Participant Information Sheet

Estimating the prevalence of sleep apnoea during pregnancy in Auckland: A feasibility study

Prevalence of **O**bstructive **S**leep **A**pnoea during Pregnancy, Auckland (**POSA**)

Formal Study title: Estimating the prevalence of screening positive for and testing positive for sleep apnoea during pregnancy among a sample of people birthing in and around Auckland, New Zealand: A feasibility study

Lead Study Doctor: Kathleen Antony

Study Site: University of Auckland, Waitemata, Middlemore, Auckland

Contact phone number: 9 373 7599 ext 82012

Ethics committee ref.: **2023 EXP 18527**

You are invited to take part in a study estimating how common sleep apnoea is among people who are pregnant.

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.

This Participant Information Sheet will help you decide if you'd like to take part. 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 13 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

Voluntary Participation and Withdrawal From This Study

Participation in this study is voluntary. You are free to decline to participate or to withdraw from the study at any time without experiencing any disadvantage or negative impact on your care.

What is the purpose of the study?

Sleep apnoea means that a person's airway or air tube is blocked while they are sleeping. This means that air cannot move in and out of their lungs. One symptom of sleep apnoea is snoring. When air cannot move in and out of the lungs, the blood doesn't get the oxygen it

needs, and this means that the amount of blood in the body is less. This is bad. When there is less oxygen in the blood, this can be dangerous for someone who is pregnant and their baby. When oxygen levels are low in the blood, this also can cause blood pressure to be higher. When a pregnant person has high blood pressure during pregnancy, this can also be dangerous for the pregnant person and their baby.

What is good is that if someone does have sleep apnoea, a sleep problem, there is treatment that can help.

The purpose of this study is to estimate the prevalence of sleep apnoea among pregnant people who live within or around Auckland, Aotearoa. This means we are estimating how common sleep apnoea is among pregnant people who live around here.

We are also studying whether it is possible for pregnant people who might need sleep tests to complete these sleep tests before the pregnancy is finished. If someone has a sleep problem, we would also like to know if pregnant people here are willing to have the sleep problem treated.

The results will be reported by ethnicity because we want to know whether this condition impacts people of some ethnicities more than others. This will help us know if community engagement might be helpful, and for whom.

We are also studying things that might make it easier or harder for someone to complete a sleep test while they are pregnant.

Knowing how common this condition is during pregnancy will let us know if we need to study if more or offer treatment to more people.

There is some evidence that treating sleep apnoea during pregnancy might prevent someone from developing preeclampsia, which is a serious complication of pregnancy.

We want to know whether sleep apnoea is common so we know whether it is worthwhile to see whether treating it would be helpful.

HOW IS THE STUDY DESIGNED?

This study is only for pregnant people who are getting prenatal care in clinics or hospitals within and around Auckland and who plan to deliver within or around Auckland.

We plan to recruit up to 1000 pregnant people.

If you choose to participate, the minimum among of participation would be:

- Completing a survey about your sleep during this pregnancy.
- Allowing us to look at your health/ medical record so we know whether you have any medical problems or whether you develop pregnancy problems during this pregnancy

If your survey answers suggest that you probably don't have a sleep problem, then your participation will be complete.

If your survey answers suggest that you might have a high chance of possibly having a sleep problem, we will contact you about further steps. These will be discussed further in this consent document.

Throughout the study, we will monitor things that make sleep test completion or use of treatment easier or harder so that we can try to improve the experience of those who need sleep tests or treatment.

We hope to make access to the sleep tests easier and easier to access, for those who need sleep tests.

We hope to make treatment easier and easier to use or tolerate, for those who need treatment.

WHO CAN TAKE PART IN THE STUDY?

