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Interventions to enable communication for adult patients requiring an artificial airway with or without mechanical ventilator support (Protocol)

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[Intervention Protocol]

Interventions to enable communication for adult patients requiring an artificial airway with or without mechanical ventilator support

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

The primary objective of this review is to assess the effectiveness of communication aids for patients requiring an artificial airway (endotracheal or tracheostomy tube), defined as the proportion of patients able to:

- use a non-vocal communication aid to communicate at least one symptom, need or preference; or
- use a voice enabling communication aid to phonate to produce at least one intelligible word.

Secondary objectives are to assess the effects on:

- time to communication (non-vocal aid) of a symptom, need or preference or time to phonation of intelligible speech (voice enabling aid);
- patient and/or communication partner (family, friend, caregiver or healthcare professional with whom a patient may interact) reported perceptions of communication including: ease/difficulty, satisfaction/frustration, aid/technique usability and acceptability/unacceptability;
- communication frequency, quality, success, and efficiency;
- health-related quality of life/satisfaction with life;
- emotional and psychological distress;
- length of stay and healthcare utilisation costs; and

- adverse events including: respiratory instability (altered respiratory rate; oxygen desaturation); haemodynamic instability (tachy/bradycardia; hyper/hypotension); need for tracheostomy change; use of physical restraints; treatment interference.

BACKGROUND

Description of the condition

Provision of interventions to enable patient communication is a fundamental patient right (Joint Commission 2010). For patients requiring an artificial airway, establishing communication is particularly challenging. An artificial airway is established through endotracheal intubation (a tube inserted through the mouth or nose into the trachea) or a tracheostomy (a tube inserted into the trachea through a surgical opening in the neck). The trachea is the windpipe that conveys air from the larynx (the voice box that contains the vocal cords) to the lower airways of the lungs during breathing. Patients that require an artificial airway include those that require invasive mechanical ventilation (breathing support from a machine) in an intensive care unit (ICU), or another acute care location such as a specialised centre for mechanical ventilator weaning or step down/up or intermediate care unit. Patients with chronic respiratory failure (inability to breathe adequately for an extended period and without recovery of lung function) may require a tracheostomy and invasive mechanical ventilation in the long term in care locations such as a hospital ward, rehabilitation unit, long-term care centre, or living in the home. This prolonged exposure to an artificial airway results in prolonged impairment of communication and reliance on communication aids (Huttmann 2018). An artificial airway without invasive mechanical ventilation may be required for secretion management or because their own airway is damaged or inflamed (swollen) after mechanical ventilation is discontinued.

To facilitate invasive mechanical ventilation, the endotracheal or tracheostomy tube has an inflatable cuff (balloon) that inflates into the trachea. When inflated, the cuff directs all gas (air plus an enhanced oxygen supply) to the patient's lungs via the endotracheal or tracheostomy tube. The cuff stops any airflow from the patient's lower airways reaching the larynx and the vocal cords during expiration (breathing out). This laryngeal airflow causes the vocal cords to vibrate which enables phonation (production of speech) (McGrath 2018), and is how voice is generated under normal conditions. For patients experiencing inability to communicate with their own voice, alternative and augmentative communication methods are needed. Unaided communication relies on mouthing words, gestures, nodding, body language and facial expressions. However, mouthing words is frequently difficult to understand and subject to misinterpretation (Carroll 2004). Reduced muscle strength and altered cognition (ability to think) also may make unaided communication methods difficult for patients to use and difficult for communication partners to interpret. Options for aided communication include non-vocal aids i.e. *visual-based* augmentative and alternative communication aids including writing equipment, communication boards or digital apps that convey symptoms and basic needs without generating speech. Other non-vocal *sound-based* augmentative and alternative communication aids include speech generating aids that generate static and dynamic digitised sound such as voice output communication aids (VOCA), speech generating software, and eye gaze technology. Another speech generating option is the electrolarynx, a device that generates sound (not voice) via transmission of vibration through soft tissue, which is recognisable as speech with movement of the lips, tongue, and jaw (articulators) (Shimizu 2013).

For patients with prolonged need for invasive mechanical ventilation and tracheostomy, vocal communication can be restored by voice enabling aids that reestablish airflow through the larynx. Most voice enabling aids require deflation of the cuff of the artificial airway. Cuff deflation and the reestablishment of voice can be considered part of the weaning process i.e. the process that establishes unsupported breathing (Ambrosino 2018). However, the ability to tolerate cuff deflation depends on the patient's cough strength enabling effective clearance of mucous, and bulbar (nerve) function enabling swallowing of saliva (Hunt 2015). Acquired swallowing disorders associated with artificial airways are common and, during cuff deflation, may cause saliva, liquids, food, or vomit to enter the lungs with devastating consequences such as pneumonia (lung infection), pneumonitis (lung inflammation), the need to reinsert an endotracheal or tracheostomy tube, prolonged ICU length of stay, and death (Macht 2013). In patients in whom cuff deflation may be unsafe, certain voice enabling aids achieve vocal communication by delivery of a supply of air between the inflated cuff and the vocal cords. A glossary of terms can be found in Appendix 1.

Description of the intervention

For the purposes of this review, one or more of the following communication aids or techniques are interventions eligible for inclusion. We will group communication aids into the following categories:

- non-vocal aids i.e. augmentative and alternative communication aids using visual-based communication
- speech generating aids i.e. augmentative and alternative communication aids using sound-based communication that is

not the patient's own voice

- voice enabling aids or techniques that require cuff deflation
- voice enabling aids that do not require cuff deflation or without a cuff

Augmentative and alternative communication is an umbrella term that includes unaided and aided communication that supplements or replaces verbal communication. Voice enabling aids or techniques facilitate return of the patient's own voice and therefore do not fit under this umbrella term (ASHA 2019) (Figure 1).

Figure 1.

