

School of Pharmacy Level 3, Building 505, 85 Park Rd, Grafton, Auckland 1023, New Zealand +64 9 923 5524 Postal address: School of Pharmacy Faculty of Medical and Health Sciences The University of Auckland Private Bag 92019 Auckland 1142 New Zealand

PARTICIPANT INFORMATION SHEET

Study title: Digi-Predict Asthma: Digital predictors of asthma attacks

Name of researchers: Drs Amy Chan, Matire Harwood, Alana Cavadino, Partha Roop, Jeff Harrison

Contact email address for primary researcher: <u>a.chan@auckland.ac.nz</u>

Voluntary Invitation to Participate

We're inviting you to take part in our study on digital predictors of asthma attacks. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

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 – it sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 16 pages long. Please make sure you have read and understood all the pages. Thank you for taking your time to consider this invitation.

What is the purpose of this research?

Smart devices and technologies are now used more and more to help with asthma management. These technologies, including smartwatches, smartphones and smart devices, give us new information about the body that could help us predict when your asthma may be getting worse and when an attack may be about to happen. Research from overseas tells us that there may be changes in the body that happens before an attack that can be detected by these



technologies. This means we can potentially create an alert system based on these changes in the body to alert someone of an attack before it happens.

Our aim is to ultimately develop a method that can predict an asthma attack using information from smart devices and artificial intelligence (AI) to help pick up changes that may be happening in the body that may signal an impending attack. AI is a type of computer science that allows machines to learn from experience and data so that it can find patterns in data that we may not otherwise see with the usual computer and mathematical techniques. This means we may be able to prevent asthma attacks from happening in the future as AI can help us identify an attack earlier.

To do this, we need to capture certain physiological aspects from those with asthma, who have had an attack in the past. We need to collect data from about 300 people with asthma for 6 months so that we can find out how body changes (e.g. changes in heart rate, medication use, peak flow, or sleep) may be related to your asthma symptoms. These physiological aspects will be captured through the use of study provided smart devices: a smart inhaler ('Hailie'), smartwatch (Fitbit watch), a cough monitoring app on your phone or provided smartphone, and the apps linked with the smart devices. We will also provide a study research app to help you use these research devices. There will be a demonstration by the team of how to use these devices and we will be on-hand to provide support if you have any questions. There will also be questionnaires to complete every 2 weeks about your general health and asthma. Participation means data will be collected from these devices over 6 months and a visit at baseline and at the end of the study. This study is funded by the Health Research Council of New Zealand, Auckland Medical Research Foundation and Life AI Corp.

How is the study designed?

We will be recruiting 300 people with asthma from Auckland and Waikato regions. Each person will be given several smart devices to use for 6 months. Using these smart devices, we will gather information on medication use, cough, and physiological measures such as heart rate, breathing rate, heart rate variability, sleep quality, number of footsteps taken during the day and distance travelled. We will need to get information on your location data from your smartphone so we can see if the weather and environment (e.g. air quality, pollen levels) around you is related to your asthma. We will also get information about your wellbeing and asthma by asking you some standard questions every 2 weeks. These information that we collect will be used with AI to produce a prediction model based on the patterns we observe between the data collected and asthma control and attacks. This can then be used in the future to predict a person's risk of asthma attacks.

To recruit the number of participants we require, the project's expected duration will be 2-3 years, but each participant will only be involved for six months. Each person will be assessed at a study visit in person at the start and end of the study to give out and collect the devices, and also check your lung function and asthma.

Who can take part in the study?



You are invited to take part in this study because you are 12 years old or older and have recently seen your doctor or visited the hospital for an asthma attack in the last year, or are interested in using technology to help us understand more about asthma attacks. Your healthcare team has either given you information about this study, or you may have found out about this study via posters, email lists, social media, word of mouth or other advertisements. We'll choose people to invite with a range of ages, gender and smoking status, and with different types of asthma triggers.

