PARTICIPANT INFORMATION STATEMENT

Virtual Model of Antenatal Asthma Care
(VMAC study)

Invitation

We are inviting you to participate in a research study. This study evaluates the suitability of 2 types of asthma care in pregnancy. 1) virtual (tele/video conferencing) and 2) face-to-face (in person). This study is being conducted by a team of researchers from the John Hunter Hospital, the Hunter Medical Research Institute and the University of Newcastle. The researchers include Prof. Peter Gibson, Prof. Vanessa McDonald, Dr. Andrew Woods, Dr. Penny Reeves, Dr. Dennis Thomas, Alison Beverley, Jennifer Rutherford and Dr. Henry Murray.

Before you decide whether or not to participate in this study, it is important to understand the purpose of the study and what is involved. Therefore, please take the time to read the following information carefully. Please also discuss it with others if you wish.

1. What is the purpose of this study?

We are inviting pregnant women with asthma to participate in this study. Uncontrolled asthma in pregnancy may harm you and your baby. Self-management education and clinical care may help to control your asthma. Traditionally, it is provided as a face-to-face service which largely depends on the availability of both you and your healthcare team. To address this, we have developed a virtual model of care to provide the same service remotely (i.e., via tele or video conferencing). Women can access care at a convenient place and time. In this study, we are testing the suitability of this new approach.

2. Who can participate in this research?

To participate in this study

- You must be over the age of 18 years.
- You must be pregnant.
- You have a diagnosis of asthma (doctor's diagnosis and asthma symptoms in the last 12 months OR medication use for asthma in the last 12 months).
- You have access to a telephone.
- You are willing to complete baseline and follow-up telephone interviews.

This study is not suitable for you if you

- Are unable to speak and understand English.

3. What will my participation in the study involve?

This study involves 3 telephone interviews and 2 asthma care appointments. There is also an opportunity for a subgroup of participants to take part in an additional in-depth interview with a researcher.

- **Screening and consenting telephone interview.** If you are interested in this study, the next step is completing a telephone screening 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.

- **Baseline 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. 15 minutes.

- **Follow-up telephone interview.** The follow-up interview will take place 4 months after starting the study. During this interview, we will ask some questions about your current health status and complete a few questionnaires. This call may take approx. 15 minutes.

- **Study Groups.** After the baseline interview, you will be randomly (like tossing a coin) allocated to one of two different groups.

  Women in **group one** will receive 2 virtual consultations on asthma management in pregnancy. One from a nurse specialist and another one from a respiratory physician. These virtual consultations will use either a phone or a video platform to provide care. The consultations will cover clinical assessment, feedback, asthma self-management education and answer any questions you may have.

  Women in **group two** will receive 2 face-to-face consultations on asthma management in pregnancy. One from a nurse specialist and another one from a respiratory physician. This face-to-face consultation will be conducted at JHH asthma clinics. These in person consultations will cover clinical assessment which may include spirometry, feedback, asthma self-management education and answer any questions you may have.

  Women in both groups will also receive written asthma educational materials, reinforcing text messages and a link to a self-management smartphone application to download. Each session will take approx. 30 minutes (depending on how much you have to say).

- **In-depth interview.** In addition to the study visits discussed above, we would also like to invite a smaller group of participants to participate in an interview. This interview will be like a conversation where the researcher will ask you some questions about your experience with asthma and pregnancy, the antenatal asthma service, and any difficulties you may have experienced during your treatment. The researcher will also enquire about the facilitators that may have improved your experience. The interview may take around 1 hour and will be audio-recorded. You may ask for the recording to be stopped and for any sections to be edited or deleted at any time during the interview. You can also edit a transcript of the interview, if you request it. 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. To compensate your time to attend the in-depth interview, you will receive a $50 gift voucher.

4. Do I have to take part in this research study?

Participation in this study is voluntary. It is completely up to you whether or not you participate. Your decision will not affect your relationship with the John Hunter Hospital or the Hunter Medical Research Institute or the University of Newcastle. Your decision will not affect the treatment you receive at present or in the future. It will not affect your relationship with the staff caring for you.

5. What if I want to withdraw from the research study later after starting?

You may withdraw at any time. You can withdraw from the study by contacting the research team via phone, text message or email. The contact details are provided below.

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason. If you decide to withdraw from the study, you have the option of withdrawing all data relating to you. An exception to this is in the case of a serious study related health issue, the data needs to be retained for regulatory reporting.

6. What are the possible risks, side-effects and/or discomforts?

We do not foresee any risks from your participation in this research other than time commitments. The study interviews may cause some discomfort. It is not our aim to ask questions that might be upsetting, stressful or uncomfortable. However, it is possible that these feelings may come up for you as you talk about your experiences. You are free to not answer any questions or withdraw from the study at any point. There might be also some risks that are presently unknown or unforeseeable.

If you feel concerned or upset, you can contact Newcastle Mental Health Crisis Team 1800 001 511 or John Hunter Hospital Psychiatric Liaison Team 02 49213660.

7. What are the possible benefits to participation?

The support you receive as part of this study might help you to better manage your asthma during pregnancy. However, it is also possible that you may not benefit anything from this study. Involvement in the study is purely voluntary. You may withdraw at any time.

8. What are the benefits to other people in the future?

This study may help us to establish the feasibility and efficacy of a virtual model of asthma care compared to a face-to-face model which will help the national-wide implementation of the new model of care.

9. How is this study being paid for?

This study is being supported by the Hunter New England Local Health District (HNELHD) Telehealth Research Initiative.

10. How will my confidentiality be protected?

All information you provide will be securely stored electronically on password-protected University computers hosted at Hunter Medical Research Institute using a secure database. Your contact details will be used for research purposes only, i.e., contacting you for the study. Such information remains confidential and will not be given to any other person except as required by law.

11. What happens with the results?

The results of the study will be available to you at the completion of the study. De-identified group data will be presented in scientific journals and at research conferences. During the screening interview, the researcher will ask your interest in receiving the study results. If interested, the summary of study results will be sent to you via either email or hardcopy mail.

12. What should I do if I want to discuss this study further before I decide?

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 study coordinator:

Dr. Dennis Thomas
T: 02 40420199
Email: Dennis.Thomas@newcastle.edu.au
Hunter Medical Research Institute
The University of Newcastle
Lot 1, Kookaburra Cct, New Lambton Heights NSW 2305.

13. Ethics and governance

Ethics. This research has been **approved** by the Hunter New England Human Research Ethics Committee of Hunter New England Local Health District, Reference 2021/ETH11076.

Governance. The conduct of this research has been **authorised** by the Hunter New England Local Health District to be conducted at the John Hunter Hospital site.

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 the **HNE Research Office**, Hunter New England Local Health District, Level 3, POD, HMRI, Lot 1 Kookaburra Circuit, New Lambton Heights NSW 2305. Telephone 02 4921 4140. Email HNELHD-ResearchOffice@health.nsw.gov.au and quote the reference number **2021/ETH11076.**

Thank you for taking the time to consider this study.