



Participant Information Leaflet - Template

Study Title	The lived experience of electrolarynx users.
Research Site(s)	Online(Zoom)
Principal Investigator(s) and Co- Investigator(s) (Study Team) (insert names, titles and contact details including Trinity School/Department/Unit)	<u>Principal Investigator:</u> Claudia Panikkassery: Student, MSc Clinical Speech and Language Studies. panikkac@tcd.ie Research Supervisor: Dr.Ciaran Kenny:Assistant Professor at the Department of Clinical Speech and Language Studies, Trinity College Dublin. Ciaran.kenny@tcd.ie
Data Controller(s)	Trinity College Dublin (research data)
Data Protection Officer (Research Data)	Data Protection Officer Secretary's Office Trinity College Dublin Dublin 2



Invitation Paragraph

You are invited to participate in a research study conducted by Claudia Panikkassery (Researcher) and Dr Ciaran Kenny (Research Supervisor) at Trinity College Dublin. Before you decide whether to take part, please read this information leaflet carefully and discuss it with your family and friends, if you wish. If anything is unclear or you would like more information, please do reply to this email. Don't feel rushed or pressured to participate or make a quick decision. You should understand the risk and purpose of the study.

This leaflet has four parts:

Part 1 - The Study

Part 2 - Data Protection

Part 3 - Approval, Organising and Funding

Part 4 - Future Research (if personal data will be used in future research)

Part 5 - Further Information

Part 6 - Next Steps



Part 1 - The Study

Why is this study being done?

This study wants to learn about the real-life experiences of people who use an electrolarynx, especially how they adapt to and accept their new voice. By understanding these experiences more fully, speech and language therapists can better support electrolarynx users and improve the support they offer.

Why have I been invited to take part in this study?

We are interested in understanding the lived experiences of electrolarynx users aged 18 or older. You are invited to participate in this study as you are a regular electrolarynx user. Your experiences and insights will be extremely useful in understanding the real-world challenges and successes of electrolarynx use. We are seeking to learn directly from people who live with and adapt to this communication method every day.

Do I have to take part?

No, you do not have to take part in this study if you do not want to. It is completely your choice. After you read the whole leaflet and understand the risks and purpose of the study, you can decide if you want to continue or not. If you want to stop, that is completely fine. We will also obtain your verbal consent on the day of data collection.

What does taking part in the study involve?

If you decide to take part in the interview, the principal investigator will email you the participant information leaflet (this letter) along with the consent form. After carefully reading the information leaflet, you can reply to the email panikkac@tcd.ie (email of principal investigator) by giving consent to participate in the study. Verbal consent will also be taken on the day of the interview.

Once the participant gives consent, the principal investigator will schedule an interview within a minimum of 3 days by emailing a Zoom link and a participant code to be used to store your data. Trinity College Dublin's Zoom platform will be used for this purpose.

Participants can attend the interview at a location of their convenience. The researcher will be taking interviews in a private location where conversations cannot be overheard. The



interview will be 30-60 minutes long, which will be conducted by Claudia Panikkassery (principal investigator)

The interview will be video-recorded and stored in an anonymous folder for analysis accessible only to the principal investigator and the research supervisor.

What are the possible benefits of taking part?

Participating in the study may not directly benefit you. However, we hope this study may help us to better understand the lived experience of electrolarynx users, which may help SLTs to better understand the communication needs of electrolarynx users.

What happens if I change my mind and wish to withdraw from the study?

Your participation in this study is voluntary, and you can change your mind and withdraw from the study even without giving a reason. If you want to withdraw from the study, please contact panikkac@tcd.ie (principal investigator) and ciarán.kenny@tcd.ie

Please note, however, that once the data is collected, it will be immediately anonymised. Also, we will not be able to remove the data post analysis period.

Are there any possible disadvantages or risks from taking part?

There are no known risks involved in this study. At all times, the participants' well-being is prioritized. In the event of emotional upset, participants will be given a break or stop at any time. If participants are upset, they will be encouraged to speak with a friend or a family member for support.

What will happen to the results of the study?

The study's results will be published. No information that reveals your identity will be disclosed. Some quotes from the interview will be used, but your identity will remain anonymous.