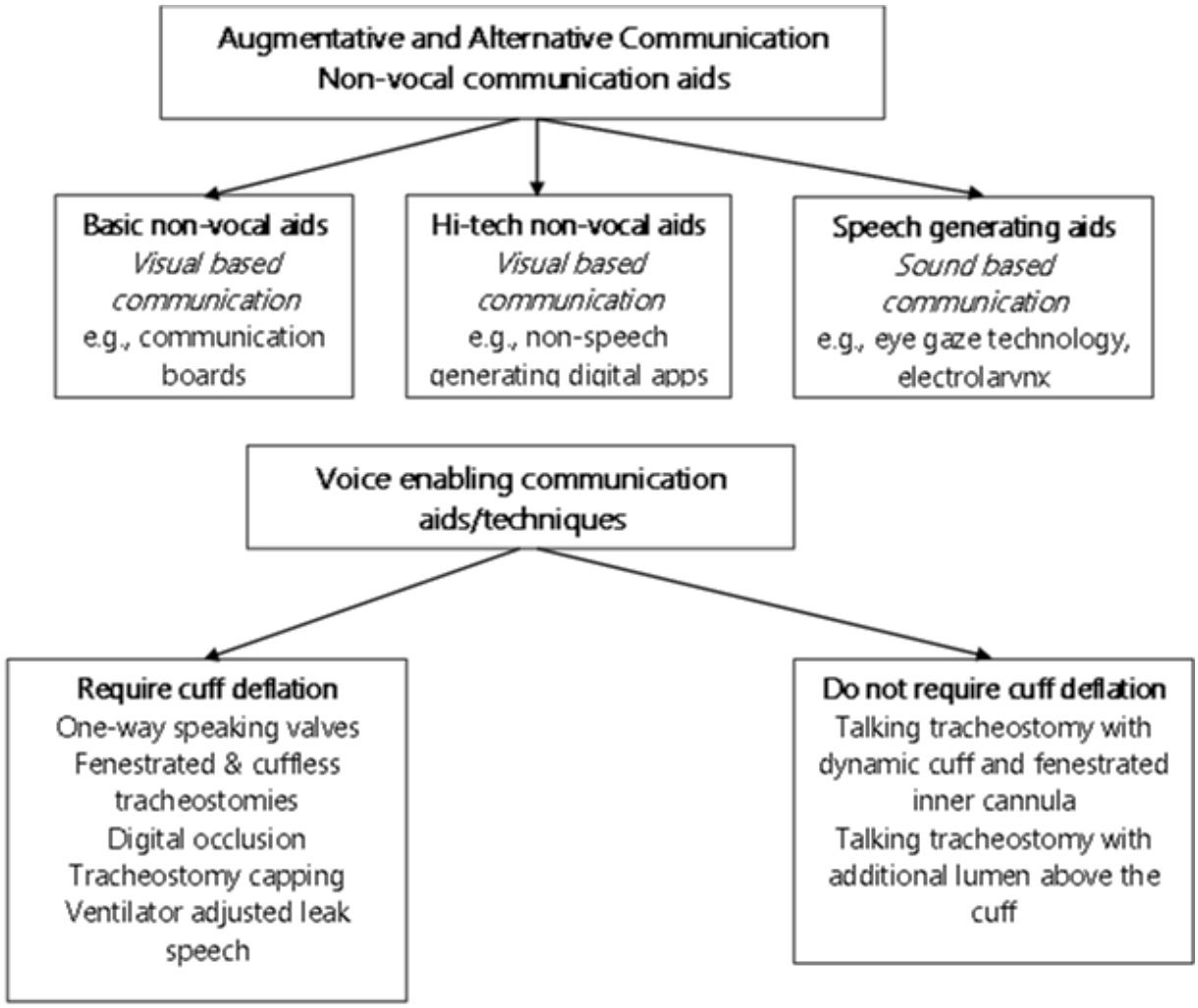

Figure 1: Communication Enabling Aids

Augmentative and alternative communication: non-vocal aids

Basic non-vocal visual augmentative and alternative communication aids include pen and paper or other writing equipment, communication board comprising letters, words or pictures, or communication cards again comprising letters, words or pictures. High tech non-vocal visual augmentative and alternative communication aids include computer software programs and digital applications that do not generate speech such as the Society of Critical Care Medicine Patient Communicator app (https://itunes.apple.com/us/app/patient-communicator/id732242570?mt=8) for use on tablets or smart phones. These visual communication aids require hand dexterity coordination and muscle strength as well as intact cognitive abilities. These abilities may be compromised due to extreme physical stress and fatigue, muscle weakness, and emotional or psychological distress, all of which are common to patients experiencing critical illness (Chlan 2015; Menzel 1998). Dexterity, muscle strength, and nerve function may also be compromised or absent in patients with neuromuscular disorders (disorders that affect muscle and nerve function), or those with total loss of nerve innervation such as patients requiring an artificial airway and breathing support due to high spinal cord injury. Other disadvantages of basic and high technology visual communication aids include being imprecise, cumbersome, costly, and prone to breakage (Hashmi 2010).

Augmentative and alternative communication: speech generating aids

Speech generating augmentative and alternative communication aids are those that use sound based communication that is not the patient's own voice. Speech-generating aids convert text to generate static and dynamic digitalised (uses human voice), synthesised (computer-generated) speech, (or a combination thereof) and include voice output communication aids (VOCAs), text to speech digital apps and software, and eye-gaze technology. Eye-gaze technology uses near infrared micro-projectors, optical sensors, image processing, and mathematical models to determine eye position and gaze point (Garry 2016). By gaze dwelling on text or symbols, patients can generate speech. Again, speech generating aids have significant limitations associated with cognitive and fine or gross motor capacity, time required to generate messages, and lack of device familiarity (Happ 2004).

