Dr Dennis Thomas
Senior Research Fellow
The University of Newcastle

Hunter Medical Research Institute
Level 2, East Wing
1 Kookaburra Circuit
New Lambton Heights 2305
Ph: (02) 4042 0199 | Fax (02) 4042 0046

Email: dennis.thomas@newcastle.edu.au

Participant Information Sheet.

Study title: The effectiveness and cost effectiveness of a centralised, national digital asthma care program compared to enhanced usual care: A randomised controlled tele-trial.
Study known as: Asthma Connect
Protocol Number: DIGITAL TEAM/2023
Principal Investigator: Dr Dennis Thomas
Project sponsor: University of Newcastle
Funding: Australia Government Department of Health and Aged Care Medical Research Future Fund (MRFF).

1. Why am I receiving this information sheet?

You are being invited to take part in this research study because you indicated that you have asthma. This study is being done to learn about a new centralised, national digital asthma care program.

Joining the study is entirely up to you. Before you decide if you want to join, you should understand why the study is being done and what it would mean for you. This information sheet tells you about the study. Please take your time to read it carefully. Then ask the study team if anything is not clear or if you would like more information. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your doctor. If you decide to join the study and later change your mind, you will be able to stop at any time without giving a reason.

2. What is the research study about?

The University of Newcastle has teamed up with Asthma Australia to develop a digital program for asthma care and management. This new program hopes to help people with asthma better manage their condition. The digital program includes telehealth consultations, a mobile app, a web app and educational text messages (SMS). The purpose of the research is to test how effective this program is in helping people with asthma manage their symptoms.

3. Who is conducting the research?

This research is being conducted by researchers from the University of Newcastle's School of Medicine and Public Health in collaboration with Asthma Australia. Asthma Australia is a not-for-profit organisation and the leading charity for people with asthma and their communities for over 60 years.

4. Who can participate in the research?

This research study is recruiting people who are adults with asthma who have access to a smart phone and the internet. This study is not suited to you if you cannot speak, read, or understand English or if you are currently undertaking telephone calls with Asthma Australia Asthma Educators.

5. What does the study involve?

If you choose to take part in the study, you will be asked to take part in the following activities.:

Activity	Description
Screening and consenting telephone interview.	In this interview, we will explain the study in detail and check whether the study is appropriate for you. You will also have an opportunity to ask questions and seek clarifications on any matter related to the study. At the end of this call, if you are eligible and still interested, we will obtain your verbal consent over the phone (this will be audio recorded). This call may take approx. 15 minutes.
Initial telephone interview.	This interview can be completed at the same time as the screening interview, or it can be scheduled at another time if more convenient. During this interview, we will ask some questions about your circumstances, your current health status and complete a few questionnaires. This call may take approx. 40 minutes. You will be reimbursed $40 (in the form of an online debit gift card sent as an email) to compensate your time to attend the initial telephone interview.
Group assignment.	You will be randomly (like tossing a coin) assigned to a group: control or test. You will be given the materials and activities pertaining only to the allocated group. If you wish, we will inform your doctor about your participation in this study and a summary of the initial assessments.
Control group only.	If you are in the control group, you will get educational materials about asthma. These will be emailed or mailed to you. After the completion of the study, if you wish, the research group will refer you to Asthma Australia for further asthma education and you will get access to the digital platforms when they are available to the public. To maintain the integrity of the study, we request that you do not contact Asthma Australia during the study period.
Test group only.	If you are in the test group, your contact details will be sent to Asthma Australia. They will contact you to book telehealth appointments with you. During the first appointment, the educator will explain the digital platforms that will be available to you. This includes the mobile app, web app and educational text messages (SMS). The educator will then ask you questions about your asthma. They may create some asthma goals with you and provide education on various aspects of asthma. This first appointment will last around 45 to 60 minutes.

