Methodology Special Issue

Investigating the Effects of Acoustic Therapy on the Nasal Microbiome and Well-being

Jude Oluwapelumi Alao[1], Kelvin Lau[1], David White[2], Kevin Lee[3], Chris Puli'uvea[3], Jim Bartley[4]

[1] School of Public Health and Interdisciplinary Studies, Auckland University of Technology, Auckland, New Zealand

[2] BioDesign Research Hub, New Zealand College of Chiropractic

[3] School of Science, Auckland University of Technology, Auckland, New Zealand

[4] Department of Surgery, University of Auckland, Auckland, New Zealand

Abstract:

This study aims to investigate the effects of acoustic therapy on the nasal microbiome, immune responses, and overall well-being in patients with allergic rhinitis (AR) and chronic rhinosinusitis (CRS). Utilizing the Goodair® NoseBuds, a low-cost acoustic device developed by the AUT BioDesign Lab, this research explores the potential of nasal mechanostimulation to increase endogenous nitric oxide production, improve nasal health, and alleviate AR and CRS symptoms. Participants will use the device twice daily over a four-week period, and the study will assess changes in nasal microbiome composition, inflammation markers, and patient-reported outcomes, such as symptom severity and quality of life. Data will be analysed through bioinformatics and statistical methods to identify correlations between acoustic therapy and immune or microbial changes. This research offers an innovative, non-pharmaceutical alternative for managing AR and CRS, with the potential to reduce reliance on traditional medications and improve patient outcomes.

Research Questions

1. How does acoustic therapy influence the composition and diversity of the nasal microbiome in individuals diagnosed with AR and CRS?
2. What immunological changes occur in response to acoustic therapy in AR and CRS patients, and how do these changes relate to symptom improvements?
3. How do patients perceive the effects of acoustic therapy on their symptom severity, quality of life, and mental well-being when managing AR and CRS?

Research objectives

My research objectives are focused on exploring the potential of acoustic therapy as a non-pharmaceutical treatment for AR and CRS. Specifically, I aim to:

1. Investigate how acoustic therapy affects the nasal microbiome's composition and diversity in patients with AR and CRS.
2. Analyse the immunological changes associated with acoustic therapy and their relationship to symptom alleviation in these patients.
3. Assess patient-reported outcomes related to symptom severity, quality of life, and mental well-being following the use of acoustic therapy.