You can participate in this study if you are

- At least 16 years old
- Able to speak or understand English
- You plan to birth within or around Auckland
- You are less than 34 weeks pregnant

You cannot participate in this study if:

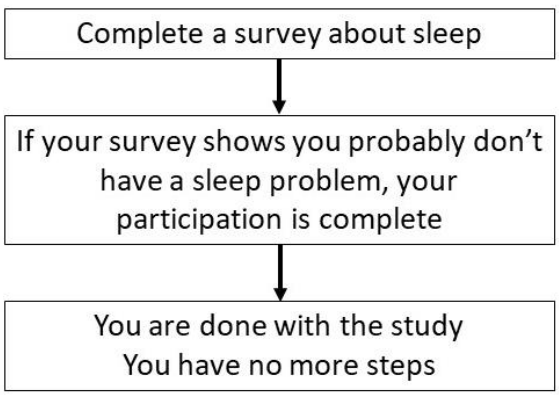
- You are unable or unwilling to provide consent, or permission
- Your baby has a major anomaly likely to require significant intervention or surgery after birth

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

If you choose to participate, the minimum among of participation would be:

- Completing a survey about your sleep during this pregnancy
    - This survey will take about 5-10 minutes to complete
    - This one survey can be completed today, if you would like.
    - This survey will ask questions about your sleep and about whether you snore.
    - You are welcome to contact other people or whānau during the survey if you would like.
    - This survey will also ask you your height and weight. You may leave these blank if you prefer or if you do not know the answer.
    - You will be notified of the result of your sleep survey today.
        - If some portions are left blank, we may need to call you at a future date with your sleep survey result.
- Allowing us to look at your health/ medical record so we know whether you have any medical problems or whether you develop pregnancy problems during this pregnancy
- We will also ask you optional questions about what you think might make it easier or harder for someone who is pregnant to complete an overnight sleep test, if someone were to need one
- You can do this sleep survey even if you do not want to do a sleep test at any point.

What your participation will involve if your sleep survey shows that you probably don't have a sleep problem:



The following steps are also voluntary.
We would only request further participation if your sleep survey suggests that you might have a sleep problem.

If your survey answers suggest that you might have a high chance of possibly having a sleep problem, the following will happen:

- We will contact you via phone and/or email to let you know that there might be a high chance that you have a sleep problem
- We will ask your permission to place a referral for an overnight sleep test.
    - Overnight sleep tests would occur at your own home using a device that our team will show you how to set up.
    - These overnight sleep tests will be performed at no cost to you.
- You have the right to say that you don't want a referral for sleep testing.
- You have the right to not complete a sleep test if a referral is placed.
- You have the right to decline further participation or withdraw from the study at this point.

If you do agree to have a sleep test, this will occur as follows:

- The sleep test will be performed at your own home and you will sleep in your own home
- The sleep test will not cost you money.
- The sleep lab will contact you to discuss a date for the sleep test
- You will be asked to travel to the sleep lab to have a sleep technician help you learn to place the sleep testing monitors on yourself.
    - The sleep technician may also place the monitors on you and you may wear them home
- You will sleep while wearing the monitors overnight
- You will be asked to return the sleep testing equipment
- If this is not possible for you, we will work with you to see if we can find a way to make this work for you

After your sleep test is completed, we will contact you via phone and/or email with the test result and to advise on next steps.

- If your sleep test shows that you do not have sleep apnoea, no further active participation is requested. We will request to review your medical record to obtain pregnancy outcome data.

