Participant Information Sheet

Acoustic Therapy for Better Breathing: Helping Individuals with nasal congestion

Formal Study title: Exploring the Feasibility of Acoustic Therapy for Nasal Health and Well-being in Allergic Rhinitis and Chronic Rhinosinusitis

Study Supervisor: Dr Kelvin Lau

Study Sites: **Auckland University of Technology City Campus** (55 Wellesley Street East, Auckland Central, Auckland 1010), **Auckland University of Technology North Campus** (90 Akoranga Drive, Northcote, Auckland 0627), **AUT South Campus** (640 Great South Road, Manukau City Centre, Auckland 2025), **AUT Millennium** (17 Antares Place, Rosedale, Auckland 0632)

Contact phone number: *+64 9 921 9666 ext. 8062*

Ethics committee ref.: 22987

You are invited to take part in a study looking at the use of acoustic therapy to improve nasal health and overall well-being in people with allergic rhinitis (hay fever) and chronic rhinosinusitis (long-term nasal congestion). 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 12 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

Voluntary Participation and Withdrawal From This Study

Your participation in this research is voluntary (it is your choice) and whether or not you choose to participate will neither advantage nor disadvantage you. Should you decide to take part, you will be required to sign a Consent Form at the beginning of your study visit. You can withdraw from the study at any time. If you choose to withdraw from the study, you will be offered the choice between having any data identifiable as belonging to you removed or allowing it to continue to be used. However, once the findings have been produced, removal of your data may not be possible.

WHAT IS THE PURPOSE OF THE STUDY?

Allergic Rhinitis (AR), often known as hay fever, is a common condition that affects the nose and eyes, causing symptoms like a stuffy or runny nose, sneezing, and itchy, watery eyes. It's usually triggered by things like pollen, dust, or animal fur. AR can also interfere with sleep, making people feel tired and irritable.

Chronic Rhinosinusitis (CRS) is a related condition that causes long-term inflammation in the nose and sinuses. This leads to symptoms such as nasal congestion, facial pain, and trouble smelling. Both AR and CRS can also make other respiratory issues, like asthma and COPD, worse, which can be very uncomfortable and result in higher healthcare costs and missed days from work or school.

This study aims to explore how acoustic therapy (vibration therapy) can help people with AR and CRS by looking at changes in the bacteria and fungi in the nose, as well as the immune response and overall well-being. Participants will provide blood and nasal swab samples to help analyse immune cells and nasal bacteria. They will use an acoustic breathing device, and after 4 weeks, their samples and well-being will be reassessed to see how things have changed. We will also gather feedback from users about the device.

The results of this study could lead to a new treatment option for AR and CRS, helping improve people's quality of life. Additionally, the study will add to our understanding of nasal bacteria and immune responses, which could benefit larger communities by offering better ways to manage these conditions. All data will be kept anonymous to protect participants' privacy.

HOW IS THE STUDY DESIGNED?

Study Participation
This study will take place in Aotearoa New Zealand and involve around 30 participants.

Duration and Visits
Participants will be involved in the study for at least 8 weeks. There will be three visits to the clinic: one before the treatment starts, one after the treatment ends, and a follow-up visit a few weeks later to see if the treatment’s effects last. Each visit will last up to one hour.

Intervention Details
Participants will use a small and lightweight Nosebuds device, which helps with breathing. They will wear it for 10 minutes, twice a day, for four weeks. The device works by using humming to improve breathing and applies acoustic therapy to both nostrils at the same time. It can work for up to 30 minutes to an hour before needing to be recharged. This study will not involve any random assignments, meaning everyone in the study will use the same device.

Assessments
During the study, several assessments will be done. Participants will provide blood samples (up to 4 ml) to measure inflammation and nasal swabs to identify bacteria, fungi, and potentially immune markers in the nose. Participants will also fill out questionnaires about their overall well-being, including questions on stress, anxiety, and sleep problems. These assessments will help track changes in the nasal microbiome and immune system (cytokines, proteins, and cells) before and after the treatment period.

