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| Title | **The ACoUSTiC Study – Exploring the potential benefits of Above CUff VocaliSation in TraCheostomy** |
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**Online Participant Information Sheet for**

**The ACoUSTiC Study – Exploring the potential benefits of Above CUff VocaliSation in TraCheostomy**

We would like to invite you to take part in a University of Leeds and Leeds Teaching Hospitals NHS Trust research study. Before you decide whether you would like to take part, it is important for you to understand why the research is being done, what it would involve for you and how the information you provide will be used.

Please take time to read the following information carefully and decide whether or not you wish to take part and complete this online survey.

If there is anything that is not clear, or you would like more information you can contact us:

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**Summary of the Research**

Tracheostomy weaning practice varies widely both within and between hospitals, because of the lack of evidence supporting any particular approach. Many patients with tracheostomies have the tracheostomy cuff inflated for prolonged periods of time, resulting in an inability to voice, which can lead to extreme levels of frustration, and impaired swallowing. Above Cuff Vocalisation (ACV) is a technique that uses the sub-glottic port of a tracheostomy tube to apply an external airflow through the larynx (voice box). There is some evidence to support its use in enabling patients to communicate and improving swallow function. However, there is limited evidence around how it should be used and it is hypothesised that application of this technique varies widely internationally.

**Aims of this study:**

1. To identify the extent of ACV use worldwide
2. To evaluate how ACV is being used in care
3. To investigate barriers to ACV implementation
4. To evaluate how tracheostomy weaning practice may impact on ACV use
5. To evaluate healthcare professionals opinions of ACV

**Why is this research needed?**

This research is important to establish current international practice. The findings of this study will help to inform the design of an ACV treatment protocol which will be used in feasibility study to explore the potential benefits of ACV.

**What does taking part involve?**

We are asking you to complete this short online survey. It should take you no more than 30 minutes if you use ACV in your setting. Even if you do not use Above Cuff Vocalisation we would still like you to complete the survey, in this case the survey should take you no more than 10-15 minutes. We would like multiple surveys to be completed by different individuals within a hospital setting, as we would like to have a range of disciplines complete the survey providing different perspectives. As an individual your response will be anonymous, but we do require the name of your hospital.

There is no other commitment to this study following the completion of the survey. However, at the end of the questionnaire there is an opportunity for you to state whether you would be interested in participating in a short follow-up telephone/Skype interview.

**What are the potential benefits of participation?**

There may or may not be direct benefits to you as an individual in taking part. However, the results of this study will contribute to the development of an ACV treatment protocol to be evaluated in a feasibility study.

**How will I consent to participate?**

We ask that you confirm your consent online before completing the online survey. Involvement in this survey is voluntary and you can withdraw from this study up until the point of completing the survey and clicking on ‘submit’. At this point, we are unable to identify or withdraw your survey responses.

**How will the information be stored?**

All the information you provide will be stored in password protected files the University of Leeds network. This information will be kept securely for a minimum of 10 years. All information will be kept strictly confidential and we comply with the General Data Protection Regulation (2018) and the Data Protection Act (2018). The University of Leeds is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Leeds will keep identifiable information about you (e.g. consent forms) for 10 years after the study has finished. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information at <http://www.leeds.ac.uk/secretariat/data_protection.html> or by contacting (r.messenger-clark@adm.leeds.ac.uk) or Adrian Slater (a.j.slater@adm.leeds.ac.uk) in the Secretariat at the University of Leeds.

**How will this research be shared?**

The research will be reported as part of a PhD thesis, presented at conferences and submitted for publication in scientific journals. Research findings will also be shared with the public using written summaries, presentations and via social media. Confidentiality of participants will be maintained at all times. We may use some of the things you write as quotes for illustrative purposes in the reporting of the results. If we do use your words then we will do so anonymously and make sure that neither you, or the place you work, are identifiable to others from the quotes we include. With your consent, the anonymised data will also be placed in a Research Repository, this is a secure place to store the data produced in the long-term, so that this data can be available for other research studies in the future. Access to this anonymised data will be restricted. The data in the Research Repository will be kept for a minimum of 10 years, and may be retained indefinitely.

**Who has reviewed this study?**

This study has been reviewed and ethical approval sought from the University of Leeds, School of Medicine Research Ethics Committee (SoMREC/SHREC project number 18-037.

**What do I do now?**

If you wish to participate in this research, please continue to the following page and complete the consent form to start the online survey.

**What if there is a problem?**

If you have concerns about any aspect of this project, please feel free to contact Professor Chris Bojke (c.bojke@leeds.ac.uk) who is the supervisor for this project.