitation.

# What’s this research study for?

Smart monitoring devices and mobile-health (mHealth) technologies are used more and more to help with asthma self-management. These technologies, including smartwatches and smartphones, give new ways for people with asthma to monitor their condition with the least interruption to their lives. Smart devices can replace the burden of daily monitoring, helping people to look after their asthma so that they manage their treatment and avoid attacks. Examples are smart inhalers, and smart watches.

To develop a useful and safe system for people with asthma, we need to collect information using new smart technologies alongside the traditional daily symptom and peak flow diary. We can then compare the two sets of readings to develop systems that detect worsening asthma using smart devices and potentially reducing the need for burdensome data entry.

The aim of this study is to collect these two sets of data from about 30 people for 6 months. We’ll use the findings to develop a method that can accurately predict an asthma attack using smart devices and symptom diaries. In the future this could be used in a connected asthma system to help people look after their asthma and avoid troublesome attacks.

# Summary of the study

This study is split into 2 phases:

1. *Daily questionnaire monitoring for one month.*
2. *Smart device monitoring for six months.* 30 participants who kept a regular diary in phase 1 will be given three smart devices (smart inhaler, smart peak flow meter, smartwatch) to collect data automatically as you use the devices, in addition to completing daily and weekly questionnaires. We’ll choose people to invite for this phase with a range of ages, gender and smoking status, and with different types of asthma triggers.

At the end of phase 2, we’ll send a questionnaire asking for feedback about using the smart devices and whether you think they could be useful to help you look after your asthma.

# Can I take part?

To take part in phase 1, you must:

* Be at least 18 and living in the UK
* Have been told by a doctor that you have asthma.
* Have needed at least one course of oral steroids (prednisolone) for an asthma attack in the past 12 months
* Have an Android smartphone from 2016 onwards (e.g. Samsung Galaxy S7, Xiaomi Mi 5, Huawei P9) or iPhone 7 or later with Bluetooth

To take part in phase 2, you would also need to:

* Have completed at least half the daily questionnaires in phase 1
* Intend to live in the UK for the next 6 months
* Be prescribed with a relief inhaler (blue “puffer”) that works with the FindAir ONE smart inhaler device. This device fits on top of the canister in most standard “pMDI” inhalers (see picture). The smart inhaler device does not fit on an Airomir Autohaler inhaler or on other types of devices (such as accuhalers, breath-actuated inhalers). If you’re not sure about the inhaler device you’re using please contact us. Some common brand names of suitable inhalers are:
	+ Ventolin and other versions of salbutamol if the inhaler is the same shape inhaler as Ventolin
	+ Salamol
	+ Airomir
	+ Fostair
	+ Budiair

OK – pMDI inhalers:



Not OK:



You cannot take part in this study if you:

* Have other conditions causing asthma-like symptoms
* Are aged under 18
* Are unable to provide valid consent (e.g. cognitive impairment, learning disabilities)
* Are unable to use an app and respond to questions in English

# What will happen if I decide to take part?

Thank you for completing Phase 1. We’re inviting you to go on now to phase 2.If you decide that you’d like to take part, please go the recruitment website

<https://www.ed.ac.uk/usher/aukcar/knowledge-hub/projects/aamos-00>

and complete the eligibility check

<https://edinburgh.onlinesurveys.ac.uk/aamos-00-phase-2-eligibility>

## Using Mobistudy for Phase 2

You’ll need to keep on using the study App that you have been using in Phase 1. Phase 2 of this study will appear as a new study in Mobistudy. You will be invited to join the phase 2 study like phase 1. The data collection functions will only be available during the study period. For phase 2, the study period is 6 months from consent.

In the front page, the tasks for today listed under “Today’s pending tasks” for phase 2 will be:

* completing the daily questionnaire,
* completing the weekly questionnaire,
* taking three peak flow measurements,
* uploading data from the smartwatch.

To navigate around Mobistudy, use the navigation bar at the bottom of the screen which will bring up the other areas of the app.

This is usually straightforward. There are some more detailed instructions here, and we’re happy to talk you through the process if it’s not clear.

<https://www.ed.ac.uk/files/atoms/files/aamos-00_phase_2_detailed_information_v1.1_2021_05_21.docx>

## Devices

We will send you three smart monitoring devices:

* Smart inhaler, FindAir ONE (FindAir, <https://findair.eu/>). This can be attached to the canister part of your pMDI relief inhaler and it measures when you use your inhaler. It can be reattached to a different inhaler if you change relief inhalers during the study.
* Smart peak flow meter, Smart Peak Flow Meter (Smart Respiratory Products Ltd, <https://smartpeakflow.co.uk/>). The peak flow meter will measure your peak expiratory flow (PEF), a measurement of how quickly you can blow air out of your lungs.
* Smartwatch, Xiaomi Band 3 (Xiaomi, <https://www.mi.com/uk/>). The smartwatch will have the monitoring app loaded ready for you to use. The watch will be collecting your heart rate, step count, and activity data.

