A speech recognition application as a communication aid for acute and critical care patients with tracheostomies

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GLOSSARY OF ABBREVIATIONS

Abbreviation / Acronym	Full Wording
AAC	Augmentative and Alternative Communication
ACV	Above Cuff Vocalisation
AI	Artificial Intelligence
BACCN	British Association of Critical Care Nurses
BHSCT	Belfast Health and Social Care Trust
CAM-ICU	Confusion Assessment Method in the Intensive Care Unit
CI	Chief Investigator
CORE-Q	Consolidated Criteria for Reporting Qualitative Research
CSIT	Centre for Secure Information Technologies
GCP	Good Clinical Practice
HADS	Hospital Anxiety and Depression Scale
HRQoL	Health Related Quality of Life
IES-R	Impact of Events Scale (Revised)
MDT	Multidisciplinary team
MoCA-BLIND	Montreal Cognitive Assessment-BLIND
NI	Northern Ireland
NICE	National Institute for Health and Care Excellence
PHA	Public Health Agency
PI	Principal Investigator
PPI	Patient and Public Involvement
PTSD	Post-Traumatic Stress Disorder
QUB	Queen's University Belfast
REC	Research Ethics Committee
SRAVI	Speech Recognition Application for Voice Impaired
UKGDPR	UK General Data Protection Regulation
VSR	Visual Speech Recognition
WHSCT	Western Health and Social Care Trust

PROTOCOL SUMMARY

Protocol Title	A mixed method prospective observational cohort study to test Speech Recognition Application for the Voice Impaired (SRAVI) as a communication aid for acute and critical care patients with tracheostomies.
Health condition(s) or problem(s) studied	Adults admitted to acute or critical care units with a tracheostomy.
Study design	Multi-site, prospective observational cohort study.
Study Aim and Objectives	**Aim:** To establish the feasibility and acceptability of implementing Speech Recognition Application for the Voice Impaired (SRAVI) for acute and critical care patients with a tracheostomy who are unable to communicate using verbal speech. **Objectives:** 1. To evaluate patients' capability in using SRAVI and barriers to its use. 2. To measure accuracy of SRAVI. 3. To explore the experience of patients, their significant others, and acute and critical care multidisciplinary team (MDT) members with and without the use of SRAVI. 4. To assess recruitment and collection of clinical outcomes.
Study Intervention	Speech Recognition Application for the Voice Impaired (SRAVI)
Comparator	None
Primary outcome	1. Patient capability to use SRAVI 2. User acceptability of the intervention
Secondary outcomes	1. Feasibility of collection of clinical data measures: a. Duration of critical care length of stay b. Duration of hospital length of stay c. Delirium occurrence during critical care stay d. Health Related Quality of Life (HRQoL) e. Anxiety and depression f. Post-Traumatic Stress Disorder (PTSD) g. Cognitive status 2. Estimation of recruitment and retention to inform design of a clinical trial. 3. Identification of additional important outcomes reported by patients, relatives, and healthcare professionals.
Key inclusion and exclusion criteria	**Patient inclusion criteria:** 1. Patients aged 18 years and over 2. Patients who acquire a tracheostomy in acute or critical care

	3. Patients can move lips in a way that articulates words 4. Able to communicate in English (a current requirement of the technology) **Patient exclusion criteria:** 1. Patient declined consent
Study setting	Three critical care units in Northern Ireland: Royal Victoria Hospital (RVH), Belfast; City Hospital, Belfast and Altnagelvin Hospital, Derry and a regional head and neck centre, RVH Belfast.
Sample size	A minimum target of 55 patients.
Study Duration	18 months

STUDY TEAM

Chief Investigator	Professor Bronagh Blackwood Wellcome-Wolfson Institute for Experimental Medicine, Queen's University Belfast (QUB)
Co-investigators	Carla McClintock (Research Fellow) Wellcome-Wolfson Institute for Experimental Medicine, QUB & Western Health and Social Care Trust (WHSCT) (Altnagelvin Hospital)
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	Chantal Davies PPI Representative
Study Sponsor	Queen's University Belfast

1. BACKGROUND AND RATIONALE

1.1 Background Information

Voice represents one of the most fundamental components of human communication. Yet when patients are admitted to hospital their ability to effectively communicate may be temporarily or permanently compromised by the nature of their illness and treatment.

Critical Care

In the UK, approximately 10,000 patients annually undergo a tracheostomy (1). A paradigm shift in critical care management towards lighter sedation in mechanically ventilated patients has increased the number of patients potentially able to communicate while awake (2). An advantage of tracheostomy is that patients can have reductions or cessation of sedative medication but may find themselves in a situation where they are alert, yet still reliant on positive pressure ventilator support. This almost universally requires an inflated tracheostomy tube cuff to deliver the pressure generated by the ventilator to the lungs. For the majority of these patients who remain significantly ventilator-dependent or have a considerable aspiration risk that inhibits cuff deflation, the continued presence of the inflated cuff by necessity 'seals off' the upper airway, preventing effective oral communication (3).

The impact of altered communication function has been described as one of the most stressful events of critical care admission (4) and the presence of a tracheostomy tube with an inflated cuff significantly impacts upon an individual's ability to effectively communicate, interact, and participate within the healthcare system (5). Nearly two-thirds of ventilated patients report communication as difficult, and this contributes to negative emotions during critical care (6,7). Patients report loss of voice leading directly to frustration (8), panic (9), anger (10), fear (11), a sense of depersonalisation, powerlessness, and a sense of futility (12, 13). Importantly emotional distress experienced during critical care is a predictor of negative psychological outcomes during recovery. Anxiety (14, 15), depression (16, 17), PTSD (18, 19) and intrusive and delusional memories (20, 21) have been reported as frequent sequelae for many critical care survivors. Delirium, a form of acute brain dysfunction that is common during critical illness, has consistently been

shown to be associated with long-term cognitive impairment. Impaired communication may contribute to delirium. Cognitive dysfunction following critical care discharge has been demonstrated in up to 66% of survivors, with impairments documented in one-third up to six years after hospital discharge (22).

Acute Care

In the UK approximately 12,400 new cases of head and neck cancer are diagnosed annually. Accounting for 3% of all new cancer cases, it is the 8th most common cancer in the UK (23). For some patients with laryngeal carcinoma, total laryngectomy is a treatment option (24). This surgical procedure involves the disconnection of the airway following removal of laryngeal structures and part of the upper trachea. Although an effective cancer treatment, the resulting permanent tracheostomy is at the expense of the patient's natural voice (25). Whilst many patients adapt well to new forms of communication, some experience considerable psychosocial burden. Greater levels of depression and anxiety have been reported in 30% of TL patients (26). Loss of natural voice is also associated with decreased social activity with an estimated 40% of patients experiencing social withdrawal (27).