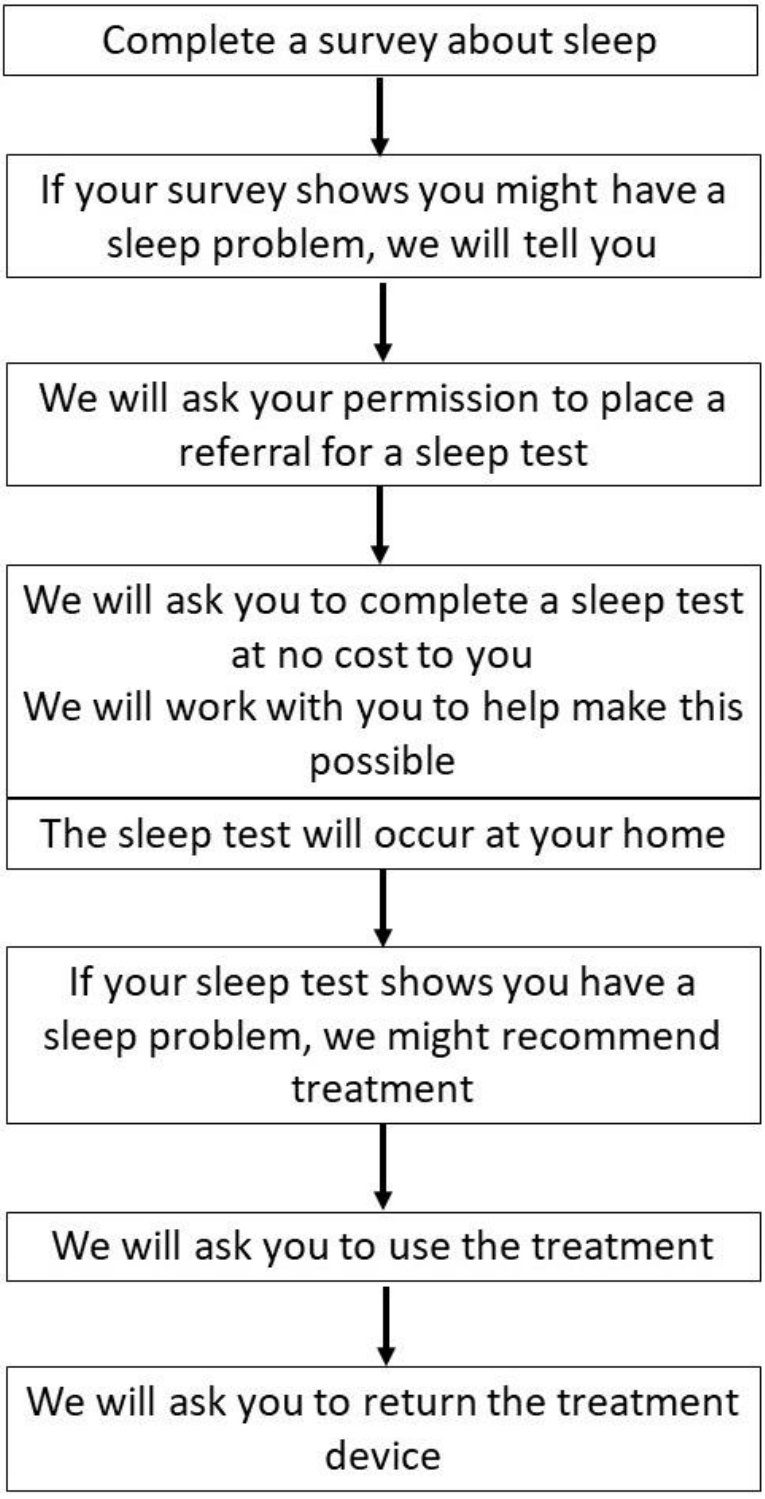
If your sleep test result shows that you have sleep apnoea and that treatment is needed, the following will occur:

- We will contact you with this result via phone and/or email with the test result and to advise on next steps.
- We will provide a sleep apnoea treatment machine, which is called a continuous positive airway pressure machine or CPAP machine to you at no cost to you.
- We will ask you to use this machine when you sleep.
- This machine will automatically track whether you are using the machine.
- If you are not using the machine, we may contact you via phone and/or email to answer any questions or concerns you have, or about barriers for you using it. The purpose of the questions is to see if we can help make the machine easier to use. We might also

ask if you think any other alternative treatments or different devices might work better for you.

- At the end of the study, after you have your baby, we will ask you to return the CPAP machine.
- We will also inform your general practitioner that you had a sleep problem during pregnancy so that they can arrange any needed follow-up.

What your participation will involve if your sleep survey shows that you might have a sleep problem:



WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

- There are no anticipated physical risks to participation in this study.
- There may be some discomforts associated with answering survey questions. If this is the case for you, you may skip those questions.
- If a sleep test is recommended and you choose to complete an overnight sleep test, there may be discomforts with wearing the testing device. There are no safety concerns for the testing device itself or with performing sleep tests during pregnancy. We will work with you to ensure the test is as comfortable as possible.
- If treatment with CPAP is recommended to you, there may be discomforts with wearing this. We will work with you to ensure that the CPAP is as comfortable as possible. If you are unable to tolerate it, we will work with you to seek alternative options for treatment.
- There is a risk of loss of confidentiality, which means there is a small chance that the data we collect could be seen by someone outside the study. All data will be stored securely on secure servers housed by the University of Auckland, and paper data will be stored in a locked cabinet in a locked office. More details on data security are discussed below on page 9.
- If there is any new information about adverse effects related to this study that become available during the study that may have an impact on your health, we will notify you. Because the testing and treatments are known to be safe, we do not expect this to be the case.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

In this study we might diagnose you with a health condition that was not previously known. We will also offer treatment for a sleep problem, if you have a sleep problem.
If you have a sleep problem and we diagnose it and treat it, you might benefit.