The electrolarynx, or artificial larynx, is a distinct type of speech generating augmentative and alternative communication aid that enables phonation with movement of the articulators but does not restore the patient's own voice. It also does not produce digitised speech and therefore is dissimilar to other speech-generating aids. The electrolarynx transmits electronic sound source vibrations through soft tissue, either at the neck, at the level of the glottis, or less commonly the cheek. Although phonation may be relatively easy to achieve with an electrolarynx, intelligibility of speech may be impaired in patients who are dysarthric (those who have weakness or difficulty controlling the muscles used for speech) or those who have an endotracheal tube in place (Rose 2018). Other barriers to use of the electrolarynx include muscle strength and coordination to enable appropriate device placement and to hold the device in place.

Voice enabling communication aids requiring cuff deflation or without a cuff

Voice enabling communication aids and techniques, i.e. those that aid return of patient voice, include those that require artificial airway cuff deflation and those that do not as they deliver a supply of air between an inflated cuff and the vocal cords. Voice enabling communication aids that require cuff deflation include one-way speaking valves such as the Passy Muir® or Montgomery® speaking valves that open on inspiration allowing gas from the upper airway into the trachea and close on expiration thus diverting gas to the vocal cords. Other voice enabling communication aids requiring cuff deflation include speaking or fenestrated tracheostomy tubes. Fenestrated tracheostomies have an additional opening on the shaft of the tube that directs gas towards the vocal cords. Voice enabling communication techniques, i.e. those that enable return of patient voice and require cuff deflation but do not require an aid include digital occlusion of the tracheostomy tube, tracheostomy capping, and ventilator adjusted leak speech. Digital occlusion involves covering of the opening of the tracheostomy tube with a gloved finger. With the cuff deflated, digital occlusion or placing a cap on the tracheostomy tube opening (capping) again redirects the flow of gas from the patient's upper airway to the vocal cords (Morris 2015). Ventilator adjusted leak speech requires the ventilator (breathing machine) to be adjusted to give bigger breaths during inspiration to compensate for loss of gas due to the deflated cuff. As humans normally speak during expiration, patients need training to time speech with the inspiratory phase of gas delivery from the mechanical ventilator (Hoit 2003; Morris 2015). Another option is a cuffless (a tube without a balloon) tracheostomy tubes that are used for patients with prolonged need for a tracheostomy and ability to swallow their own saliva. Similar to a deflated cuff, the absence of the cuff means some of the airflow is directed to the larynx enabling speech.

Voice enabling communication aids without cuff deflation

Voice enabling communication aids that do not require cuff deflation include more recently developed talking tracheostomy designs such as the Blom® tracheostomy system (Pulmodyne, Indianapolis, IN); the Portex® Trach-Talk™ Blue Line® Tracheostomy Tube (Smiths Medical, Dublin, OH); and the Bivona® Mid-Range Aire-Cuf® and Fome-Cuf® Tracheostomy Tubes with Talk Attachment (Smiths Medical, Dublin, OH). The Blom® tracheostomy system comprises a fenestrated, cuffed tracheostomy tube combined with a proprietary speech inner cannula (Adam 2015; Kunduk 2010). An inner cannula is an additional tube

placed within the tracheostomy tube, which is more commonly used for enabling cleaning of the tracheal lumen to prevent mucus build up. At the end of inspiration (breathing in), a flap valve closes the end of the tracheotomy tube. Increasing pressure forces a second bubble valve to collapse allowing gas to pass through the fenestrations to the vocal cards. The Portex® Trach-Talk™ Blue Line® Tracheostomy Tube and the Bivona® Mid-Range Aire-Cuf® and Fome-Cuf® Tracheostomy Tubes with Talk Attachment have an additional lumen above the cuff through which gas is administered to facilitate phonation. However, a disadvantage of this additional lumen is that it quickly becomes encumbered by secretions which cannot easily be removed (Pandian 2014).

How the intervention might work

Non-vocal, speech generating and voice enabling communication aids or techniques help patients with artificial airways to alert healthcare workers to troublesome and distressing symptoms, express needs and preferences, participate in decision-making relating to care goals, and, in some cases, end-of-life, and to interact with family members and loved ones (Grossbach 2011). A recent randomised controlled trial of early cuff deflation and insertion of a one-way speaking valve during mechanical ventilation including 30 tracheostomised patients undergoing prolonged ventilator weaning demonstrated earlier return to phonation with few adverse events (Freeman-Sanderson 2016). There is some evidence that communication aids influence patient satisfaction (Stovsky 1988), increase communication frequency, and decrease difficulty associated with communication (Happ 2014). Identification of communication aids that effectively meet individual patient needs may relieve emotional and psychological distress including anxiety, agitation, frustration, and loneliness; and improve symptom identification, sleep, patient safety, outlook and sense of recovery, quality of and satisfaction with life (Freeman-Sanderson 2018; Huttmann 2018).

Why it is important to do this review

Inability to communicate is one of the top stressors for patients with an artificial airway (endotracheal or tracheostomy tube) in critical care, long-term care, or home environments (Huttmann 2018; Johnston 1990; Rose 2014a). Being unable to communicate when critically ill and requiring an artificial airway has negative outcomes that include: significant emotional distress (anxiety, panic, anger, agitation, loss of control); unrecognised pain and delirium; and sleeplessness (Breckenridge 2014; Khalaila 2011; Menzel 1998 Stein-Parbury 2000). Qualitative studies characterise patient recall of inability to communicate during mechanical ventilation as frustrating, challenging, troublesome, and horrid (Flinterud 2015; Guttormson 2015). A qualitative study of communication for individuals receiving home ventilation described their experience in terms of a long and lonely struggle to find a voice (Carroll 2007; Laakso 2011). Other deleterious consequences in ICU settings due to agitation associated with an inability to communicate include increased use of physical restraints, treatment interference such as patient removal of the endotracheal tube, intravenous lines or nasogastric tubes (tube placed in the stomach) or catheters (tube placed in the bladder or other locations of the body). Other negative consequences of agitation arising from inability to communicate include injury to self and healthcare professionals (Bartlett 2008). Patient inability to communicate in a manner that can be understood also creates stress and frustration for family members (Broyles 2012) and healthcare professionals (Magnus 2006; Nilsen 2014), and limits patient ability to participate in care decisions. For individuals with chronic respiratory insufficiency requiring tracheostomy in long-term care or home environments, inability or impaired ability to communicate negatively influences quality of life and life satisfaction (Huttmann 2018), psychological functioning, independence, and social interactions (Carroll 2007).