In addition to laryngectomy (a planned procedure resulting in a permanent tracheostomy), various scenarios in the acute care setting may necessitate a temporary tracheostomy. Reasons may include upper airway obstruction resulting from conditions such as vocal cord paralysis, tracheal or laryngeal stenosis, infection, or trauma. A tracheostomy establishes an alternative pathway for air to bypass the upper airway, thereby facilitating its passage into the lungs.

1.2 Rationale for the study

Augmentative and Alternative Communication (AAC) strategies describe a wide spectrum of tools, technologies, and/or approaches used to solve communicative challenges in patients who are unable to communicate through verbal speech (28).

Critical Care

AAC is not always effective in the critical care setting as strategies for voiceless patients are often too complex for this population. Critical illness neuropathy and

altered cognitive functioning often mean that patients lack the manual dexterity to use such aids (29). Low-tech communication aids including pen and paper and communication boards have been described as tedious, limited, and slow (30) whilst high-tech aids such as eye-gazing systems use bespoke hardware and require significant patient learning (31). Although one-way speaking valves have been successfully used to restore audible and meaningful speech in patients after tracheostomy placement (32-33), criteria for selection of candidates for use includes the ability to tolerate tracheostomy cuff deflation. Above Cuff Vocalisation (ACV) may be helpful for those patients who cannot tolerate cuff deflation as this technique uses the subglottic suction port of the tracheostomy tube to deliver a low flow of air or oxygen backwards up the port to exit above the cuff (34). Gas flow can then travel upwards through the trachea, pass through the vocal cords, and exit via the mouth, resulting in audible vocalisation. However, this is a relatively new technique with numerous contraindications and requires further research (35). There is a need to develop more effective AAC strategies for critical care patients.

Unaided modalities such as silent articulation of speech, gesturing, and body language remain the primary mode of communication used by critical care tracheostomy patients despite evidence showing that they are frustrating, insufficient, and characterised by patients not being understood (36-37). The inability to accurately interpret what patients are trying to say also frequently results in staff experiencing feelings of incompetence and despair (38-39). Studies have described typical communication between patients and healthcare professionals as brief and targeting primarily basic medical needs due to the difficulty in understanding what the patient wishes to say (40). Critical care patients describe their needs as multi-dimensional (41) and have highlighted the need for easy to use and intuitive communication aids (42-43). Impaired communication can prevent non-vocal tracheostomy patients from not only expressing their needs and symptoms but also emotions, and from participating in decisions regarding their own treatment (44). The integration of reliable communication interventions at the bedside is essential to decreasing the challenges and vulnerabilities experienced by critical care patients recovering from events resulting in sudden speechlessness.

Acute Care

Whilst recent years has seen significant advances in voice restoration techniques following total laryngectomy, in the immediate postoperative period, low-tech strategies including writing and communication boards are frequently utilised. Alternative options such as oesophageal speech or electrolarynx speech are often difficult to learn effectively (45). Tracheo-Esophageal Speech (TE-speech), a voice prosthesis, may also be utilised but successful TE-speech is not guaranteed with outcomes in voice quality and intelligibility differing between patients (46).

For patients in acute care undergoing emergency tracheostomy, communication strategies closely resemble those used in critical care settings and the immediate postoperative period for total laryngectomy patients.

1.3 Rationale for the intervention

Speech Recognition Application for the Voice Impaired (SRAVI) is a novel communication aid developed by Liopa (a company formed by Queen's University Belfast (QUB) and the Centre for Security Information Technologies (CSIT), QUB). SRAVI is an application-based lip-reading system, and the application ('app') can be downloaded onto any device with a standard forward facing camera (e.g., smartphone, tablet). When the device is held in front of a patient, it will track lip movement and identify phrases being mouthed (Figure 1).

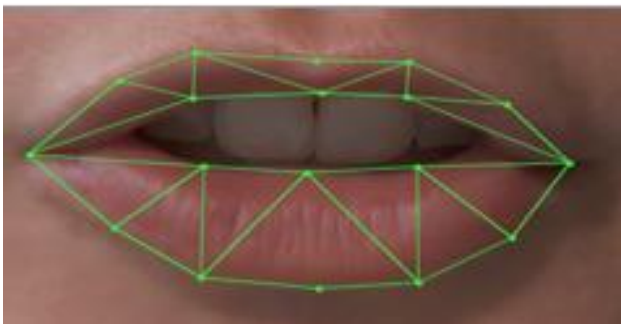


Figure 1: SRAVI application (47)

SRAVI has been in trial by the Lancashire Teaching Hospitals NHS Foundation Trust since 2019. The phase 1 trial included 15 patients who had lost their ability to speak from having tracheostomies and 33 critical care staff members (48). During this initial phase, rapid cycles of testing confirmed that SRAVI can be used to communicate from a list of the most common and important phases as identified by patients and staff with

good accuracy. As SRAVI is based upon artificial intelligence (AI) algorithms, it was important to determine that the app will read the patients' lips better as they continue using it. Critically, Phase I proved that SRAVI returns the correct phrase that has been lip-read with greater than 90% accuracy. The recognition system is able to discern the correct phrase in the top 3 with 100% accuracy. The longer the patients used SRAVI, the better the app became at interpreting what they were saying (Figure 2).