WHO CAN TAKE PART IN THE STUDY?

Why Have You Been Chosen?
You have been chosen to participate in this study because you reside in Aotearoa New Zealand, are between the ages of 18 and 80, and have been diagnosed with AR or CRS. Your

participation will help us understand the effects of the acoustic breathing device on these conditions.

Inclusion and Exclusion Criteria
To participate, you must meet the following criteria:

Inclusion Criteria:
- Reside in Aotearoa New Zealand
- Be a non-smoker
- Be between the ages of 18 and 80
- Have a diagnosis of AR or CRS
- Be willing to use the acoustic device for the next four weeks

Exclusion Criteria:
- Fixed structural cause of nasal congestion
  - moderate or severe septal deviation
  - moderate or severe nasal valve collapse
  - Grade 3-4 polyps
- Current nasal crusting or ulceration on rhinoscopy
- History of severe nose bleeding within the last 3 months
- Anticoagulation use (acetylsalicylic acid allowed)
- Known pregnancy
- Allergic sensitivity to silicone or any other component of the device
- Inability to read and understand English
- Inability to perform treatment due to underlying medical condition.
- Nasal swab taken within the past seven days- clinic visits can be re-scheduled for a later date.

Medication and Lifestyle Restrictions
Participants will not be asked to adhere to any specific medication or lifestyle restrictions during the study. However, it is important that you continue to use any prescribed medications as directed by your healthcare provider, especially if you have respiratory conditions, to prevent any potential serious health risks. For this study, you will be asked to use the acoustic device as instructed and attend all scheduled visits. If you have any questions about your eligibility, concerns about your medications, or need further assistance, please contact the study supervisor using the details provided at the end of this Participant Information Sheet.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

Duration of Visits and Assessments
- Pre-Treatment Visit: Up to 1 hour.
- Daily Use of Device: 10 minutes, twice daily, for four weeks.
- Post-Treatment Visit: Up to 1 hour.
- Follow-Up Visit: At 4-8 weeks after the initial sample collection.

Table of Assessments

Assessment	Pre-Treatment Visit	Daily (4 Weeks)	Post-Treatment Visit	Follow-Up Visit
Consent Form	X			
Pre-treatment Questionnaire	X			
Well-Being Questionnaire	X		X	X
Blood Sample	X		X	X

Assessment	Pre-Treatment Visit	Daily (4 Weeks)	Post-Treatment Visit	Follow-Up Visit
Nasal Swab	X		X	X
Device Usage Training	X			
Daily Device Usage		X (10 mins, 2x/day)		
Device Usage Diary		X		
Feedback on Study			X	X

What Will Happen in This Research?

Pre-Treatment Visit

You will be invited to attend a pre-treatment visit with the research team at the study location, which will last up to one hour. At the beginning of the visit, you will have the opportunity to ask any questions before completing the Consent Form and pre-treatment questionnaire. During the visit, you will undergo a nasal examination by an ENT doctor, complete a well-being questionnaire, provide a blood sample, and have a nasal swab collection. You will also be shown how to use the Nosebuds device. All individuals participating in the study will be asked whether it is appropriate for the clinical investigator to examine the nose and whether they agree with the device being placed in their nose, and their head being touched, as head is considered sacred in some cultures.

Using the Acoustic Device

Following the pre-treatment visit, participants will be requested to use the study device for at least 10 minutes, twice daily, for the next four weeks. The device may help improve breathing through humming. To use the Nosebuds device at home, start by removing the device from the case. It comes with pre-installed tips, and you should ensure the device fits comfortably in your nostrils, not too tight or too loose. The device should stay in place without falling out. To turn the Nosebuds on, press and hold the power symbol for one second. You will hear a light hum, indicating the device is working. You will need to use the device for 20 minutes daily. You can either use it in one continuous session or break it into two 10-minute sessions. After you're done, press and hold the power symbol again for one second to turn the device off. A full charge provides around 30 minutes or more of use, so ensure the device is fully charged for optimal performance.