To take part in the study, you must:

- Be at least 12 years older or older
- Have been told by a doctor that you have asthma
- Have had an asthma attack in the past 12 months
- Using asthma inhalers prescribed by a New Zealand health practitioner
- Living in Auckland or Hamilton or able to travel to these regions for the study visits
- Own or be willing to use a smartphone with Bluetooth that is compatible with the study devices (e.g. Samsung Galaxy S7, Xiaomi Mi 5, Huawei P9) or iPhone 7 or later with Bluetooth
- Be available and willing to use the smart devices you are given for 6 months
- Understand the study procedures and willing to give informed consent to take part

You cannot take part in this study if you:

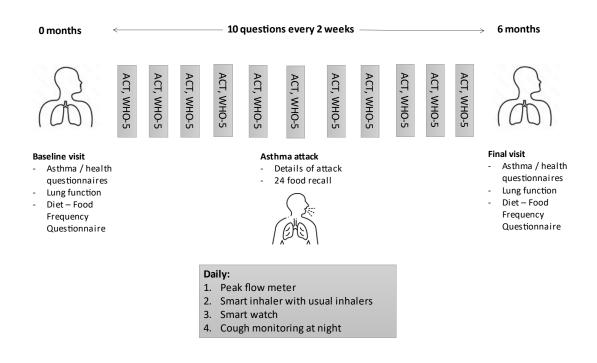
- Are aged under 12 years old
- Use inhalers that are not compatible with the smart inhaler devices
- Have other lung conditions causing asthma-like symptoms
- Have no history of asthma attacks
- Have smoked for over 10 pack-years (e.g. smoked a pack a day for 10 years, or two packs a day for 5 years)
- Are unable to provide valid consent or follow study procedures (e.g. cognitive impairment)
- Are unable to attend the study visits
- Are unable or not interested in using a smart phone or smart devices

What will participating in the study involve?

Taking part in the study will involve interacting with the research team at the study visits, answering some questionnaires, and using the smart devices that you are given for six months. There will be two study visits in person – one at baseline (enrolment) and one at 6 months. The visits will take place at The University of Auckland Grafton campus but they can take place at your place of residence if it is difficult for you to come to the University of Auckland. At the initial visit at start of the study, you will be provided with the required smart devices (including smart phone if you are unable to use your own) and instructions and a demonstration of how to use these devices. You will be asked some questions and your lung function will be checked. It is expected that these study visits would take up to 2 to 3 hours. In between these visits, you'll have some short questionnaires to complete



either online or over the phone every 2 weeks. These will take up to 5-10 minutes to complete. See the diagram below which shows the tasks you need to do:



Exceptions are made for wearing the smart watch for example when charging the watch and when having a shower or when there is any discomfort in your wrist. However, some information will require interaction with you through questionnaires – for example, about your asthma control and how you are feeling. We will ask these at the start of the study and every 2 weeks through a the study research app developed by the research team or if you prefer, we can collect this information over the phone. To help with the study tasks, you will receive daily notifications to prompt you to complete these tasks. The notifications come up passively and can be dismissed or disabled if you wish. We will also check in with you with a quick text or phone call each month (whichever you prefer) to see how you are doing with the technology and devices.

To use the smart devices, you will not need to create any user accounts – this will be done for you and you will be provided with details of the account using an email address and password created for you so that you won't need to use your own personal emails to login. These accounts will sync your health data with the apps. To allow transfer of data from the smart devices, Bluetooth will need to be switched on. To send the data (upload), your smartphone will need to be



connected to the internet. You won't need WiFi internet for the devices to work however you do need access to internet a few times a week to allow the data to be uploaded. If you don't have WiFi – we can work out cover mobile data costs for the duration of the study. At the end of the study, we will collect the studyprovided devices from your home to minimise travel for you though you can keep the smart watch if you wish. You can also keep using the cough monitoring app.