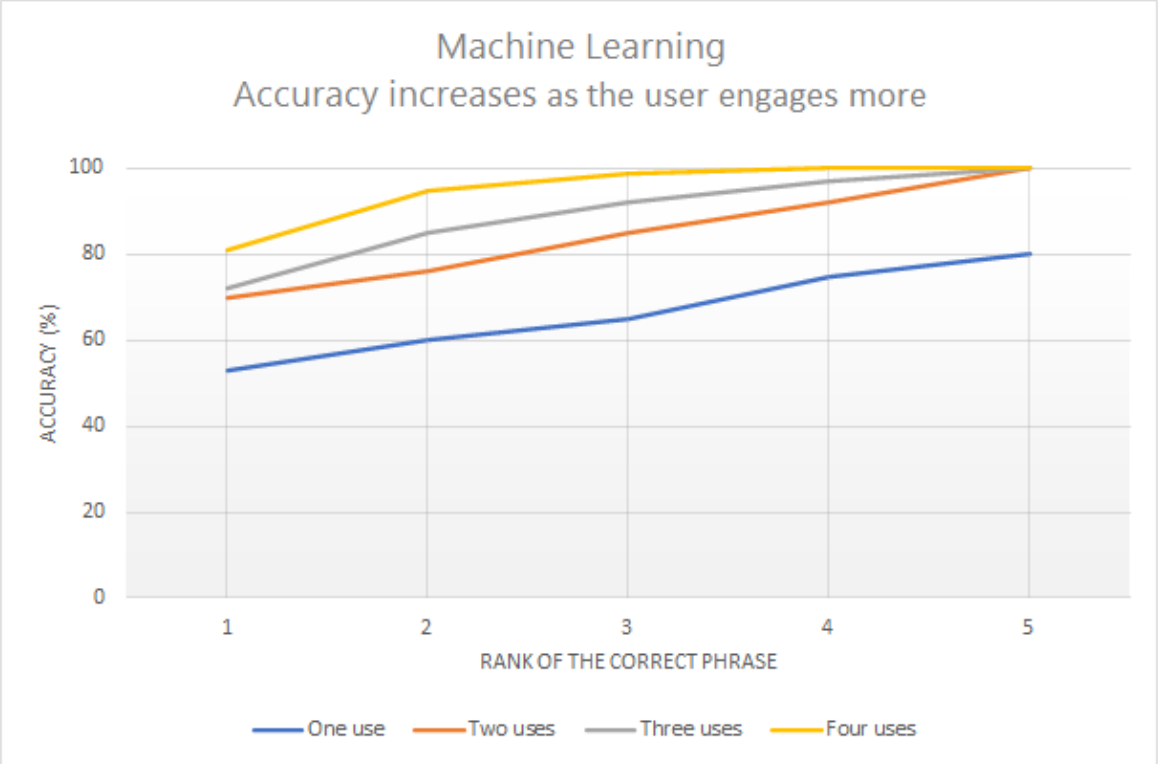


Figure 2: Accuracy and SRAVI engagement (49)

Compared to the limited alternatives available, SRAVI potentially could provide an easier, more accurate, and cost-effective method for communication between tracheostomy patients, healthcare professionals, and relatives.

2. RESEARCH AIM AND OBJECTIVES

2.1 Research Aim

The overarching aim of this research is to establish the feasibility and acceptability of SRAVI for adult acute and critical care patients with a tracheostomy who are unable to communicate using verbal speech.

2.2 Research Objectives

1. To evaluate patients' capability in using SRAVI and barriers to its use.
2. To measure accuracy of SRAVI.
3. To explore the experience of patients, their significant others, and acute and critical care multidisciplinary team (MDT) members with and without the use of SRAVI.
4. To assess recruitment and collection of clinical outcomes.

3. STUDY DESIGN AND SETTING

3.1 Study Design

This is a mixed-method, multi-centre prospective observational cohort study to establish the feasibility of SRAVI. Mixed methods include:

- A multi-centre prospective observational cohort study of SRAVI as an addition to usual communication aids.
- Qualitative interviews to inform future study design by exploring patients', their significant others and the acute and critical care MDTs' subjective experiences of the study intervention and outcome measures.

3.2 Study Setting

The study will be conducted at four sites: the 32- bed regional critical care unit based at the Royal Victoria Hospital (RVH), Belfast, NI; the 10- bed general critical care unit based at the City Hospital, Belfast, the 10-bed general critical care unit based at Altnagelvin Hospital, Derry, NI and a regional head and neck centre based at RVH Belfast

3.3 Sample Size

The sample size is based on previous critical care feasibility studies showing a participation rate of 50%. Due to the onset of the SARS-CoV-2 pandemic, the role and timing of tracheostomy for patients requiring critical care for coronavirus disease (COVID-19) remains unclear (50). To circumvent this, pre-COVID19 local audit data has been used to estimate sample size. In 2019, an average of 70 tracheostomies were completed in Royal Victoria Hospital, Belfast, 20 in City Hospital, Belfast and 20

in Altnagelvin Hospital, Derry. We aim to recruit as many patients as possible but aiming for a minimum target of 55 patients.

For every patient recruited to the prospective observational cohort study, we will aim to undertake two interviews as part of the qualitative component of the study (i.e., the patient and their significant other). We will also aim to host a minimum of five staff focus groups and will include a representative sample of medical, nursing and allied healthcare professionals of various grades with no more than eight participants per session.

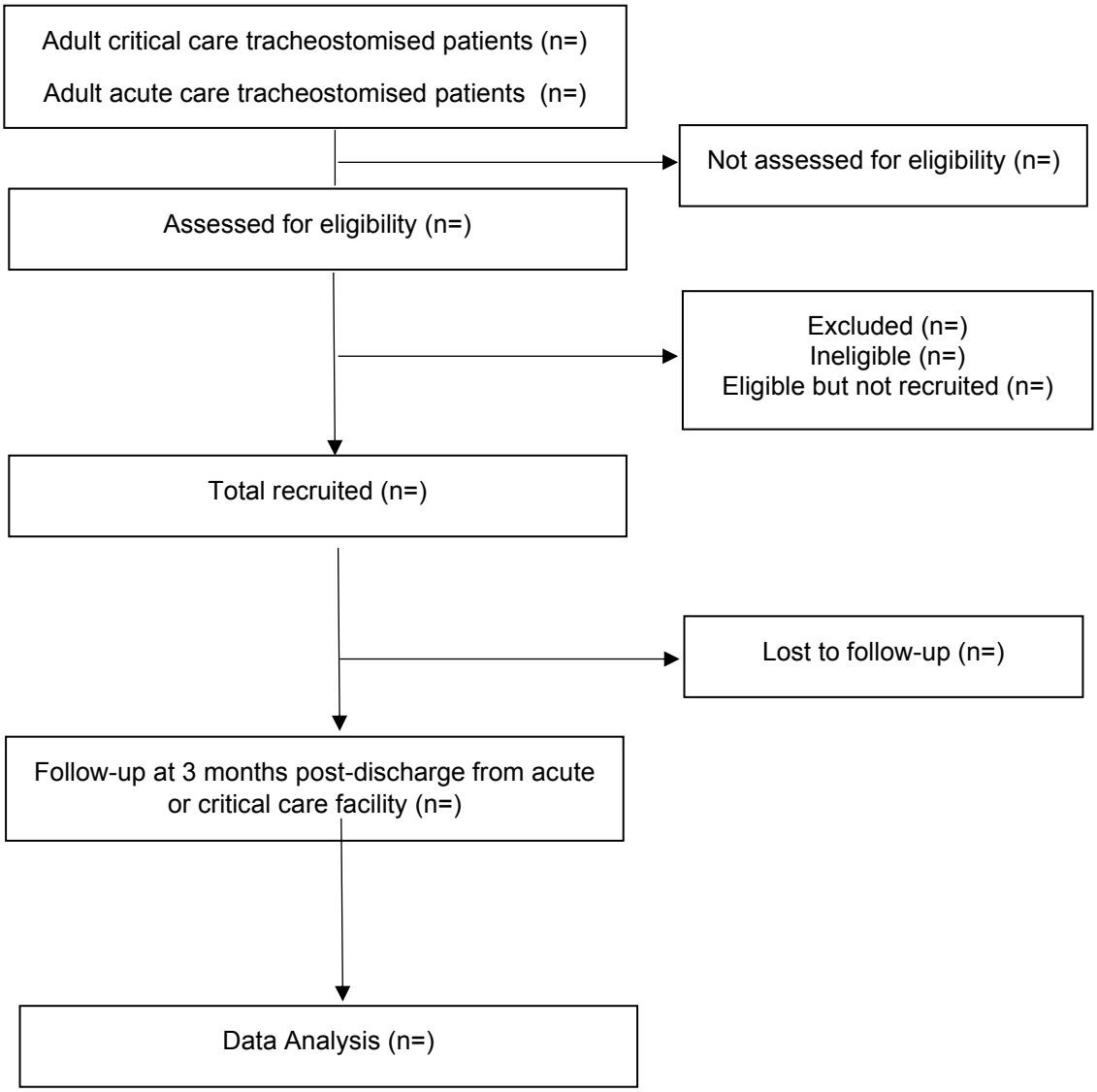
Therefore, a feasible target recruitment is 150 participants. However, in keeping with the principles of rigorous qualitative research we will be responsive to the study context and anticipate that in some cases fewer interviews/focus groups will be conducted and in others, additional interviews/focus groups will be conducted to achieve data saturation.

3.4 Duration of study

The proposed study duration is 18 months.

- **Recruitment phase**: patient recruitment is estimated to take 14 months.
- **Treatment phase**: SRAVI in addition to usual communication aids will be used for the duration of the patient's acute or critical care stay.
- **Follow-up phase**: 3 months after acute or critical care discharge.
- **End of study**: is defined as the last 3-month observation of the last patient in the follow-up phase of the study and is anticipated to be 17 months after recruitment of the first patient.

3.5 Study schematic diagram



3.6 Primary Outcome Measure

1. Capability of patients to use SRAVI as defined by:
    - Measurement of frequency of use.
    - Measurement of words correctly captured.
    - Measurement of frequency of patients who could not use SRAVI and reverted to other communication aids.
2. Acceptability of SRAVI as a communication aid as expressed in qualitative interviews with patients, family and the MDT.

3.7 Secondary Outcome Measures

1. Enrolment: the ability to identify eligible patients over the study period.
2. Consent: the number of patients consenting to be included as a proportion of all patients approached about the study, with reasons for non-consent.
3. Retention and dropout rates:
    - Number of patients who commence the intervention as a proportion of the number recruited, with reasons for non-compliance.
    - Number of patients who continue the intervention as a proportion of the number recruited, with reasons for non-continuation.
    - Qualitative assessment of barriers/facilitators to data collection and participant retention

4. Data collection of outcome measures:
    I. Duration of critical care length of stay
    II. Duration of hospital length of stay
    III. Delirium occurrence during critical care stay (delirium positive on CAM-ICU)
    IV. Clinical outcomes at 3-months post-critical care discharge
        a. Health related Quality of Life measured by the European Quality of Life-5 Dimensions (EQoL-5D)
        b. Anxiety and depression measured by the Hospital Anxiety and Depression Scale (HADS).
        c. Posttraumatic stress measures by the Impact of Events Scale-Revised (IES-R).
        d. Cognitive status measured by the Montreal Cognitive Assessment-BLIND (MOCA-BLIND).
5. Identification of additional important outcomes (by qualitative interviews).

3.8 Study Intervention

All consenting participants will receive access to SRAVI, a communication aid for speech-impaired patients. SRAVI is a software-based mobile application (‘app’) and can be downloaded onto any device with a standard forward facing camera (e.g., smartphone, tablet). SRAVI has been registered with the Medical and Healthcare

products Regulatory Agency (MHRA) and CE marked for intended use. SRAVI is based on LipRead, Liopa's Visual Speech Recognition (VSR) platform. Specifically, the LipRead technology can determine speech by analysing the movements of a user's lips as they speak into a camera. These lip movements are known as visemes and are the visual equivalent of a phoneme or unit of sound in spoken language.

A flow chart showing how the video data is passed through the system is shown in Figure 3. Using the device camera, SRAVI records a video of the patient mouthing a phrase. The patient's ID is entered by the device user. The video file is stored in an archive with restricted access. A record of users and phrases is stored anonymously in a database. This video is sent to a secure server with data encrypted at rest and during transit, meaning that the data cannot be viewed by any third parties. Video clips will be retained for the lifetime of the study to enable Liopa to improve the system over time and to run all data through at the conclusion of the study to provide updated accuracy results. Once the video reaches the server, LipRead technology detects and tracks the lip movements and converts those into text on the device screen within a few seconds (Figure 3). SRAVI can adapt to an individual's lip movements over time, which means it becomes increasingly accurate the more it is used.

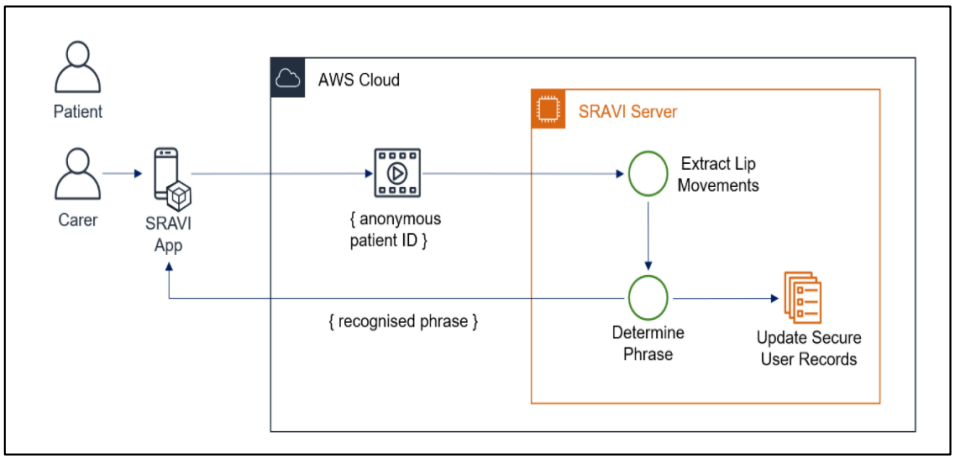


Figure 3: How SRAVI works (51)

4. Screening, recruitment, and consent

4.1 Eligibility Criteria

All patients admitted to the acute and critical care facilities during the study period and fulfilling the following inclusion criteria will be eligible.

4.1.1 Inclusion Criteria

- Patients aged 18 years and over at the time of screening
- Have a tracheostomy in-situ that was inserted during current acute or critical care admission
- Able to communicate in English (a current requirement of the technology)
- Able to move lips in a way that articulates words

4.1.2 Exclusion Criteria

- Patient declined consent

4.2 Recruitment and Screening Procedure

The research fellow will consult members of the acute and critical care team at each study site daily to establish the eligibility of acute and critical care tracheotomised patients. All patients who meet all the inclusion criteria and none of the exclusion criteria will be eligible for inclusion in data analysis. Authorised nursing/medical staff on the delegation log will confirm eligibility. A screening log will be maintained that will include details of the number of participants excluded and the reason for exclusion.

4.3 Consent

4.3.1 Informed Consent Procedure

It is the responsibility of the Principal Investigator (PI) (or designee) to ensure that written informed consent is obtained for each participant prior to entry into the prospective observational cohort study. Consent may be obtained by the PI or an appropriately trained member of the research team. The PI (or designee) taking informed consent must be Good Clinical Practice (GCP) trained, suitably qualified and experienced and have been delegated this duty by the PI on the delegation log.

Where patients' representatives require further clarification about the benefits and risks of participating, this will be provided by the research team.

Critical Care

4.3.2 Informed Advice from Personal Consultee

Patients in critical care are typically incapacitated by the nature of their critical illness such that they are typically unable to give informed consent for participation themselves. The Northern Ireland Mental Capacity Act (52) states that family members or next of kin must be involved in the process of providing advice where their next of kin lacks mental capacity at the time of study recruitment. Once a potential participant has been screened for inclusion, a member of the research team will seek advice from a personal consultee (who may be a relative, partner or friend of the participant). This will normally take place during a face-to face meeting. A research team member will describe the study to the individual, and provide them with a Covering Statement, Information Sheet and Personal Consultee Declaration. The researcher will seek their views about whether the patient should take part in the study. They will be asked about their opinion of the wishes and feelings of the patient if they had capacity.

After the researcher has checked that the information sheet is understood, the researcher will invite the personal consultee to sign the form and will then countersign it. A copy of the form will be placed in the patient's medical notes, a copy given to the personal consultee and the original filed in the study site file. (CRF).

If the personal consultee is not available at site, the researcher may contact the personal consultee by telephone and seek verbal agreement. This verbal agreement will be recorded in the Consultee Telephone Agreement Form. The Consultee Telephone Agreement Form will be signed by a second member of staff who witnessed the telephone advice. This witness may be a member of the site study team or member of the critical care team. A copy of the Consultee Telephone Agreement Form will be placed in the patient's medical notes and the original filed in

the CRF. Written agreement will be obtained as soon as possible and if this is not obtained, a patient will not be recruited into this study.

4.3.3 Approval by a Professional Consultee

In the event that there is no personal consultee, authorisation to recruit the patient will be sought from a professional consultee (a doctor unrelated to the research study team). The professional consultee will be informed about the study by a member of the research team and given a copy of the Professional Consultee Form and a copy of the Covering Statement, Consultee Information Sheet and Consultee Declaration. If the professional consultee decides that the patient is suitable for entry into the study, they will be asked to complete the relevant authorisation form. A copy of the authorisation form will be placed in the patient's medical notes and the original filed in the study site file. In the event that a personal consultee is identified after professional consultee advice is obtained, the above process for Informed Advice from Personal Consultee will be followed and all advice forms will be filed as instructed above.

4.3.4 Informed Participant Consent following recovered mental capacity

If a patient regains capacity to consent, they will be approached by the research fellow who will give them background information on the study and will explain who gave agreement for them to participate in the study. The consent to continue process will include: assessment and documentation of capacity; providing the Patient Information Sheet and Consent Form for Participant with Recovered Capacity; allowing sufficient time for the patient to understand the material and ask questions; obtaining written informed consent. If the patient agrees to continue in the study, they will be asked to sign the Consent Form for Participant with Recovered Capacity Form which will then be counter signed by a member of the research team. The original copy of the Participant with Recovered Capacity Form will be filed in the study site file, a copy filed in the patient's medical notes and a copy provided to the patient.

If the patient refuses consent, the patient will be asked to specify whether they will allow data collected so far to be entered into the analysis. In the situation that the

patient does not consent to any data collected to be used, no data will be entered into the analysis and no further data will be collected. Any video files collected will be deleted. In the rare event that the patient does not regain capacity to consent, analysis will proceed based on the MDT decision to include the patient in the study based on an assessment that it is in the patient's best interest. Participants will be contacted by the research fellow three months' post-critical care discharge to collect long term outcomes. The research fellow will conduct these either face-to-face, virtually or by telephone. Three months has been deemed appropriate as National Institute for Health and Care Excellence (NICE) (53) guidelines advocate a review of patients at this stage to determine the extent of their recovery. Research also indicates that patients will have gained a certain distance from the acute event causing critical illness and therefore it is easier for them to discuss their ICU experience (54-55). If the participant declines on-going participation in the study, no further follow-up will take place.

4.3.5 Informed Consent- Patients with Capacity (Acute Care- Total Laryngectomy)

The study will be discussed with potential participants during their face-to-face preoperative assessment appointment at the outpatient clinic. A member of the research team or a GCP trained member of the clinical team will provide potential participants with a participant information sheet. Upon admission to hospital for surgery, a member of the research team or GCP trained clinical team member will ask patients' views on if they wish to participate in the study and answer any questions they may have. Should they agree to participate in the study, written informed consent will be obtained.

4.3.6 Informed Consent- Patients with Capacity (Acute care-Tracheostomy)

Once a potential participant has been screened for inclusion, a member of the research team will approach the patient where they will describe the study to the individual and provide them with a Participant Information Sheet. The researcher will seek their views about whether they wish to participate in the study. This will normally take place during a face-to face meeting. After the researcher has checked that the information sheet is understood, the researcher will invite the patient to sign the consent form and will then countersign it. A copy of the form will be placed in the

patient's medical notes, a copy given to the patient and the original filed in the study site file. (CRF).

4.4 Detail of Intervention

Following personal or professional consultee advice or informed consent, a patient will be entered into the research study as a participant. Participants will have access to SRAVI ideally on the day they are recruited or within 24 hours of recruitment. Staff will be instructed to offer SRAVI as the first choice of communication aid. This will not preclude participants from using other communication aids normally used in the acute or critical care unit, e.g., communication boards, pen and paper, gesturing, head nods and speaking valves. The SRAVI app will automatically capture frequency of use.

TIDieR item	Descriptor	Item
1	Brief name	A speech recognition app delivered in acute and critical care to tracheostomised patients.
2	Why	To facilitate communication in tracheostomised critical care patients
3	What materials	• Tablets/smartphones • SRAVI app
4	What procedures	SRAVI is held in front of a patient to track their lip movements and identify phrases being mouthed. If the patient is assessed to be well enough, they may hold the device themselves. A video of the patient's face is captured by the device camera and sent to the VSR engine for processing. The phrase being spoken is identified from a pre-defined list and translated to text on the device screen.
5	Who provides	Acute and critical care healthcare professionals (and potentially patient and carers) will provide the intervention and will be appropriately trained to use the intervention.
6	How	Face to face at patient's bedside in acute and critical care
7	Where	Three critical care unit in NI: Royal Victoria Hospital, Belfast, City Hospital, Belfast and Altnagelvin Hospital, Derry and a regional head and neck centre, RVH, Belfast.
8	When and how much	Patients will have continued access to SRAVI from the day they are recruited into the study up until they no longer require the app (or discharge from the acute or critical care facility)
9	Tailoring	Not applicable
10	How well	Not applicable

Table 1: Intervention description using the Template for Intervention Description and Replication (TIDieR) checklist (56).

5. Data Collection and Management

Data collection will be restricted to variables required to define patient characteristics at enrolment; to monitor the use of SRAVI and other communication aids and record any adverse events; to record feasibility and clinical outcomes of this study. All patient data will be collected by the research fellow and recorded on study-specific paper proformas initially at patient's bedside. Information on paper copies will be

transferred to an identical electronic version of these proformas and stored into the study database at QUB. Patient identification on any study-specific proformas will be through their unique trial identifier, allocated to them at the time of recruitment.

All documentation and study records will be stored securely according to applicable legislation and regulatory standards. Access to stored information will be restricted to authorised personnel (i.e., research fellow and academic supervisors). Study documentation and data will be archived after completion of the study in keeping with the applicable regulatory requirements.
Video files captured by the SRAVI app will be stored by Liopa Ltd. in an archive with restricted access. Data will be encrypted at rest and during transit meaning that data cannot be viewed by a third party. A record of users and phrases will be stored anonymously in a database that will only be accessible to the research team.
Written informed consent will be taken prior to any video recording and uploading of images. Video clips will be retained for the lifetime of the study to enable Liopa to improve the system over time and to run all data through at the conclusion of the study to provide updated accuracy results.

5.1 Data Variables

All data will be collected by the research team and recorded in the study case report form (CRF).

5.1.1 Baseline data

The following baseline data for all participants will be collected 24 hours preceding recruitment into study:

- Inclusion/exclusion criteria and eligibility screen
- Sex
- Age on admission to hospital
- Date of acute/critical care admission
- Admission diagnosis
- Date of tracheostomy insertion during acute/critical care

These details will be collected from patients' medical notes and relevant bedside documentation (i.e., observation and medication charts).

5.1.2 Daily data collected

- CAM-ICU score (critical care patients only)
- Frequency of SRAVI delivery
- Compliance with SRAVI use
- Adverse events

5.1.3 Feasibility and clinical outcome data collected in acute/critical care

- Screening
- Recruitment rates
- Adverse events
- Delirium (critical care patients only)

5.1.4 Data collected after critical care discharge

- Duration of critical care stay

Data collected during virtual/telephone/face to face follow-up 3 months following acute or critical care discharge

- Health related quality of life (HRQoL)
- Post-Traumatic Stress Disorder (PTSD)
- Anxiety and depression
- Cognitive status

5.2 Quantitative Study Instruments

Delirium screening is part of standard care across the three critical care study sites. It is determined using the CAM-ICU, a highly sensitive evaluation of delirium in critical care patients (57-59). A healthcare professional completes a series of assessment variables and tests the patient for attention and cognition with a positive result (delirium present) or negative result (no delirium present).

The EQ-5D is a generic health-related quality of life instrument which has been extensively validated and been shown to be reliable across many patient groups including critical care (60-61). It is a brief, simple questionnaire in which respondents

describe their current health state in five dimensions: mobility, ability to self-care, ability to undertake usual activities, pain and discomfort, and anxiety and depression.

Anxiety and depressions will be measured using Hospital Anxiety and Depression Scale (HADS) (62). A 14-item self-administered instrument it has been extensively validated with a review of 747 identified studies (63) concluding that HADS performs well in assessing symptom severity and case level of anxiety disorders and depression in somatic patients and gives clinically meaningful results as a psychological screening tool. The good reliability and stability of HADS have also been successfully demonstrated in in the aftermath of critical illness (64-65).

PTSD will be measured using the Impact of Events Scale (Revised) (IES-R). This is a 22-item self-report measure that assesses subjective distress caused by traumatic events. It is a revised version of the 15-item IES (66) and contains seven additional items related to the hyperarousal symptoms of PTSD. Experts in long-term outcome by consensus have recommended the IES-R as one core outcome measure for mental health following critical illness (67).

Cognitive status will be measured using the Montreal Cognitive Assessment (MoCA)-BLIND screening instrument. This 13-item instrument is a widely used measure in research to evaluate for cognitive impairment. It assesses memory, attention, language, recall, orientation, and abstraction. MoCA is the clinical instrument most applicable to use in the ICU population (68).

5.3 Data Analysis

Descriptive analysis will be used to analyse data from the prospective observational cohort study. Numbers of patients screened, eligible, recruited, consented, and withdrawn from the study will be reported. Baseline demographic and clinical data will be summarised for study participants. Continuous variables will be summarised as mean (standard deviation) and median (interquartile range) and categorical variables will be summarised as number (percent).

Twenty five percent of all data variables collected by the research fellow during baseline, intervention and follow-up phases of this study will be independently

reviewed by another clinician using the baseline, intervention, follow up and quality of life proformas devised for this study.

6 WITHDRAWAL FROM STUDY

Participants may withdraw or be withdrawn (by patient or their Consultee or acute/critical care consultant responsible for their care) from the study at any time without prejudice. If the participant is withdrawn, the treating clinician responsible for their care will determine the safest and most appropriate way to continue the care outside of the study protocol. Only anonymised data recorded up to the point of withdrawal will be included in the study analysis. A log will be maintained that details number of participants withdrawn and the reasons for withdrawal.

7. QUALITATIVE INTERVIEWS AND FOCUS GROUPS

Interviews and focus groups will complement data from the prospective observational cohort study, providing a depth and breadth of understanding regarding the barriers and facilitators to the study design and intervention. Interviews and focus groups will be conducted by the research fellow with skills in interviewing vulnerable populations. Interview schedules and focus group topic guides will be developed from discussions within the research team, the patient advisory group, and from literature around study participation. The schedules/guides will include a pre-defined list of questions that will be informed by the objectives of the study. The schedule/guides will enable all participants to be asked similar questions and thus permit comparison of themes across each subject during data analysis (69). However, it will be flexible enough to allow the interviewer or interviewee to diverge to pursue an idea or response in greater detail.

7.1 Process

7.1.1 Patients and their significant others

Individual, semi-structured, recorded interviews will be conducted with patients and/or their significant others to gain insight into their experience of communication whilst tracheostomised in acute or critical care. Patients/significant others will be approached by a member of the direct care team in the period after critical care discharge and prior to imminent hospital discharge to ascertain if the research team can discuss the study interview with them. If in agreement, a member of the

research team will undertake an assessment of suitability to participate in interviews. If this is not possible, interviews will be carried out at a location and time convenient to participants up to three months following acute/critical care discharge, either in hospital, in participants own homes, by telephone or by virtual online meeting as preferred. Interviews will last between 30-60 minutes.

7.1.2 Acute/Critical care MDT members

Audio-recorded focus groups will be conducted with members of the MDT. Experiences, beliefs, and perceptions in using communication aids, including SRAVI, will be explored in addition to barriers and facilitators about recruitment, retention, and ease of collecting outcomes in the acute/critical care unit. Focus groups will take place either face-to-face, in a suitable location within the workplace, or virtually if necessary. Staff will be invited to take part in the study during working hours with the permission of their line manager. Each focus group will last between 30-60 minutes.

If due to availability of clinical staff and if for participant convenience an individual interview is preferred, then an interview will take place. Interviews will take place either face-to-face, in a suitable location within the workplace, or virtually if necessary. Staff will be invited to take part in the study during working hours with the permission of their line manager. Each interview will last between 20-45 minutes.

7.2 Consent

7.2.1 Patients and/or significant others

Patients and relatives will be approached by a member of the direct care team to ascertain if they are willing to be contacted by the research team about participation in the study. Consent-to-be-contacted forms will also be available for interested relatives to complete. Consent will then be taken at the point of invitation by a member of the research team. A participant information sheet will be provided to patients and/or significant others who express an interest in joining the study. The participant information sheet will inform potential participants about the purpose of the qualitative interviews and what their role will be as well as their rights.

7.2.2 Acute/Critical care MDT members

Acute and critical care staff will be informed about the study aims and methods at team meetings and daily briefs. A participant information sheet will be provided to staff who express an interest in joining the study. Posters outlining details of the study will be displayed at appropriate locations in each participating facility. Posters will include contact details that interested staff can email should they wish to participate.

Consent-to-be-contacted forms will also be available in each unit and interested staff can complete this form and leave it in a 'voting box' in a specified location on the ward for retrieval by study personnel. Acute and critical care MDT members' participation will start at the point of consent and finish at the end of the focus group or interview. At the time of focus groups or interviews, participants will be asked to review the study information sheet and sign a consent form, or verbally agree if the meeting is virtual.

7.3 Qualitative Data Collection

With the permission of participants, all interviews and focus groups will be audio recorded and professionally transcribed verbatim using an authorised transcription service. All identifying information will be removed prior to analysis. Transcriptions will be reviewed and verified prior to analysis by the research fellow by comparing the audio and written versions to identify errors. Following transcription, audio-recordings will be deleted.

Subject to legislative requirements, including the UK General Data Protection Regulation (UKGDPR) (70), all transcripts and consent forms will be securely stored either electronically on a password-protected computer or in a locked cabinet in QUB to which only the research team will have access. Consent forms will be locked separately from transcripts.

7.4 Qualitative Data Analysis

Analysis will be carried out concurrent with data collection so that new information can be incorporated into subsequent interviews. Qualitative data will be subjected to a thematic analysis, using Newell and Burnard's (71) framework. This approach will permit an inductive process of drawing out important data-driven themes and a deductive process relating the major themes that emerge to the pre-defined objectives of the research. A process of constant comparison, reading, and re-

reading of the data will enable identification of emerging themes. The process will be facilitated by using a computer-assisted qualitative data software package, NVIVO.

To reduce the element of lone researcher bias and to make analysis more rigorous, codes will be verified by a second party, the research fellow's supervisor. This has been chosen in favour of participant validation which may be hindered by participants changing their perceptions because of temporal effects post critical illness or potential changes in their situations. To further promote integrity and reliability during the data analysis process, other strategies will be introduced. Field notes will be written immediately after each interview and a reflective diary maintained, aiming to reduce the potential for the researcher's values, beliefs, and preconceptions to influence subsequent findings.

8. SAFETY REPORTING

This study is considered to be low risk as the intervention is a communication aid, carrying minimal health risks. SRAVI has been registered with the MHRA, and CE marked for intended use. In line with MHRA guidance, the device will fully comply with the requirements of The Medical Device Regulations (2017/745).

8.1 Definitions

All adverse events (AEs) which occur during the course of participants' involvement in this study will be appropriately recorded and reported in order to ensure their continuing safety. AEs will be classified according to the following categories:

- Adverse Event
- Adverse Device Effect (ADE)
- Serious Adverse Event
- Serious Adverse Device Effect (SADE)
- Unanticipated Serious Adverse Device Effect (USADE)

8.1.1 Adverse Event

An AE is defined as any untoward medical occurrence in a study participant. Events and complications associated with the patient's underlying medical condition will not be considered adverse events (AE).

8.1.2 Adverse Device Effect (ADE)

An Adverse Event (AE) related to the use of an investigational medical device. This includes any AE resulting from insufficiencies or inadequacies in the instructions for use, the deployment, implantation or operation of the medical device or any malfunction. This also includes any AE that is a result of an error in use or intentional misuse of the medical device.

8.1.3 Serious Adverse Event

A serious adverse event (SAE) is defined as an untoward occurrence that:

- Results in death
- Is life-threatening
- Requires hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability or incapacity
- Is any other important medical event(s) that carries a real, not hypothetical, risk of one of the outcomes above

8.1.4 Serious Device Effect (SADE)

An Adverse Device Effect (ADE) that results in:

- Death
- Life threatening illness or injury
- Hospitalisation, or prolongation of existing hospitalisation
- Persistent or significant disability or incapacity
- Is otherwise considered medically significant by the Investigator

8.1.5 Unanticipated Serious Adverse Device Effect (USADE)

Serious adverse device effect which by its nature, incidence, severity, or outcome has not been identified in the current version of the risk analysis report.

8.2 Assessment of Causality

AEs will be clinically assessed by the PI or medically qualified designee at each study site for causality based on the available information, i.e., the relationship of the AE to the intervention. Causality assessment decisions must be made by a medically qualified doctor. For the purposes of this study the causality should be assessed using the categories below.

Unrelated: There is no evidence of any causal relationship to the medical device
Unlikely: The relationship with the use of the investigational medical device seems not relevant and/or the event can be reasonably explained by another cause.
Possible: The relationship with the use of the device is weak but cannot be ruled out completely
Probable: The relationship with the investigational medical device seems relevant and/or the event cannot be reasonably be explained by another cause.
Causal Relationship: The serious event is associated with the investigational medical device beyond reasonable doubt.

8.3 Reporting and Recording

AEs and SAEs will be recorded and reported for each patient until acute/critical care discharge. All reported AEs and SAEs will be recorded in the medical notes of the patients.

Risks within this study are considered to be minimal. It is considered highly unlikely that participants will suffer any adverse consequences as a result of receiving SRAVI plus usual care. If in the opinion of a registered medical practitioner in acute/critical care, an SAE that occurs to a research participant is classified as:

- Related: that is, it resulted from delivery of the intervention, and

- Unexpected: that is, the type of event or complication not expected or associated with the patient's underlying medical condition and recovery period in acute/critical care

then the CI will be responsible for expedited reporting of the SAE to the sponsor and the REC which issued the favourable ethical opinion. This will be done within 24 hours of the event occurring. If it is determined that the serious adverse event is related, then the intervention will be promptly discontinued and recorded in case report form.