Communication impairment during hospitalisation has implications for the quality and safety of care and is a modifiable risk factor for adverse events (Bartlett 2008). The Joint Commission, a healthcare-organisation accreditation organisation in the US, has produced standards that mandate identifying patients' oral and written communication needs and undertaking reasonable efforts to establish alternative communication strategies for patients unable to speak (Joint Commission 2010). Therefore, healthcare organisations and providers are obliged to identify and use the most effective methods to augment patient communication and restore patient voice.

Despite the well-recognised deleterious consequences of inability to communicate using other means, there is evidence of variable and, in some cases, limited adoption of communication aids and lack of prioritisation of communication by healthcare professionals (Happ 2011). A 2013 Canadian survey of 201 Canadian intensive care units found only 11% used high tech visual- or sound-based communication aids and 30% did not use one-way speaking valves (Rose 2014b). A 2016 systematic review of communication aids for mechanically ventilated patients in the ICU unable to tolerate cuff deflation identified 29 studies including randomised, quasi-randomised and observational studies (Ten Hoorn 2016). All studies had small sample sizes, were judged low- to moderate-quality, and only four had a comparator group. Importantly, this review excluded studies of voice enabling communication aids for patients able to tolerate cuff deflation. These authors presented a narrative review identifying four communication types; low tech communication boards, speaking tracheostomy tubes used with an inflated cuff, the electrolarynx, and high-tech sound generating aids, all of which were found to improve communication ability. These authors used their data to suggest a communication algorithm and recommend multi-component communication interventions be adopted in the ICU individualised to patient need (Ten Hoorn 2016).

Our systematic review will summarise the evidence and assess the

effectiveness of communication aids for patients that require an artificial airway (endotracheal or tracheostomy tube) with or without cuff deflation irrespective of care location. It therefore updates and extends previous systematic reviews that focussed only on an ICU population, or that excluded communication aids for patients able to tolerate cuff deflation. This will inform clinical practice with the aim of enabling decisions about effective and individualised communication aids and techniques for this patient population. Through the conduct of this review, we will identify evidence gaps that will inform future research related to communication aids for patients requiring an artificial airway with or without cuff deflation. At present, it is unclear which communication aids are most effective for the range of patients requiring an artificial airway. Our proposed review aims to address this uncertainty and will be relevant to patients; communication partners including family members, friends, caregivers and healthcare professionals working with patients requiring an artificial airway; healthcare decision makers; and researchers working in this field.

OBJECTIVES

The primary objective of this review is to assess the effectiveness of communication aids for patients requiring an artificial airway (endotracheal or tracheostomy tube), defined as the proportion of patients able to:

- use a non-vocal communication aid to communicate at least one symptom, need or preference; or
- use a voice enabling communication aid to phonate to produce at least one intelligible word.

Secondary objectives are to assess the effects on:

- time to communication (non-vocal aid) of a symptom, need or preference or time to phonation of intelligible speech (voice enabling aid);
- patient and/or communication partner (family, friend, caregiver or healthcare professional with whom a patient may interact) reported perceptions of communication including: ease/difficulty, satisfaction/frustration, aid/technique usability and acceptability/unacceptability;
- communication frequency, quality, success, and efficiency;
- health-related quality of life/satisfaction with life;
- emotional and psychological distress;
- length of stay and healthcare utilisation costs; and
- adverse events including: respiratory instability (altered respiratory rate; oxygen desaturation); haemodynamic instability (tachy/bradycardia; hyper/hypotension); need for tracheostomy change; use of physical restraints; treatment interference.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised, quasi-randomised (a trial in which randomisation is attempted but subject to potential manipulation, such as allocating participants by day of the week, date or birth, or sequence of entry into trial), and controlled parallel group trials without randomisation as we anticipate that few, if any, properly randomised controlled trials will have been conducted in the area of communication or speech aids for patients requiring an artificial airway. We will exclude randomised cross-over trials. As we anticipate improving the ability to communicate using communication or speech aids for patients requiring an artificial airway with or without mechanical ventilation may be considered a quality improvement imperative, we will include controlled before and after (CBA) studies.

We will include CBA studies meeting the following criteria:

- At least two intervention sites and two control sites;
- The timing of study periods for control and intervention groups is comparable (i.e. pre- and post-intervention periods of measurement are the same); and
- Intervention and control groups are comparable on key characteristics such as study population and intervention evaluated.

Types of participants

We will include studies reporting on adults aged 16 and over that required an artificial airway with or without invasive mechanical ventilation and their communication partners (family members, friends, caregivers and healthcare professionals). Adults may be receiving care in an ICU, specialised centre for mechanical ventilator weaning, step down/up or intermediate care unit, hospital ward, rehabilitation, long-term care, or be living in the home. We will document the reason for the artificial airway, type of artificial airway, length of time requiring an artificial airway prior to study enrolment, need for mechanical ventilation, as well as the presence of pre-existing conditions such as dementia, stroke, aphasia, dysarthria, dyspraxia, developmental disability, or other impairment of speech language or cognition.

We will exclude studies of children under 16 years of age due to developmental issues associated with communication and ability to complete measures as well as the role parents assume in communication.

Types of interventions

We will include studies that evaluate an intervention that includes a non-vocal (visual or speech generating) communication aid or a voice enabling communication aid (Figure 1) used for patients with an artificial airway (endotracheal or tracheostomy tube) with or without invasive mechanical ventilation.

We will include the following as comparisons:

- Usual practice that does not include routine or standardised use of communication aids;
- Usual practice that includes non-vocal or voice enabling communication aids used as standard of care;
- Active comparator i.e. non-vocal or voice enabling communication aids not used as standard care.

We will exclude the following communication aids or techniques:

- Communication aids used during non-invasive ventilation (i.e. ventilation delivered via a mask) for enhancing voice audibility as non-invasive ventilation does not require an artificial airway e.g. the Dolores One acoustic throat sensor;
- Communication aids used for enhancing voice audibility without any form of mechanical ventilation as these are used without an artificial airway; and
- Oesophageal and tracheoesophageal speech as these are techniques that cause mucosal vibration in the pharyngoesophageal segment (nasal cavity to top of oesophagus) used in patients following laryngectomy (removal of the voice box) and do not require an artificial airway (Van Sluis 2018).

Types of outcome measures

We will not use reported outcomes as a criterion for including studies.

Primary outcomes

Depending on the nature of the intervention (non-vocal or voice enabling aid) under investigation, our primary outcome is the proportion of patients able to:

- use a non-vocal communication aid to communicate at least one symptom, need or preference; or
- use a voice enabling communication aid to phonate to produce at least one intelligible word.

Secondary outcomes

Our secondary outcomes include:

- Time to communication (non-vocal aid) of a symptom, need or preference or time to phonation of intelligible speech (voice enabling aid);
- Patient and/or communication partner (family, friend, caregiver or healthcare professional with whom a patient may interact) reported perceptions of communication including: ease/difficulty, satisfaction/frustration, aid/technique usability and acceptability/unacceptability;
- Communication frequency, quality, success, and efficiency;
- Health-related quality of life/satisfaction with life;
- Emotional and psychological distress;
- Length of stay and healthcare utilisation costs; and
- Adverse events including: respiratory instability (altered respiratory rate; oxygen desaturation); haemodynamic instability (tachy/bradycardia; hyper/hypotension); need for tracheostomy change; use of physical restraints; treatment interference.

Main outcomes for 'Summary of Findings' (SoF) table

We will include the following outcomes in our SoF table.

- Proportion of study participants able to communicate a symptom, need, or preference; or phonate or produce intelligible speech;
- Health-related quality of life/satisfaction with life;
- Emotional and psychological distress;
- Length of stay and healthcare utilisation costs;
- Adverse events including: respiratory instability (altered respiratory rate; oxygen desaturation); haemodynamic instability (tachy/bradycardia; hyper/hypotension); need for tracheostomy change due to secretion encumbrance; use of physical restraints; treatment interference.

Search methods for identification of studies

Electronic searches

We will search electronic databases from inception to present time including the most recent issue of MEDLINE (OvidSP), Embase (OvidSP), CINAHL (EBSCOhost), and ISI Web of Science. We present the search strategy for MEDLINE (OvidSP) in Appendix 2. This search strategy has been iteratively developed between the research team and an experienced information specialist. We will tailor the search strategy to other databases and present in our review. The core search strategy will be reviewed prior to execution by another senior information specialist using the Peer Review for Electronic Search Strategies (PRESS) template (McGowan 2016). We will apply a filter to remove animal-only studies and opinion pieces (e.g. editorials, letters). We will not impose language or other restrictions. We will apply the 2008 Cochrane Highly Sensitive Search Strategy filter for randomised controlled trials as well as a filter for non-randomised intervention studies.

Searching other resources

We will search the Cochrane Library which includes the Cochrane Database of Systematic Reviews (DSR), Cochrane Central Register of Controlled Trials (CENTRAL), Database of Abstracts

of Reviews of Effects (DARE), the Health Technology Assessment Database (HTA database) and the NHS Economic Evaluation Database (NHS EED). We will search for systematic reviews using PROSPERO and the Joanna Briggs Institute EBP Database. We will perform a grey literature search of relevant databases and web sites using resources listed in Canadian Agency for Drugs and Technologies in Heath's (CADTH) Grey Matters (http://www.cadth.ca/en/resources/finding-evidence-is/grey-matters). We will search for unpublished studies and ongoing trials on the International Clinical Trials Registry Platform (http://apps.who.int/trialsearch). We will examine reference lists of relevant studies and reviews and will contact corresponding authors of included studies for details of additional published or unpublished work and advice as to other relevant studies.

Data collection and analysis

Selection of studies

Two authors (LR, A-LS) will independently screen titles and abstracts of electronic and manual search results to identify citations possibly meeting eligibility criteria. We will retrieve and two authors will independently examine for eligibility the full-text publications of all potentially relevant articles identified by either author. We will resolve any disagreements though discussion and, if unable to achieve consensus, will refer to an independent arbiter (AA). All potentially-relevant papers excluded at this stage will be listed as excluded studies, with reasons for exclusion provided in the 'Characteristics of excluded studies' table. We will provide citation details and available information on eligible ongoing studies. We will collate and report details of duplicate publications, so that each study (rather than each report) is the unit of interest in the review. We will report the screening and study selection process in an adapted Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow chart (Liberati 2009).

Data extraction and management

Two authors in pairs (CD, AA or OS, NH) will extract data independently from eligible studies. We will develop and pilot and iteratively refine a data extraction form using a modified version of the Cochrane Consumers and Communication Group Data Extraction Template (available at: http://cccrg.cochrane.org/author-resources). We will extract the study aim, study design, inclusion and exclusion criteria, participant characteristics, description of the intervention and comparison group, description of training of participants and/or communication partners in use of the non-vocal communication or speech aid, study outcomes, study results including complications and adverse events, funding source, and study author declaration of interests. Any discrepancies will be resolved by discussion until consensus is reached, or through consultation with a third author (LR), where necessary. All extracted data will be entered into RevMan (Review Manager 2014) by one review author (LR), and will be checked for accuracy against the data extraction sheets by a second review author working independently (A-LS). For CBA studies, we will also extract data on confounding factors, methods used to control confounding, and multiple effects estimates.

Assessment of risk of bias in included studies

We will assess and report on methodological risk of bias of included studies based on guidance from the Cochrane Handbook (Higgins 2011) and the Cochrane Consumers and Communication Review Group (Ryan 2013). For RCTs, two authors in pairs (CD, AA or OS, NH) will assess independently the risk of bias in the following domains: random sequence generation; allocation sequence concealment; blinding (participants, personnel); blinding (outcome assessment); completeness of outcome data; selective outcome reporting; and other sources of bias including role of the study funder and investigator declaration of interest. We will determine blinding separately for different outcomes as blinding has the potential to differently affect subjective versus objective outcome measures.

These two assessors will judge independently each domain as being at high, low, or unclear risk of bias based on the criteria provided by Higgins 2011. We will provide a quote from the study report that illustrates our assessment and a justification for our judgement for each item in the risk of bias table. Disagreements on judgements relating to risk of bias will be resolved by discussion to reach consensus, and referred to a third author (LR) if consensus cannot be reached. We will contact study authors for additional information enabling clarification of study methods to inform our assessment of risk of bias, as required.

Studies will be deemed to be at high risk of bias if they are scored as being at high or unclear risk of bias for either the sequence generation or allocation concealment domains, based on growing empirical evidence that these factors are particularly important potential sources of bias (Higgins 2011). We will determine quasi-RCTs as being at a high risk of bias for the random sequence generation domain of the 'Risk of bias' tool. We will assess CBA studies against the same criteria as RCTs but report them as being at high risk of bias on both the random sequence generation and allocation sequence concealment items. We will exclude CBA studies that are not reasonably comparable at baseline.

Measures of treatment effect

Given the expected methodological heterogeneity, we will present individual study and pooled effect estimates separately for randomised and quasi-randomised trials, and for CBA studies. For dichotomous outcomes including proportion of participants able to phonate, produce intelligible speech, or communicate, and adverse events, we will analyse data based on the number of events

and the number of people assessed in both intervention and comparison groups. For each study, we will calculate risk ratios (RRs) with 95% confidence intervals (CIs). Pooled risk ratios and 95% CIs will be calculated using a DerSimonian and Laird random-effects model. For continuous outcomes including self-reported quality of life measures, we will calculate the study level mean difference (MD) and associated 95% CI. Pooled weighted mean differences and 95% CIs will be calculated using the inverse of the variance method for weighting. If more than one study measures the same outcome using different tools, we will calculate the pooled standardised mean difference (SMD) and 95% CI weighted by using the inverse variance method in Review Manager (Review Manager 2014). For CBAs, we will calculate RR with 95% CIs for dichotomous outcomes and SMDs and 95% Cis for continuous outcomes.

Unit of analysis issues

For parallel group design trials, we will use individual study participants as the unit of analysis. If we identify multi-arm studies, we will first aim to combine groups to create a single pairwise comparison, as recommended by the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). If combining groups is not possible or feasible, we will select only one treatment and control group from each study. If we identify relevant cluster-randomised RCTs, we will check for unit-of-analysis errors. If errors are found, and sufficient information is available, we will reanalyse the data using the appropriate unit of analysis, by taking into account the intracluster correlation (ICC). We will obtain estimates of the ICC by contacting authors of included studies, or impute them using estimates from external sources. If it not possible to obtain sufficient information to reanalyse the data, we will report effect estimates and annotate these as 'unit-of-analysis errors'.

Dealing with missing data

We will attempt to contact study authors (maximum of 3 emails) to obtain missing data (participant, outcome, or summary data). For participant data, we will, where possible, conduct analysis on an intention-to-treat basis; otherwise, data will be analysed as reported. We will report on the loss to follow-up and assess as a source of potential bias.

Assessment of heterogeneity

Where studies are considered similar enough (based on consideration of study populations, and interventions) to allow pooling of data using meta-analysis, we will assess the degree of clinical and methodological heterogeneity with visual inspection of forest plots of trial-level effects and by examining the Chi² test for heterogeneity. We will quantify heterogeneity using the I^2 statistic with $I^2 > 50\%$ representing substantial heterogeneity (Higgins 2011). However, we will interpret this value considering the size and direction of effects and the strength of the evidence for heterogeneity, based on the P value from the Chi² test ($P < 0.05$, considered significant heterogeneity) (Higgins 2011).
Where we detect substantial clinical, methodological, or statistical heterogeneity across included studies, we will not report pooled results from the meta-analysis but will use a narrative approach to data synthesis. We will attempt to explore possible clinical or methodological reasons for this variation by grouping studies that are similar in terms of study population and intervention type to explore differences in intervention effects.

Assessment of reporting biases

We will assess reporting bias qualitatively based on the characteristics of the included studies (e.g. if only small studies that indicate positive findings are identified for inclusion), and if information that we obtain from contacting experts and authors of studies suggests that there are relevant unpublished studies. To assess publication bias, if we identify 10 or more studies, we will construct a funnel plot of the treatment effect for the primary outcome against trial precision (standard error) and formally test for funnel plot asymmetry (Eggers 1997; Peters 2006).

Data synthesis

We will provide a descriptive synthesis of the key demographic and clinical data from the identified studies. We will meta-analyse data if there are sufficient studies with interventions that are similar enough in terms of participants, settings, intervention, comparison, and outcome measures to ensure meaningful conclusions from a statistically pooled result. We will analyse and present data from randomised trials and quasi-RCTs and from CBAs separately, but compare narratively. Due to the anticipated variability in the populations and interventions of included studies, for binary outcomes, we will calculate pooled risk ratios and 95% CIs using a DerSimonian and Laird random-effects model. For continuous outcomes, we will calculate the study level MD and associated 95% CI. Pooled weighted mean differences and 95% CIs will be calculated using the inverse of the variance method for weighting. If required, we will log transform continuous skewed data. If more than one study measures the same outcome using different tools, we will calculate the pooled standardised mean difference (SMD) and 95% CI weighted by using the inverse variance method in Review Manager (Review Manager 2014).
If an outcome is reported within the same study using two types of measurement (e.g, self-report of communication frequency versus independent observation) we will report both results narratively but will include only the measure at least risk of bias (i.e. independent observation, in this scenario) in analyses of treatment effect. If multiple time-points are measured and reported for the same outcome within a study, we will include the result reported most

proximally to receiving the intervention. If multiple time-points are identified across studies, we will perform subgroup analyses of these time points if sufficient studies are available. For studies enrolling participants in an ICU, we will include ICU length of stay and healthcare utilisation costs as opposed to those reported after ICU.

If we are unable to pool the data statistically using meta-analysis, we will provide a narrative synthesis of results. We will present the results pertaining to our review outcomes organised by intervention categories (e.g. non-vocal aids versus voice enabling aids) and by population (e.g. acute or critical care setting versus long-term care or home setting). Within these categories, we will explore the following comparisons:

- Usual practice that does not include routine or standardised use of communication aids;
- Usual practice that includes non-vocal or voice enabling communication aid used as standard of care; and
- Active comparator i.e. non-vocal or voice enabling communication aids not used as standard of care.

Subgroup analysis and investigation of heterogeneity

If we identify sufficient studies, we will perform statistical subgroup analyses using appropriate interaction tests of (1) intervention categories (e.g. non-vocal aids versus voice enabling aids); and (2) by study population (e.g. acute or critical care setting versus long-term care or home setting). Further, if we have sufficient studies, we will perform statistical subgroup analyses within intervention categories i.e. comparing low versus high tech non-vocal aids and comparing voice enabling aids that require cuff deflation and those that do not. If there are too few included studies to warrant statistical subgroup analyses, we will narratively explore relationships in the data according to these subgroups.

Sensitivity analysis

If we identify sufficient studies, we will conduct a sensitivity analysis for the primary outcome, excluding studies determined to be at highest risk of bias. If randomised and quasi-randomised trials are identified, we will conduct a sensitivity analysis removing the quasi-randomised trials.

Summary of findings table

We will prepare a 'Summary of findings' table presenting the results of synthesis, informed by methods described in chapter 11 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2011). We will present the results of synthesis (meta-analysis or narrative synthesis) for major comparisons and review outcomes, as outlined in the Types of outcome measures section. We will provide a source and rationale for each assumed risk cited in the table, and will use the GRADE system to rank the quality of the evidence using the GRADEprofiler (GRADEpro) software (Schünemann 2011).

Assessing the quality of the evidence

We will assess and report evidence quality using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system for each outcome in the following domains: study limitations, consistency, imprecision, indirectness, and publication bias. Two authors will independently assess evidence quality as implemented and described in the GRADEprofiler (GRADEpro) software (Schünemann 2011).

Ensuring relevance to decisions in healthcare

This protocol was informed by consultation with key stakeholders with expertise and decision-making authority in speech language pathology as well as two consumer referees (family caregiver for a patient experiencing acute endotracheal intubation and subsequent prolonged ventilation requiring tracheostomy and use of communication aids). The protocol and review will receive feedback from at least one consumer referee in addition to a health professional as part of the Cochrane Consumers and Communication Group's standard editorial process.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. Glossary of terms

Alternative and augmentative communication aids: basic and high tech aids that facilitate communication. These aids do not include aids or techniques that restore patient voice i.e. non-vocal communication aids.
Articulators: lips, tongue and jaw
Artificial airway: tubes to assist breathing required to deliver breathing support from a machine
Bradycardia: slow heart rate
Bulbar function: function of the nerves that control swallowing
Catheter: tube placed in the bladder or other locations of the body
Chronic respiratory failure: inability to breathe adequately for an extended period and without recovery of lung function
Cognition: ability to think
Communication partner: family member, friend, caregiver or healthcare professional with whom a patient may interact
Cuffless tracheostomy tubes: a tracheostomy tube without a balloon that separates the airways from mouth/nose/voicebox
Digital occlusion: covering of the opening of the tracheostomy tube with a gloved finger to divert airflow to the vocal cords
Digitised speech devices: devices that use recorded human speech
Electrolarynx: a device that generates sound (not voice) via transmission of vibrations through soft tissue under the jaw or on the cheek, which is recognisable as speech with movement of the lips, tongue and jaw
Endotracheal intubation: a breathing tube inserted through the mouth or nose into the trachea

Expiration: breathing out
Eye-gaze technology: Users focus their eye gaze on words or phrases which a computer system generates into speech.
Fenestrated tracheostomy: tube with an additional opening on the shaft of the tube that directs gas towards the vocal cords
Hyper/hypotension: high or low blood pressure
Inflatable cuff: balloon towards the base of an endotracheal or tracheostomy tube that inflates into the trachea separating the airways from mouth/nose/voicebox
Inner cannula: additional tube placed within the tracheostomy tube which is more commonly used for enabling cleaning of the tracheal lumen to prevent mucus build up
Inspiration: breathing in
Invasive ventilation: breathing support from a machine via an artificial airway
Larynx: voice box that contains the vocal cords
Mechanical ventilation: breathing support from a machine. Breathing support from a machine can be provided via an artificial airway and is referred to as invasive mechanical ventilation. Alternatively, breathing support from a machine can be provided via a mask and is referred to as non-invasive ventilation.
Nasogastric tube: tube placed in the nose that runs all the way to the stomach
Non-invasive ventilation: breathing support from a machine provided via a mask
Non-vocal communication aids: communication aids that do not restore the patient's own voice
Phonation: production of speech
Pneumonia: infection of the lungs
Pneumonitis: inflammation of the lungs
Synthesised speech devices: devices that use computer- generated speech
Tachycardia: fast heart rate
Trachea: windpipe
Tracheostomy: a tube inserted into the trachea through a surgical opening in the neck
Treatment interference: patient removal of the endotracheal tube, intravenous lines or nasogastric tubes (tube placed in the stomach) or catheters (tube placed in the bladder or other locations of the body)
Upper airway: the nose, nasal cavity, mouth, throat, and the part of the windpipe above the voice box
Voice enabling communication aids: communication aids that restore the patient's own voice
Voice output communication aid: electronic speech generating device
Weaning: the process that establishes breathing that is not supported by a breathing machine