We will also ask for your feedback at the end of the study about using the smart devices and whether you think they could be useful to help you look after your asthma. We will do this as part of the last study visit. At the end of the study, we will also obtain data from the Ministry of Health national data collections to confirm information about hospitalisations and medication use. These data are already routinely collected and held by the Ministry of Health. With your permission, we will ask the Ministry of Health to provide this data.

The key part of the study is to find out what risk factors may be related to asthma attacks. As such, one of the main tasks for being part of this study is to report attacks when they happen. You can do this via the study app. When an attack happens, you'll be asked some questions about what you did to manage your attack, what food you had prior to the attack, and for females of childbearing age, the date of your last period. If you don't wish to answer some questions, you can skip this and let us know. You can complete these questions in your own time when you are feeling better after your attack.

We will continue you on your usual medication regimen prescribed by your usual asthma healthcare provider, though for salbutamol we may provide you with Ventolin® specifically as this device is compatible with the Hailie® smart inhaler. No other changes will be made. We will inform your usual healthcare provider that we will be supplying your medication.

<u>Duration</u>: Should you be willing to participate, your involvement in the study will be for up to six months. During this timeframe, most data will be acquired without the need for your interaction with the smart devices and smartphone. Some of this data will be collected when you are asleep at night while other data will be when you are awake, and from asking you questions directly.

What are some possible risks of this study?

This study involves collection of a large amount of information using different technologies to help us build a model using AI to predict when an asthma attack might occur. The data that are collected will be coded (deidentified) however with the use of AI, there are possible risks of re-identification as it uses data from multiple sources. The study also collected location data so we can see how environment and weather related to your location affects your asthma. There is a risk that the location data may be sufficient to identify participants when combined with other data. To minimise this, we have a study advisory group comprising national and international experts in AI who will regularly review our data management policies and audit the use of AI. See also 'what will happen to my information' section below.



In terms of impacts on health, there are no foreseeable health risks from participating in this study, as the study is only designed to monitor your asthma status and we are not testing a new intervention nor changing your asthma management. We do not expect any incidental findings to arise because of this study. However, the research team will advise your general practitioner (GP) of your participation if the research team identify any issues with your asthma that needs management by your GP. Should you experience any worsening of your asthma during the study, you should speak with your GP.

The study is not designed to give you any advice about the treatment and management of your asthma. You will continue to take the treatment prescribed by your healthcare provider and manage your asthma as you usually would, though we do ask that you use your peak flow meter daily in line with asthma guidelines. 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 are some possible benefits?

Taking part in the study means filling in questionnaires, and using new technologies, to monitor your health and asthma, which may give you extra information about yourself which you may find useful. However, it is important to know that these information are for your interest only at the moment, as they are not yet validated and we advise you not to change your treatment based on the information. You will get to experience using smart devices and some of the newest monitoring technologies for asthma firsthand. You'll need to return the smart inhaler devices (and smart spacer if provided). If you wish, you can also keep the smart watch at the end of the study and continue to use the cough monitoring app.

Taking part will help develop a new risk prediction system for asthma attack s that will benefit yourself and the asthma community. You will also be prioritised to take part in future studies of any asthma attack risk prediction tools developed.

Will any costs be reimbursed?

There will be a small koha for participation in the study – you will be given \$100 worth of digital gift cards from Giftpay in two stages: \$50 at the beginning of the study and \$50 if you remain till the end of the six month study. Giftpay is a digital gift card that allows you to buy what you want from 30+ brands across New Zealand and online including from Farmers, Whitcoulls, and Countdown.

You will also be reimbursed up to \$20 petrol vouchers for any transport costs if you come to The University of Auckland Grafton site for your study visits over the course of the study. The devices do not require continuous data to work so it is expected that there will be limited impact on mobile data usage as we only expect the data to be uploaded when connected to WiFi. However if you do not have access to WiFi, we can cover mobile data costs for an unlimited data plan.



As mentioned, you will be able to keep the smart watch after the study has ended. This has its own app that you can download and use. You will also be able to continue to use the cough monitoring app should you wish.

What if something goes wrong?

If you were injured in this study, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

What information will be collected and how?

You will be provided with the following smart devices and associated apps:

- Hailie[™] inhaler sensor(s) for each of your inhaled medication (if you have more than 3 inhalers, we will provide sensors for your main preventer and reliever medications)
- Resmonics[™] cough sensor
- Fitbit™ smartwatch
- Study application to manage research tasks

A smartphone may also be offered to participants who do not wish to use their personal phone for the study, or for those who do not have a smartphone that is able to pair with the provided smart devices. Some participants may also be offered the use of a smart (digital) spacer depending on stock availability.

The following data will be collected over a six-month period and will be sent to our research team when the device apps are connected to the internet without needing your input.

Medication data (via Hailie® sensors):



- Date / time of inhaler doses

- Number of doses
- Inhaler technique (inhalation, inspiratory flow, angle of inhaler, inhaler shaking)

© 2022 Adherium (NZ) Ltd



Night-time cough data (via Resmonics[™] app):



- Date/time of cough (only if coughing at night)
- Number of coughs
- Type of cough (e.g. dry/wet)

Smart watch data (via Fitbit[™] watches):



You are required to wear a smartwatch throughout the day and night. This device monitors physiological wellbeing. The data captured are:

- Resting Heart Rate
- Instantaneous Heart Rate
- Activity (step count)
- Activity intensity
- Heart Rate Variability During sleep
- Breathing Rate During sleep
- Skin Temperature During sleep
- Oxygen Saturation During sleep
- Sleep Score
- Stress Score (if available on your smart watch)

Smart (digital) spacer:



Some participants will be offered a digital spacer to use instead of their usual traditional spacer. There is limited stock so only some participants may be offered this when the stock is available in New Zealand. The data captured are:

- inhaler use
- inhalation technique

Diet, asthma and wellbeing data

These data will be provided by you from answering questionnaires. These questionnaires are on an app designed by our research team which we will provide to you on your phone or the study smartphone.

You will be required to install the apps that pair with the smart devices via Bluetooth on your smartphone or the study smartphone. Data will sync from the devices to the app(s), which will periodically transfer the data captured/stored on the smart devices to the smartphone and onwards to the online smart device



servers which will be copied and downloaded by the research team throughout the study. We will set up account details for you to access the different smart device services required for this study. The only purpose of the study-provided account(s) is so the smart devices can function correctly. The accounts will be created through the device services and we will only use a unique participant number and a unique email address that we will create only for the study so you will not be identifiable. Data collected will be stored under the participant's provided device account.

Location tracking (GPS functionality) will be enabled on the smart phone and collected by the study research app . The accuracy of the location tracking will depend on the smart phone functionality, which at present is able to record close to exact location. The purpose of enabling location tracking is to allow us to gather data on what is happening in the environment near your location so we can see how environmental changes (such as weather or air quality changes) is related to your asthma. Location data is only updated when you move more than 100m from your last location.

At the end of the study, you will need to return the smart inhaler devices provided to you for the purpose of the study. You can keep the smart watch if you wish. The collection of the smart inhaler(s) will be done at the final 6 month visit by the research team, or if you wish to withdraw from the study earlier, a researcher will contact you to organise the most convenient way for you to return the devices. The default is for a researcher to schedule a delivery pickup.

What will happen to my information?

Data storage, retention, destruction, and future use

During this study the researchers will take a note of some information about you and your study participation. This includes the results of any study questionnaires and assessments. If needed, information from your medical records, for example data from national health collections held by the Ministry of Health, and from your GP may also be collected. You cannot take part in this study if you do not consent to the collection of this information.

Identifiable Information

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). The following groups may have access to your identifiable information:

- Research staff to complete study assessments
- Your GP may be notified of your participation in this study with your consent.
- Your usual doctor (your GP or specialist), if a study test gives an unexpected result that could be important for your health or well-being. This allows appropriate follow-up to be arranged.

De-identified (Coded) Information



To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the researcher. Instead, you will be identified by a code. The researcher will keep a list linking your code with your name, so that you can be identified by your coded data if needed.

The following groups may have access to your coded information, which may be sent and stored overseas:

- The researchers for the purposes of this study.
- People and companies working with or for the researcher, for the purposes of this study such as the suppliers of the smart devices (this may include approximately 20 people from approximately 5-8 different companies). As this study uses third-party devices that are not made by the University (e.g. Fitbit watches, Adherium smartinhalers etc), there is a chance that your data will be used by the commercial companies that are making the devices, such as for improvement of their products and services.
- Regulatory or other governmental agencies worldwide.

The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

Future Research Using Your Information.

This study involves collection of data from smart devices that could be useful for future health research. If you agree, your coded information (i.e. deidentified without your name) may be used for future research related to asthma and / or other medical and/or scientific research that is unrelated to the current study.

There is a chance this future research may be conducted overseas. As the research is taking place some time in the future, it will not be possible to tell you when this future research is undertaken using your information, nor will it possible to get your reports about the research that is done using your information. Your information may be shared with other researchers or companies. Your information may also be added to information from other studies, to form much larger sets of data.

If you agree, your information may be used indefinitely for future research unless you withdraw your consent. However, it may be extremely difficult or impossible to access your information, or withdraw consent for its use, once your information has been shared for future research.

Security and Storage of Your Information.

Your identifiable and coded information will be entered into electronic case record forms and collected via the study app. The case record forms will be held at The University of Auckland server during the study. After the study it is transferred to a secure dedicated file storage system created for this project and maintained by The University of Auckland, and stored for at least 10 years after the youngest participant turns 16, then destroyed. The study app data will be stored on Firebase, an application development platform provided by Google and



standard cloud data storage, largely using Amazon Web Services. All storage will comply with local and/or international data security guidelines.

The study will involve data collection using several smart devices and their associated mobile apps. The data collected is owned by the research team for the purposes of the study, but can be accessed by the companies who make the devices. As these are third-part companies that are not affiliated with The University of Auckland, each of these have their own data management and security policies. Whilst we do not have control over their privacy policies, our team has agreed with each of the manufacturers to ensure that only deidentified data are collected by the manufacturers. The researchers also have control over the data collection – for example, the start/stop dates of data collection, and what data parameters are recorded.

To help protect the privacy of participants, the research team will create a unique account for you using only your coded unique identifier ID, without any direct identifiers, rather than using any of your personal details to create the accounts. Only coded IDs and study email address (not personal emails) will be used for the participant to log into the apps. The data may be used by some device companies for purposes unrelated to this study such as quality improvement of their product however in all cases, the data will be coded (deidentified) and comply with local and/or international data storage and security guidelines.

Below are the specific data management details for each device. You can scan the QR code to read about their respective privacy polices:



Adherium[™] manufacturers the Hailie[™] inhaler sensors. Adherium[™] will have access to Hailie sensor-specific technical data to monitor device performance. They need to collect this data to comply with their obligations as a device manufacturer and to provide technical support, if needed. Adherium[™] uses industry standard data storage in the Microsoft Azure SQL database based in Australia. Deidentified data generated within the current study will only be shared with Adherium [™] subcontractors for the purposes of delivery of their service. The data from the Hailie[™] device(s) will first go to the Hailie[™] server in Australia, then will be downloaded and copied by the research team at The University of Auckland. You can read the Hailie[™] privacy policy at https://www.hailie.com/pages/privacy-policy#it



Data from the smart watch will be collected by the respective smart watch companies (Fitbit[™]). You can read the Fitbit[™] privacy policy here: <u>https://www.fitbit.com/global/us/legal/privacy-policy</u>



Data on cough will be collected by Resmonics[™]. The cough detection algorithm uses very short audio segments (less than one second each) to detect cough. These segments are too short to recognize conversations. The recordings will be analysed on your or the study smartphone. The cough frequency and an encrypted copy of the recording will be stored on an password-protected and HIPAA-compliant



server. The detection algorithm provider (Resmonics[™]) will also have access to the recordings to improve and extend their symptom analysis algorithms and the right to sublicense the data to third parties, for example research teams and companies. They will only have access to de-identified and coded data. Their privacy policy is here: <u>https://resmonics.ai/privacy-policy-nz</u>

If you experience an asthma attack, you will be invited to provide information about the food you ate in the last 24 hours so we can see if there is a relationship between dietary intake and asthma attacks. This data will be collected via the Research Diet Diary app produced by Xyris. Xyris Software can access Diet Diary users' data for troubleshooting and bug-fixing purposes. However, they only access this data only with express permission from the user in question. Xyris uses industry standard cloud data storage, largely using Amazon Web Services. Amazon Web Services data (which includes Research Food Diary users' data) is stored in the Sydney, Australia data centre, however, for disaster recovery purposes the data is replicated in other data centres, possibly overseas. All unidentifiable data generated within the current study could be shared with third parties. It will be archived in a publicly-accessible data repository for long-term preservation and sharing. All of the data they share with third parties will be anonymised, which means that it will NOT be linked to your study ID number, your name or any other information that can identify you. Their privacy policy is here: https://support.easydietdiary.com/hc/enus/articles/202429019-Privacy-Policy

For participants with a smart (digital) spacer, data from the digital spacer will be collected by Trudell Medical Ltd, the manufacturer of the smart spacer.

The de-identified data from any questionnaires you complete and smart devices will be kept and archived on The University of Auckland secure password protected server until 10 years after the youngest participant turns 16 years old. During this time, if you consent, the data collected from the study can be used by other researchers who want to learn more about asthma and health, and using smart devices to help improve asthma and other health conditions, which may not be directly related to this study.

We take the confidential storage of data very seriously and will follow the procedures of the University of Auckland. All data collected will be coded with a unique participant number so that it's coded (see 'coded' information above) 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. Published results will not contain any identifiable personal data.

Risks with data





Although every effort will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g., making it harder for you to get or keep a job or health insurance) is currently very small, but may increase in the future as people find new ways of tracing information.

Although your coded information is maintained by researchers here in New Zealand, it will be hosted on severs or cloud platforms for each of the smart devices which may be located overseas (see "Security and storage of your information" section). Other countries may have lower levels of data protection than New Zealand. There may be no New Zealand representation on overseas organisations which make decisions about the use of your information. There is a risk that overseas researchers may work with information in a way that is not culturally appropriate for New Zealanders.

Rights to Access Your Information

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected. If you have any questions about the collection and use of information about you, you should contact the research team.

Rights to Withdraw Your Information.

You may withdraw your consent for the collection and use of your information at any time, by informing the research team.

If you withdraw your consent, your study participation will end, and the research team will stop collecting information from you.

At the point of withdrawal, you will be asked whether you would like the information collected up until your withdrawal from the study to be deleted or continue to be used and included in the study. The data will be deleted or continue to be used depending on your choice.

Ownership Rights.

This project will collect data mainly for research purposes. The information from this study may lead to discoveries and inventions or the development of a commercial product. The rights to these will belong to the study's Primary Investigator, Dr Amy Chan. You and your family will not receive any financial benefits or compensation, nor have any rights in any developments, inventions, or other discoveries that might come from this information.

Use of New Technologies (e.g., Artificial Intelligence, Health Apps).

The study will involve the use of several apps. This is necessary as it enables the retrieval of data from the smart devices – the smart inhaler(s) and smartwatch. Participants will be assigned accounts that are de-identified for the purposes of



linking with the apps. Anyone outside of the research team cannot use the information gathered and the information cannot be used to identify you. The data will be synced to online servers and is encrypted by the suppliers of the smart devices. You are not expected to subscribe to any paid app features for the smart devices.