Low risk to participants will be further ensured through confidential and anonymous storing of their data and giving participants the opportunity to express their thoughts and opinions about the intervention they received without judgement or influence. The research team will ensure that the needs of the study are not placed above the wellbeing of participants. Although physical harm is unlikely in this study, risks can also include psychosocial harm. Traumatic memories may be triggered, and questions asked during interviews might bring to the surface distress which participants might wish to discuss. As an experienced critical care nurse, the research fellow will undertake interviews. Should any participant become distressed the interview will be stopped. Additionally, the research fellow will plan for provision of information about services which participants might solicit to discuss their needs.

The research team will also be sensitive to the expectations and opinion of participants regarding potential benefits of the research. Prior to the commencement of the study, the research fellow will formally discuss these expectations with individuals. Participants will also be debriefed at the study conclusion to provide information, clarify any issues or misconceptions and to monitor any negative effects which were unforeseen and require intervention.

9. End of study

The study will be stopped prematurely if:

- Mandated by REC
- Mandated by the Sponsor
- Funding for the study ceases

The REC that originally gave a favourable opinion of the study will be notified in writing once the study has been concluded or if it is terminated early.

10. ETHICAL & REGULATORY CONSIDERATIONS

Ethical Approval: The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki. To protect the rights, safety wellbeing and dignity of the participants who may potentially be involved in this study, the study protocol will be approved by the Office for Research Ethics Committees Northern Ireland.

Good Clinical Practice: The study will comply with the principles of GCP, the requirements and standards set out by the EU directive 2001/20/EC and the applicable regulatory requirements in the UK and the Research Governance Framework.

10.1 Access to Study Data

In agreement with the CI, the study team will provide direct access to source data and study related documentation for all study related monitoring, audits, ethics committee review and regulatory inspections. Consent from patients and/or family members for direct access to data will also be obtained. The patients' confidentiality will be maintained and will not be made publicly available to the extent permitted by the applicable laws and regulations.

10.2 Study Committees

Data integrity and study credibility depends on factors such as ensuring adherence to study protocols and using quality control measures to establish high standards for data quality.

10.2.1 Study Management Group

The Study Management Group (SMG) will be established and chaired by the CI. This group will have responsibility for the day-to-day operational management of the study and regular meetings of the SMG will be held to discuss and monitor progress. The discussions of the SMG will be formally minuted and a record kept in the Main Study

File. A SMG consisting of the CI, research fellow and nominated co-investigators will meet bi-monthly, and the CI will chair meetings.

10.2.2 Patient advisory group

The patient advisory group has been convened and will be involved for the duration of the study until summary findings have been disseminated to the general public and relevant acute/critical care patient groups. This group involves six adults who previously experienced a tracheostomy whilst in acute/critical care. They have been involved and formed part of a larger focus group (including general members of the public) who were consulted when the research fellow was developing the proposed intervention for this study. They have provided valuable feedback on the proposed intervention and patient-related materials for this study (i.e., consent forms, patient information leaflets). They have also provided novel insights for the study team on the outcomes that were important to them while tracheostomised in acute/critical care. All past-patient members of the focus group reported that their main outcome from a communication intervention would be for it to be easy to use and enable better understanding between healthcare professionals, relatives, and patients. The research fellow will agree to keep the patient advisory group updated on study developments as the study progresses. At the end of the study, the research fellow and the patient advisory group will co-design and co-write the lay summary of findings from this study, which will be disseminated to members of the general public and laryngectomy and intensive care-related patient and family support groups.

10.3 Sponsorship

QUB will act as Sponsor for the study and the CI will take overall responsibility for the conduct of the study.

10.4 Funding

This study is funded by the Research and Development Division of the Public Health Agency (PHA), NI as part of a Doctoral Fellowship.

10.5 Contributorship

The CI and all co-investigators contributed to the study design and along with the SMG were involved in the development and finalisation of the protocol.

10.6 Patient and Public Involvement

This study has a patient advisory group. Details outlined in section 10.2.2 of this protocol.

10.7 Competing interests

There are no conflicts of interest in this study and no commercial funding provided for this project. The project has been funded by the Research and Development division of the PHA, NI.

10.8 Indemnity

QUB will provide indemnity for the negligent and non-negligent harms caused to patients by the design of the research protocol.

10.9 Study protocol compliance

A protocol deviation is defined as an incident which deviates from the normal expectation of a particular part of the study process. Any deviations from the protocol will be fully documented.

A serious breach is defined as a deviation from the study protocol or GCP which is likely to effect to a significant degree:

- The safety or physical or mental integrity of the subjects of the study
- The scientific value of the study

The site principal investigator will be responsible for ensuring that serious breaches are reported directly to the CI and Sponsor within one working day of becoming aware of the breach.

10.9.1 Protocol amendments

The CI will conduct the study in compliance with the protocol given approval/ favourable opinion by the Ethics Committee and the appropriate regulatory authority. Changes to the protocol may require competent authority/ethics committee

approval/favourable opinion prior to implementation, except when modification is needed to eliminate an immediate hazard to patients. The CI in collaboration with the sponsor will submit all protocol modifications to the competent authority/research ethics committees for review in accordance with the governing regulations. Any deviations from the protocol will be fully documented on the protocol deviation form in the case report form.

10.9.2 Patient confidentiality

The participant's study identifier, name, address, and other contact details of all patients will be kept separate. The CI or co-investigator will keep these details in a locked filing cabinet. All documentation regarding the study will identify the patients by the assigned unique study identifier. Computers where information will be stored will be password protected. Patient confidentiality will be maintained at every stage and will not be made publicly available to the extent permitted by the applicable laws and regulations. Due care will be taken to ensure data safety, integrity, and compliance with the Data Protection Act.

11. DISSEMINATION POLICY

11.1 Study results

The prospective observational cohort study will be reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (71). To ensure adequate reporting of qualitative data, the Consolidated Criteria for Reporting Qualitative Research (COREQ-32) item checklist (72), a consolidated reporting framework for qualitative designs will be followed.
Dissemination will be achieved in several ways. We will present findings at national and international meetings with open access abstracts online. We will also aim to publish the findings in high quality peer-reviewed open access journals. This will ensure that results are readily accessible to the public, healthcare professionals and scientists. We will also share a summary of the main study findings with ICU Steps (a patient support group for members of the public who have experienced a critical care stay in the past) and relevant laryngectomy support groups. We will also disseminate results to the British Association of Critical Care Nurses (BACCN), the Global Tracheostomy Collaborative and Intensive Care Society.

11.2 Authors

The CI, co-investigators and members of the study team who contributed to the design, conduct, interpretation, and reporting of this study will be recognised by granting them authorship on the final study report.

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