To use the device, insert the Nosebuds into your nostrils while the device is turned on. Breathe through your nose and keep your mouth closed, aiming to breathe deeply from your belly. While wearing the Nosebuds, you are free to continue with your normal activities. Some people may feel lightheaded at first due to rapid breathing. If this happens, pause, relax, and slow your breathing down. You will adjust quickly to the device.

Throughout the study, the study manager will contact you weekly to monitor your progress, ensure you are using the device correctly, address any issues you might have, and gather feedback on your experience.

Post-Treatment Visit
After four weeks, you will attend a post-treatment visit, which will also last up to one hour. During this visit, you will undergo another nasal examination by the ENT doctor, provide another blood sample and nasal swab collection, complete the well-being questionnaire again, and fill out a feedback form about your experience with the device. You are welcome to bring a support person or whānau to the study visits.

Follow-Up Visit
Four to eight weeks after the post-treatment visit, you will return for a final follow-up visit, which will last up to one hour. During this visit, you will undergo a final nasal examination by the ENT doctor, provide a blood sample and nasal swab collection, complete a well-being questionnaire and feedback questionnaire, and provide feedback on your experience with the therapy and any long-term effects you may have noticed. You will be asked not to use the device during this period before your follow-up visit. You are welcome to bring a support person if desired.

WHAT WILL HAPPEN TO MY *BLOOD* SAMPLES AND NASAL SWAB?

How Samples Are Identified
Each sample you provide will be labelled with a unique identification code to ensure your privacy and confidentiality. This code will be used to track the samples throughout the study, and your personal information will not be directly associated with the samples.

Sample Storage and Shipping
Blood and nasal swab samples will be securely stored in restricted-access freezers at AUT City Campus in Auckland, New Zealand, until analysis. These samples may be stored alongside other samples in the same facility. To determine the composition of the nasal microbiome, microbial DNA will be extracted from the nasal swabs for further analysis, which will be sent to AZENTA Genomics Centre (China) for sequencing of the microbial DNA. No sequencing of human cells will occur in this evaluation.

Duration of Sample Storage
Your samples will be kept for a minimum of 10 years. After this period, they will be disposed of by a medical waste contractor. If you would like, a karakia can be performed to acknowledge the wairua of the samples before they are destroyed. Your contact information will also be retained for at least 10 years.

Rights to Withdraw Samples
You have the right to withdraw your samples at any time during or after the study, up until the point of analysis. If you choose to withdraw your samples, they will not be analysed or used for any further research. However, once the samples have been analysed, they cannot be

returned. If further unspecified analysis is required after the study, you will be contacted for consent. If we are unable to reach you, no additional analysis will be conducted.

You may hold beliefs about a sacred and shared value of all or any tissue samples removed. There are a range of views held by Māori around these issues; some iwis disagree with storage of samples 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.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

Foreseeable Risks and Side-Effects
Participation in this study poses no significant risks. The Nosebuds device is designed to integrate seamlessly into your daily routine without causing disruptions. However, it might take a few days to get accustomed to wearing the device. If you experience an allergic flare-up while using the device, you may reduce the usage time. If you continue to encounter difficulties, stop using the device and contact the study coordinator for further assistance.
There are minor risks associated with blood and nasal swab collection, including:

- **Blood Sample Collection**: Slight chance of minor bruising from needle insertion and minimal discomfort. Extremely rare possibility of infection, mitigated by using aseptic techniques.
- **Nasal Swab Collection**: Minimal discomfort, with a very low risk of infection.

These risks will be managed by ensuring that all procedures are conducted by experienced individuals using approved antiseptic techniques. The study will be halted immediately if any adverse effects arise or if continuing the study is deemed detrimental to your well-being.

Reproductive Risks and Contraception
There are no specific reproductive risks or the need for contraception associated with this study. However, pregnant individuals are excluded from participation due to potential impacts on the study results, as pregnancy can affect the nasal microbiome and immune marker results.