	You may be required to attend a telehealth session with a doctor. If needed and if you are interested, your asthma educator will arrange this for you. Some-weeks later, the second telehealth session will be scheduled. During this session, the educator will check on your progress with your asthma goals. The educator will answer your questions about asthma, asthma management, and the digital platforms. The appointment duration may vary from 15 to 60 minutes. If needed and if you are interested, additional telehealth appointments might be scheduled. You will get access to the mobile app, web app and educational text messages (SMS) throughout the study. The educational text messages provide general information about asthma and other conditions that may affect your asthma, such as smoking, mental health, rhinitis, dysfunctional breathing, reflux, and lifestyle factors including diet, exercise, and obesity. You will receive text messages only on the conditions you have and are interested in receiving support for. You can stop and start receiving text messages at any time, using the instructions in the mobile App and web app.
Follow-up (both groups).	You will be asked to take part in three follow-up telephone interviews during the study. These interviews will be conducted by a researcher at approximately 3-months, 6-months, and 12-months after the initial telephone interview. Each interview is expected to take around 15 to 30 minutes to complete. To compensate you for your time, you will receive a $30 gift card for each interview completed. To ensure the study is successful, we need as many participants as possible to complete all the follow-up interviews. If you wish to schedule or reschedule an interview at a specific time, you can do this by contacting a researcher. If you do not wish to attend an interview, and you communicate this with one of the researchers, you will not be contacted for that interview. If you wish to withdraw from the study, you can do so by notifying a researcher, and you will not be contacted further. If we receive no response or contact from you for a follow-up interview, we may try to contact you using telephone calls, text messages, or emails up to ten times over ~4 weeks.
Video calls (both groups).	At baseline, and the 6-month follow-up interview, you will be invited to join a video call. During these video calls, the researcher will ask you to show them how you take your inhaled asthma medicines. These calls will take up to 5 minutes. This is an optional component, and you can decline to participate in video calls. Your decision to participate in video calls does not affect your participation in this study.
Services Australia Consented Data Release (both groups).	As part of the Medicare Benefits Scheme (MBS) and Pharmaceutical Benefits Scheme (PBS), Services Australia collects information about the use of healthcare services and medications in Australia. With participant consent, this information can be used in research studies.

	With your consent, this study will collect your Commonwealth health information, as provided by Services Australia, to compare the use of healthcare services and medications between test group and control group participants. This is an optional component; you can decline to provide this information to researchers, and that decision does not affect your participation in the study. You can also withdraw your consent to this component at any time without affecting your participation in the main study. Please see the separate Services Australia Participant Information Document. After reading this document, you may decide if you consent to Services Australia providing study researchers with your Commonwealth health information. To consent to this, during Screening and Consenting or the Initial Telephone Interview, you will be asked to sign a separate electronic or paper consent form. If you choose to consent via paper form, the form and reply-paid envelope will be mailed to your residential address. Please see the Services Australia Participant Consent Form. This will authorise the study to access your Commonwealth health information provided by Services Australia. Data received from Services Australia by study researchers will be stored on secure, password-protected, University-owned computers and servers physically located within Australian borders. Services Australia is not involved in this research other than to provide the information that you have consented to the release of, should you decide to participate in this study. Services Australia has confirmed that this research and any associated documents have received approval from a Human Research Ethics Committee (HREC) that is registered with and operates within guidelines set out by the National Health and Medical Research Council (NHMRC).
In-depth interview/focus group (test group only).	If you are in the test group, you may be asked to attend an online or in person interview based on your convenience. This will take place after the 6-month follow-up call. This interview will ask you for your views on the digital program. We would like to understand any benefits or concerns considered as part of the Program. That is, what worked and what didn't; what you valued or did not value about the program, and any barriers you may have experienced with your care. Participants will be requested to respect the privacy of fellow participants and not repeat what is said in the focus group to others. This session will be run by experienced researchers and will take around 60-90 minutes. Only up to 50 participants in the test group will be offered this opportunity. The in-depth interview is an optional component, and you can decline to participate in the in-depth interview. Your decision to participate in in-depth interview does not affect your participation in this study. If you take part in this session, you will be offered a $60 gift card to compensate you for your time.