Research Design

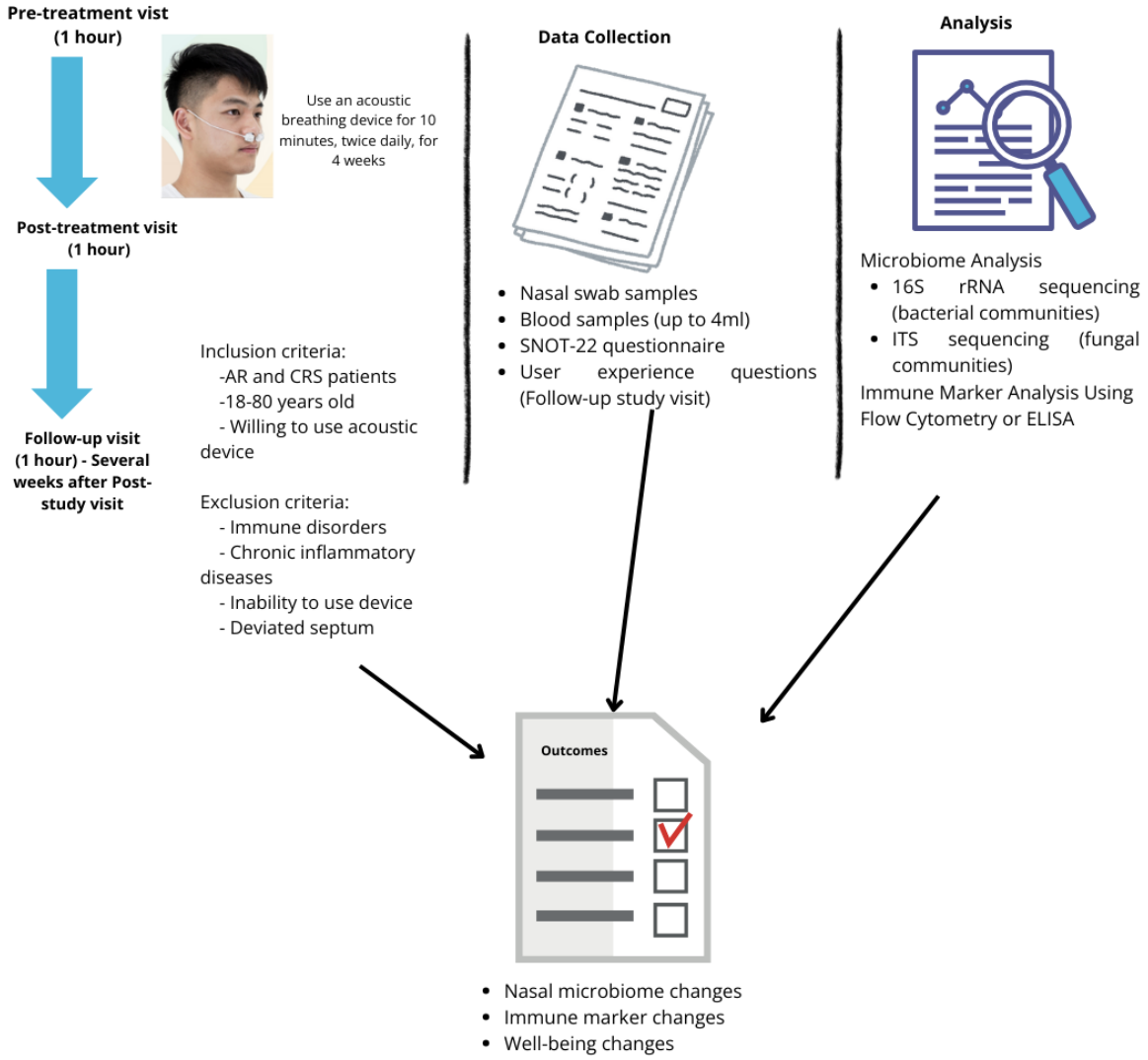

Figure 1. Flowchart displaying proposed Research Design

Research Methods

In this study, I will use a mixed-methods approach that integrates both quantitative and qualitative data. I will employ 16S rRNA sequencing to assess bacterial communities and ITS sequencing to analyse fungal communities in the nasal microbiome. Blood samples will be analysed to measure immunological markers which are relevant to allergic and inflammatory responses (Gokani et al., 2023; Wang et al., 2023).

To evaluate patient-reported outcomes, I will use the Sino-Nasal Outcome Test (SNOT-22), a validated tool for assessing the severity of symptoms and quality of life (Behnke et al., 2023).

Measurements

I will measure the following variables:

- Nasal Microbiome Composition: The diversity and abundance of bacterial and fungal communities in nasal swabs will be examined through DNA sequencing.
- Immune Markers: Levels of specific inflammation markers will be measured in blood samples via flow cytometry or ELISA to assess the immune response.
- Symptom Severity and Quality of Life: SNOT-22 scores will be used to quantify patient-reported symptoms and their impact on daily life.

Sample

The study will include 20-30 participants diagnosed with AR or CRS, aged 18-80. Participants will be recruited from clinics and public advertisements. Inclusion criteria include a willingness to use the acoustic therapy device for the study's duration, while exclusion criteria include any history of immune disorders or contraindications, such as nasal polyps.

Data Collection Process

Participants will attend three study visits (pre-treatment, post-treatment and follow-up visit), with weekly follow-ups via calls from me. During the pre-treatment visit, nasal swabs, blood samples, and baseline SNOT-22 data will be collected. Participants will use the Goodair® NoseBuds device for 10 minutes, twice daily, over a 4-week period. At the second visit (post-treatment), another set of nasal swabs, blood samples, and SNOT-22 data will be collected, along with feedback on device usability. A follow-up visit will occur several weeks after the post-treatment visit to assess long-term effects.

Data Analysis Technique

The microbiome data will be analysed using bioinformatics software to examine changes in microbial composition and diversity. Cytokine levels will be measured using ELISA or flow cytometry. Statistical analysis, using tools like PRIMER-e software, will be employed to identify correlations between microbiome changes, immune markers, and patient-reported outcomes.

Ethical Considerations

Ethical approval will be sought from the Health and Disability Ethics Committee (HDEC) and AUT Ethics Committee (AUTEC).

Participants will be fully informed about the study procedures, and informed consent will be obtained. Only de-identified nasal microbiome DNA will be sent overseas for analysis to ensure data privacy. Any significant findings that could impact a participant's health will be communicated to them and their GP.

Reliability and Validity

To ensure reliability, standardized protocols will be followed for collecting and storing biological samples. Validated tools such as the SNOT-22 questionnaire will be used to gather consistent patient-reported outcomes. Multiple imputation methods will be used to handle missing data, ensuring robustness in the analysis.

Limitations of the Methodology

Potential limitations include the small sample size, which may limit the generalizability of findings, and participant adherence to using the device regularly.

Words of wisdom

Ensure clear communication across interdisciplinary teams and maintain flexibility in your methodology. Invest in robust data management early and be prepared to adapt your approach as challenges arise.

Conclusion

Looking back at the early stages of this research, I initially felt excitement but also uncertainty about managing such a complex and interdisciplinary project. Over time, however, I have become more confident, not only in the methodology but also in the study's potential impact. My understanding of how the nasal microbiome, immune system, and well-being are intertwined has deepened, reinforcing my belief in holistic, non-invasive approaches to treatment.

At this stage, I am both energized by the progress and aware of the challenges ahead, but overall, I feel much more prepared and clear-headed about the path forward.

References

Behnke, J., Dundervill, C., Bulbul, M., Armeni, M., Ramadan, H. H., & Makary, C. A. (2023). Using the sino-nasal outcome test (SNOT-22) to study outcome of treatment of nasal obstruction. *American Journal of Otolaryngology*, *44*(4), 103879. https://doi.org/10.1016/j.amjoto.2023.103879

Gokani, S. A., Espehana, A., Pratas, A. C., Luke, L., Sharma, E., Mattock, J., Gavrilovic, J., Clark, A., Wileman, T., & Philpott, C. M. (2023). Systematic Review of Protein Biomarkers in Adult Patients With Chronic Rhinosinusitis. *American Journal of Rhinology & Allergy*, *37*(6), 705–729. https://doi.org/10.1177/19458924231190568

Wang, J., Zhou, Y., Zhang, H., Hu, L., Liu, J., Wang, L., Wang, T., Zhang, H., Cong, L., & Wang, Q. (2023). Pathogenesis of allergic diseases and implications for therapeutic interventions. *Signal Transduction and Targeted Therapy*, *8*(1), 138. https://doi.org/10.1038/s41392-023-01344-4