Investigator's Responsibility
The investigator is responsible for ensuring that care is provided to participants during the study. Any symptoms or adverse effects experienced during the study will be documented, and you are encouraged to report them to the investigator promptly. If new information about adverse effects related to the study becomes available that may impact your health, you will be informed immediately.

Participant Care and Support
- If you have an allergic flare-up, stop using the device immediately and seek advice from a health professional. We can help connect you with a registered health professional if needed.
- If difficulties persist, contact the study coordinator for assistance.

Safety and Monitoring
- All blood and nasal swab collections will be performed by experienced professionals using sterile techniques.
- Any adverse effects will be promptly addressed, and the study will be stopped if necessary to protect your well-being.
- If abnormal results are identified that may affect your health, you will be notified by the investigator. You may choose to share these results with your GP.
- Providing your GP's contact details is optional. If you do not wish to provide this information, it will not affect your participation in the study.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

Benefits of Participating in This Study

Direct Benefits

By participating in this study, you may or may not experience an improvement in your symptoms associated with AR and CRS. The Nosebuds device is designed to provide acoustic therapy. Research has shown that acoustic therapy can enhance the body's innate defence system, potentially leading to reduced inflammation and improved overall nasal health. This novel treatment could provide you with relief and improve your well-being.

Indirect Benefits

Your participation will contribute to research as part of a PhD qualification for a member of the research team. The insights gained from this study could lead to the development of a relatively inexpensive treatment option that complements existing therapies for AR and CRS. This research has the potential to advance medical knowledge and help develop new treatments, benefiting others who suffer from these conditions in the future.

WHAT ARE THE ALTERNATIVES TO TAKING PART?

Participants in this study will have the option to continue with their standard medical treatments for AR or CRS, such as antihistamines, nasal sprays, or other prescribed therapies. Participation in the study is voluntary, and individuals can choose to pursue these conventional treatments without taking part in the acoustic therapy intervention being investigated.

WILL ANY COSTS BE REIMBURSED?

Costs and Compensation

No Costs Incurred

There will be no financial cost to you for taking part in this study. All expenses related to the study procedures are covered by the research team.

Compensation and Reimbursement

As a token of appreciation for your participation, you will receive the following:

- Supermarket Voucher: A $30 supermarket voucher upon completion of each study visit.
- Study Device: The Nosebuds device, which you will be allowed to keep at the end of the study.

Travel Costs

Please note that travel costs will not be reimbursed for participation in this study.

Parking

Free parking can be arranged for participants when they sign up for their first visit.

WHAT IF SOMETHING GOES WRONG?

In the unlikely event that you are 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 researchers will record information about you and your participation. This includes the results of any study assessments, such as blood sample analysis, nasal swab tests, and questionnaire responses. 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.

Identifiable Information

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). Only researchers involved in the study will have access to your identifiable information. In rare circumstances, it may be necessary for the Study Doctor 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 ensure 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 research manager will keep a list linking your code with your name, so that you can be identified by your coded data if needed. Regulatory or other governmental agencies worldwide may have access to your coded information, which may be sent and stored overseas.

Additionally, anonymised data may be used in the study. Once data is anonymised, all identifiers, including the study code, will be removed, making it impossible to trace the data back to you. Anonymised data will be used for future research purposes, but cannot be accessed, corrected, or withdrawn once it has been anonymised.

The results of the study will be published and presented, but not in a form that would reasonably be expected to identify you. A summary of the results from this study will be made publicly available, including to the device manufacturer, but this report will not contain your coded or decoded information.

Security and Storage of Your Information

Your information and data, including identifiable data, will be held securely at the AUT City Campus during the study. After the study concludes, the data will be transferred to a secure archiving site where it will be stored for a minimum of ten years before being destroyed.

To ensure the safety and integrity of the microbiome data, multiple backup copies will be maintained. One copy will be stored on an AUT computer. Another copy will be saved to Microsoft OneDrive, and a third copy will be stored on a High Performance Computing system for analysis.