6. Do you have to take part in this research study?

No. Taking part in this research study is voluntary. If you do not want to take part, you do not have to. If you agree to take part, you can withdraw from the study at any time without giving a reason.

Your choice to withdraw from the study will not affect your relationship with the University of Newcastle or Asthma Australia. It will not affect your relationship with any other organisations involved in this research. It will not affect the care you receive at present or in the future.

You also have the choice to withdraw data collected from you, up until it is de-identified or published.

7. What is the benefit of taking part in this research study?

By taking part, you will help us test and develop this new program, which is intended to help thousands of people like you better manage their asthma. Participants in the test group will get access to the digital platforms during and beyond the study, for as long as Asthma Australia supports the platforms. Participants in the control group will be referred to Asthma Australia after the study for asthma management and they will get access to the digital platforms when they are available to the public and for as long as Asthma Australia supports the platforms.

8. Are there any risks associated with participating in this research?

We do not foresee any risks to you from taking part in this study. Some of the research activities may involve a change in how you manage your asthma. These changes are based on best practise medical advice and are entirely voluntary. They should not pose a risk to you or your health. There may be some risks that are unknown or unforeseeable.

It is not our aim for you to feel uncomfortable, upset, or distressed. However, it is possible that these feelings may come up due to some research activities or some questions asked. You may choose to not take part in any research activities. You can choose to not answer questions or parts of questions. If you have any concerns about research activities, you can withdraw from the study at any time.

If you feel upset, and would like to speak to someone, one of the researchers can arrange professional support. If you indicate that you are anxious or depressed, the research team may ask if you would like to speak to someone. The research team can arrange professional support for you. You can also contact the Newcastle Mental Health Crisis Team (1800 001 511) or John Hunter Hospital Psychiatric Liaison Team (02 4921 3660).

9. How will your privacy be protected?

Participants in the test group will be asked to agree to the terms and conditions of using the program, privacy policy of the app, and enter some details about themselves and their asthma. Asthma Educators at Asthma Australia will also collect additional information as part of the asthma assessment for the purpose of delivering the intervention. This information will be stored securely in the Asthma Connect portal. The personal and health information entered into the app is also accessible through the Asthma Connect portal. All information you provided will be encrypted and stored securely. The information collected may include:

- Personal information (name, date of birth, sex at birth, email, phone number, suburb, state, postcode).

- Doctor/General practitioner information.
- Health information relating to your asthma (height, weight, written asthma action plan, asthma medications, details of previous asthma attacks, allergies, asthma symptoms, asthma triggers, other comorbid conditions, asthma management goals, and things preventing you from managing your asthma).
- Personal preferences for profile, SMS, and telehealth settings.

To access the app, you need to create an account and it is not mandatory to enter any details, except for name, year of birth, phone number, and email. Where participants consent, the information collected will be transferred to Asthma Australia's content management system, ActiveCampaign, to enable the provision of ongoing support after the study. All these platforms (the mobile app, web app, Asthma Connect portal, and ActiveCampaign) are hosted on the same password-protected, secure server, Amazon Web Services (AWS), physically located within Australia and managed by Asthma Australia.

Only authorised Asthma Australia staff and nominated HMRI staff will have access to this data. The company responsible for delivering the Asthma Connect application build (https://zyrous.com/) will also require access to the system to perform fixes and routine maintenance. Zyrous is contractually bound to comply with the University of Newcastle's ethical requirements for confidentiality. Zyrous privacy policy can be accessed via https://zyrous.com/privacy-policy/.

All personal details collected by researchers and entered into the digital platforms will be viewed, used, and stored according to the University's *Research Data and Materials Management Guideline, Commonwealth Privacy Laws* and the *New South Wales Health Records and Information Privacy Act 2002*. All names and personal details will remain private. All information you provide to the researchers will be securely stored on password-protected University computers, hosted at the Hunter Medical Research Institute, using secure, password protected data management software called REDCap. All conversations will be kept private, including but not pertaining to information provided in either in answering a study question or information provided unsolicited. No information pertaining to you will be given to any other person without your consent, except as required by law.

Please note that if you take part in a focus group, researchers cannot guarantee full confidentiality. Participants will be asked to respect your privacy and not to repeat what is said at the focus group. Focus group conversations will be audio recorded. Recordings will be stored securely at the Hunter Medical Research Institute. Recordings will be de-identified and transcribed by an Australian transcription service (Pacific Transcription), who are certified in Information Security Management. This service will be required to abide by the above privacy guidelines and agree to a confidentiality agreement. This includes the storage of audio recordings in a secure, password protected cloud server, hosted within Australia. The privacy policy of Pacific Transcription can be accessed at: https://www.pacifictranscription.com.au/wp-content/uploads/2025/05/AU-NZ-Pacific-Privacy-Policy.pdf

By consenting to this study, you permit any information provided to be used as part of the study assessment, in published manuscripts, study reports, and at conference presentations. All research data will be deidentified prior to publishing or presenting study results. Data will be kept for a period of 15 years from the completion of the study.

10. How will information collected by the research team be used?

Your contact details will be used for research purposes only, i.e., contacting you for the study. Data collected will be de-identified and analysed. De-identified group data will be presented in scientific journals, study reports, and at research conferences. The results of the study will be available to you at the completion of the study. During the screening interview, the researcher will ask your interest in receiving the study results. If interested, a summary of study results will be sent to you via email or hardcopy mail.

If you take part in a focus group or interview, you may request the opportunity to review the recording. You may edit or erase any contribution you had. This will not be possible after the recording is de-identified. Direct quotes from the sessions may be used in publications. These will be presented in such a way that you will not be identifiable.

11. What you need to do to provide consent to participate

Read this Participant Information Statement in its entirety. Be sure that you understand all the information provided before agreeing to participate. The study staff will contact you in a few days to discuss the study in detail. They will also check your eligibility and willingness to take part in the study. They will obtain your verbal consent to participate in the study if you are eligible and interested.

12. What if you want to withdraw from the research study?

You may withdraw from the study at any time. To do so, please fill in the Participant Withdrawal form provided below. Please send the filled form to the research team, at AsthmaConnect@newcastle.edu.au, or by mail to:

ASTHMA CONNECT, Lot 1, Level 2 East, HMRI building, 1 Kookaburra Circuit, New Lambton Heights, NSW, 2305.

Alternatively, you can verbally withdraw from the study by contacting the research team. Please do so on 02 4042 0111.

13. Do you need more information?

The study staff will contact you in a few days to discuss the study in detail. They will also check your eligibility and willingness to take part in the study. If you would like to know more at any stage, please do not hesitate to contact the Principal Investigator or research team at AsthmaConnect@newcastle.edu.au:

Dr Dennis Thomas
Principal Investigator
University of Newcastle.

Hunter Medical Research Institute.
Level 2 East
1 Kookaburra Circuit
New Lambton Heights, NSW, 2305.
Tel: 02 4042 0199.

E: dennis.thomas@newcastle.edu.au.

14. Ethics

This project has been approved by the University of Newcastle's Human Research Ethics Committee, Approval No. H-2024-0146.

Concerns or complaints about this research: Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, please contact

Human Research Ethics Officer.
Research and Innovation Services.
University of Newcastle.
University Drive, Callaghan NSW 2308, Australia.
Phone: (02) 4921 6333
Email: Human-Ethics@newcastle.edu.au

Thank you for your time and for reading this information.

Participant Withdrawal Form

(Complete only if you want to withdraw from the study after starting)

I wish to WITHDRAW my consent to take part in the ASTHMA CONNECT study.

Participant Name	
Participant Signature	
Date	

This withdrawal of participation should be forwarded to:

Study Principal Investigator Dr Dennis Thomas
Email AsthmaConnect@newcastle.edu.au.
Phone 02 4042 0111.
Postal Address Level 2 East
Hunter Medical Research Institute.
Lot 1, Kookaburra Circuit,
New Lambton Heights NSW 2305.