- Your sleep might improve.
- Your energy might improve.
- Your snoring might improve.
- Your pregnancy outcomes might be better than they would have been if you hadn't been in this study.

If you do not have a sleep problem, participating in this study probably will not benefit you, but it will benefit our general knowledge about sleep during pregnancy and whether sleep problems might cause pregnancy problems and whether treating them might help.

WHAT ARE THE ALTERNATIVES TO TAKING PART?

Alternatives to taking part in this study are to not participate. If you are concerned about your sleep, but you do not want to be in this study, please tell your lead maternity carer and they can arrange sleep testing for you.

WILL ANY COSTS BE REIMBURSED?

There is no cost to participating in this study.

A small payment or koha will be provided for completing the sleep survey.

If you need a sleep test, this will not cost you money.

If you need treatment with a CPAP machine, this will not cost you money.

A payment or koha will be provided for completing an overnight sleep test, if you need one.

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 WILL HAPPEN TO MY INFORMATION?

During this study the study doctors, research coordinators, and other staff will record information about you and your study participation. This includes the results of any study assessments such as the sleep survey result and information about your health. We will later record information about your pregnancy outcomes. If needed, information from your hospital records and your GP may also be collected. You cannot take part in this study if you do not consent to the collection of this information.

This study will not be collecting any blood, urine, or tissue specimen.

We will collect background health information and data on pregnancy outcomes.
You may hold beliefs about a sacred and shared value of all or any data. The cultural issues associated with holding your data should be discussed with your family/ whānau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of data citing whakapapa and advise their people to consult before participating in research where this occurs. However, it is acknowledged that individuals have the right to choose.

Deidentified data will be shared with iwi and community groups in accordance with data sovereignty agreements. Any data shared or published will be deidentified and reported in aggregate.

<u>Identifiable Information</u>

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:

- Researchers and research coordinators

- Study site staff

The following groups may also have access to your identifiable information if you might have a sleep problem and need a sleep test:

- Your GP may be notified of your participation in this study if you are diagnosed with a sleep problem. This will allow them to arrange follow-up after you have your baby.
- Sleep clinic staff, to help you set up a sleep test and process and report your test results.
- Ethics committees, if the study or site is audited. Audits are done to make sure that participants are protected, the study is run properly, and the data collected is correct.
- Rarely, it may be necessary for Dr. Antony to share your information with other people – for example, if there is a serious threat to public health or safety, or to the life or health of you or another person OR if the information is required in certain legal situations.

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 Dr. Antony. Instead, you will be identified by a code. Dr. Antony 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:

- Biostatisticians, or people who will be analysing the data from the study, who are researchers on the study
- Researchers on the study

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.

If you agree, your coded information may be used for future research related to sleep apnoea and/ or its treatment during pregnancy. Allowing your coded information to be used for future research is voluntary.

If you agree, your coded information may also be used for other medical and/or scientific research that is unrelated to the current study. This is also voluntary.

This future research may be conducted overseas. You will not be told when future research is undertaken using your information. Your information may be shared widely with other researchers or companies. Your information may also be added to information from other studies, to form much larger sets of data.

You will get reports or other information about any / some research that is done using your information if you would like. Please inform us if you would like to have the final report from this study.

Your sleep survey results and (if performed) sleep test results will be given to you when the results are known.

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 coded and shared for future research.

Security and Storage of Your Information.

Your identifiable information is held at the University of Auckland during the study. After the study it is transferred to a secure archiving site and stored for at least 10 years and then destroyed. Your coded information will be entered into electronic case report forms and stored securely online. All storage will comply with local and/or international data security guidelines.

Risks.

Although efforts 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.

This research includes basic information such as your ethnic group, geographic region, age, and sex. It is possible that this research could one day help people in the same groups as you. However, it is also possible that research findings could be used inappropriately to support negative stereotypes, stigmatize, or discriminate against members of the same groups as you.