No personal identifying information will be sent overseas during the sequencing process. The microbial sequence data will identify only microbes and will be sent directly to the research team for secure storage.

Risks

Although every effort will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised data, there is no absolute guarantee that you cannot be identified. The current risk of people accessing or misusing your information (e.g., affecting your ability to obtain or keep a job or health insurance) is very small but may increase as new methods for tracing information are developed. Your personal or identifying information will not be sent overseas. Only data

related to the microorganisms from your nostrils, which cannot be used to identify you, will be sent to AZENTA Genomics Centre for sequencing to find out what microbes are in the samples.

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 corrections to any information you disagree with.

If you would like to access the results of your screening and safety tests during the study, please let us know. You may access other study-specific information before the study is over, but this could result in your withdrawal from the study to protect the study's scientific integrity.

Rights to Withdraw Your Information

You may withdraw your consent for the collection and use of your information at any time, by informing the Study Supervisor using the contact details at the end of this document. If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.

If you agree, information collected up until your withdrawal from the study will continue to be used and included in the study. You may ask for it to be deleted when you withdraw, unless you withdraw after the study analyses have been undertaken.

Ownership Rights

Information from this study may lead to improvements in the existing Nosebuds device or the development of new commercial products. The rights to these improvements and products will belong to the manufacturer of the device. 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.

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 AUT *School of Clinical Sciences Komiti Mātauranga Māori* about the collection, ownership, and use of study data.

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

If you wish to withdraw from the study at any point, please inform the Study Manager or the Study Supervisor. Their contact details are provided at the end of this document. If you withdraw, any data collected up to that point will remain in the study but no new information will be collected.

If you decide to withdraw before the final study visit, you will be asked to return the study device (Nosebuds) to the research team. However, if you choose to remain in the study until completion, the device will be yours to keep at the conclusion of the study, with no cost to you for retaining it.

CAN I FIND OUT THE RESULTS OF THE STUDY?

Participants will be provided with a plain English summary of the study results if requested. This summary will be available approximately six months after the study concludes. To

receive this summary, please indicate your interest on the Consent Form or inform the Study Coordinator at any time during the study.

WHO IS FUNDING THE STUDY?

The investigators conducting this study are affiliated with AUT. The investigators have received funding from the university at the school and faculty level to conduct this research to understand the effects of acoustic therapy on nasal health and overall wellbeing. The investigators do not have financial interests in the device.

AUT is a minor shareholder in the company that manufactures the acoustic device being used in this study. The device is being provided to the study for free by My Better Breathing Ltd, the manufacturer, who is focused on entering the commercial market for nasal decongestion. To manage potential conflicts of interest, the study team is committed to ensuring transparency in all relationships and has implemented measures to prevent any undue influence on the study outcomes.

WHO HAS APPROVED THE STUDY?

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC, reference 2025 EXP 22987), who check that studies meet established ethical standards. Additionally, this study has been approved by the Auckland University of Technology Ethics Committee, ensuring that it adheres to the highest ethical standards.

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:

Name, position: Kelvin Lau; Study Supervisor
Telephone number: +64 9 921 9666 ext. 8062
Email: kelvin.lau@aut.ac.nz

For Māori cultural support please contact:
Name: Wiremu McFater; OLR registrar
Telephone number: 021 02661219
Email: wiremum1@adhb.govt.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/

If you experience any distressing thoughts or emotions after reflecting on your answers in this survey, it may be helpful to talk to someone close to you. Additional support is available through the following services:

- Healthline: For general health advice, call 0800 611 116, available 24/7.
- Need to Talk? Free call or text 1737 at any time to speak with a trained counsellor.

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

Acoustic Therapy for Better Breathing: Helping Individuals with nasal congestion

Please read through and tick where necessary 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, whanau/ 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 the future use of my data and/or samples for research purposes beyond this study.	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.	Yes ☐	No ☐
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 ☐
I would like a karakia to be performed before my samples are destroyed.	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: