**PARTICIPANT INFORMATION SHEET: AAMOS-00 Phase 1**

“Mobile device monitoring to inform prediction of

asthma attacks: an observational study (AAMOS-00) Phase 1”

We’re inviting you to take part in our study. Before you make a decision, you need to take 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 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?

Please go to our recruitment website to do an online eligibility check.

There’s a short online questionnaire to complete to check that you are eligible to take part. You also tell us about the reliever inhaler that you’re using so we can let you know if it’s suitable for the smart inhaler device.

<https://edinburgh.onlinesurveys.ac.uk/aamos-00-phase-1-eligibility>

If you’re eligible and definitely want to take part in the study, we’ll ask you to sign a consent form.

## Downloading the study app

Mobistudy is an open-source site. It’s hosted at Malmö University, Sweden. It lets different research teams carry out mHealth research (<https://mobistudy.org/>). The study we’re inviting you to join is on it. There is no need to join other studies that you may be eligible to join, but this is up to you.

You will be asked to download the Mobistudy app from the Apple App Store or Google Play and create an account.

<https://apps.apple.com/us/app/id1462273500>

<https://play.google.com/store/apps/details?id=org.mobistudy.app>

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

<https://www.ed.ac.uk/files/atoms/files/aamos-00_phase_1_detailed_information_v1_2021_01_11.docx>

## Getting started with Mobistudy

After downloading Mobistudy, you have to register. You need to give the following information to create your profile:

* Email address, to identify you and allow login to the app
* Name and surname

You will also need to give some information to check you are eligible to take part in the available studies:

* Date of birth
* Sex
* Weight
* Height
* Long term conditions
* Regular medication

If you’re uncomfortable giving any of the above information to Mobistudy, we can make alternative arrangements.

After registering and logging into Mobistudy, you’ll see the invitation to join this study.

## Using Mobistudy

The front page will have all the tasks for today listed under “Today’s pending tasks”, and for phase 1 this will be the questionnaire.

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

We will be using Mobistudy to collect the study data. The data collection functions will only be available during the study period. For phase 1, the study period is 1st March 2021 – 31st March 2021. For phase 2, the study period is 1st April 2021 – 31st October 2021.

## Phase 1

The first questionnaire after enrolling onto the study will ask for some personal information including height, weight, ethnic group, and smoking history. There are a few questions about your asthma including your asthma triggers and the inhalers you use.

There are 6 questions to complete every day. This will take about 2 minutes of your time. These ask about your asthma symptoms, inhaler use, and asthma triggers you’ve had.

There is a weekly questionnaire that will ask about your asthma symptoms in more detail and visits to your GP or the hospital about your asthma. This will take about 5 minutes of your time.

Here’s the data we’ll be collecting in phase 1:

* Height, weight, ethnic group, smoking history, about your asthma at the start of phase 1 using Mobistudy
* Daily asthma questionnaire using Mobistudy
* Weekly asthma questionnaire using Mobistudy

We know it’s hard to complete questions every day, and we expect that most people will forget or not be able to complete some readings. However, for phase 2, we need to recruit people able to complete daily questionnaires as regularly as possible and this is one of the things we will consider when we choose people to help with it. Other factors are that we want people in Phase 2 with a range of ages, gender, type of asthma triggers, and smoking status. This way we’ll get a balanced picture of how the smart devices detect changes in asthma control.

## Phase 2

In this phase you’ll be given 3 smart monitoring devices (smart inhaler, smart peak flow meter, smartwatch) to monitor your daily asthma condition. There’s more information about phase 2 in the information leaflet we’ll send you if we invite you to help us with this phase. You can choose whether or not you want to take part in phase 2 after you have read that information.

If you have any questions in the meantime, just get in touch. Use the contact details at the bottom of this document.

# 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 need to take part in phase 1 of the study to be able to go on and take part in phase 2.

Taking part will help develop a new asthma self-management system that could help people living with asthma.

# 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 to cover the approximate cost of the mobile data you use to take part in phase 1 of our study.

# 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 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.

The anonymised questionnaire data will be kept and archived in Edinburgh DataShare (a digital storehouse of research data produced at the University of Edinburgh) for ever. This will mean that data collected 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 projects 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