Appendix 2. MEDLINE search strategy

1 exp Respiration, Artificial/
2 exp Ventilators, Mechanical/
3 ((artificial* or mechanical*) adj3 (respirat* or ventilat*)).tw,kf.
4 artificial airway?.tw,kf.
5 (high-frequency adj3 ventilat*).tw,kf.
6 ((assist* or support* or wean*) adj3 (respirat* or ventilat*)).tw,kf.
7 ((liquid or fluorocarbon or fluoro-carbon) adj3 ventilat*).tw,kf.
8 (invasive* adj3 ventilat*).tw,kf.
9 controlled ventilation.tw,kf.
10 (airway pressure release adj3 ventilat*).tw,kf.
11 APRV.tw,kf.
12 IPPB.tw,kf.
13 Airway Extubation/
14 exp Intubation, Intratracheal/
15 (intubat* or extubat* or detubat*).tw,kf.
16 Tracheostomy/
17 tracheo?tom*.tw,kf.
18 (endotrachea* adj3 (tube? or tubat* or ventilat*)).tw,kf.
19 Ventilator Weaning/

20 (ventilat* adj3 (wean* or liberat*)).tw,kf.
21 or/1-20 [INVASIVE MECHANICAL VENTILATION/TRACHEOSTOMY]
22 Communication/
23 exp Communication Barriers/
24 Communication Disorders/
25 exp Nonverbal Communication/
26 communicat*.tw,kf.
27 Phonation/
28 phonat*.tw,kf.
29 Communication Aids for Disabled/
30 ((speech or speak* or talk* or voice?) adj3 (aid? or app or apps or application* or board? or device? or digital* or software or technolog* or tool?)).tw,kf.
31 (artificial larynx* or electrolarynx* or electro-larynx*).tw,kf.
32 ((speech or speak* or talk* or voice?) adj3 electronic*).tw,kf.
33 ((speech or speak* or talk* or voice?) adj3 synthesi*).tw,kf.
34 ((fenestrat* or speech or speak* or talk* or voice?) adj3 tracheo?tom*).tw,kf.
35 ((speech or speak* or talk* or voice?) adj3 valve?).tw,kf.
36 (VOCA or VOCAs).tw,kf.
37 ((eye or eyes) adj2 (gaze? or gazing) adj3 (aid? or app or apps or application* or board? or device? or digital* or software or technolog* or tool?)).tw,kf.
38 ((gaze? or gazing) adj3 (text or symbol?)).tw,kf.
39 or/22-38 [COMMUNICATION/BARRIERS/DEVICES]
40 21 and 39 [COMMUNICATION/BARRIERS/DEVICES - INVASIVE MECHANICAL VENTILATION/TRACHEOSTOMY]
41 exp Child/ not (exp Adult/ or Adolescent/)
42 exp Infant/ not (exp Adult/ or Adolescent/)
43 40 not (41 or 42) [CHILD-/INFANT-ONLY REMOVED]
44 (controlled clinical trial or randomized controlled trial).pt.
45 clinical trials as topic.sh.
46 exp Randomized Controlled Trials as Topic/
47 (randomi#ed or randomi#ation? or randomly or RCT? or placebo*).tw,kf.
48 ((singl* or doubl* or trebl* or tripl*) adj (mask* or blind* or dumm*)).tw,kf.
49 trial.ti.
50 or/44-49 [RCTS]
51 controlled clinical trial.pt.
52 Controlled Clinical Trial/ or Controlled Clinical Trials as Topic/
53 (control* adj2 trial*).tw,kf.
54 Non-Randomized Controlled Trials as Topic/
55 (nonrandom* or non-random* or quasi-random* or quasi-experiment*).tw,kf.
56 (nRCT or nRCTs or non-RCT?).tw,kf.
57 Controlled Before-After Studies/
58 (control* adj3 ("before and after" or "before after")).tw,kf.
59 or/51-58 [QUASI-RANDOMIZED, CBA]
60 43 and 50 [RCTS]
61 43 and 61 [QUASI-RANDOMIZED, CBA]
62 62 or 63 [RCTS, QUASI-RANDOMIZED, CBA]
63 exp Animals/ not (exp Animals/ and Humans/)
64 64 not 65 [ANIMAL-ONLY REMOVED]
65 (comment or editorial or news or newspaper article).pt.
66 (letter not (controlled clinical trial or randomized controlled trial)).pt.
67 66 not (67 or 68) [OPINION PIECES REMOVED]

CONTRIBUTIONS OF AUTHORS

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Undertaking manual searches: LR

Screening search results: LR, ALS

Organizing retrieval of papers: LR

Screening retrieved papers against inclusion criteria: LR, ALS

Appraising quality of papers: AA, NH, OS, CD

Abstracting data from papers: AA, NH, OS, CD

Writing to authors of papers for additional information: LR

Providing additional data about papers: LR

Obtaining and screening data on unpublished studies: LR

Data management for the review: LR

Entering data into Review Manager 5 (Review Manager 2014): LR

Review Manager 5 statistical data: LR, DF

Other statistical analysis not using Review Manager 5: DF

Interpretation of data: All authors

Statistical inferences: All authors

Writing the review: All authors

Securing funding for the review: LR

Performing previous work that was the foundation of the present study: Not applicable

Guarantor for the review (one author): LR

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Louise Rose: none known

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Orla Smith: none known

Craig Dale: none known

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