### Smart inhaler

The data is collected within the device and transferred when connected to your phone via Bluetooth. The FindAir app will need to be downloaded for the data to be saved, which needs an email address for registration. The FindAir app will send the data to their server in Poland, where it will be retrieved by the study team. Once the FindAir app is downloaded and you have registered, we will provide you with a “partner code” which can be entered in the settings. Your smart inhaler will need to be connected and activated with the FindAir app. This will then connect your inhaler data automatically.

The device has a non-changeable battery which should last about a year, so won’t need any charging throughout the study.

### Smart peak flow meter

To use the device, you need to connect it to your phone as a headphone device - either plugged directly into the audio jack of your phone or connected via Bluetooth with an adapter if your phone does not possess an audio jack. We’ll give you the Bluetooth adapter.

The smart peak flow meter won’t need any charging, but the Bluetooth adapter will. The smart peak flow meter needs light to work - this can be anything from a desk lamp to a window to the outside. The mouthpiece device should be cleaned regularly with water and soap for hygiene.

The peak flow measurement takes 3 blows and it will save the best blow. During the COVID-19 pandemic, we ask that you do the peak flow measurement without anyone directly in front of you for 2 meters.

### Smartwatch

You need to wear this watch as often as is comfortable, including during sleep. The data will be collected on the watch and transferred when it’s connected to your phone via Bluetooth. The data from the smartwatch will go directly to Mobistudy. The smartwatch needs weekly charging.

All the data from the questionnaires and devices will be stored in Mobistudy’s server at the University of Malmo. Here’s the data we’ll be collecting:

* Peak flow (PEF) using the Smart Peak Flow Meter
* Heart rate using smartwatch
* Step count using smartwatch
* Activity intensity using smartwatch
* Location (GPS) using Mobistudy
* Inhaler usage using FindAir ONE
* Questionnaire data using Mobistudy

A daily and weekly questionnaire similar to the one in phase 1 will be asked in phase 2. From the smartwatch three data will be recorded every minute, heart rate, step count, and activity intensity. The GPS location will be collected with your smartphone, which will be used to connect with local weather forecasts by the Met Office, Open Weather Map, and Ambee.

The inhaler usage will be stored on FindAir’s server in Poland before being copied to the University of Edinburgh. For the data to move from the smart inhaler to your phone, you will need to download the FindAir app and have it running in the background.

Apple App Store: <https://apps.apple.com/us/app/findair-asthma-diary/id1515944881>

Google Play: <https://play.google.com/store/apps/details?id=eu.findair&hl=en>

Detailed instructions about device usage and care are available here

<https://www.ed.ac.uk/files/atoms/files/aamos-00_phase_2_detailed_information_v1.1_2021_05_21.docx>

## End of phase 2

Before you leave this study there is a final questionnaire for you to give your feedback and point-of-view about the acceptability and usefulness of the monitoring system.

# Are there any risks from taking part in the study?

There are no foreseeable risks to participating in this study, as the app is only designed to monitor your asthma status. The study will not give you any advice about the treatment and management of your asthma. You will continue to take the treatment prescribed by your healthcare provider. If you develop any symptoms or have any concerns about your asthma, you should use your usual treatment and contact your healthcare provider according to their advice.

# What if something goes wrong?

You will not be monitored medically in this study. If you have any concerns about your asthma or are feeling distressed, please contact your GP.

The University of Edinburgh, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

# What are the advantages of taking part?

Filling in symptom diaries and using the devices daily will give you information about your asthma which you may find useful. You can experience smart monitoring devices first hand by taking part in phase 2 of the study. You’ll be able to keep all 3 devices when it’s finished.

Taking part will help develop a new asthma self-management system that will benefit the asthma community. You will also be prioritised to take part in the first pilot study of AAMOS.

# Will I be paid for taking part in this study?

No, patients will not be compensated in cash for their time in the study – but we’ll help with the cost of network data by giving you a £5 voucher per month to cover the approximate cost of the mobile data you use in phase 2.

Also, you will be able to keep all three smart monitoring devices at the end of phase 2. The FindAir ONE and Smart Peak Flow Meter have their own apps that you can download and use to continue monitoring your own asthma. The FindAir ONE has a battery life of 12 months - you can use the device until it runs out of charge. Monitoring apps on the smartwatch will continue to function if you want to use the smartwatch after the study. If you don’t want to keep the watch, we’ll send you a return paid packaging so that you can return it to the research team.