<u>Māori Data Sovereignty</u>

Māori data sovereignty is about protecting information or knowledge that is about (or comes from) Māori people. We recognise the taonga of the data collected for this study. To help protect this taonga:

- We have formed a Māori advisory group for the study that will discuss at regular intervals about the collection, ownership, and use of study data.
- We will hold huis 3 times a year with the Māori advisory group to discuss any issues around the entire study design, recruitment procedures, consult on interpretation and dissemination of results.

What happens after the study or if I change my mind?

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. Your participation is entirely voluntary, and you may decline the invitation to participate. If you choose not to participate, you may contact any of the investigators found in the contact details section.

If you withdraw from this study, you must return any devices provided to you as part of the study. These include the smart inhaler, smartwatch and if applicable, the study smartphone. Please endeavour to return these devices to us in a timely manner and in good condition, so that other people can have the chance to use these.

When you withdraw, please let us know if you would like the data collected from the time you consented to participate in the study till the time you withdraw from the study to be used or if you would like this data deleted forever.

At study end, there will be a final export of collected data and a check to see if any questionnaires or documentation are outstanding. The study-provided account(s) that have been set up for the purposes of using the smart devices will be discontinued, and the smart devices and study smart phone (if provided) will be reset to factory settings with deletion of your data on these devices.

Can I find out the results of the study?

At the end of the six months, you may request a copy of the data recorded from the smart devices. The data captured by the devices can be accessed via the device apps at any time. Guidance on how to view this data will be provided and demonstrated at the start of the study.



We'll present the findings of the study at conferences for healthcare professionals, and technology developers. We'll also publish them in peer-reviewed research journals. If you would like to receive the results, please indicate this on the consent form and we'll send you a link to a summary of the results and any published papers describing the study's outcome when they are published.

In the future, we'll use the data collected to develop a risk prediction tool for asthma attacks. With your consent, we can keep your contact details so that we can alert you to future project(s) that may be of interest. Please indicate this on the consent form below if you are interested.

Who is funding this study?

This study is funded by the Health Research Council (HRC) of New Zealand, Auckland Medical Research Foundation and by Life AI Corp. The webpage containing details about this project is found here: <u>https://www.hrc.govt.nz/resources/research-repository/data-driven-approachpredicting-asthma-attacks-aotearoa</u> and <u>https://www.medicalresearch.org.nz/post/artificial-intelligence-in-health-careasthma-patients-breathing-easier</u>

The supply of smart phones has been supported by 2Degrees and One NZ.

Who has approved the study?

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The Southern Health and Disability Ethics Committee has approved this study.

Who can I contact for more information or if I have concerns?

If you have any questions, concerns, or complaints about the study at any stage, you can contact:

Dr Amy Chan, Primary investigator

+64 9 923 5524

<u>a.chan@auckland.ac.nz</u>

Professor Partha Roop, Co-investigator

+64 9 923 5583

p.roop@auckland.ac.nz

Professor Jeff Harrison, Co-investigator

+64 9 923 2144

<u>jeff.harrison@auckland.ac.nz</u>



If you want to talk to someone who is not involved with the study, you can contact an independent health and disability advocate on:

Phone:	0800 555 050
Fax:	0800 2 SUPPORT (0800 2787 7678)
Email:	advocacy@advocacy.org.nz
Website:	https://www.advocacy.org.nz/

If you require Māori cultural support, talk to your whānau in the first instance. You may also contact our chair of our Maori advisory Group Dr Braden Te Ao (<u>b.teao@auckland.ac.nz</u>), the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 486 8324 ext 2324, or contact the Auckland and Waitematā District Health Boards Māori Research Committee or Māori Research Advisor by phoning 09 4868920 ext 3204 to discuss any questions or complaints about the study.

For concerns of an ethical nature, you can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone:	0800 4 ETHIC
Email:	hdecs@health.govt.nz

Approved by the Southern Health and Disability Ethics Committee on 13 February 2023. Reference Number 2023 FULL 13541