Part 2 - Data Protection

What information about me (personal data) will be used for this study? Will my medical records be accessed?

Data Collected

Contact details: Name & Email Address

Recorded interviews: Video recording

Data containing health information

Who will access my personal data?

Only the principal investigator, Claudia Panikkassery, and the research supervisor, Dr. Ciaran Kenny, will have access to your data. They will collect the information listed above and replace your name with a code before uploading it to Trinity College Dublin's secure research database. This means your information cannot be directly linked back to you. The research team will only access the coded data.

How is the information kept confidential and secure?

We will protect your privacy. This means keeping your personal information safe and confidential. We will store all personal data in a password-protected file and make it pseudonymous to protect your identity. The original data will be encrypted and kept in a secure folder on the Trinity College Dublin computer network. Only the researcher and their supervisor will have access to files with identifiable information.

Your interviews will be completely private. We will only use a secure Zoom account provided by Trinity College Dublin.

The researcher and their supervisor have been trained in data protection. They follow professional ethics rules to keep your information confidential.

How long will my personal information used for this study be retained for?

Your personal information will be retained until results are obtained, which is approximately 4-5 months post interview. After this period, the principal investigator will securely delete the personal information.



The video recording will be retained until it has been transcribed and content verified after which it will be deleted securely.

What is the lawful (legal) basis to use my personal data?

We will only use your personal information for this research project, which is needed to facilitate your participation in the study.

What are my rights under Data Protection law?

You are entitled to:

- object to our use of your personal data or any further use;
- request access to your personal data and to receive a copy of it (up to the point of anonymisation)
- request that inaccurate personal data be corrected or deleted;
- request restriction of our use of your personal data (if it is inaccurate);
- Request deletion of your data.

By law, you can exercise the above rights in relation to your personal data, unless the request would make it impossible or very difficult to conduct the research. For example, if the study results/information are to be published, then we may not be able to delete them. You can exercise these rights by contacting your study principal investigator at panikkac@tcd.ie or the Trinity College Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland at dataprotection@tcd.ie



Part 3 - Approval, Organising and Funding

Has this study been approved by a research ethics committee?

Yes, this study has been approved by the Research Ethics Committee of the School of Linguistic, Speech & Communication Sciences, Trinity College Dublin on ____.

Who is organising and funding this study?

This study is being undertaken by Claudia Panikkassery as part of their Master's studies. It is self-funded.

Is there any payment for taking part?

No, we are not paying participants to take part in the study.

Part 4 - Further Information

Who should I contact for information or concerns?

If you have any concerns or questions, you can contact:

Principal Investigator: Claudia Panikkassery :panikkac@tcd.ie

Research supervisor: Dr.Ciaran Kenny: Ciaran.kenny@tcd.ie

Data Protection Officer, Trinity College Dublin: Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website: www.dataprotection.ie

Under GDPR, if you are not satisfied with how your data is being processed, you have the right to raise a concern with the Office of the Data Protection Commission, 21 Fitzwilliam Square South, Dublin 2, Ireland. Website: www.dataprotection.ie



Part 6 - Next Steps

Next steps

If you would like to take part in this study, please contact the Principal investigator at panikkac@tcd.ie, who will arrange a mutually suitable date and time for the interview.

Will I be contacted again?

We will contact you in seven (7) days' time, to give you time to consider your participation in the study. If we do not hear back from you, we will contact you on one further occasion, and if we do not hear from you after that, we will not contact you again.

Thank you for taking the time to read this Participant Information Leaflet.

You will be given a copy of this Leaflet and the signed Consent Form to keep. Please retain these for future reference.

Glossary

Anonymised Data	https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.12.pdf
Coded data	https://www.tcd.ie/dataprotection/assets/pdf/2.11.4.12.pdf
Data Controller	https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.1.pdf
Data Subject	https://gdpr-info.eu/art-4-gdpr/
Masked data	https://www.tcd.ie/dataprotection/assets/pdf/2.11.4.12.pdf
Personal data	https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.2.pdf https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.3.pdf
Pseudonymised data	https://www.tcd.ie/dataprotection/assets/pdf/2.11.4.12.pdf
Special Categories of Personal Data	https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.4.pdf



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