IRAS project ID: 281480

App for asthma connected plus (A4A+)

Invitation

This is an invitation to take part in a research study. Before you make a decision please read the following information carefully.

First we will explain the background to the study and how the study will be conducted. Then we will explain what will happen if you decide to take part.

Take time to consider if you would like to take part. It may be helpful to discuss with friends or family, or your GP, and if anything remains unclear please contact us directly (please contact Dr Io Hui - phone : 01316515143 or email : io.hui@ed.ac.uk)

To be eligible for this study, you must be

- 16 years or over,
- Diagnosed with asthma by your doctor,
- Using a pMDI inhaler (this is the commonly used aerosol 'puffer'). The smart inhaler is deigned to work with Seretide, Flixode, Fostair, Ventolin, Atrodil, Aspulmo, Comboterol, Amos, Serevent, Budiair pMDI, and may not work with other pMDIs.
- Registered with a general practice in the UK

Why are we doing the study?

Understanding about your asthma and what triggers it, knowing how to manage it day to day, and how to respond to worsening symptoms are important tasks of living with asthma. We know that having an personalised action plan agreed with your asthma nurse or GP leads to better day to day control of asthma symptoms, less time off work or school and also reduces the risk of an asthma attack.

You can learn more about asthma action plans at: https://www.asthma.org.uk/advice/manage-your-asthma/action-plan/

Emerging technologies, such as smart inhalers and other smart gadgets that connect to the internet to auto collect and transfer data, can support you to manage your asthma. From our recent study, we know that patients prefer intelligent systems to capture their peak flows, environmental factors and asthma symptoms without actively having to enter the data themselves. They also want real time advice to support their self-management decisions.

In this study, we want to explore how patients and their clinicians use and adopt a 'connected asthma' app in a real life setting.

What is involved if I decide to take part? We will invite 10 patients to use our app with three smart devices for a month and tell us whether you think they are easy to use, what you like about the app and what you think could be better. If you decide to take part, we will invite you for two interviews (pre study and post study , approximately one hour interview). Because of the pandemic, the interviews will be arranged using telephone or video-conferencing. If the lockdown has been eased, we will also provide an option of face-to-face interview.

- In the pre study interview, we will check your inhaler devices to make sure it can fit on the inhaler sensors. If so, we will provide you one smart inhaler sensor, a peak flow meter and a fitness watch. We will ask you about how you connect the devices to our app and explore how you manage your daily asthma.
- You will use the devices and app for a month. You can share your logs with your GP/asthma nurse. We will ask your permission to approach your GP/asthma nurse for their feedback on reading your logs.
- In the post study interview, we will ask you to tell us how you used the devices and app to look after your asthma.

What are the three devices that I will be given ? We will provide you the Findair One smart inhaler, Polar Ignite, Smart peak flow meter/MIR Smartone peak flow meter. You need to download the Polar and Findair apps in order to connect their devices to our app The data you enter on the Polar and Findair app will be stored in their device cloud. Their data policy can be found here: Polar - https://www.polar.com/uk-en/legal/privacy-notice#toc3; Findair - https://findair.eu/privacy-policy-mobile-app.html.

findair POLAR SMART PEAKFLOW SMARTONE®

Do I need to return the smart devices after the study? No, you do not need to return the devices after the study. However, our app service will be stopped after the study. You can keep using the smart devices with the apps developed by the individual companies. For the Findair smart inhaler, you will be able to use the device with their app until the sensor built-in battery has used up (that's usually around 11 months).

Do the companies provide product warranties when I keep using the devices after the study? No, we provide the devices to you for the research purposes. Therefore, the device companies do not provide product warranties on the use of devices.

I have already using the device(s). Can I join take part in this study with my device(s)?

Yes, we welcome people to take part in our study with their existing device from Findair, Polar, Smart peak flow meter and Smart one. Please contact us and we will check if your device model can be connected to our platform.

Who will be leading this study? Professor Hilary Pinnock will lead the study, Dr. Io Hui is the co-lead of this project, supported by Emeritus Professor Brian McKinstry

Professor Hilary Pinnock

Dr Io Hui

Emeritus Professor Brian McKinstry

What is the role of Tactuum Ltd in this study? Tactuum is our technology partner, they help us to build the app, manage the app database and make it available for you to use.

What does the 'connected asthma' app do?

The system is connected with three smart devices (smart inhaler, smart peak flow meter and smart activity tracker) and an app. The devices can transfer the numbers of puffs that you have taken from your current inhaler, your peak flow, sleep pattern, exercise and exercise path to the app. Using the app, you can track and understand your asthma and capture useful data to help you manage your asthma. It can store the information captured from the smart devices that we will provide for you. You can also make logs about your asthma manually on the app. You can choose to share this information with your doctor or nurse. The app includes an action plan which your doctor or nurse can help you fill in. If you have asthma symptoms it will suggest that you look at your action plan and follow the instructions from your clinicians (including any previous advice they may have given you). Other features include links to the latest news about asthma, and a medication reminder. We hope to also provide quick links to the outdoor environmental conditions (e.g. temperature, humidity and particulate matter(PM) level). As an add on feature for Covid-19 pandemic, you will be able to manually enter your body temperature on the app.

All data you enter in the app including your log data, name and email address will be stored in the app database, hosted by the Tactuum Ltd. Your name and email address will be used to share the summary report to your GP/Asthma nurse. The log data will help us to understand your usage pattern and inform our discussions during the interview. Tactuum will manage the database securely, and comply with GDPR.

What doesn't the 'connected asthma' app do?

The app does not recommend or advise you to do or change anything. If you have asthma symptoms it will suggest that you look at your action plan and follow the instructions from your clinicians. The app does not provide you with a communication channel with your doctor or asthma nurse. Do not rely on the app in case of emergency or if your asthma get worse. If you have any concerns or issues with your health, you must contact your health professionals.

There are no clinicians monitoring your asthma reading. You are responsible for getting advice or help if your asthma deteriorates.

Will this app use up my data plan? The quantity of data used by the app is very small and is unlikely to have a significant effect on your data plan. We will provide a £10 data voucher if you are worry about the data usage that may affect your current data plan or do not have a data plan on your phone.

About funding and organisation? The study is part of a research programme for the Asthma UK Centre for Applied Research. The study is being funded by the MRC Confidence in Concept and has received favourable ethical opinion from the South East Scotland Research Ethics Committee 02 (ref: 20/SS/0081).

How will we choose who to invite ? You will be asked to fill in an online expression of interest form (https://www.ed.ac.uk/usher/a4a-connected/register-to-take-part). The form has a few questions about you and your asthma experience. We will look at the information on the expression of interest form and choose a range of people with different viewpoints and experience for our study. We will then contact selected people, answer any questions and make arrangements for the interview.

Can I be sure that what I say will be kept confidential? Yes. Any information about you, and everything that you say will be kept strictly confidential. Your name and contact details will be kept securely at the University of Edinburgh. The interviews will be audio recorded and everything that you tell us will be written out and anonymised before we review and analyse our findings.

Who will transcribe the interview ? The interview will be transcribed by the University authorised transcription service or trained transcripter in our Usher Institute.

What will happen to the results of the study? We will send you a summary of our findings at the end of the study. Findings will be posted on the AUKCAR website (https://www.ed.ac.uk/usher/a4a-connected), presented at conferences and published in a journal. Quotes or key findings will always be made anonymous in any outputs. Information may also be kept for future research

Will taking part affect the treatment I receive for my asthma? No. Taking part, or deciding not to take part, in the study will not affect the care you receive from your practice, or the hospital.

Do I have to take part? No, it is up to you to choose whether you take part or not. Please take time to consider and, if it would help, discuss with friends, family or your GP.

Can I change my mind about taking part? Yes. You may change your mind at any time and don't have to give a reason.

What if I want to withdraw from the study? Agreeing to participate in this project does not oblige you to remain in the study nor have any further obligation to this study. If, at any stage, you no longer want to be part of the study, please inform the researcher (Dr. Io Hui, io.hui@ed.ac.uk). You should note that your data may be used in the production of formal research outputs (e.g. journal articles, conference papers, theses and reports) prior to your withdrawal and so you are advised to contact the research team at the earliest opportunity should you wish to withdraw from the study. On specific request we will destroy all your identifiable answers, but we will need to use the data collected prior to your withdrawal, and to maintain our record of your having consented and withdrawn.

What are the benefits of taking part? Taking part in this research may not benefit you personally. However, being involved in the study will help us to develop better self-management systems for people with asthma.

Are there any risks if I decide to take part? No. Your treatment will not be affected: we are only asking for your opinions.

What is the online consent process if I chose to have a video interview? We will send the consent form to you before the interview by using our University email. If you have already decided to participate you could choose to complete it and return the consent form to us before our initial interview. If you are not yet sure or have any questions, then before our researcher starts the interview, he/she will go through the information and consent items with you. If you have not returned a completed form, you can initial the boxes and sign on the form before we start the interview, show us the completed form in front of the camera, then return the form to us via email after the interview. The researcher will then sign the form and return a copy to the you for your records. If you have returned a completed form to us, the researcher will countersign the form once you have confirmed verbally that you are still happy to participate and send you a copy of the completed form for your record.

Data protection and confidentiality Your data will be processed in accordance with Data Protection Law. All information collected about you will be kept strictly confidential. If you consent to being audio recorded, all recordings will be destroyed once they have been transcribed. Your data will only be viewed by the researcher/research team. All electronic data will be stored on a password-protected computer file and all paper records will be stored in a locked filing cabinet. Your consent information will be kept separately from your responses in order to minimise risk. For general information about how we use your data go to: https://www.ed.ac.uk/records-management/privacy-notice-research

Questions

I have some questions about the study: Io hui will be pleased to answer any questions. **phone**: 01316515143 or **email**: io.hui@ed.ac.uk

To speak with an independent researcher you can contact Bruce Mason, a researcher who is not part of the study team by: **phone**: 0131 650 2680 or **email**: bruce.mason@ed.ac.uk

If you wish to make a complaint about the study please contact NHS Lothian: NHS Lothian Complaints Team, 2nd Floor, Waverley Gate,2-4 Waterloo Place, Edinburgh, EH1 3EG **phone**: 0131 536 3370 or **email:** feedback@nhslothian.scot.nhs.uk

"I want to take part ! "

Please scan the QR code or click on this link

(https://www.ed.ac.uk/usher/a4a-connected/register-to-take-part) to complete the expression of interest form.

Thank you for taking the time to read this information sheet

Data Protection Information Sheet

Connected asthma: implementing Internet-of-Things (IoT) solution to support asthma self-management

The EU General Data Protection Regulation (GDPR), along with the UK Data Protection Act, governs the processing (holding or use) of personal data in the UK.

You are receiving this as you are considering being a participant on this clinical research study. The information below details what data will be held about you and who will hold or store this.

University of Edinburgh is the sponsor and NHS Lothian are the co-sponsors for this study based in the UK. We will use information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The sponsor will keep identifiable information about you until the research team have published results so that the researcher can send you copies of papers. In reality, this may be longer than 12 months after the study has ended.

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Providing personal data directly

The University of Edinburgh will use a) your name and contact email/telephone number to contact you about the research study and to oversee the quality of the study. If you choose to share your summary report to your GP/asthma nurse, your name and email address will be shown on the report and b) your home address to send you the smart devices. Individuals from the University of Edinburgh and regulatory organisations may look at research records to check the accuracy of the research study. The only people in the University of Edinburgh who will have access to information that identifies you will be people who need to contact you about the project recruitment results and the project findings or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, or contact details.

The University of Edinburgh will keep identifiable information about you from this study until the research team have published results so that the researcher can send you copies of papers. In reality, this may be longer than 12 months after the study has ended.

Use of data for future research

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and

care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you as an individual, such as insurance.

Contact for further information

You can find out more about how we use your information and our legal basis for doing so in our Privacy Notice at www.accord.scot.

For further information on the use of personal data by NHS sites, please link to the Health Research Authority (HRA) website; https://www.hra.nhs.uk/information-about-patients/.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO) at https://ico.org.uk/.

Data Protection Officer contact information:

University of Edinburgh
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