# What will happen if I don’t want to carry on with the study?

If, at any time after agreeing to take part, you change your mind about being involved in this study you are free to withdraw without giving a reason. We’ll ask if we may keep the data collected up to that point to be used in our analysis. You will also have the choice to have all your study data deleted and not used for subsequent research.

# Will my taking part in this study be kept confidential?

We take the confidential storage of data very seriously and will follow the procedures of the University of Edinburgh (see additional GDPR information). All data collected from your daily diary (see “what will happen to my data” below) will be coded with a study number so that it’s made anonymous and can only be linked to your personal information by members of the research team. Information about you will be stored electronically on a secure server and only people with usernames and passwords can access it.

Inspections and audits make sure we are carrying out the study to comply with the UK regulations. If our study is inspected representatives of the University sponsor (ACCORD), research ethics committee (REC), and independent inspectors may have access to personal information. They are bound by the same confidentiality rules as the research team.

Published results will not contain any personal data.

# What will happen to my data?

The University of Edinburgh is the data controller for this study. You can read the University of Edinburgh’s data policy at <https://www.ed.ac.uk/information-services/about/policies-and-regulations/research-data-policy>.

Data gathered with Mobistudy will be stored at Malmö University, then copied to the University of Edinburgh. Mobistudy is GDPR compliant organisation. To safeguard rights, Mobistudy will only collect the minimum of information that identifies you (your name and email address) and this personal data will be detached from the questionnaire and smart device data and stored separately. The data will remain encrypted at storage and in transfer. Your data will remain on Mobistudy for as long as you keep your Mobistudy profile. You can read Mobistudy’s privacy policy at <https://mobistudy.org/appPrivacyPolicy.html>. Only the research team will have access to personal data, which will be securely destroyed three years after the end of the study.

Your inhaler data from using the FindAir will first go to FindAir’s server in Poland, it will then be downloaded and copied by the research team at the University of Edinburgh. You can read FindAir’s privacy policy at <https://findair.eu/privacy-policy-mobile-app.html>.

Your questionnaire answers, smart peak flow measurements and data from the smartwatch will go through Mobistudy and be copied by the research team at the University of Edinburgh.

The anonymised daily and weekly data from questionnaire and smart devices will be kept and archived in Edinburgh DataShare (a digital repository of research data produced at the University of Edinburgh) for ever. This will mean that data collected data from the study can be used by other researchers in the future who want to learn more about asthma and using smart devices to help patients with asthma.

The date, time, and IP address of your login and when you send data in Mobistudy will be logged for security reasons and kept for 5 years. The study team can’t access this data.

# Where can you find out more about how your information is used?

You can find out more about how we use your information

* at <https://www.ed.ac.uk/records-management/privacy-notice-research>
* at [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)
* our leaflet available from [ [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch) ]
* by asking one of the research team
* by sending an email to rena.gertz@ed.ac.uk, or
* by ringing us on 0131 242 9446.

# What will happen to the results of the research study?

We’ll present the findings of the results from Phases 1 and 2 of this study at conferences for healthcare professionals, and technology developers. We’ll also publish them in peer-reviewed research journals. We’ll send you a summary of our findings and a link to the papers when they are published.

In the future, we’ll use the data collected to develop a monitoring and feedback system to help people manage their asthma. With your consent, we can keep your contact details so that we can alert you to future project that may be of interest.

# Complaint statement

If you want to complain about any aspects of the study or with the way you have been treated or approached, please contact ACCORD:

The University of Edinburgh,

The Queen’s Medical Research Institute,

47 Little France Crescent,

Edinburgh

EH16 4TJ

Or phone: 0131 242 9446 or email: resgov@accord.scot

# Who is sponsoring, organising and funding the research?

This study is sponsored by the University of Edinburgh’s Academic and Clinical Central Office for Research and Development (ACCORD), a partnership between the University of Edinburgh and NHS Lothian Health Board. The study is funded through financial support from the Asthma UK Centre for Applied Research (AUKCAR, <https://www.aukcar.ac.uk/>).

The researcher is Kevin Tsang, an AUKCAR PhD student (<https://www.aukcar.ac.uk/what-we-do/postgraduate/current-students/kevin-tsang>). His PhD supervisors are Dr Syed Ahmar Shah, Professor Hilary Pinnock, and Professor Andrew Wilson.

   

# Who has reviewed the study?

This study has been reviewed and approved by the NHS Research Ethics Committee (REC).

# Further information and contact details

We hope this information sheet has answered your questions about this study but if you want to know more, please do not hesitate to get in touch with:

Kevin Tsang, email: k.c.h.tsang@sms.ed.ac.uk

Dr Ahmar Shah, email: ahmar.shah@ed.ac.uk

To speak with a researcher independent of the research team, you can contact Dr Saturnino Luz at s.luz@ed.ac.uk