We plan to use this data to identify differences in access to sleep testing during pregnancy, and to work to improve access and increase equity in testing for and treating sleep problems during pregnancy. We hope that testing and treating for sleep problems may ultimately improve pregnancy outcomes and improve equity.

Regarding Māori data and Māori data sovereignty, whānau or other support people may be present for all portions of this study and potential participants will be welcome to consult with whānau or other support people prior to or during participation if they would like to do so.

De-identified data will be available to Māori in accordance with data sovereignty agreements. Publications resulting from this project will be distributed to Māori and publications will be provided to any who request access via request to the principal investigator in accordance with data sovereignty agreements.

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.

Please ask if you would like to access the results of your screening results and test results during the study. You may access other study-specific information before the study is over.

If you have any questions about the collection and use of information about you, you should ask Dr. Antony. Her contact information is at the end of this document.

Rights to Withdraw Your Information.

You may withdraw your consent for the collection and use of your information at any time, by informing your Study Doctor. Details are provided below.

Use of Technology

- The sleep survey will be available to complete via tablet device, which are available at the clinic today. You may also complete the survey via a weblink to the survey on your own phone or device.
- No special app or software is needed to complete this survey.
- If you would prefer to complete the sleep survey on paper, paper copies are also available. Please ask the coordinator for a copy for a paper form if you prefer.
- This data will be directly entered securely online.
- Identifiable information, such as your name and date of birth, will be collected.
- This survey will be entered into the same secure online database that the University of Auckland uses for other studies and projects. Data is stored on a password protected server. Data is not shared with third parties or anyone not involved with the research.

Māori Data Sovereignty

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 consulted with Iwi United Engaged about the collection, ownership, and use of study data. Contact information is: iue.net.nz/contact/ or misty@iue.net.nz
- We allow Māori organisations to access de-identified study data, for uses that may benefit Māori.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

- If you wish to withdraw from the study, please email Dr. Kathleen Antony at Kathleen.Antony@auckland.ac.nz
- If you withdraw from the study, your data will be withdrawn unless you specify that you would like us to leave your data in the study.
- If you withdraw from the study after data analysis is completed and the results have been published, it may not be possible for us to remove your data from that publication.
- If you withdraw from the study after data has been coded or deidentified in such a manner that we cannot determine which data is from you, it may not be possible for us to remove your data.
- If you withdraw from the study and have a CPAP machine, we will ask for you to return the machine to us.

CAN I FIND OUT THE RESULTS OF THE STUDY?

Participants will be provided with a plain English summary of study results, if requested. If the results are not yet available, we will discuss the expected timeframe for when results will be available.

WHO IS FUNDING THE STUDY?

Funding for this study is being sought from the University of Auckland's internal funding sources including the Department of Obstetrics and Gynaecology and from Faculty Development Funds.

Funding is also being sought from the Maurice and Phyllis Paykel Trust and device manufacturers.

The investigator is affiliated with the University of Auckland.

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 [insert Committee name] has approved this study.

WHO DO 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:

Kathleen Antony, Principal Investigator
09 373 7599 ext 82012
kathleen.antony@auckland.ac.nz

If you want to talk to someone who isn't 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/

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Email:	hdecs@health.govt.nz
Phone:	0800 400 569 (Ministry of Health general enquiries)

Consent Form

Estimating the prevalence of sleep apnoea during pregnancy in Auckland:
A feasibility study

An interpreter is available upon request

Please tick to indicate you consent to the following

I have read the Participant Information Sheet, or have had it read to me in a language I understand, and I fully comprehend what it says.		
I have been given sufficient time to consider whether or not to participate in this study.		
I have had the opportunity to use a legal representative, whānau/ family support or a friend to help me ask questions and understand the study.		
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.		
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.		
I consent to the research staff collecting and processing my information, including information about my health.		
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.	Yes ☐	No ☐
I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.		
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.		
I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.		
I understand the compensation provisions in case of injury during the study.		
I know who to contact if I have any questions about the study in general.		

I understand my responsibilities as a study participant.

I wish to receive a summary of the results from the study.	Yes ☐	No ☐

Declaration by participant:
I hereby consent to take part in this study.

Participant's name:

Signature: Date:

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name:

Signature: Date: