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Advancing practice in voice rehabilitation with **VITAL**
A novel **voice** **t**herapy **a**pproach for people with **l**aryngectomy

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Thesis submitted in fulfilment of the requirements for the degree of
Doctor of Philosophy



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June 2024

DECLARATION

I, Freya Sparks, confirm that the work presented in this thesis is my own.
Where information has been derived from other sources, I confirm that this has
been indicated in the thesis.

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ABBREVIATIONS |

AHP	Allied health professional
ASHA	American Speech-Language-Hearing Association
BAHNO	British Association of Head and Neck Oncologists
CASA-Q	Cough and Sputum Assessment Questionnaire
COM-B	Capability, Opportunity, Motivation – Behaviour model
DAG	Diversity advisor group
dB	Decibels
EMST	Expiratory muscle strength training
EORTC	European Organisation for Research and Treatment of Cancer
ESRC	Economic and Social Research Council
FEV1	Forced expiratory volume in one second
GRBAS	Grade, Roughness, Breathiness, Aesthenia, Strain scale
GRIPP2	Guidance for Reporting Involvement of Patients and Public short-form
HCP	Healthcare professionals
HCPC	Health and Care Professions Council
HME	Heat-moisture exchanger
HPV	Human papillomavirus
MDT	Multidisciplinary team
MEP	Maximum expiratory pressure
MPT	Maximum phonation time
MRC	Medical Research Council
NALC	National Association of Laryngectomy Clubs
NHS	National Health Service
NHLBI	National Heart, Lung and Blood Institute
NICE	National Institute for Clinical Excellence
NIHR	National Institute for Health Research
PAG	Patient advisory group
PEDRO	Physiotherapy Evidence Database
PF	Peak Flow

PICO	Population, Intervention, Comparison, Outcome
PRISMA	Preferred reporting items for systematic reviews and meta-analyses
PROSPERO	Prospective register of systematic reviews
PWL	People/person with laryngectomy
PWL-B	People/person with laryngectomy from the Bengali community
QOL	Quality of life
RCSLT	Royal College of Speech and Language Therapists
ROBIN-T	Risk of bias in N-of-1 trials
ROI	Republic of Ireland
RTSS	Rehabilitation Treatment Specification System
SECEL	Self-Evaluation of Communication Experiences after Laryngectomy
SHI	Speech Handicap Index
SLP	Speech and Language Pathologist
SLT	Speech and Language Therapist / Therapy
STOPS	Sunderland Tracheoesophageal Voice Perceptual Scale
SRQR	Standards for Reporting Qualitative Research
TIDieR	Template for Intervention Description and Replication
UK	United Kingdom
VHI/VHI-10	Voice Handicap Index and Voice Handicap Index short form
V-RQOL	Voice-Related Quality of Life questionnaire

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ABSTRACT|

BACKGROUND:

Laryngectomy is a surgical procedure which results in the permanent removal of the larynx. Laryngectomy has a devastating impact on communication; and it is no longer possible to produce voice in a conventional manner. Surgical voice restoration is an alternative communication modality offered to people with laryngectomy (PWL), which is consistently shown to give favourable outcomes for quality of life and satisfaction when compared with other post-laryngectomy communication methods. However, whilst surgical voice restoration enables PWL to produce an alternative voice, called tracheoesophageal voice, quality varies significantly and may be difficult to establish. There is an absence of communication interventions for PWL and limited literature to inform clinical practice. Furthermore, PWL have not been included in research or intervention development as stakeholders. This study encompassed aspects of the preliminary development phase of a novel voice therapy intervention for tracheoesophageal speakers.

AIMS:

1. To establish current knowledge, identify and evaluate existing evidence on tracheoesophageal voice rehabilitation
2. To understand what approaches SLTs currently use in clinical practice, and to identify barriers and facilitators to implementation of tracheoesophageal voice therapy
3. To establish the views, experiences and priorities of PWL regarding tracheoesophageal voice rehabilitation
4. To identify the potential components of a novel tracheoesophageal voice therapy

METHODS:

Intervention development aligned to the Medical Research Council framework for developing and evaluating complex interventions. Patient and diversity advisory groups informed the study design. The following methodologies were used to meet the corresponding aims above:

1. Systematic literature review of behavioural interventions for tracheoesophageal voice
2. A survey of UK and Irish SLTs' clinical practice and beliefs
3. Qualitative study using focus group methodology with PWL
4. Co-design study with PWL and SLT stakeholders; and a small study testing the feasibility of Expiratory Muscle Strength Training with PWL

OUTCOMES:

The study found existing evidence for tracheoesophageal voice rehabilitation is insufficient to inform clinical practice. SLTs were motivated to provide intervention, however, the lack of evidence and clinical guidelines, and insufficient resourcing were barriers to implementation. Qualitative, feasibility and co-design studies established that PWL want a personalised, collaborative intervention that embeds impairment-based voice interventions in a holistic framework to support activity and participation.

CONCLUSIONS:

The study has identified the components of an acceptable intervention through stakeholder co-design and feasibility study. This has culminated in a preliminary theory, informed by stakeholder partnership. The findings will guide further development and refinement of the intervention, leading towards feasibility testing of a novel tracheoesophageal voice therapy intervention, which is acceptable and meaningful to PWL.

PERSONAL STATEMENT |

The roots of this research stem from two places. A feeling of curiosity and a feeling of frustration about not being able to do more for people with laryngectomy. During my time as a PhD student, I have noticed that people have a tendency to ask, why? What drives you to undertake a doctoral project? The simple answer is the wish to know more, to offer more and, ultimately, to make things better for the people I work with.

I qualified as a Speech and Language Therapist (SLT) in 2008. Early on in my training I knew I wanted to work with adults, and I was drawn to the specialism of ENT and Head and Neck Cancer. For a newly qualified SLT there is rarely a direct route into the specialism and posts can be scarce. The first years of my career were therefore spent across inpatient caseloads, working within general surgery and trauma, neurosurgery and acute medicine where I could gain experience of tracheostomy and altered anatomy. I would volunteer each week to trail along with the visiting ENT doctor who provided a satellite service to the hospital; offering to carry a heavy, old-fashioned light box for the nasendoscope, which I would clean in exchange for a glimpse at images and ad hoc learning as we walked between wards.

Over time the bartering paid off and I joined an ENT / Head and Neck cancer team in 2010. I recall being rather nervous of the Clinical Lead SLT when I started in post and the learning curve was steep. However, seven years later, I was the Clinical Lead myself with all the experience and clinical competencies that brings. Yet despite my experience, I found myself constrained with the rehabilitation that I was offering to our laryngectomy community. I did not feel that I was doing enough or had sufficient rehabilitation approaches available to provide the support that service users deserved.

In particular, this troubled me in relation to our tracheoesophageal speakers. After laryngectomy, surgical voice restoration is often referred to as the gold standard of communication restoration. This term is problematic, however. The notion of a gold standard suggests that there is nothing better; so where does this leave people who are unhappy with

their ‘gold standard’ voice? As a person without a laryngectomy, I cannot begin to comprehend the devastation of complete voice loss. Voice is more than just a sound or a means of communication; it is part of our identity and contributes to our sense of self. Telling someone they have the best option available, when they are deeply troubled by their altered voice, became increasingly uncomfortable.

I was curious about what other SLTs were doing in their clinical practice with tracheoesophageal speakers. I soon came to realise that, as SLTs, we were not fully addressing voice rehabilitation for people with laryngectomy and instead this work was missed in the competing priorities of a prosthesis change or supporting other needs within a short appointment time. I recall spending a morning delivering outpatient voice therapy to non-cancer patients. My afternoon followed in a laryngectomy clinic and I began to question why was I not using the same morning’s voice therapy approaches to support voice prosthesis users. There was a clear mismatch between my practice of benign and oncological voice rehabilitation. Rather than consider what was transferrable, I had compartmentalised these two service user groups.

These moments led to many informal conversations with colleagues and people with laryngectomy that gradually shaped the research idea. As a person aligned to, but not living with, laryngectomy I have privilege in regard to communication. I am fortunate to have a voice which is congruous with my identity, which matches my appearance and sounds ‘normal’. As the treating SLT, it may be perceived that I hold power within the therapeutic relationship. I did not, therefore, want to make assumptions about what people with laryngectomy wanted or felt. Nor did I want to assume that tracheoesophageal voice needed ‘fixing’ against a laryngeal voice standard. Further conversations with people with laryngectomy demonstrated that voice change was hugely significant, yet for various reasons optimisation was not being raised or addressed overtly within SLT sessions. The issue was important for many people with laryngectomy. The PhD focus group study would later go on to explore the experience of tracheoesophageal voice use in detail, echoing and expanding sentiments raised in these formative discussions of the research idea.

I am grateful to the people with laryngectomy who gave space to have these conversations. They presented me with a rationale for the research, championed the need for this study, shaped the research idea, encouraged me and gave me the 'why' to complete this work. Of course, there remains much to be done in the field of tracheoesophageal voice rehabilitation; this thesis is the beginning of a workstream in this emergent area. I look forward to continuing with the guidance and support of our service users.

CHAPTER 1 | INTRODUCTION

This doctoral study reports on the development of a novel communication intervention for people with laryngectomy (PWL). The intervention aims to address the significant communication impairment produced as an unavoidable consequence of laryngectomy, a surgical treatment for advanced head and neck cancer. Specifically, the study centres on the development of a voice therapy intervention for people who use a voice prosthesis to communicate after laryngectomy (tracheoesophageal speakers). The study aligns to phase one (developing the intervention) of the Medical Research Council (MRC) updated framework for developing and evaluating complex interventions (Skivington et al., 2021).

This chapter provides background information and outlines the aims and stages of the study. Head and neck cancer, laryngectomy, tracheoesophageal voice and related impacts are described and contextualised. Chapters Two to Seven inform intervention development. Chapter two explains tracheoesophageal voice production in detail and contrasts this with laryngeal voice production, to provide a theoretical basis for adapting voice therapy interventions to alaryngeal voice. Chapter Three consists of a systematic review, which identifies and critically appraises the existing evidence base within this clinical area. Chapter Four establishes the current picture of communication rehabilitation after laryngectomy through a survey of United Kingdom (UK) and Irish Speech and Language Therapists' (SLT) clinical practice. In Chapter Five, focus group methodology is used to understand the experience, views and priorities of tracheoesophageal speakers. Chapter Six reports on the use of co-design workshops with service users and stakeholders to refine the intervention. Chapter Seven investigates the use of expiratory muscle strength training (EMST) after laryngectomy to explore the feasibility of incorporating this training into a tracheoesophageal voice intervention. In Chapter Eight the overall results and outcomes of the doctoral study are discussed.

The MRC framework for complex intervention development (Skivington et al., 2021) outlines four iterative phases: intervention development, feasibility, implementation and evaluation.

This study is situated in the intervention development phase of the MRC framework with the aim of leading to later testing of feasibility and acceptability of a novel intervention. Further guidance on what the intervention development phase should include is elaborated by O’Cathain et al. (2019) and provides a scaffold for this study. Table 1.1 illustrates the key actions of the additional guidance and shows how they relate to the components of this study; the key actions are proposed as dynamic and non-sequential.

Action and Processes	Study components
Plan the development process. Identify the problem to be targeted and refine it. Assess whether an intervention is needed. Obtain sufficient resources for the intervention development.	Pre-doctoral clinical experience and patient engagement work informed the research proposal for the doctoral study. Funding acquired for study.
Involve stakeholders who will deliver, use and benefit from the intervention. Work closely with stakeholders throughout the development. Integrate stakeholder involvement into the process. Identify the best ways of working with stakeholder groups.	Convening of a Patient Advisory Group and Diversity Advisor Group at the start of the study. Use of co-design with stakeholders (Chapter Six).
Bring together a team and establish decision-making processes. Include people with relevant expertise. Agree on a process for making decisions.	Establishment of a supervisory team of experts in intervention development methodologies and the clinical specialism. Agreement on roles and responsibilities.
Review published research evidence. Review existing evidence to identify existing interventions and to establish the evidence for each component of the intervention.	Completion of a systematic review of tracheoesophageal voice therapy (Chapter Three).
Draw on existing theories. Identify existing theories to inform the intervention, at the start of the process.	Drawing on the theoretical basis of laryngeal voice therapy to identify transferrable components (Chapter Two).

Action and Processes	Study components
	Building on existing research on the use of EMST (Chapter Seven).
Articulate programme theory. Develop a programme theory that draws on existing theories, represented by a logic model.	Discussion (Chapter Eight) synthesises thesis outcomes and presents a preliminary framework.
Undertake primary data collection. Use a wide range of research methods to explore the context of the intervention and to measure change in intermediate outcomes.	The study applies qualitative and quantitative research methods and partnership approaches (Chapters Four-Seven).
Understand context for future implementation of the intervention. Understand the context in which the intervention is implemented and the factors that may affect implementation. Identify barriers and facilitators to future implementation of the intervention.	A survey of clinical practice was completed (Chapter Four) which explores SLTs' barriers to implementation. Focus groups (Chapter Five) and co-design (Chapter Six) further inform the context from service user and SLT perspectives
Define and refine the intervention. Generate ideas about content, format and delivery with stakeholders.	The use of co-design with SLT and service user stakeholders to generate and trial intervention content (Chapter Six). The feasibility of EMST as a component of the intervention is assessed (Chapter Seven)
End the development phase. Describe the intervention to support translation outside of the study. Write up the intervention development process so that quality can be assessed, and the processes can be evaluated.	The intervention development process is written up within this thesis and disseminated. Intervention components and preliminary programme theory are described (Chapter Eight).

Table 1.1: Intervention development framework adapted from O'Cathain et al., 2019

1.1. PATIENT AND PUBLIC INVOLVEMENT AND ENGAGEMENT

Stakeholder involvement was central to all stages of the doctoral study to ensure the study was meaningful and relevant to PWL. Patient and public involvement and engagement work commenced at the pre-doctoral stage, to inform the doctoral study proposal. A small grant was awarded from the National Institute of Health Research (NIHR) Enabling Involvement Fund to support two patient engagement groups for the pre-doctoral work. In total the groups were attended by six PWL and one spouse of a PWL, consisting of four male and three female attendees. The group commented on the overall concept of the doctoral study, concluding that it was an important area to research and providing agreement with the proposed study design. Participants emphasised that PWL should be strongly involved in the ongoing study and queried whether the study could be run in partnership with an industry partner. On discussion participants acknowledged that industry partnership would not be feasible during the doctoral study, however, it was agreed that dissemination of study findings to industry partners and leading equipment suppliers would be an important aspect of the final dissemination and research impact plan.

On commencement of the doctoral study a Patient Advisory Group (PAG) was convened to inform the progression of the study and provide feedback and guidance. The PAG included five PWL, of which three were male and two female. All group members had a voice prosthesis. Three group members (two male, one female) used tracheoesophageal voice as their primary communication modality, with electrolarynx as a back-up modality. One PWL predominantly used oesophageal voice by preference but was adept at producing tracheoesophageal voice; and one group member used tracheoesophageal voice in quiet, one-to-one communication whereas an electrolarynx was used in other situations.

The PAG undertook the following actions:

- Review of the systematic review aims and search strategy, where no actions were advised
- Consultation on the design of the clinician survey including review of survey questions, and reflection on the outcomes of the survey

- Consultation on the design of the focus group study, including advice on the timing and location/modality of the focus groups and review of the proposed topic guide. This led to inclusion of prompt questions on what wider support PWL received after laryngectomy
- Consultation on the proposal for the EMST study to identify the acceptability and relevance of the study within the doctoral project
- Review outcomes of completed studies to advise on key messages for dissemination

As the study progressed, a Diversity Advisory Group (DAG) was convened, which included three allied health professionals (AHPs) from minority ethnic communities to support the engagement of PWL from the local Bangladeshi community with the study. This included one SLT, one SLT assistant and one Radiographer. The DAG contributed strongly to the design and recruitment strategy of the co-design study. Specifically, the DAG provided guidance on approaches to community engagement, timing and location of meetings, cultural appropriacy of meeting content and dissemination of related information. Two members of the DAG also participated in the co-design as co-facilitators and interpreters.

1.2. HEAD AND NECK CANCER

A head and neck cancer diagnosis describes a malignancy within the oral cavity, nasal cavity or sinuses, ear, pharynx, salivary glands or larynx (NHS, 2021). There are over 12,000 new cases of head and neck cancer every year in the UK, the majority of which occur in the larynx (Cancer Research UK, 2019). Incidence of head and neck cancer has increased by 34% in the UK since the early 1990s (Cancer Research UK, 2021) and is projected to continue rising globally alongside increase in mortality rates (Gormley et al., 2022). Head and neck cancer is the seventh most common cancer type worldwide (Creaney et al., 2022). In the UK it is the eighth most commonly diagnosed cancer, rising to the fourth most common in UK males alone (Cancer Research UK, 2019). Head and neck cancer disproportionately affects men with 69% of UK cases diagnosed in men versus 31% diagnosed in females (Cancer Research UK, 2021). Furthermore, men are more likely to be diagnosed at an advanced stage of disease

than women (Creaney et al., 2022). However, incidence is increasing at a higher rate in females (Bosetti et al., 2020). In keeping with overall cancer risk, head and neck cancer incidence increases with age, with the majority of cases diagnosed in people over 60 years of age (Kouka et al., 2023).

The primary risk factors for developing a head and neck cancer are tobacco and alcohol consumption (Shaw and Beasley, 2016); and the combined consumption of alcohol and tobacco further increases the risk of developing cancer (Liberale et al., 2023). Other risk factors include opiate use, betel nut chewing, previous radiation exposure, Epstein-Barr virus infection and occupational exposure (National Cancer Institute, 2021). Occupational exposure refers to workplace exposure to materials associated with risk of developing a head and neck cancer (Khetan et al., 2020). Specific occupations and industries present high risk, for example: electronic equipment assembly, communication equipment manufacturing, welding and printing, which involve exposure to solvents (Carton et al., 2017); and construction work through exposure to asbestos and cement dust (Purdue et al., 2006). Several materials are known to carry risk, including industrial dusts such as sawdust (nasal and laryngeal cancer), metal dust (laryngeal cancer) and leather dust (head and neck cancer of non-specific site), (Langevin et al., 2013); and asbestos (Purdue et al., 2006). Sinonasal cancer is associated with occupational benzene exposure (Godono et al., 2024), whereas diesel exposure may be associated with laryngeal cancer (Seyyedsalehi et al., 2024). Longer duration of the exposing occupation increases risk of cancer (Langevin et al., 2013).

In recent years human papillomavirus (HPV) has been identified as a novel risk factor for head and neck cancer, particularly those that occur in the oropharynx (Sabatini and Chiocca, 2020). HPV positive tumours have a better prognosis for progression-free and disease-free survival, with lower rates of mortality and recurrence when compared with HPV negative cases (O'Rourke et al., 2012). Lower socioeconomic status and poor oral hygiene are characteristics of HPV negative cancers (Sabatini and Chiocca, 2020).

In general, poor socioeconomic markers are associated with increased risk of head and neck cancer, such as residing in a deprived area, low educational level and lifetime experience of unemployment (Al-Dakkak, 2010); however, these factors were not significant when smoking

and alcohol were adjusted for (Conway et al., 2010). In the UK, head and neck cancer is strongly linked with deprivation. Incidence rates are 64% higher in females and 101% higher in males in the most deprived quintile compared with the least deprived (Cancer Research UK, 2021). Racial disparities also exist in head and neck cancer; Black patients have worse overall survival rates, present with more advanced disease and have longer treatment times compared with White patients (Baliga, 2023). This is also observed in clinical trials, where Black participants consistently have worse outcomes in comparison to matched control White participants (Liu et al., 2023). This is discussed further in relation to the co-design study in Chapter Six.

Most head and neck cancers are squamous cell carcinomas, which arise from abnormal growth of squamous cells in the mucosal epithelium (Johnson et al., 2020). As head and neck cancers are heterogenous and may arise in various sub-sites, the severity and extent of a head and neck cancer is defined through the use of a staging system (Worsham, 2011). This classifies the disease by the size and depth of the tumour within the primary area of the cancer (T stage), the extent of spread to regional lymph nodes (N stage) and the presence or absence of distant metastatic spread (M stage), (Shah and Montero, 2018). The TNM staging of a specific cancer case is then combined to give an overall number staging of the cancer, which is used to inform prognosis and treatment planning. Overall staging ranges from zero to stage four, where stage four sub-categories represent an advanced cancer (Macmillan, 2022). To ensure uniformity in practice, the staging classifications are set out by the American Joint Committee on Cancer (AJCC) Cancer Staging Manual, 8th edition (Amin et al., 2017).

Since HPV positive cancers are biologically distinct from HPV negative cancers and are more responsive to treatment (Valero and Shah, 2021), the AJCC staging differs for HPV positive cancers. Overall stages for HPV negative cancers are described in Table 1.2 below. Most head and neck cancers in the UK are diagnosed at an advanced stage of disease, i.e. stage three or four (Creaney et al., 2022), which leads to the requirement for more complex treatment options, such as laryngectomy; or non-curative approaches to disease control (Worsham, 2011).

Overall stage	Description
Stage 0	Carcinoma in situ or pre-cancerous cell changes that have not spread Abnormal cells detected in the mucosa that may progress if not treated
Stage 1	Early-stage tumour of no more than two centimetres (cm) with no spread to lymph nodes
Stage 2	A tumour larger than two cm but not more than four cm with no spread to lymph nodes
Stage 3	A cancer that is larger than four cm, or has spread to an ipsilateral lymph node where the lymph node is less than three cm
Stage 4a	An advanced tumour of any size which has spread to nearby areas of the head and neck, without nodal disease or with spread to one ipsilateral lymph node of less than three cm; no spread to distant areas of the body. Or a tumour of any size that has not spread to distant areas of the body, with one of the following - - an ipsilateral lymph node of three to six cm - One contralateral lymph node of less than six cm - Two or more lymph nodes of less than six cm on either side of the neck
Stage 4b	A deeply invasive tumour (TMN stage T4b) with or without nodal disease, which has not spread to distant areas of the body. Or a tumour of any size which has spread to one or more large lymph node, but has not spread to distant areas of the body
Stage 4c	A tumour of any size, with any nodal staging which has spread to distant areas of the body

Table 1.2: Overall cancer staging adapted from Memorial Sloan Kettering Cancer Centre, 2024.

1.3. HEAD AND NECK CANCER TREATMENT

Treatment of head and neck cancer may consist of one or multiple modalities from surgery, chemotherapy, radiotherapy or immunotherapy. Surgery followed by radiotherapy, or primary chemoradiotherapy are the main treatments for head and neck cancer (Anderson et al., 2021; Ronen et al., 2023). The main treatment modalities are summarised in Table 1.3.

Treatment modality	Description
Surgery	Surgery is a procedure in which tissues are examined, removed or repaired. Surgery may be an open procedure, where a large incision is made into the body; or transoral, where surgery is completed using a minimally invasive route of access such as via the oral cavity. Transoral surgery may involve laser resection of tissues, or it may be robotic, where the surgery is assisted by a machine controlled by the surgeon.
Chemotherapy	Chemotherapy uses cytotoxic drugs to destroy cancer cells. Chemotherapy disrupts the process by which cancer cells grow and divide, however, this can also affect healthy cells leading to side effects.
Radiotherapy	Radiotherapy uses radiation to destroy cancer cells within the area that the radiotherapy is administered. Again healthy cells may be affected by radiotherapy leading to side effects.
Immunotherapy	Immunotherapy uses the immune system to find and attack cancer cells. There are several types of immunotherapy that engage the immune system through different processes. Immunotherapy may also cause side effects as it leads the immune system to become overactive, which can cause inflammation

Table 1.3: Main treatment modalities for head and neck cancer.

Adapted from Macmillan Cancer Support, 2024.

Treatment and rehabilitation of head and neck cancer is complex and involves multidisciplinary care (Goyal et al., 2022). This creates considerable economic impact with five-year costs in England estimated at £309 million for treatment of oropharyngeal, laryngeal and oral cancer alone, excluding therapeutic rehabilitation (Keeping et al., 2018). The economic burden is also experienced by patients and is considered as a financial toxicity of cancer treatment (Ngan et al., 2023) which consists of direct costs such as additional heating, transport to treatment costs, special foods; and indirect financial burden through loss of income (Ngan et al., 2023). The National Cancer Survivorship Initiative surveyed cancer patients, finding that the average economic cost to the patient of attending a single outpatient appointment was £41, mostly due to time away from work, which increased to an

average of £437 for clinic visits over a five-year treatment and follow-up period (NHS Improvement, 2012).

1.4. HEAD AND NECK CANCER SURVIVORSHIP

All head and neck cancer treatment modalities result in side effects which may be transient, long-term or which emerge years after treatment. This produces a significant double burden of morbidity arising from both the cancer itself and the treatment (Cocks et al., 2016). This burden may encompass impairments to communication, swallowing and breathing in addition to changes to appearance, impact on psychological and social well-being; and quality of life (Lin et al., 2020). Radiotherapy, in particular, may result in significant toxicities such as xerostomia, osteoradionecrosis, reduced wound healing, poor vascularity, trismus and late onset fibrosis (Brook, 2020).

Survivorship after a head and neck cancer diagnosis is increasing (Nguyen and Ringash, 2018), with 19-59% of people with head and neck cancer in England predicted to survive for ten years or more (Cancer Research UK, 2021). The increase in survival therefore results in more people living longer with complex needs and presents increasing demands on healthcare services (NHS Improvement, 2012). At the end of cancer treatment, many people present with unmet needs or ongoing challenges, as a consequence of treatment (Armes et al., 2009). The European consensus guidelines advocate for long-term follow-up post treatment to assess and manage late stage and existing treatment side effects, emphasising that individualised multidisciplinary care is essential in survivorship (Verdonck-de Leeuw et al., 2022). The American Head and Neck society consensus guidelines also advocate for multidisciplinary rehabilitation in survivorship, alongside consideration of holistic support needs and support for return to work (Goyal et al., 2022). It is recognised that interventions to support cancer survivors should be developed and tested in a comparable process to the support developed for other long-term conditions (NHS Improvement, 2013).

1.5. LARYNGECTOMY

Total laryngectomy is a surgical procedure, offered most commonly as a curative treatment for advanced (stage three or four) head and neck cancer affecting the larynx and hypopharynx (Hoffman, 2021). Laryngectomy may be carried out alone, or as part of a multi-modality treatment plan. Primary laryngectomy refers to the surgical procedure as the sole cancer treatment, or as an initial treatment prior to radiotherapy and/or chemotherapy. A laryngectomy which is performed after radiotherapy, due to recurrence of the cancer, is called a salvage laryngectomy. Laryngectomy is not typically offered as a palliative procedure due to the significant impact on function, which is incompatible with the aims of palliative care to improve comfort and quality at the end of life (Rome et al., 2011).

Less commonly, laryngectomy may also be offered to treat a non-functional larynx, which affects a proportion of head and neck cancer survivors following previous cancer treatment (Escalante et al., 2021). Non-functional larynx arises when fibrosis and radionecrosis of tissues occur in the absence of disease, as a severe late effect of previous radiotherapy (Theunissen et al., 2012). This may result in airway compromise, severe dysphagia (difficulty swallowing) and dysphonia (impaired voice quality), which greatly impact function (Hutcheson et al., 2012). Risk of developing a non-functional larynx is associated with pulmonary comorbidities and previous treatment with non-intensity modulated radiation (Wu et al., 2021). In rare cases, laryngectomy is required following severe laryngeal trauma (Cho et al., 2022; Retinasekharan et al., 2022). Whilst laryngectomy secondary to trauma was not an exclusion criterion of the doctoral study, all participants in the study had primary or salvage laryngectomy for treatment of cancer.

The increased rate of survivorship after head and neck cancer is a favourable statistic, and PWL often survive long-term after surgery. However, quality of life (QOL) is affected and therefore there is a growing population of people living with laryngectomy as a long-term condition, which requires ongoing SLT rehabilitation. It is acknowledged that the quality of laryngectomy data reporting is low (Govender et al., 2021) and there are no existing sources which provide up-to-date figures on how many PWL are living in the UK. Data from Macmillan

Cancer Support reported that over 5,000 PWL were living in the UK with a laryngectomy in 2017 (Macmillan, 2017) and 299 records of SLT intervention for PWL were reported in the 2014 National Head and Neck Cancer Audit (Health and Social Care Information Centre, 2015). These figures are not current, however, and are likely to be an underestimate, as the audit notes the low information submission rates for SLT intervention. Furthermore, functional, salvage laryngectomy and laryngectomy due to trauma were excluded from the Health and Social Care Information Centre data. A more recent multi-centre audit of UK head and neck SLT units (Govender et al., 2021) received data on 1216 PWL, however, this is again likely to underestimate the true number as not all centres participated in the audit.

In addition, research relating to PWL has generally involved small sample sizes and the limitation of sample size is acknowledged within studies. For example, Fitzgerald and Perry (2016), (systematic review of pre-operative counselling) had 18 – 75 participants; van Sluis et al. (2020), (evaluation of voice outcomes after laryngectomy) had 43 participants; Chen et al. (2022), (olfactory-specific quality of life after laryngectomy) 30 participants; and Laraichi et al. (2024), (quality of life after laryngectomy) 36 participants.

1.6. LARYNGECTOMY PROCEDURE

Total laryngectomy was first performed successfully in Vienna in 1873 by Theodor Billroth and thereafter refined to improve outcomes (Mudry and Laccourreye, 2023). The surgical procedure consists of the permanent surgical removal of the hyoid bone, the laryngeal cartilages, epiglottis, vocal folds and the upper cartilage rings of the trachea. This results in the separation of the digestive and respiratory systems. The trachea is then diverted to the anterior neck, separating the upper and lower respiratory tract (Adil et al., 2022) so that the nose and mouth are no longer a functional part of the airway. Instead, breathing occurs through a stoma (surgically created hole) at the front of the neck, leading to the repositioned trachea.

During the procedure the infrahyoid muscles of the anterior neck are transected, and the suprahyoid and pharyngeal constrictor muscles are detached from the hyoid bone and thyroid cartilage respectively. The muscles are then reconstructed, as the pharynx is closed in two to three layers (University of Iowa, 2024) to create the reconstructed pharynx. During the reconstruction, the vibratory segment is created within the reconstructed pharynx from the thyropharyngeus and cricopharyngeus pharyngeal constrictor muscles. The vibratory segment is an area where tissues are set into vibratory motion as pulmonary air passes through the reconstructed pharynx, thus creating a novel source of sound (Wetmore et al., 1985). The closure techniques of the pharynx and their relationship to tracheoesophageal voice production are elaborated in Chapter Two, where laryngeal and tracheoesophageal voice production are explored in detail. Figures 1.1 and 1.2 illustrate the changes in anatomy from before to after laryngectomy.

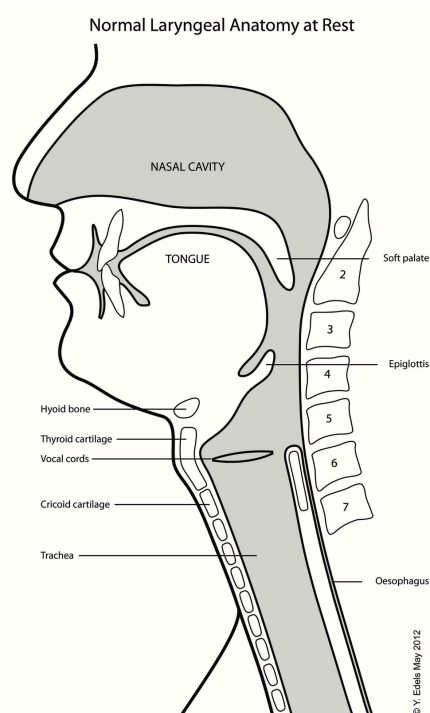


Figure 1.1: Normal laryngeal anatomy
(Images used with permission of Edels, 2012)

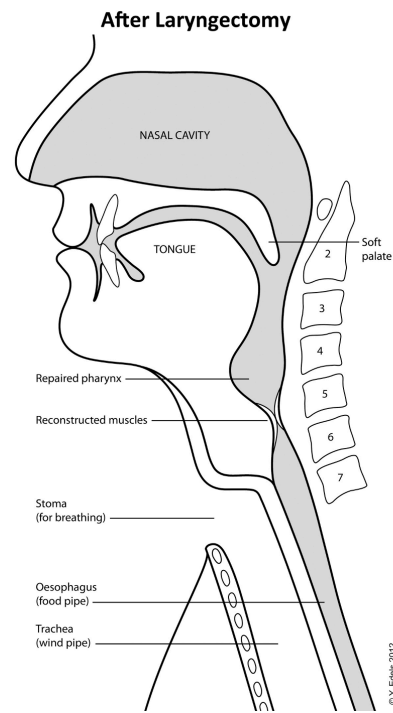


Figure 1.2: Post-laryngectomy anatomy

1.7. RECONSTRUCTION POST LARYNGECTOMY

In some cases, it is not possible to close the pharynx directly (primary closure) therefore additional tissue is needed to reconstruct the defect left by the removal of the larynx, or where a larger resection of the pharynx is necessary for disease control. This is pertinent as insufficient diameter of the reconstructed pharynx in primary closure may negatively impact swallow function and risk of stenosis (Hui et al., 1996). Additionally, tissue may be used to reinforce a primary closure where there are risk factors for poor wound healing, such as with salvage laryngectomy (Bussu et al., 2014).

Extended reconstruction may be carried out using regional pedicled or free flap reconstruction techniques (Harris et al., 2020). Pedicled flaps use donor tissue from an adjacent area without disrupting the blood supply. The tissue is lifted with the blood vessels remaining attached whilst the tissue is moved into the recipient position (Pink et al., 2017). The most common pedicled flap is the pectoralis major (Chotipanich, 2021). Free flaps use donor tissue and blood vessels from a more distant region, which are detached, transferred and anastomosed (surgically attached) to the recipient area to ensure a blood supply (Basaran et al., 2021). Typically, free flaps may use tissues from the radial forearm, anterior-lateral thigh or jejunum (Chotipanich, 2021). In cases where the extent of the cancer requires surgical resection of the hypopharynx and cervical oesophagus, a gastric pull-up may be required to reconstruct the defect (Krdžalić and Brkić, 2007). In this procedure the stomach is brought up into the neck and anastomosed with the remainder of the pharynx, which may be completed with an additional free flap to reinforce the reconstruction (Reilly, Sridharan and Hancock, 2016). In extended reconstructions there will typically be an area of apposition which will become the primary area of vibration, akin to the vibratory segment created in a primary closure laryngectomy. The choice of reconstructive technique is dependent on patient specific factors such as the size of the defect, the availability and viability of donor tissues, and wound healing factors (Tonsbeek et al., 2023). Choice may also be influenced by the preference of the surgeon or surgical centre, and familiarity with techniques (van der Kamp, Rinkel and Eerenstein, 2017).

1.8. COMPLICATIONS POST LARYNGECTOMY

Laryngectomy is a complex surgical procedure, and the timeline and ease of post-operative recovery differs between individuals. Many people due to undergo laryngectomy present with comorbidities such as diabetes, cardiovascular disease and chronic lung or liver disease; which correlate with increased length of hospital stay (Ceachir et al., 2014; Crosetti et al., 2016). Furthermore, the presence of more than two comorbidities is correlated with worse QOL outcomes post-operatively (Woodard et al., 2007). The most common complications in the post-operative stage are wound infections, haemorrhage, haematoma, chyle leak (leakage of chyle fluid following inadvertent damage to the left thoracic duct during surgery, [Leović et al., 2022]), flap failure, tracheostomal stenosis (narrowing of the neck stoma) and pharyngocutaneous fistula (tract between the neopharynx and the skin of the neck), which may impair recovery and rehabilitation of speech and swallowing (Damrose and Doyle, 2019). Tracheostoma and neopharyngeal stenosis may also occur as late complications (Ceachir et al., 2014). Late stage neopharyngeal stricture or stenosis is particularly associated with radiotherapy (Farlow, Rosko and Spector, 2019). Salvage laryngectomy results in higher rates of post-surgical complication compared to a primary total laryngectomy (Woodard et al., 2007; Sullivan et al., 2020). Additionally, surgery for non-functional larynx has a high complication rate (Theunissen et al., 2012), particularly of pharyngocutaneous fistula (Escalante et al., 2021).

1.9. CHANGES TO COMMUNICATION, BREATHING AND SWALLOWING

The primary functions of the larynx are respiration, phonation and swallowing (Andaloro and Widrich, 2023). The permanent removal of the larynx therefore has a significant detrimental impact on these functions. This doctoral study focuses on communication post-laryngectomy; however, it is of note that swallowing and breathing are also affected and interlinked with communication. Reference is therefore made to swallowing where relevant throughout the thesis, and Chapters Two and Seven explore further the relationship between post-laryngectomy communication and breathing.

After laryngectomy, anatomy is altered so that the trachea is separated from the resected larynx and rerouted to open at the front of the neck. The nose and mouth are therefore no longer involved in respiration, and breathing occurs via the neck stoma (Adil et al., 2022). Due to the altered anatomy of the airway, humidification of the respiratory tract is reduced. Previously, air entering the respiratory tract would be warmed, filtered and humidified by the cilia and mucous membranes of the upper airway as it is inhaled through the nose and mouth (Tracheostomy Education, 2022). After surgery, as a result of the air being inhaled directly into the trachea via the neck stoma, the lungs receive air which is colder, drier and unfiltered. The impact of the upper airway loss is significant. Air temperature of 22 degrees Celsius and 40% relative humidity will increase to 32 degrees Celsius and 99% relative humidity when it reaches the trachea, if inhaled via the upper airway; however, air inhaled directly to the trachea via a neck stoma will reach only 28 degrees Celsius and 50% relative humidity (Bien et al., 2020). The reduction in temperature and humidity causes the lungs to produce excess mucus, which may be thicker and drier, necessitating increased coughing and creating risk of thick mucus blocking the airway (Ebersole et al., 2020). An alternative humidification system is therefore required to maintain pulmonary health. This can be achieved through the use of consumable equipment which covers the neck stoma. These products protect the stoma and, in some cases, enable the attachment of humidification devices.

The simplest form of protecting the stoma and increasing humidification is through the use of a fabric stoma protector. These consist of a bib-shaped fabric, which is worn around the neck and may be tucked into clothing to create a seal over the stoma (Figure 1.3). Fabric stoma protectors contain a thin foam layer between the fabric, which provides some warming, and humidification of inhaled air (Quail et al., 2016). Similarly, the stoma can be covered by a smaller foam protector (Figure 1.4). However, the optimal approach to protecting the stoma is through the use of adhesive baseplates. A baseplate is a circular or oval adhesive, which is attached to the skin around the stoma (Figure 1.5). This creates a more robust seal around the stoma compared with other types of stoma protector (Hennessy et al., 2020) and allows for the connection of a heat-moisture exchanger (HME) humidification device.



Figure 1.3: Fabric stoma protector



Figure 1.4: Foam stoma protector

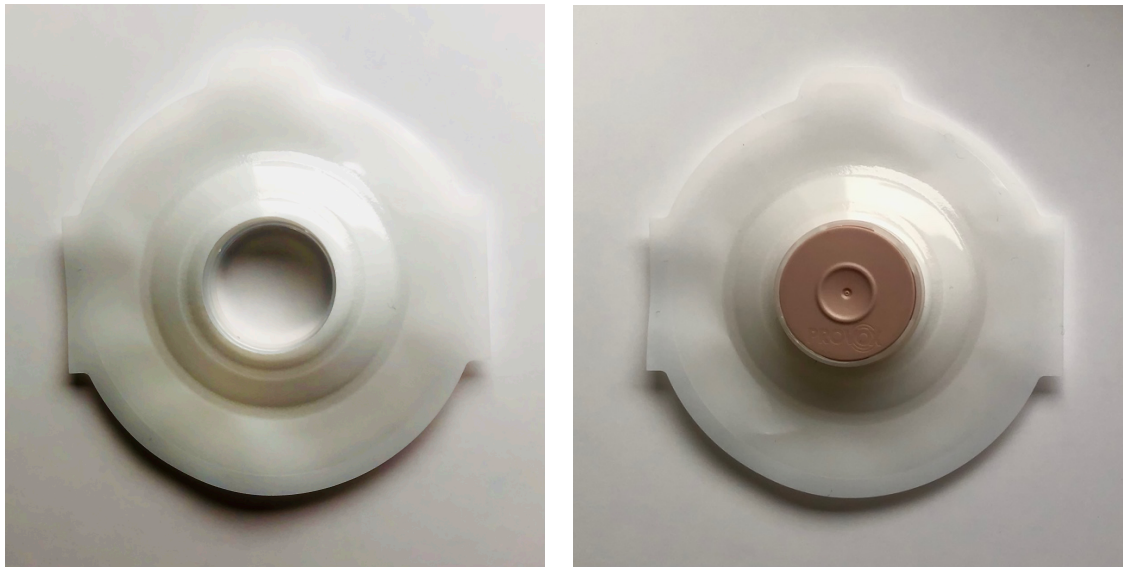


Figure 1.5: Adhesive baseplate without and with HME

An HME is a small circular device which fits into a baseplate, with the aim of warming, humidifying and filtering inhaled air to replace the function of the lost upper airway (Mérol et al., 2012). The device consists of a plastic casing with a foam insert in the centre (Figure 1.6). The HME functions by trapping the heat and moisture of air exhaled via the stoma which is then transferred back to inhaled air to increase temperature and humidity (Tracheostomy Education, 2022). Use of an HME is beneficial for airway health and related symptoms when compared to non-use of an HME and is considered the optimal approach to restoring humidification (Dunton et al., 2023). Regular HME use reduces irritation and dryness of the trachea, reduces mucus production and plugs, reduces the frequency of coughing, and improves sleep, voice quality and QOL (Ahmed et al., 2023). HME use can also support PWL to occlude the stoma when producing tracheoesophageal voice (Ackerstaff et al., 2003).

In addition to humidification properties, a special type of device can enable the PWL to speak without needing to manually occlude the stoma. Hands-free devices incorporating HMEs (Figure 1.7) contain a silicone membrane which remains open for breathing but which closes during speech in response to expiratory pressure (Lorenz et al., 2006). Hands-free devices provide the benefit of not requiring the use of manual occlusion to speak, however, they can be challenging for PWL to adjust to. Effective usage requires a highly-adhesive baseplate or strong seal around a laryngectomy tube or button, and some users experience difficulty

adjusting to the increased resistance to breathing produced by the hands-free device (Lansaat et al., 2017).



Figure 1.6: Heat moisture exchanger (HME)



Figure 1.7: Hands-free device

Another commonly used equipment is the laryngectomy tube (Figure 1.8). This is a small, single lumen silicone tube which is inserted into the stoma to maintain a safe aperture for breathing. A laryngectomy tube is not always required or may be required only for a short time; for example, to maintain stoma size during post-operative healing and oedema. The recommendation to wear a laryngectomy tube is therefore dependent on patient-specific factors and surgical recommendations. The primary purpose of the laryngectomy tube is to maintain the stoma size and therefore humidification is still required. HME and hands-free devices are sized to fit within the stomal component of the laryngectomy tube (Figure 1.9), or a stoma protector may be worn over the tube.



Figure 1.8: Laryngectomy tube



Figure 1.9: Laryngectomy tube with HME attached

Laryngectomy has devastating and irreversible outcomes for communication. The surgical procedure necessitates the permanent removal of the vocal folds, which generate the sound of the voice. Laryngeal voice production is described in detail in Chapter Two. After laryngectomy it is therefore no longer possible for the individual to produce a laryngeal voice or vocalised sounds, in the absence of the vocal folds. There is, consequently, a complete loss of the ability to use a conventional voice to speak and communicate. This communication loss results in complex changes to QOL and social participation (Sharpe et al., 2019). An alternative method of communication is therefore required to address communication barriers.

1.10. COMMUNICATION OPTIONS POST LARYNGECTOMY

After laryngectomy there are four main methods of alternative communication:

1.10.1. ELECTROLARYNX

An electrolarynx is a hand-held electromechanical device producing vibration, which is held against the neck or face. The electrolarynx induces the mucosa of the neopharynx or oral cavity to vibrate at a constant fundamental frequency (Kaye, Tang and Sinclair, 2017). This produces a monotone sound vibration which is intended to replace the loss of sound vibration previously generated by the excised vocal folds. Vibration is transmitted through the tissues where it can be shaped into speech sounds by the articulators. This enables nuances of the speaker's articulation and oral resonance to be maintained. Electrolarynx is a less invasive form of communication restoration as, in contrast to surgical voice restoration it does not require an additional surgical procedure; however, electrolaryngeal voice quality can be considered robotic or mechanical (Pan et al., 2024). Listeners perceive electrolaryngeal speech as unnatural and a less favourable sound in comparison to tracheoesophageal speech (Cox and Doyle, 2014). Additionally, electrolaryngeal speech takes longer to produce resulting in modified articulatory behaviours (Weiss, Yeni-Komshian and Heinz, 2005). The use of clear speech strategies, such as over-articulation and slowed speech rate, do not improve auditory perceptual judgements of listener acceptability (Cox and Doyle, 2018). Speech intelligibility varies widely between electrolarynx users, which is attributed to lack of frequency variation, device noise and non-distinction between voiced and voiceless phonemes (Cox et al., 2020). Successful electrolarynx use is associated with higher social support and the absence of tube-feeding (Pan et al., 2024). In the same study (Pan et al., 2024) less than half of the 196 participants were deemed successful electrolarynx users, whereas Cox and Doyle (2014) found that successful usage was highly variable across participants (n = 40).

1.10.2. OESOPHAGEAL VOICE

To produce oesophageal voice, air is inhaled or injected into the reconstructed throat through swallowing air or creating negative pressure with movement of the tongue, which draws air into the neopharynx. As the air is released back into the throat, the release of air creates vibration of the neopharyngeal mucosa and turbulence within the column of air, which creates sound, to be shaped into speech by the articulators (Elmiyeh et al., 2010). Anatomical variations, such as a narrow neopharyngeal diameter, and the limited reserve to hold air within the oesophagus may result in short phonation times and high levels of effort to produce oesophageal voice (Kaye, Tang and Sinclair, 2017). Maximum phonation time in oesophageal voice users is significantly lower when compared with trachoesophageal voice users (Allegra et al., 2019). Due to the effort and short breath-to-syllables ratio of oesophageal speech, PWL experience difficulty learning the technique and dissatisfaction with the quality (Plotas et al., 2024). When compared with tracheoesophageal speakers, oesophageal voice users experience significantly higher voice related impact as measured by the Voice Handicap Index (VHI), (Dragičević et al., 2020). It is estimated that only one third of PWL are able to learn oesophageal speech, with just 10% achieving clear speech (Lorenz, 2017). In comparison to laryngeal voice, oesophageal voice has lower intelligibility and quality (Prosek and Vreeland, 2001) due to perturbation in fundamental frequency, extraneous noise and low intensity (Ezzine, Di Martino and Frikha, 2022). Further research is required to understand the impact of oesophageal speech on quality of life (Plotas et al., 2024).

1.10.3. SILENT ARTICULATION

Use of exaggerated articulation in the absence of sound can be an effective means of communication for the conversation partner to lip read. This may occur within a total communication approach with the additional use of gesture, facial expression or writing and text-to-speech apps, if literacy is sufficient. A total communication approach to support silent articulation is pertinent as studies of lip-reading efficacy have demonstrated low accuracy of interpretation (Altieri, Pisoni and Townsend, 2011). Early proof-of-concept work has highlighted the potential application of speech recognition technology for PWL who use silent

articulation. Such technology uses surface electromyography (Meltzner et al., 2017) or magnetic sensors (Gonzalez and Green, 2018) to recognise facial and neck muscle activity during articulation, which can be used to produce synthesised voice or speech-to-text outputs. These technologies remain in development, however, and are not yet in practical use.

1.10.4. SURGICAL VOICE RESTORATION

Surgical voice restoration involves the deliberate creation of a tract between the trachea and oesophagus, called a tracheoesophageal puncture. The tracheoesophageal puncture may be created during the laryngectomy surgery, as a primary tracheoesophageal puncture; or as a secondary procedure at a later time, after the laryngectomy surgery, which is a secondary tracheoesophageal puncture. Systematic reviews of primary versus secondary tracheoesophageal puncture outcomes found no difference in voice acquisition or overall surgical complication rates (Luu et al., 2018; Chakravarty et al., 2018). However, when pharyngocutaneous fistula rates were considered in isolation they were found to be more prevalent following primary tracheoesophageal puncture (Chakravarty et al., 2018). No robust data exists to definitively guide the decision for primary or secondary tracheoesophageal puncture therefore this may be led by surgical preferences and MDT opinion (Luu et al., 2018); however, Chakravarty et al. (2018) advocate for primary tracheoesophageal puncture balanced alongside the individual risk of pharyngocutaneous fistula. The majority of tracheoesophageal punctures are carried out as secondary procedure, however, this finding is based upon data from North American population studies which may be influenced by differences in national healthcare systems (Sethi and Deschler, 2018).

Once the tracheoesophageal puncture is created, a small silicone device, called a voice prosthesis, is placed into the tract. A voice prosthesis is a one-way valve which opens to allow air to pass on voicing but remains closed at rest and during swallowing. Once the voice prosthesis is inserted into the tracheoesophageal puncture, exhaled air from the lungs passes from the trachea into the neopharynx via the voice prosthesis. As air reaches the reconstructed pharynx, the vibratory properties of the mucosa create an alaryngeal voice,

i.e., a voice produced in the absence of a larynx. For air to pass via the prosthesis, the stoma must be briefly closed off with a finger or HME to ensure that air is directed through the prosthesis rather than out via the stoma (Figure 1.10). This communication method is interchangeably called tracheoesophageal speech or tracheoesophageal voice.

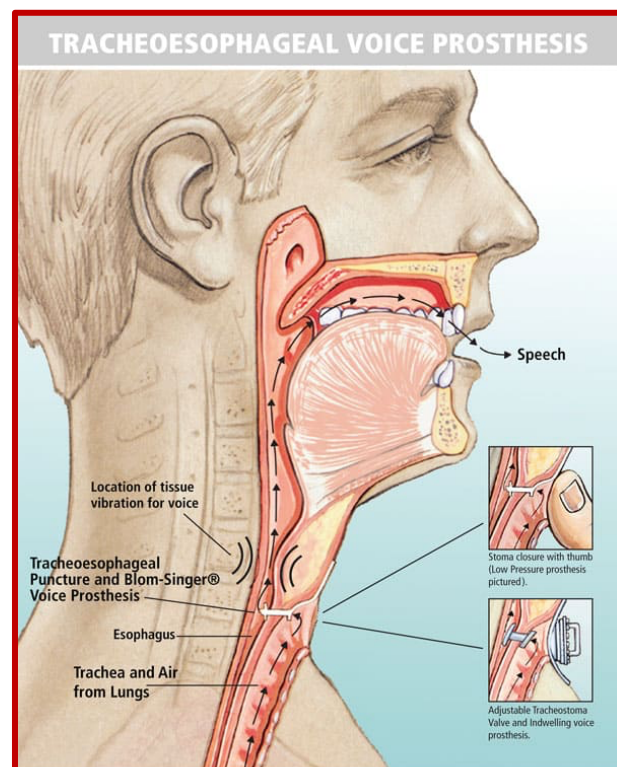


Figure 1.10: Surgical voice restoration (www.tracheostomyeducation.com)

Regular maintenance of a voice prosthesis is required, including changing for a new prosthesis, which is typically managed by the SLT or less frequently by the PWL. Data is scarce on how many PWL manage their own prosthesis changes. A study of a Scottish SLT unit found that of 970 prosthesis changes completed in a three-year period, 168 were self-changed, representing 17.3% of changes (McLachlan et al., 2022). The same study found that the need for a prosthesis change was unpredictable and more frequent within the first 12 months post laryngectomy; and PWL required on average 3.32 changes per year. Several different voice prostheses exist (Figure 1.11), which are selected based on individual patient factors. The main categorisation of voice prostheses is whether they are indwelling or

exdwelling. An indwelling prosthesis typically has a longer lifespan than an exdwelling (Brook and Goodman, 2020) and does not require the retention of a safety-tab to secure the prosthesis to the peristomal skin.

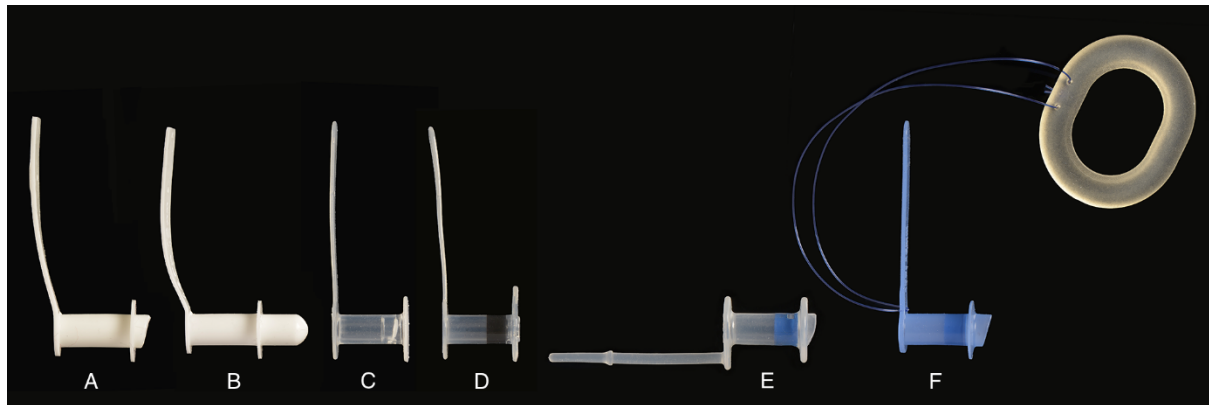


Figure 1.11: Common voice prosthesis types

A: Blom-Singer low pressure exdwelling; B: Blom-Singer duckbill exdwelling; C: Blom-Singer classic indwelling; D: Blom-Singer advantage indwelling; E: Provox Vega indwelling; F: Provox non-indwelling

1.10.5. A FOCUS ON TRACHEOESOPHAGEAL VOICE REHABILITATION

The underlying mechanisms of the communication modalities identified above and reasons for their usage differ widely. It cannot therefore be assumed that the priorities, experiences and rehabilitation aims of PWL using different communication modalities are transferrable. Each communication modality merits further research into the specific needs of the users and the best rehabilitation approaches to optimise the resulting voice. The focus of the current work is on tracheoesophageal voice rehabilitation.

Following laryngectomy, surgical voice restoration is currently offered as the optimal alternative for re-establishing spoken communication with tracheoesophageal voice (Kazi et al., 2007). Furthermore, people who acquire voice with a prosthesis at an early-stage report better emotional states when compared with non-voice prosthesis users (Gunjawate and Ravi, 2021). Several systematic reviews conclude that tracheoesophageal voice is the most favourable method of communication restoration after laryngectomy according to acoustic and perceptual outcomes (van Sluis et al., 2018; Mohamed et al., 2021), however, there is

not a single best method that can be applied to all PWL (Mohamed et al., 2021) and the relatively higher communicative performance of tracheoesophageal voice does not necessarily correlate with higher quality of life (Maniaci et al., 2024). It has been demonstrated, however, that PWL experience improved quality of life after surgical voice restoration compared with their time using a different communication modality, prior to the surgical voice restoration procedure (Bourmand, Olsson and Fijany, 2024).

Despite tracheoesophageal voice being identified as the optimal method of communication post laryngectomy, the quality of tracheoesophageal voice remains insufficient to many PWL. Research should therefore seek to enhance the rehabilitation available to tracheoesophageal speakers, in order to optimise tracheoesophageal voice. Section 1.12 describes the current picture of tracheoesophageal voice rehabilitation and elaborates on the challenges of tracheoesophageal voice to provide further context and rationale.

1.11. THE IMPACT OF LARYNGECTOMY

People with head and neck cancer experience high levels of emotional distress and significantly elevated risk of suicide, in comparison with the general population and other cancer types (Twigg et al., 2020). Furthermore, people who live with head and neck cancer experience a high prevalence of pain (Bolnykh et al., 2024) and cancer-related fatigue, particularly if female and at advanced stage of disease (Sharp et al., 2023). Decisional conflict and decisional regret around head and neck cancer treatment are highly prevalent, within a limited evidence base (Heirman et al., 2024). Following a diagnosis of head and neck cancer, 53% of people report a decrease in QOL (Terro, 2017) and more than 30% report issues with anxiety, sadness or depression (Gotze, 2015); with communication problems being one of the most commonly cited concerns (Rogers et al., 2012).

The loss of voice after laryngectomy causes significant distress, fear, depression and passivity (de Maddalena, 2002). Laryngectomy is a significant variable in reduced communicative participation (Bolt et al., 2016) and has negative consequences for QOL, activity and

participation (Lundstrom et al., 2009). The loss of self-expression, changes to communicative participation and social roles influence self-identity and adjustment after laryngectomy (Bickford et al., 2018). Moreover, PWL experience challenges returning to work, with the altered communication affecting impressions of employability (Knollhoff, 2021).

In an earlier literature review of caregiver impact, (Krouse et al., 2004) the absence of studies on impact was highlighted, with advocacy for the development of resources and interventions to support caregivers of PWL. Studies in this area remain limited, however. Informal carers of people with head and neck cancer experience high caregiver burden and unmet support needs (van Hof et al., 2023). The impact of laryngectomy specifically, also reaches to partners and caregivers who experience psychological distress following the surgery (Meyer et al., 2015; Verdonck-de Leeuw et al., 2007). Partners of PWL experience a negative impact on their social life and sexual relationship, and distress related to how others interact with their PWL partner (Offerman et al., 2015).

1.12. THE CURRENT PICTURE OF TRACHEOESOPHAGEAL VOICE REHABILITATION

The prevalence of surgical voice restoration is reflected in the most recent National Head and Neck Cancer Audit (2015), which showed that tracheoesophageal voice was the most common primary communication method at three months post-surgery with 69% of PWL recorded as using a voice prosthesis (HSCIC, 2015). This finding was broadly consistent with a more recent audit of UK SLT services, which found 71% of PWL used tracheoesophageal voice (Woodman et al., 2024). The same audit found that sex and time post-surgery were significant factors in tracheoesophageal voice use, with 63% of females using a prosthesis compared to 73% of males; and an average time post-surgery of 98 months in prosthesis users compared to 79 months for PWL who do not use a prosthesis (Woodman et al., 2024).

Despite the emergence of tracheoesophageal voice as the preferred communication method after laryngectomy, there remain significant challenges to communication. Whilst surgical

voice restoration gives PWL the ability to produce a voice, the quality and functionality of that voice can vary significantly; whilst some may struggle to produce any voice at all via the prosthesis. Tracheoesophageal voice can be difficult to produce, presenting significant barriers to activity and participation that impact negatively on QOL (Lee et al., 2010). In some cases, the voice is not sufficiently intelligible to be a functional means of communication (de Maddalena et al., 1992). There are clear differences between the sound of tracheoesophageal voice and normally produced laryngeal voice. Typical features of tracheoesophageal voice are whispered, rough or wet voice quality, reduced pitch range and reduced volume control (Deore et al., 2011). There may be increased pitch variation (Robbins et al., 1984), lower pitch (Van As-Brooks, 2006), changes to intonation and reduced speech rate which negatively impact on listener perception (Lundstrom, 2011). Communication via telephone, in noisy environments or with unfamiliar people is problematic (Giordano et al., 2011; Bua et al., 2008), with the latter affecting 57% of tracheoesophageal voice users (Nalbadian et al., 2001).

Tracheoesophageal voice user self-ratings show a moderate level of voice-related handicap impacting on daily function, emotional health and the physical effort required to produce voice (Lundstrom, 2011). Tracheoesophageal speakers report restrictions in social, physical and emotional participation in daily activities (Schuster et al., 2003; Giordano et al., 2011). Despite the challenges of producing tracheoesophageal voice, some tracheoesophageal speakers do achieve satisfactory outcomes and a voice quality that is perceptually superior to that of other tracheoesophageal speakers. This indicates the potential to optimise the quality and function of tracheoesophageal voice in all speakers; and the urgency for a greater understanding of what rehabilitation approaches may be effective.

1.13. THE SLT ROLE IN TRACHEOESOPHAGEAL VOICE REHABILITATION

After laryngectomy, lifelong involvement with SLT is required to support voice prosthesis care and for periodic replacements of the prosthesis. SLTs have the potential to additionally support PWL to develop and maintain an alternative voice, with specific tracheoesophageal voice therapy interventions alongside routine voice prosthesis maintenance work.

Since surgical voice restoration alone may not restore functional communication, SLT intervention is essential to support PWL in learning how to produce tracheoesophageal voice and to maximise the quality and function of that voice (Xi, 2010). Singer et al. (2019) demonstrated that in the German setting, PWL that attended SLT had four times the odds of attaining any ability to speak, compared to PWL that did not have rehabilitation. However, this study did not comment on the quality of the acquired tracheoesophageal voice as there was no association of rehabilitation with subjective speech intelligibility.

The role of the SLT is reflected in the national guidelines for head and neck cancer rehabilitation (Homer and Winter, 2024) that recommend surgical voice restoration is offered to all people undergoing laryngectomy, following which long-term SLT rehabilitation is essential. However, the guidelines do not provide information on the specifics of what SLT rehabilitation should include and there is no professional consensus or existing literature review of voice therapy approaches for PWL. Similarly, there are currently no voice therapy approaches specifically for PWL who communicate with a voice prosthesis. Clinician knowledge is therefore limited on what voice therapy approaches should be used to improve tracheoesophageal voice quality and maximise communication; and there is an absence of evidence to guide clinical practice. There is a pressing need for more research in this area. Furthermore, there is limited research on the priorities of people who use a voice prosthesis in relation to communication and the intersection with QOL and participation. In this regard, more research is required on the lived experience of tracheoesophageal speakers, in order to inform intervention development (Summers, 2017).

1.14. THE NEED FOR A NOVEL APPROACH TO TRACHEOESOPHAGEAL VOICE REHABILITATION

Voice therapy after laryngectomy can improve QOL (Varghese, 2011) and speaker intelligibility (Singer et al., 2013), however, novel voice therapy approaches are required to support tracheoesophageal voice use (Moon et al., 2014). This is further necessitated by the changing treatment context where increasingly laryngectomy is performed following radiotherapy or as an extended surgical procedure, both of which increase the complexity of rehabilitation (Owen et al., 2013).

Developments in tracheoesophageal voice therapy have not kept pace with advances in other aspects of laryngectomy care, such as prosthesis technology and oncological treatment advances. As such the significant needs of PWL are not being fully met by current SLT practice. Contributions to the evidence base, exploration of clinicians' views; and greater understanding of the experiences and priorities of people with laryngectomy are required to develop an effective therapy for tracheoesophageal voice.

Transferrable knowledge may be gained from conventional approaches for laryngeal voice disorders; however, it is prudent to consider whether these approaches are feasible and acceptable to PWL. Typically, these approaches assess all aspects of voice production (musculoskeletal, laryngeal function and respiratory system) to identify therapy targets based on impairments in the subsystems of voice production. These approaches could be applied to enable tracheoesophageal speakers to modify the remaining vocal tract structures and effect changes in voice quality. Indicators of the potential of these approaches come from a small body of studies which have considered how tracheoesophageal voice could be affected by therapy approaches targeting the subsystems of voice production that remain intact following laryngectomy. Chapter Two explores this in detail.

1.15. SUMMARY OF ISSUES AND STUDY AIMS

The overall aim of this doctoral study is to complete the first stages of development of a novel tracheoesophageal Voice Therapy Approach for people with Laryngectomy (VITAL), which is relevant and acceptable to PWL. Specifically, the study seeks to address the challenges described within this chapter and to meet several areas of concern within the initial stages of intervention development:

1. There is scant clinical knowledge of how to optimise tracheoesophageal voice quality.
2. There is limited understanding of what approaches SLT clinicians use with PWL and what SLT perspectives are on what works.
3. The barriers and facilitators to SLTs providing voice rehabilitation for tracheoesophageal speakers are not well understood.
4. There is a need to identify what issues are important to PWL in terms of optimising tracheoesophageal voice quality, engaging in rehabilitation; and the transference to increasing activity and participation.
5. No specific tracheoesophageal voice therapy approaches exist and therefore this gives rise to inconsistency in clinical practice and functional outcomes.

To address these areas of concern the doctoral study uses qualitative and quantitative methodologies, as indicated below, to achieve the following aims:

1. To establish current knowledge and identify existing evidence on interventions to optimise tracheoesophageal voice, a systematic literature review was completed (Chapter Three)
2. To understand what approaches SLTs currently use in clinical practice, and to identify barriers and facilitators to implementation of tracheoesophageal voice therapy, a survey of UK and Irish SLT practice was carried out (Chapter Four)

3. To establish the views, experiences and priorities of PWL regarding tracheoesophageal voice rehabilitation, a qualitative study was completed using focus group methodology (Chapter Five)
4. The findings of the studies above were synthesised with a co-design project with stakeholders (Chapter Six); and a small study testing the feasibility of EMST as a potential component of the VITAL intervention (Chapter Seven).

This chapter has set out the current picture of tracheoesophageal voice rehabilitation and identified the challenges that this study seeks to address. Chapter Two provides further context through detailed presentation of laryngeal and tracheoesophageal voice production, and discussion of existing laryngeal voice therapy interventions.

CHAPTER 2 | LARYNGEAL AND TRACHEOESOPHAGEAL VOICE: PRODUCTION AND REHABILITATION

2.1. INTRODUCTION

This chapter presents a detailed overview of voice production and therapeutic approaches to voice rehabilitation. To give context to the issues of voice rehabilitation after laryngectomy, a model of laryngeal voice production will first be described and contrasted with tracheoesophageal voice production. The features of tracheoesophageal voice will be discussed followed by presentation of conventional laryngeal voice therapy approaches, which may be transferrable to tracheoesophageal speakers.

2.2. LARYNGEAL VOICE

2.2.1. ANATOMY OF THE VOCAL AND RESPIRATORY TRACTS

The vocal tract (Figure 2.1) is a tube-like structure consisting of the nasal and oral cavities, the pharynx and larynx, which sits directly superior to the trachea. The vocal tract enables the functions of voice production, respiration and swallowing. Anatomically, the vocal tract is equivalent to the upper respiratory tract and therefore performs the primary function of respiration by allowing airflow from and to the external environment. The tract warms air temperature as it passes through the vascular nasal and oral cavities and increases humidity as air travels through the mucous lined tract (Ball, Hossain and Padalia, 2023). Furthermore, the tract filters air entering the respiratory system and promotes immune response to pathogens through mucociliary clearance (Schwab and Zenkel, 1998) and the presence of lymphoid tissues (Randall, 2015). The structures of the tract also form a central component of the swallowing mechanism.

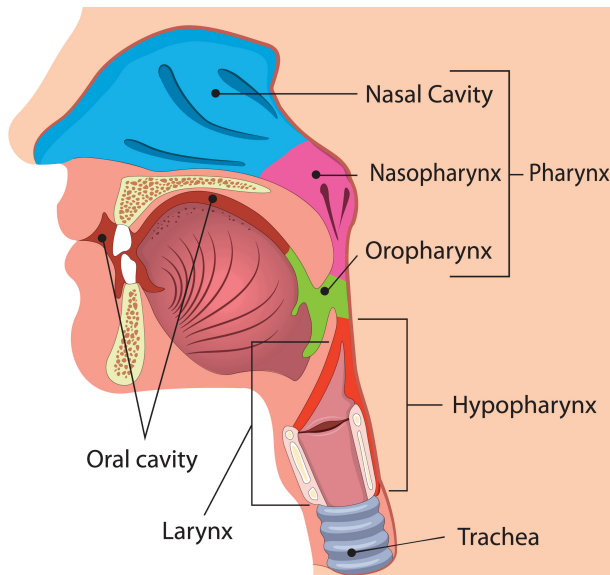


Figure 2.1: The vocal tract (Shutterstock)

The lower border of the vocal/upper respiratory tract is situated at the vocal folds, which lead inferiorly to the trachea, demarcating the start of the lower respiratory tract (Ball, Hossain and Padalia, 2023). The anatomy of the lower respiratory tract consists of the trachea, lungs and the branches of the bronchi, bronchioles and alveoli (Patwa and Shah, 2015). The trachea sits anterior to the oesophagus and is a tube of 16 to 20 c-shaped cartilaginous rings, which are connected by a posterior fibromuscular layer (trachealis muscle) and by a ciliated mucous membrane containing goblet cells (Downey and Samra, 2023). The main function of the trachea is to allow airflow to and from the lungs. The fibromuscular structure of the trachea enables the diameter of the trachea to expand on inhalation and contract during coughing and swallowing, whilst goblet cells in the mucosal lining trap allergens for clearance by the cilia (Downey and Samra, 2023). Mucociliary transport and clearance is elaborated in Chapter Six. The trachea separates at the carina into the two primary bronchi, which deliver air to the lungs. The bronchi continue to divide into smaller bronchi until they branch into bronchioles and alveoli, where gas exchange takes place for respiration (Davies, 2010).

During breathing, muscular contraction and relaxation influences the volume of the thoracic cavity (Figure 2.2). Inhalation occurs when the diaphragm contracts and lowers and the intercostal muscles contract to elevate the ribs and sternum, creating space within the thoracic cavity (Brinkman, Toro and Sharma, 2023). The lungs are joined to the thoracic cavity

by the pleura, therefore the lungs also expand to increase their volume (Mahabadi et al., 2022). The increase in lung volume leads to a decrease in pressure within the lung, which draws air from the external environment into the lung. This action is governed by Boyle's Law, which states that a volume of gas is inversely proportional to pressure (Daintith, 2009). On exhalation the process is reversed. The diaphragm and intercostal muscles relax which reduces the space within the chest cavity and causes the lungs to deflate, thereby decreasing their volume and increasing intra-lung pressure, which expels air out of the lungs (National Heart, Lung and Blood Institute, 2022). During inhalation, oxygen drawn into the lungs passes into the bloodstream via the alveoli, whereas carbon dioxide passes from the bloodstream into the alveoli before being exhaled (Davies, 2010).

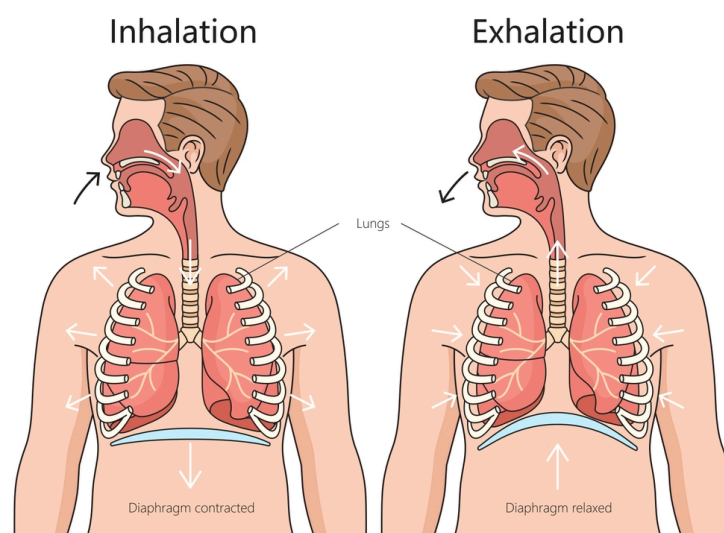


Figure 2.2: The thoracic cavity during breathing (Shutterstock)

2.2.2. LARYNGEAL ANATOMY

The larynx is a structure within the vocal tract comprising of six cartilages held together by muscles, ligaments and mucosa. It is situated in the anterior neck directly superior to the trachea at the level of third to sixth cervical vertebrae (Figure 2.3). The laryngeal cartilages provide the framework of the larynx, with three of the cartilages unpaired: the cricoid, thyroid, epiglottis; and three paired: the arytenoids, corniculates and cuneiforms (Seikel, King

and Drumright, 2005). A series of ligaments and extrinsic muscles suspend the larynx from the hyoid bone and control the raising, lowering and anterior tilt of the laryngeal structure within the neck (McFarland, 2009).

The larynx is lined by a mucous membrane of squamous epithelium (Sato et al., 2021). The inner space of the laryngeal framework is the laryngeal vestibule, extending from the aperture of the larynx to the inferior border of the cricoid cartilage, which houses the ventricular and vocal folds (Suárez-Quintanilla et al., 2023). The ventricular folds, often called the false vocal folds, are situated within the laryngeal vestibule superior to the vocal folds. The ventricular folds provide a protective function by adducting during coughing or swallowing to close the inlet to the trachea, and by secreting mucous to lubricate the vocal folds (Moon and Alipour, 2013). Whilst the ventricular folds are not active in normal voice production, they may be engaged and adducted (brought together) during disordered phonation, leading to a dysphonic voice quality (Stager et al., 2000).

The vocal folds, which are described in detail below, are attached anteriorly to the thyroid cartilage and insert posteriorly to the arytenoid cartilages (Suárez-Quintanilla et al., 2023). They sit directly above the trachea, maintaining an open position for breathing, and an adducted position for phonation (Figure 2.4). The area below the vocal folds is termed subglottic, whereas the region above the vocal folds is termed supralaryngeal or supraglottic (Saran et al., 2023). Paired intrinsic laryngeal muscles work to control the movements of the vocal folds through the actions of adducting (lateral cricoarytenoid, transverse arytenoid), abducting (posterior cricoarytenoid), elongating (cricothyroid), relaxing (thyroarytenoid) and adjusting the tension (vocalis) of the vocal folds (Bell, 2021). The ability of the larynx and vocal folds to move and adjust is pertinent as it governs aspects of voice quality such as pitch and resonance (Rakerd, Hunter and Lapine, 2019).

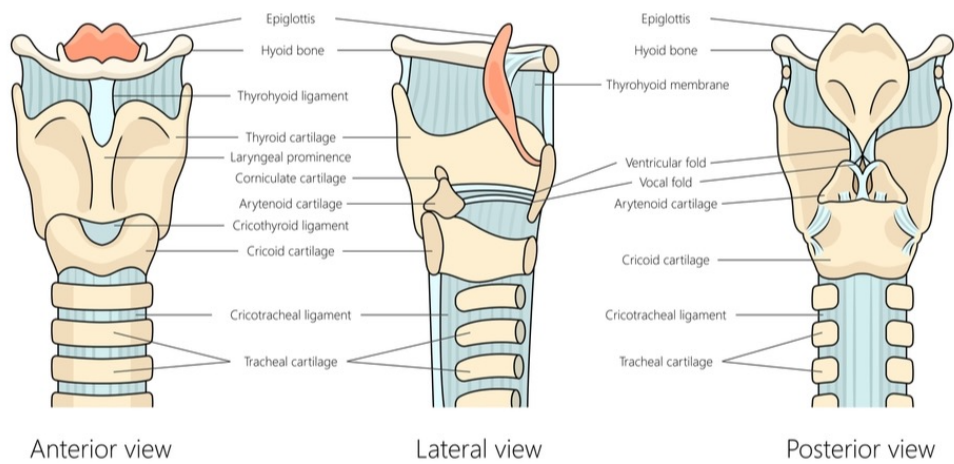


Figure 2.3: The larynx (Shutterstock)

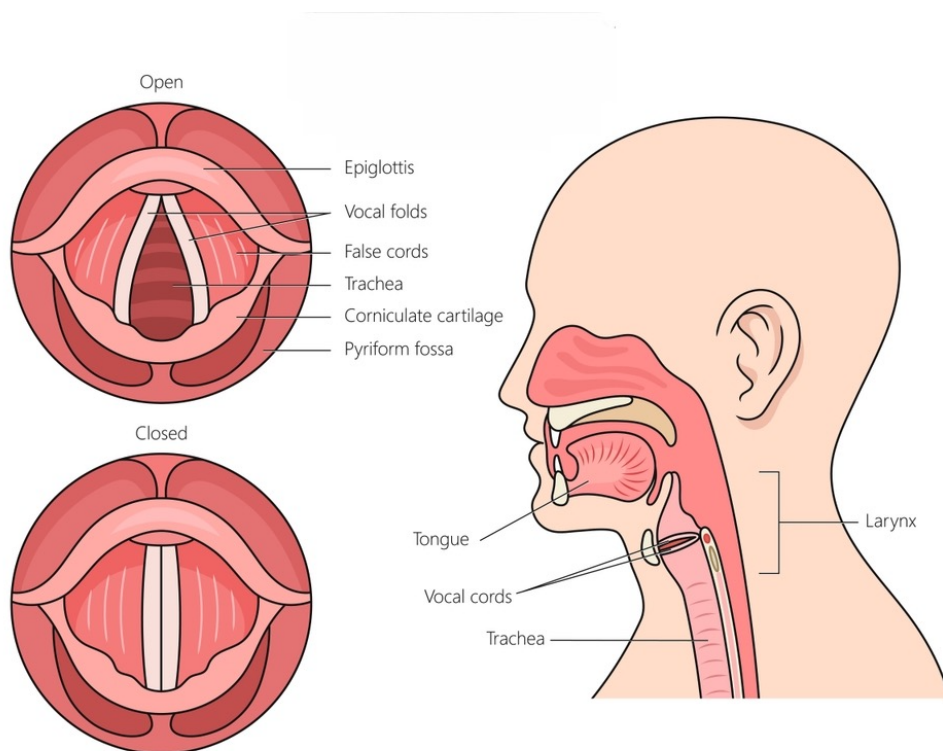


Figure 2.4: The open and adducted positions of the vocal folds (Shutterstock)

2.2.3. VOCAL FOLD ANATOMY

The vocal folds are a paired structure consisting of five muscle and mucosal layers, situated within the laryngeal vestibule (Figure 2.5). Hirano (1974) proposed the cover-body model of vocal fold structure which described the vocal folds as a muscular and ligamentous body covered by epithelium (Vahabzadeh-Hagh, Zhang and Chhetri, 2019). At the core of the vocal fold is the thyroarytenoid muscle, which is covered by the lamina propria, a connective tissue consisting of elastin fibres which enable the lengthening and shortening of the vocal folds. The lamina propria has three layers: the deep, intermediate and superficial layers. The deep and intermediate layers are grouped together to form the vocal ligament which attaches the vocal fold to the arytenoid cartilage, whereas the superficial lamina propria is gelatinous to facilitate vocal fold vibration (Saran, Georgakopoulos and Bordoni, 2023). Above the lamina propria, the most superficial layer of the vocal fold is a thin cover of squamous epithelium (Seikel, King and Drumright, 2005). The vocal fold epithelium is covered by a layer of mucus. The mucus layer serves to lubricate, to provide a physical barrier to protect the vocal fold from external irritants; and to promote a healthy laryngeal microbiome (An et al., 2022).

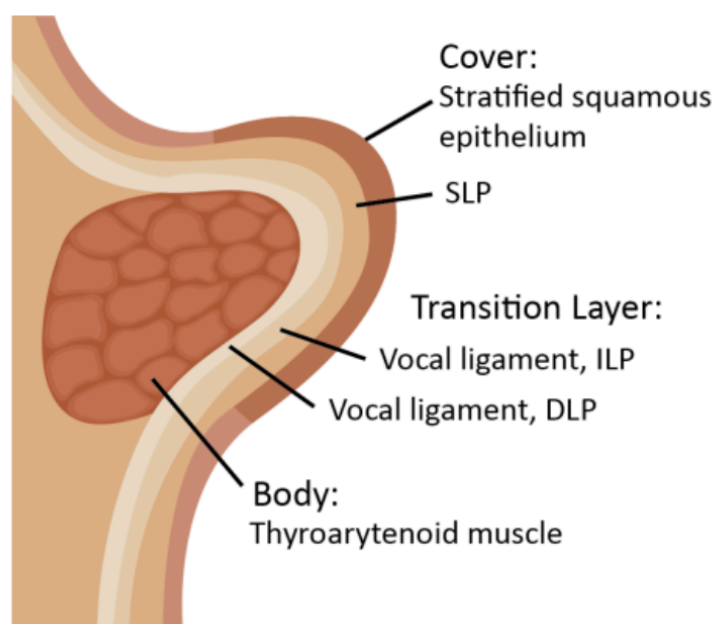


Figure 2.5: The anatomy of the vocal folds (Shutterstock)

DLP: Deep lamina propria; ILP: Intermediate lamina propria; SLP: Superficial lamina propria

2.2.4. LARYNGEAL VOICE PRODUCTION

Laryngeal voice is produced when air exiting the lungs passes through the vocal folds, causing the vocal folds to vibrate and create sound. The basic sound of the voice is then formed into speech by the shaping of the vocal tract and the articulators (Seikel, King and Drumright, 2005). This section describes laryngeal voice production in detail, demonstrating how the whole of the vocal tract is engaged in the complex interaction of airflow, pressure oscillations and vocal fold physiology required to produce voice (Mathieson, 2006).

This interaction is described as the source-filter model of voice production (Fant, 1960). The source-filter model proposes a two-level process of voice production where sound is produced at the vocal folds i.e. the source. As the sound travels through the vocal tract, the tract serves as an acoustic filter which shapes the sound produced at the vocal folds into speech. However, Fant's model does not provide a full picture of laryngeal voice production, as it does not incorporate the role of respiration as the power for phonation, therefore this section describes the model with the addition of respiration for phonation.

2.2.4.i. Power and source

For phonation to occur, pulmonary air must be generated to provide the power of the voice. This process begins with the pre-phonatory inspiratory phase (Wyke, 1983) where air is inhaled through open vocal folds. The vocal folds are then approximated by the actions of the intrinsic laryngeal muscles. Exhaled air generates aerodynamic energy in the form of pulmonary airflow, which meets the closed vocal folds, building subglottic pressure. The aerodynamic energy is then converted into acoustic energy that the listener perceives as voice (Zhuang et al., 2013). In this process it is the vocal folds that serve as energy transducers, transforming the aerodynamic energy into acoustic energy (Titze, 1992). This transformation occurs when subglottic pressure builds until the phonation threshold pressure is met and the vocal folds are set into vibratory motion (Zhang, 2016), elaborated in the following section. Aerodynamic power is lost during this process due to the resistance of the vocal folds, vocal tract and air turbulence at the glottis (Titze, 1992).

2.2.4.ii. Myoelastic-aerodynamic theory

To generate the acoustic energy perceived as voice, the vocal folds must vibrate to create a source of sound i.e. phonation. The mechanism underlying this process is termed the myoelastic-aerodynamic theory of phonation, first described by van den Berg (1958). The term myoelastic references the relationship between the elasticity of the vocal fold cover (the superficial lamina propria and the epithelium), which allows a vibratory wave to travel across the mucosa; and the muscle body of the vocal fold which elongates or slackens the vocal fold to modify the frequency of vibrations. Elaborating on myoelastic-aerodynamic theory, Švec et al. (2021) summarise the mechanism of phonation as follows:

- On exhalation, air meeting the closed vocal folds causes subglottic pressure to be higher than supraglottic pressure, which builds until phonation threshold pressure is reached.
- At this point, subglottic pressure forces the inferior margin of the vocal folds apart, followed by the superior margin, generating the mucosal wave which travels upwards and across the surface of the vocal fold. Intraglottic pressure pushes the vocal folds apart.
- The elasticity of the vocal folds allows the movement to be reversed, returning the vocal folds towards closure.
- The inferior margin of the vocal folds closes first followed by the superior margin, therefore moving the vocal folds to a divergent shape.
- This reduces intraglottal pressure, which pulls the vocal folds together and the vibratory cycle repeats.

Each oscillation of the vocal fold mucosa modifies the airflow travelling through the glottis, generating a series of air pulses into the vocal tract. These pulses of air create a sound wave, giving the acoustic property of phonation (Berke and Gerratt, 1993). The amplitude of the mucosal wave is influenced by the flexibility of the vocal fold mucosa, subglottic pressure and the compression forces of the laryngeal muscles upon the vocal folds. Amplitude is increased where the vocal folds are flexible, with higher subglottic pressure and with balanced compression forces that do not generate excess resistance to airflow through the vocal folds (Bonilha, 2016). Amplitude of the mucosal wave is perceived as loudness (McKenna and

Stepp, 2018). The frequency of mucosal wave vibration is perceived as pitch with increased frequency of vibration perceived as higher pitch and vice versa. This is governed by the action of the intrinsic laryngeal muscles which alter the length, mass and tension of the vocal folds by adjusting the position of the laryngeal cartilages, in addition to individual physical properties of the vocal folds at rest (Belyk, Lee and Brown, 2018). When the vocal folds are lengthened, and therefore under increased tension with greater spread of vocal fold mass, perceived pitch is elevated (Seikel, King and Drumright, 2005).

2.2.4.iii. Filter

In the source-filter model of voice production, the filter component refers to the way the supralaryngeal vocal tract shapes sound into meaningful speech or voice. The anatomical properties of the vocal tract exert an acoustic effect on the soundwave produced by vocal fold vibration, which is initially a simple buzzing sound until it is shaped by the tract. Within the vocal tract, the oral, nasal and pharyngeal cavities have a resonating frequency which depends on their size and shape. The speaker can modify the shape of the vocal tract to change the perceived sound of the voice (Baken and Orlikoff, 2000).

Certain harmonics are enhanced dependent on the resonant characteristics of the vocal tract, which influences perceptual voice quality (Rakerd, Hunter and Lapine, 2019). The resonant frequencies of the vocal tract are called formants, which are central to the production of vowel sounds. Each vowel sound consists of several formants, which give the vowel its specific sound and enables to the listener to distinguish between different vowels (Ladefoged, 2012). Additionally, the movement of the articulators shapes sound into consonants by modifying airflow resistance and turbulence.

2.2.4.iv. Musculoskeletal

An additional consideration in voice production is the contribution of posture and muscle tension. Muscular activity is an essential component of voice production, and a level of muscle tension is necessary for function. However, when increased tension develops within the laryngeal muscles, or externally within the muscles of the upper body it may have a detrimental impact on voice quality. This type of voice disorder is called muscle tension dysphonia (Morrison, Nicol and Rammage, 1986) and the underlying mechanism of the muscle tension may be multifactorial and specific to individual factors such as psychosocial, respiratory or neuromuscular processes. Habitual posture is also a relevant factor in voice production, where postural imbalances or maladaptation may decrease the efficiency of voice production (Picciotti et al., 2023). The two features of muscle tension and posture are often interlinked, for example, a habitual forward head posture may result in increased muscle tension in the posterior neck muscles (Cardoso et al., 2019; Desjardins et al., 2022). Postural issues also impact on respiratory function, which may result in loss of respiratory support for voicing (Koseki et al., 2019).

2.2.5. ACOUSTICS OF LARYNGEAL VOICE

Laryngeal voice can be assessed perceptually using subjective rating and assessment; however, the reliability of perceptual voice rating may be influenced by listener experience (Bele, 2005) and the voice task being assessed (Lu and Matteson, 2014). Alternatively, acoustic assessment of the voice provides an objective measure of voice quality by analysing the soundwave produced by vocal fold vibration, which may be measured against normative values (Mathieson, 2006). Acoustic analysis measures variability (perturbation) or aperiodic noise in the soundwave (Freeman and Fawcus, 2001). Measures of perturbation assess for variability between the soundwave cycles of vibration. A cycle is the time taken for the vocal fold to complete one vibration, which is equivalent to one period. In a waveform with normal periodicity, the waveform is identical between cycles, however, if there is variability (perturbation) between cycles the sound will have increased levels of aperiodic noise (Freeman and Fawcus, 2001).

Commonly used measures of perturbation are jitter and shimmer. Jitter measures variation in fundamental frequency across periods, i.e. the number of vibratory cycles occurring in one second; whilst shimmer measures variability in the amplitude of the soundwave (Li et al., 2021). Periodicity is assessed using the noise-to-harmonics ratio. A soundwave produced by voice is complex and consists of several single soundwaves combined. This complex waveform contains one main waveform which produces the fundamental frequency of the voice, and the additional waveforms which are known as harmonics.

A harmonic is a multiple of the fundamental frequency, for example where the fundamental frequency of a waveform is 100Hz, the second harmonic would have a frequency of 200Hz (Ladefoged, 1996). Harmonics are differentiated from noise, which is an irregular soundwave that is not a harmonic of the fundamental frequency. The irregular soundwave is therefore aperiodic, which is perceived as noise within the sound (Baart, 2010). Acoustic measures have clinical relevance for assessment of voice quality. High level of jitter in the voice is perceived as rough, breathy voice quality (Wolfe and Martin, 1997) and creak (Ladefoged and Maddieson, 1996). Whereas increased shimmer is associated with roughness and hoarseness (Baken and Orlikoff, 2000).

2.3. TRACHEOESOPHAGEAL VOICE

2.3.1. TRACHEOESOPHAGEAL VOICE PRODUCTION

Tracheoesophageal voice production is anatomically and physiologically different to laryngeal voice production. In the absence of a laryngeal sound source, an alternative route to phonation must be established. As indicated in Chapter One, tracheoesophageal voice is produced when exhaled air is redirected into the reconstructed pharynx via a voice prosthesis (Figure 2.6). There, the airflow causes vibration of the reconstructed pharyngeal mucosa which generates a novel sound source for shaping by the remaining vocal tract. However, the resultant voice quality differs from laryngeal voice perceptually and on acoustic measures (van Sluis et al., 2018).

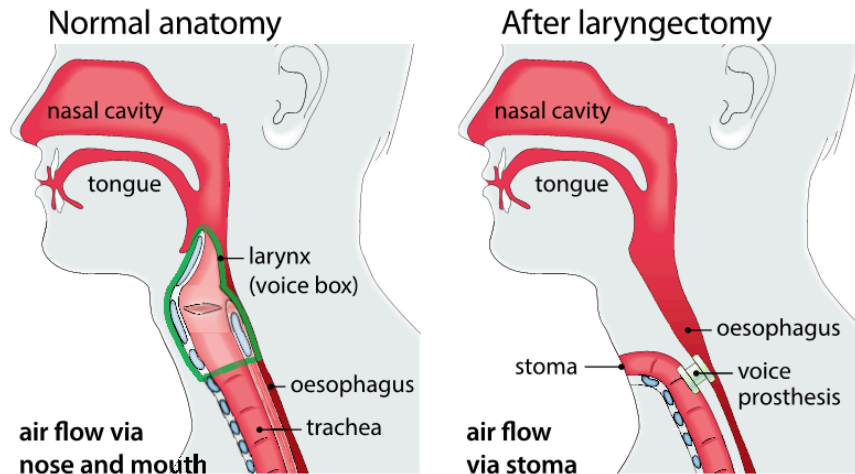


Figure 2.6: Airflow for voice after laryngectomy
(Produced with Medical Illustration, Barts Health NHS Trust)

Following resection of the larynx, tracheoesophageal voice is established through surgical voice restoration, first described by Singer and Blom (1980). Surgical voice restoration is a surgical technique in which a tract is created between the posterior tracheal wall and the upper oesophagus (Kazi, 2007), this tract is commonly referred to as a tracheoesophageal puncture. A silicone voice prosthesis is placed into the tracheoesophageal puncture, which allows egressive airflow to be directed from the trachea into the reconstructed pharynx.

To achieve this the PWL must occlude their stoma on voicing to direct the exhaled air through the voice prosthesis. A voice prosthesis contains a one-way valve which opens under the pressure of the redirected airflow, enabling the air to reach the reconstructed pharynx. The one-way valve feature of the prosthesis then remains closed at rest and during swallowing to protect against aspiration of saliva or an ingested bolus from the oesophagus into the trachea. As air is directed into the reconstructed pharynx, it reaches the pharyngoesophageal segment.

The pharyngoesophageal segment is an area of reconstruction in the throat, created in primary closure laryngectomy surgery, which consists of the inferior pharyngeal constrictor muscles (cricopharyngeus and thyropharyngeus) and the proximal cervical oesophagus

(Lundström et al., 2008); typically located at the level of cervical vertebrae C5-C7 (Zhang et al., 2019). The muscles are reconstructed so as to provide a new vibratory source for generating sound, in the absence of the vocal folds, which is termed the vibratory segment. The vibratory segment is typically around one vertebra in length, however, in some cases it may be longer, or two separate areas of vibration may be found (Wetmore et al., 1985). After laryngectomy, anatomical changes affect the power and source components of the voice production model. In most cases the filter component remains largely intact above the level of the tongue base, unless there has been an additional surgical procedure affecting the oral or nasopharyngeal spaces. However, different surgical closure techniques and reconstruction techniques may influence the vibratory and resonant properties of the reconstructed pharynx. Of note, the term reconstructed pharynx refers to the reconstructed throat after a primary closure laryngectomy as the pharyngeal constrictor muscles are retained. In extended surgeries, where partial or complete flap reconstruction is required, the area is referred to as the neopharynx to reflect the distinction that a new pharynx has been surgically created. The following section will describe and contrast tracheoesophageal voice production in the context of the power, source and filter model of voice production.

2.3.1.i. Power

After laryngectomy the lungs remain intact, however, the upper airway is altered which impacts on respiratory function. In keeping with laryngeal phonation, the lungs generate the power for tracheoesophageal phonation. Egressive airflow exiting the lungs creates a sound source as it passes through the vibratory segment, converting aerodynamic energy into acoustic energy (Grolman et al., 2008). PWL experience higher resistance on voicing compared with laryngeal phonation due to anatomical alteration and the presence of the voice prosthesis (Zhang et al., 2019). This results in airflow resistance 7.5 times greater than that of laryngeal speakers (Bohnenkamp et al., 2012). Aerodynamic power is therefore lost as the airflow reaches the voice prosthesis, and potentially due to air leak via the stoma, hence more power is required to generate sufficient phonation pressure for tracheoesophageal voice. This may be perceived by the PWL as a greater effort required for voicing. (Grolman et

al., 2008). The impact of respiratory changes after laryngectomy is elaborated in Chapter Seven.

2.3.1.ii. Source

After laryngectomy a novel source of sound is required to overcome the absence of the vocal folds. Whilst the voice prosthesis provides a conduit for airflow to the vibratory segment, it does not produce sound in itself. The vibratory capacity of the pharyngoesophageal wall mucosa, sufficient airflow pressure and rapid pressure changes in the vibratory segment were observed on fluoroscopy and manometry to be elements of successful tracheoesophageal speech (Zhang et al., 2019). These elements were seen to represent the alaryngeal vibratory source, which confirms that tracheoesophageal voice is also an aerodynamic and myoelastic process akin to laryngeal voice production; albeit with a differing vibratory source (Deschler et al., 1999). Zhang et al. (2019) hypothesise that the rapid airflow pressure changes in the reconstructed or neopharynx impact on mucosa to generate a vibratory sound source in tracheoesophageal voice, akin to pressure changes across the vocal folds which generate vocal fold vibration. They acknowledge that further testing of this hypothesis is required, however.

The interplay of appropriate pressure and resistance at the vibratory segment is a central component of effective tracheoesophageal voice. Effective tracheoesophageal voice quality is also influenced by the muscular tonicity and diameter of the vibratory segment (Búa et al., 2016). The diameter of the vibratory segment was found to be smaller in people under the age of 70 years (van As et al., 2001). A narrower vibratory segment is associated with better perceptual voice quality (van As et al., 2001; Jacobi et al., 2015), whereas excess muscular tonicity or spasm at the vibratory segment produces increased resistance which can impair airflow through the segment and prevent phonation (Hamaker and Blom, 2003).

Achieving optimal tonicity for voice is supported by cricopharyngeal myotomy (Singer and Blom, 1981). A myotomy is a procedure where muscles are cut. Cricopharyngeal myotomy involves the surgeon carefully cutting through the fibres of the cricopharyngeal muscle

during the laryngectomy procedure, whilst ensuring the excision does not extend through into the oesophagus (University of Iowa, 2024). The myotomy reduces pressure within the reconstructed pharynx, which improves the acquisition of tracheoesophageal voice and also reduces potential for dysphagia, muscle spasm and fistula development (Horowitz and Sasaki, 1993).

The muscular tone of the vibratory segment can be described as a continuum from high to low tone, or hypertonicity to hypotonicity; where optimal tonicity is considered a neutral midpoint (Hurren, Miller and Carding, 2018). Stenosis of the vibratory segment is an adjunct to the tonicity continuum that reflects an absence of vibration (Perry, 1989). Depending on the extent of hypertonicity, tracheoesophageal voice may be strained, effortful in quality or absent (Erman and Deschler, 2010). However, the relationship of hypertonicity to voice quality is variable and mild hypertonicity may still be associated with acceptable voice quality (van As et al., 2001). Hypertonicity or areas of muscle spasm may be treated with injection of botulinum toxin, which may be indicated despite cricopharyngeal myotomy (Lightbody et al., 2015).

Conversely, hypotonicity of the vibratory segment typically results in suboptimal tracheoesophageal voice quality due to reduced contact between the neopharyngeal walls, which prevents mucosal vibration (Hilgers et al., 2006). This results in a low volume, breathy, whispered voice quality (Hilgers et al., 2006). In this instance, digital occlusion with the hand or via a pressure band may be beneficial to approximate the neopharyngeal walls to achieve a stronger vibration of the mucosa (Baijens et al., 2011).

Other aspects of the vibratory segment impact tracheoesophageal voice quality (Zhang et al., 2019). Voice quality judged as good was correlated with a short segment, located higher in the neck at C4-5 vertebrae in a study of oesophageal speakers (Bentzen et al., 1976). People with a circular vibratory segment and strong mucosal wave were rated as having good or reasonable voice by SLPs, (Búa et al., 2017). Post radiation fibrosis, stricture or scarring can impair the vibratory capability of the vibratory segment over time, resulting in deterioration, non-acquisition or cessation of voice (Búa et al., 2016; Zhang et al., 2019). Stricture rates of

19% have been reported post-laryngectomy with negative impact on voice and swallowing (Sweeny et al., 2012).

In regard to perceptual aspects of tracheoesophageal voice quality, Búa et al. (2017) found that voice quality is positively correlated with intelligibility (Búa et al., 2017) whereas perceptual roughness was correlated with worse voice quality, hyperfunction and poor intelligibility. The presence of saliva in the neopharynx was associated with poorer ratings of voice quality (Búa et al., 2017; van As et al., 2001). During phonation an upward shift of the pharyngoesophageal segment by 0.5-1.5 vertebrae has been observed, which may present as higher fundamental frequency of phonation (van As et al., 2001; Lundström et al., 2008).

2.3.1.iii. Filter

Post-laryngectomy the vocal tract above the vibratory segment is significantly altered compared with the supralaryngeal vocal tract. Anatomical differences exist depending on the type of surgical closure, reconstruction and in some cases the use of tissue flaps to repair deficits. Different flap reconstructions will impact differently on voice quality; therefore, this results in heterogenous presentations of voice quality between individuals.

People with a neopharynx following extended laryngectomy surgery are less likely to have tonic or hypertonic voice, as a marker of acceptable voice quality, than people who have had a total laryngectomy alone (van As et al., 2001). In a study of tracheoesophageal speakers with differing reconstruction types, Jacobi et al. (2015) found that acoustic features of voice were worse after salvage laryngectomy, gastric pull-up and non-circumferential reconstruction, with comparatively better voice quality for people with tubed free flaps or post-operative radiotherapy. This finding is consistent with Alam et al. (2008), who found equal voice outcomes for primary closure and radial forearm free flap reconstruction, as measured by maximum phonation time and fluency. Deschler et al. (1998) compared outcomes of pectoralis major reconstruction with total laryngectomy, which found no significant differences on acoustic measures, however, trained and naïve listeners rated perceptual voice quality as superior in total laryngectomy. In an earlier small scale study

Deschler et al. (1994) compared outcomes of tubed radial forearm flap reconstruction with outcomes for total laryngectomy. Again, the authors found no significant differences on acoustic measures, yet trained and naïve listeners again rated some qualitative parameters of voice quality as superior in total laryngectomy. Vocal efficiency has been found to reduce following jejunal reconstruction in terms of the conversion of aerodynamic to acoustic energy. (Grolman et al., 2008), which may be due to the increased vibratory segment diameter of the typically wider jejunal flap.

2.3.1.iv. Musculoskeletal

Laryngectomy surgery and radiotherapy impact significantly on the musculoskeletal function of the upper body. During laryngectomy, the sternocleidomastoid muscles at the anterior neck are divided to ensure that the neck stoma is not deeply recessed (Santoro et al., 2019). The alteration to muscles of the anterior neck may lead to impaired neck mobility. Furthermore, there is potential for accessory nerve damage or sacrifice during the laryngectomy procedure, which results in pain and impairment of shoulder girdle function (Rottermund, Hamerlińska and Knapik, 2020). Impairment to shoulder function and development of scar tissue may also be a sequelae of extended laryngectomy procedures using pectoralis major flaps (Rauchenwald et al., 2021). Decreased range of movement in the shoulder is associated with reduced QOL in longterm survivors of head and neck cancer (Eickmeyer et al., 2014).

Many PWL undergo radiotherapy treatment before or following laryngectomy. Radiation induced tissue fibrosis can develop as a late-stage effect of radiotherapy, which chronically inflames tissues and reduces pliability (Djabali et al., 2021). Fibrosis may develop up to one-year post-treatment and worsens over time, causing pain, neck stiffness, trismus and lymphoedema which result in reduced QOL (Ramia et al., 2022). The presence of fibrosis in the neck and shoulder area also reduces shoulder mobility and may lead to postural alterations affecting the head and neck (DiFrancesco et al., 2020). Lymphoedema is an additional late effect of radiotherapy, prevalent in head and neck cancer survivors, which is characterised by swelling and accumulation of fluid within tissues (Jeans et

al., 2021). Similarly to fibrosis, lymphoedema is associated with pain, reduced range of movement, contractures, postural impairments, trismus and reduced QOL in survivors of head and neck cancer (Stubblefield and Weycker, 2023).

2.3.2. ACOUSTICS OF TRACHEOESOPHAGEAL VOICE

Acoustic analysis of tracheoesophageal voice is more complex than analysis of laryngeal voice. Due to the aperiodicity and low fundamental frequency present in some tracheoesophageal voices, acoustic analysis programmes are rendered unreliable (van As-Brooks et al., 2006). Where tracheoesophageal voice samples contain a clear fundamental frequency, it is feasible to calculate measures of perturbation such as jitter, shimmer and harmonics-to-noise ratio as these are based upon periodicity. The use of spectral analysis has been advised to more reliably determine acoustic markers of tracheoesophageal voice, however, analysis of perceptually poor quality tracheoesophageal voice remains problematic due to the same issue of aperiodicity (van Gogh et al., 2005). A systematic review of alaryngeal voice acoustic measures (van Sluis et al., 2018) highlights how this issue presents an inclusion bias in the literature as studies tended to include tracheoesophageal speakers with excellent and therefore periodic voice quality; noting that the few existing studies present low quality. Furthermore, the perceptual relevance of acoustic measures of tracheoesophageal voice has not yet been established (van As-Brooks et al., 2006).

In a study of 39 PWL, no difference in pitch was found between male and female tracheoesophageal speakers (van As-Brooks et al., 2006). The average male tracheoesophageal fundamental frequency was comparable to laryngeal male speech; however, average female tracheoesophageal speech was found to be significantly lower than laryngeal female speech at 115Hz versus 220Hz respectively (van As-Brooks et al., 2006). Normal laryngeal speakers were found to have lower values of jitter and shimmer, longer maximum phonation time and higher intensity compared with tracheoesophageal speakers (van Sluis et al., 2018). However, tracheoesophageal speech was found to have better acoustic values and more perceptual acceptability compared with other forms of alaryngeal speech such as oesophageal speech (van Sluis et al., 2018).

2.4. LARYNGEAL VOICE THERAPY APPROACHES

Production of laryngeal voice requires normal anatomical features, healthy mucosa within the vocal tract and for all components of the power-source-filter model to be functioning effectively. When one or more of these components is impaired, a voice disorder may arise. In this case, the principle aim of voice therapy is to identify and address the factors that are impacting on voice quality. Voice therapy interventions encompass a range of approaches such as providing information and advice, education, direct and compensatory techniques (RCSLT, 2019). Voice therapy is therefore a complex intervention (White and Carding, 2022), which may be multifactorial. SLT-led behavioural interventions for voice therapy are recommended as the primary treatment for the majority of voice disorders (Desjardins et al., 2017).

2.4.1. SYSTEMATIC REVIEWS OF LARYNGEAL VOICE THERAPY

It is beyond the scope of this chapter to complete a systematic review of all laryngeal voice interventions; therefore, a summary of relevant evidence is presented here. Existing systematic reviews of behavioural voice interventions have found a tendency towards direct voice therapy and specific techniques as more effective than indirect therapy or less defined interventions (Speyer, 2008); and improvement following voice therapy when compared with no intervention (Ruotsalainen et al., 2008). The current evidence base, however, is found to be limited across the majority of systematic reviews.

A systematic review of the association between posture and voice production found that effective posture benefits voice production by enabling unimpaired movement of the larynx and shifts in muscle tension, whereas postural imbalances impair muscular control and resonances of the voice (Cardoso, Lumini-Oliveira and Meneses, 2019). In a review of interventions to target muscle tension (da Cunha Pereira et al., 2017), a range of approaches were identified such as semi-occluded vocal tract exercises, vocal hygiene, frequency modulation, soft tissue therapies and respiratory exercises. Included studies reported

positive outcomes, however, there was heterogeneity of assessment, protocols, dosage and various methodological shortcomings; therefore, limited scope to replicate or implement the interventions. Similarly, Ogawa and Inohara (2018) found that the evidence base for voice therapy for benign vocal fold lesions is insufficient to support usage. In relation to resonant voice therapies, which predominantly target vocal fold closure, limited small scale studies were found, leading to the recommendation for a randomised controlled trial incorporating wider participant populations (Yiu, Lo and Barrett, 2017). Desjardins and Bonilha (2020) reviewed studies incorporating respiratory exercises, which again found a need for further research, particularly into the mechanism of action through which respiratory exercises may impact voice outcomes.

White and Carding (2021) conclude that further intervention development is required before efficacy of laryngeal voice interventions can be tested. Informed choice of which intervention the SLT should use is challenged by limitations in the descriptions of interventions (White and Carding, 2021), heterogeneity of study components, outcomes and use of non-standardised outcome measures (Desjardins et al., 2017). The evidence base for laryngeal voice therapy approaches is not therefore robust across approaches and requires further development.

2.4.2. A TAXONOMY OF LARYNGEAL VOICE THERAPY

In attempting to address the issue of suboptimal intervention description, Van Stan et al. (2015) developed a detailed taxonomy to classify interventions into different categories with associated terminology to standardise description. Figure 2.7 illustrates the taxonomy, which presents three overarching categorisations: indirect and direct interventions; and intervention delivery methods. Intervention delivery is categorised as intrinsic if patient-led, versus extrinsic if administered by the SLT. Voice therapy interventions are defined as indirect when using education and counselling, or direct when applying targeted approaches that modify voice production in five sub-systems. Indirect and direct interventions are further categorised as tools, which describe specific therapy approaches (Figure 2.8). The taxonomy model presents direct intervention categories as overlapping, in acknowledgement that specific interventions (tools) may effect change in more than one category.

The taxonomy provides a clear presentation of the different potential components of voice therapy, however, as it translates to theory there is not equal evidence to underpin all stated interventions. Furthermore, there is significant variance in clinical practice as to how SLTs implement a chosen intervention type if it is not detailed within a specific therapy programme. For example, an SLT may choose to work on respiratory support by following a specific approach such as Accent Method (Thyme-Frøkjær and Frøkjær-Jensen, 2021); or they may devise their own therapeutic activities and set a dosage based upon clinical judgement.

It is not within the scope of this chapter to consider the full breadth of protocol-based and ad hoc activities that SLTs may implement. The following sections will explore intervention types that have a stronger evidence base and are potentially more applicable to tracheoesophageal voice. Direct laryngeal voice intervention types are explored under the division of whether they principally target the power (respiratory), source (vocal function), filter (vocal function and musculoskeletal) or musculoskeletal components of voice production. The direct intervention types of auditory and somatosensory are not discussed here as they relate to modification of auditory, visual and somatic inputs predominantly for biofeedback. The role of the indirect interventions of education and counselling is also considered.

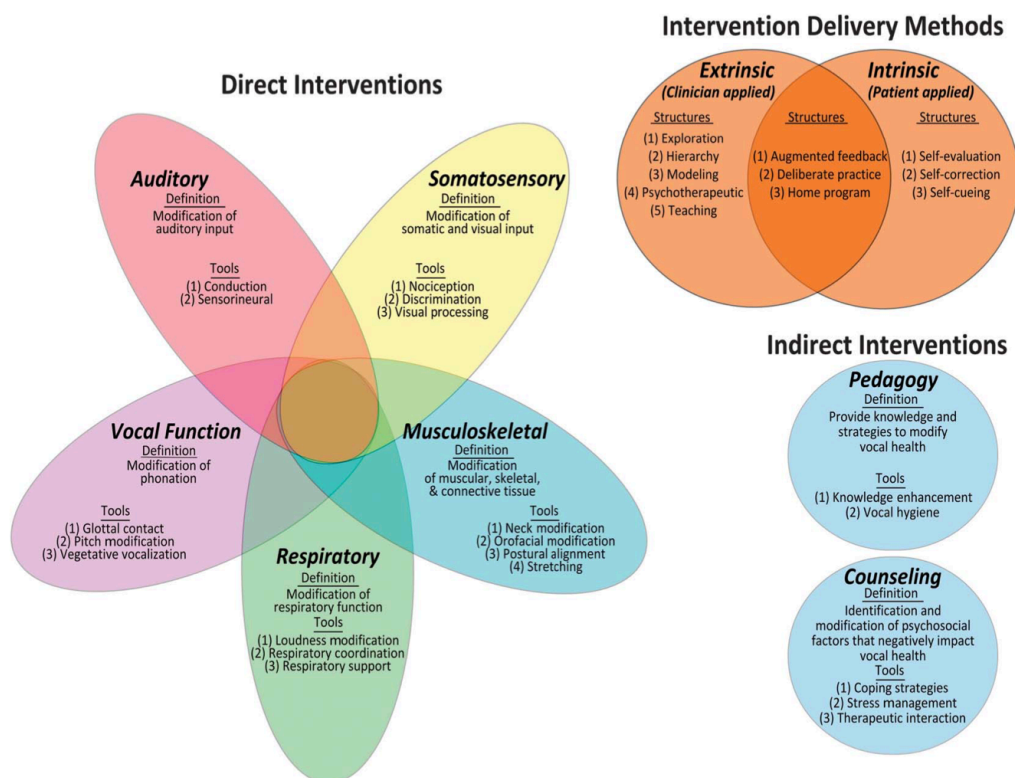


Figure 2.7: Van Stan taxonomy of voice therapy (Van Stan et al., 2015)

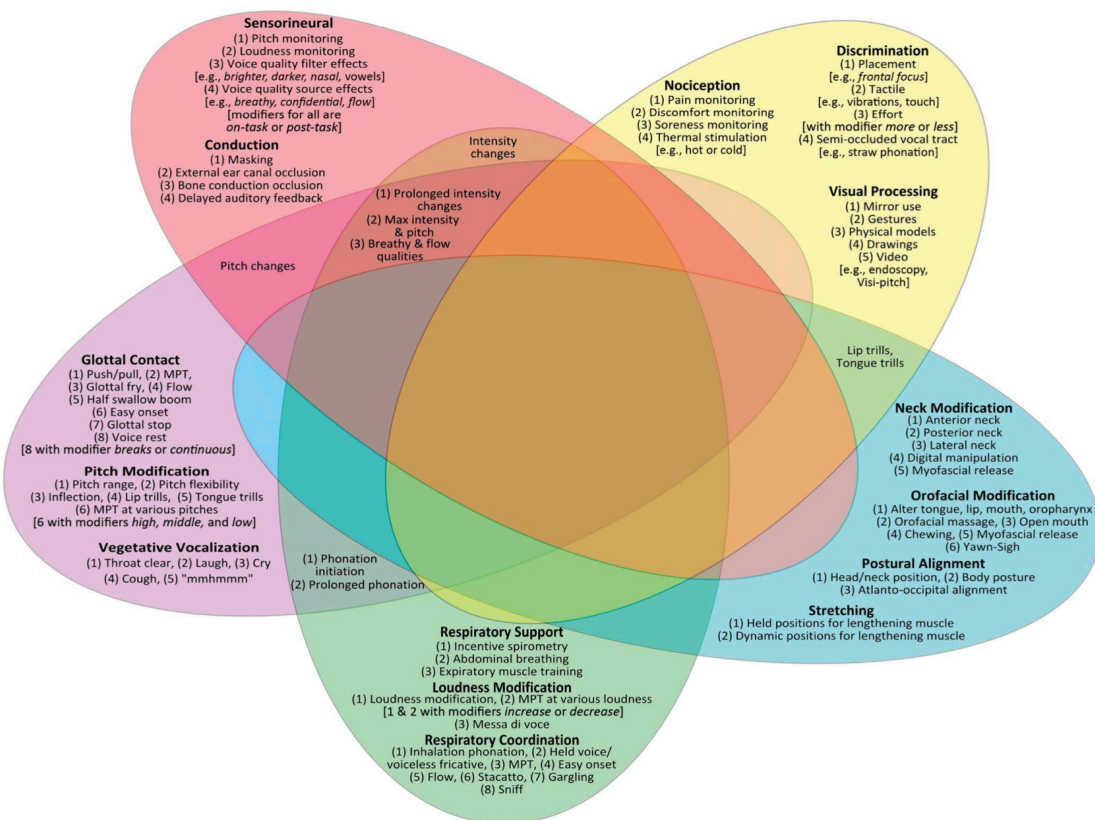


Figure 2.8: Direct intervention tools (Van Stan et al., 2015)

2.4.3. DIRECT THERAPY APPROACHES

2.4.3.i. Power

Impairments or habitual patterns that reduce the breath support available for voice production impact on the power component of the voice production model, or the respiratory category of the Van Stan taxonomy. Therapy techniques therefore aim to restore relaxed, natural breathing patterns and to ensure that the volume and expiratory flow of air is controlled against vocal fold resistance for efficient, non-effortful phonation (Mathieson, 2006). Breathing exercises are not required by all people with voice disorders and therefore tailoring to individual needs is essential (Desjardins and Bonilha, 2020). A systematic review of respiratory exercises for voice (Desjardins and Bonilha, 2020) identified several types and emphasised the need to generalise respiratory exercises to voicing activities.

Approaches to target power in the voice frequently encourage deeper inhalation of breath through the engagement of the diaphragm and expansion of the ribs. This increases the volume of the inhalation and therefore provides increased breath support for sustained phonation, leading to increased maximum phonation time (Chukwu et al., 2022). Numerous exercises exist to support abdominal or more expansive breathing, which incorporate developing awareness of breathing patterns, placement, stamina and control of the breath within the body (Shewell, 2009). Beyond increasing the volume of the breath, it is necessary to achieve coordination between breathing and phonation. The Accent Method (Thyme-Frøkjær and Frøkjær-Jensen, 2021) is a voice therapy approach which aims to optimise voice through progressive exercises that coordinate breathing with phonation, articulation and body movement. The foundation of Accent Method is to first increase control of diaphragmatic breathing which is translated through voice exercises into control of phonation and eventually speech. Accent Method has been shown to have positive effects in the treatment of benign vocal fold lesions such as nodules, polyps and contact granuloma (Abdelgoad and Alrusayyis, 2022); and to improve the acoustic parameters of jitter, shimmer and noise-to-harmonics ratio (Othman et al., 2021).

Lee Silverman Voice Treatment (Sapir, Ramig and Fox, 2011) is an intervention that was first developed to address loss of speech volume and dysarthric speech in people with Parkinson's Disease. Lee Silverman Voice Treatment is an intensive therapy course which focusses on repetitions of sustained vowel phonation at maximum intensity, and tasks to promote carry-over of vocal loudness into conversational speech. The repetitions of sustained vowel phonation require engagement of the respiratory system to elicit increased intensity, resulting in increased expiratory muscle effort (Richardson et al., 2022). Lee Silverman Voice Treatment is more effective at increasing vocal intensity in people with Parkinson's Disease compared with no treatment or respiratory therapy alone (Yuan et al., 2020). Lee Silverman Voice Treatment has also been found effective in other neurological disorders (Progressive Supranuclear Palsy – Sale et al., 2015; multiple sclerosis – Baldanzi et al., 2022). The effect of Lee Silverman Voice Treatment on vocal loudness has not been investigated in people without neurological disorders.

Respiratory muscle training, such as EMST, involves the use of devices that increase resistance during inhalation or exhalation, thereby increasing the engagement of the inspiratory or expiratory muscles. These approaches have been shown to improve maximum phonation time (Tsai et al., 2015), voice quality and increase air available for phonation (Desjardins et al., 2022). EMST is discussed in further detail below.

[2.4.3.ii. Source](#)

Voice therapy interventions targeting the source of phonation seek to modify vocal fold contact and pitch (Van Stan et al., 2015). A common approach to these interventions is the use of semi-occluded vocal tract exercises. These exercises consist of a multitude of activities which partially occlude the vocal tract during phonation. This may include using the hand to lightly cover the mouth, using humming, tongue and lip trills to occlude egressive airflow during phonation, or the use of straws and tubes to elongate the vocal tract and increase airway resistance during phonation through straws (Kapsner-Smith et al., 2015).

Semi-occluded vocal tract approaches apply a partial occlusion at the front of the vocal tract. This narrowing of the vocal tract increases supraglottic and intraglottic pressure, thereby creating increased resistance within the vocal tract. This can also be achieved by lengthening the vocal tract through the use of straw phonation (Titze, 2006). The increase in pressures within the vocal tract result in better impedance matching at the glottis, which lowers phonation threshold pressure. The result of the manipulation of pressure and resistance enables the vocal folds to vibrate more efficiently with less effort and lower collision forces between the vocal folds (Dargin and Searl, 2015). Phonation threshold pressure is elevated following prolonged voice use (Milbrath and Soloman, 2003) therefore semi-occluded vocal tract approaches can be of benefit to rebalance pressures.

Semi-occluded vocal tract exercises have a short-term effect on reducing shimmer, increasing self-perceived vocal loudness (Ford, Hunter and Deliyski, 2023), improving self-assessment of voice impairment impact (Da Silva-Antonetti et al., 2023), and reducing perceptual roughness (Kapsner-Smith et al., 2015).

Vocal Function Exercises (Stemple, 1994) contain elements of semi-occluded vocal tract exercises such as tongue or lip trills but additionally target pitch range and vocal stamina through a structured protocol of sustained vowel phonation and pitch glide activities. The protocol consists of sections on vocal warm-up, stretching (i.e. of the vocal folds via pitch glides), contracting and power which targets sustained phonation. The Vocal Function Exercise protocol focusses on phonation in isolation and does not transfer this to connected speech. Systematic review of Vocal Function Exercises demonstrated the effectiveness of Vocal Function Exercises in people with dysphonia, presbyphonia and professional voice users across acoustic, perceptual and self-reported measures of voice (Angadi, Croake and Stemple, 2019).

Other interventions targeting source impairments focus on vocal fold closure and onset of voice. Vocal fold closure, or adduction exercises may be implemented where vocal fold movement is impaired such as in cases of vocal fold palsy or paresis. Formal protocols or approaches are not reported in literature, whilst a systematic review of voice therapy interventions for vocal fold palsy found significant heterogeneity in the content, timing and

dosage of therapy (Watson et al., 2017). Interventions described focussed on techniques such as pushing and Valsalva manoeuvres, hard glottal onset, cough plus phonation and combination exercises using respiratory approaches and Vocal Function Exercises. Further research is required to understand the optimal activities and dosage, however.

The Estill voice model (Estill et al., 2005) is an approach which centers on the modification of vocal qualities by refining control of sub-sections of the vocal tract. This is achieved through practices that aim to develop control, kinesthetic and perceptual awareness (Benson, 2017). Within the Estill model, control of vocal fold closure is practiced to modify voice onset, eliciting aspirated, simultaneous or glottal onsets of phonation (Estill et al., 2005). Estill is an approach applied equally to voice rehabilitation and to training of normal voice in the field of drama and singing (Fantini et al., 2016). Despite the prevalence of Estill in voice work, few studies have investigated its effectiveness. In a study of vocally healthy teachers, Estill training was shown to improve measures of perturbation, to decrease vocal fatigue and reduce negative impacts on voice-related QOL (Grillo, 2021).

2.4.3.iii. Filter

Modifications of the filter component of voice production can also be considered using Estill training. The model presents six distinct voice qualities (speech, sob, twang, opera, falsetto and belt) that result from specific configurations of the vocal tract, under speaker control (Benson, 2017). For example, to create twang quality the speaker is required to tilt the thyroid cartilage, elevate the larynx, velum and tongue, and to retract the ventricular folds (Estill et al., 2005). Again, the evidence-base for application of the approach to voice disorders is minimal. Use of twang has been shown to elicit improved vocal outcome measures in a pilot study of people with hypophonic voice (Lombard and Steinhauer, 2005). Use of sob quality decreased severity of perceptual ratings and harmonics-to-noise ratio in a predominantly female group of people with muscle tension dysphonia (Madill et al., 2021).

Resonant voice therapy (Verdolini, 2000) is an approach which engages the source and filter components of voice production to optimise vocal tract resonance, and therefore voice

quality. The approach encourages easy vocal onset of phonation whilst producing voice which enhances kinaesthetic feedback, in the form of oral vibration and sensation within the face, lips and alveolar ridge. This is achieved through activities such as humming and practice of voice production, which progresses from phrase level into conversational speech (American Speech-Language-Hearing Association - ASHA, 2024). The core aim of Resonant Voice Therapy is to produce an efficient voice with minimal effort to reduce potential for vocal fold trauma (Stemple et al., 2010). Resonant Voice Therapy has been shown to reduce Voice Handicap Index (VHI) scores and self-rated symptom severity in a randomised controlled trial of teachers with dysphonia (Roy et al., 2003); and to improve auditory perceptual measures of voice in a before/after trial of teachers with benign vocal pathologies (Chen et al., 2007).

Other techniques seek to modify the vocal tract by relaxing the pharynx and therefore reducing, or deconstricting, muscle tension. The yawn-sigh technique aims to reduce tension arising from an overly elevated larynx and hyperfunctional muscular engagement in the pharynx. This is achieved by exaggerated yawning with an open or closed mouth, followed by a vocalised sigh on exhalation (Boone and McFarlane, 1993). This technique has been shown to widen the laryngopharynx and lower the larynx (Boone and McFarlane, 1993; Titze et al., 2003); and to reduce shimmer and noise-to-harmonics ratio (Meerschman et al., 2017). Studies were carried out in predominantly female subjects with normal voice quality, however.

2.4.3.iv. Musculoskeletal

Effective posture benefits respiratory function and voice production (Cardoso, Lumini-Oliveira and Meneses, 2017); and spinal alignment differs between dysphonic and normal speakers (Franco et al., 2014). Muscle tension dysphonia is a common presentation of voice disorder (Morrison, Nicol and Rammage, 1986). Interventions that target the musculoskeletal system are therefore pertinent in voice therapy and several different approaches exist. People with muscle tension dysphonia have been found to have higher hyoid and laryngeal positions during phonation compared to normal speakers (Lowell et al., 2012). Techniques

such as laryngeal manual therapy, (Mathieson et al., 2009), manual circumlaryngeal therapy (Roy et al., 1997) and laryngeal osteopathy seek to reduce tension in the extrinsic laryngeal muscles through massage and direct manipulation of structures, which may target lowering of the larynx.

A pilot study found reduced measures of perturbation and self-reported vocal tract discomfort following laryngeal manual therapy in a group of people with muscle tension dysphonia (Mathieson et al., 2009). A later systematic review of manual circumferential therapy (Latoszek et al., 2024) found the approach was highly effective at improving values of jitter, shimmer and noise-to-harmonics ratio, however, the review concluded that further randomised-controlled trials are required. Evidence for laryngeal osteopathy is lacking, however, a pilot study in asymptomatic singers did not find any significant change in glottal closure immediately following osteopathy (Kennard et al., 2015).

Manipulation of laryngeal structures can be considered under the umbrella of soft tissue therapies which also incorporate myofascial release and stretching. Myofascial release techniques apply sustained pressure and passive stretching with the aim of freeing fascial tissues to improve range of motion. In keeping with other approaches, evidence for myofascial release is lacking in relation to voice therapy. A study of myofascial release in teachers without voice impairment found that it had a beneficial effect on posture and increased maximum phonation time (Cardoso et al., 2023).

Within clinical practice, SLTs may implement ad hoc approaches which promote general relaxation, such as meditation or range of motion and stretching exercises for the upper body. However, research is required to formalise these approaches and identify the salient components.

2.4.4. INDIRECT THERAPY APPROACHES

2.4.4.i. Education and vocal hygiene

Education on the normal anatomy and physiology of the vocal tract and the mechanism of voice production is an essential foundation to voice therapy (Mathieson, 2006). Without understanding of these factors, service users may not have sufficient information to understand the nature of their voice disorder or the rationale for proposed voice interventions. Furthermore, understanding of the voice mechanism enables service users to take an active role in their therapy. For example, Shewell (2012) advises that breath work should commence with education and developing awareness of existing breathing patterns before progressing to improving breath control.

Beyond anatomy and physiology, education also encompasses vocal hygiene and awareness of voice use. High vocal load occurs due to extended voice use, speaking at excessive volume or due to high occupational voice use (Enflo, Sundberg and McAllister, 2013). Overuse or misuse of the voice causes phonotrauma, which causes inflammation of the vocal folds and leads to the development of benign vocal fold lesions over time (Naqvi and Gupta, 2023). High or excessive vocal load may also result in vocal fatigue, which reduces vocal stamina, increases the effort required for voicing and is associated with impaired voice quality (Lei et al., 2020). Advice may therefore be required to promote voice conservation and to support the service user to reduce vocal load or use augmentative devices, such as a personal amplifier.

Vocal hygiene concerns the implementation of lifestyle factors that promote vocal tract health, and the avoidance of behaviours that are detrimental to the vocal tract. Typically, this includes maintaining adequate hydration, eliminating smoking and excess caffeine and alcohol intake, reducing exposure to laryngeal irritants and laryngopharyngeal reflux, if present (Porcaro, 2021).

The maintenance of systemic hydration through water intake; and surface hydration via inhalation of steam are recommended to maintain the health and efficient function of the

vocal folds. A systematic review of the effects of hydration found that systemic and surface dehydration negatively affected acoustic voice measures, whereas significant improvements were gained after water intake and steam inhalation (Alves et al., 2019). However, whilst hydration improves voice quality, evidence is not yet sufficient to identify optimal hydration regimens (Sivasankar and Leydon, 2011).

The reduction of caffeine intake is widely advised in clinical practice on the basis that it has a diuretic effect and may therefore impair hydration. However, despite the common recommendation of caffeine reduction, studies have not found evidence that caffeine negatively impacts voice production (Georgalas et al., 2023; Alves et al., 2019). Few studies exist on the effect of alcohol on the voice, yet alcohol reduction is often advised on the basis that it may cause dehydration and promote acid reflux. In a study of a male sample, Wan and Huang (2008) found that smoking and alcohol in combination had an adverse effect on acoustic parameters of voice, compared with males that did not drink or smoke.

Tobacco smoking causes inflammatory changes within the larynx, which alter the vocal fold mucosa, increase values of jitter, shimmer and lower fundamental frequency and maximum phonation time compared with non-smokers (Banjara et al., 2014). Vaping is a more recent consideration in vocal hygiene. Vaping creates inflammation and impairs the vocal fold mucosa (Lungova, Wendt and Thibeault, 2022), however, in a study of male speakers, vaping was found to have less impact on acoustic parameters of voice when compared with tobacco smoking (Tuhanioglu et al., 2019).

Other common irritants that may cause inflammation of the vocal fold mucosa and alter pulmonary function are air pollution (Marcelino and Oliveira, 2005), dust, aerosols and low humidity environments (Sataloff, 1992). Furthermore, certain pharmacological medications adversely affect the voice, for example antihistamine medications have a drying effect and reduce mucosal secretions (Mathieson, 2006).

Vocal hygiene typically also encompasses advice on gastroesophageal reflux disease, which is associated with persistent throat symptoms such as hoarse voice, throat clearing, excess mucus and sensation of a lump in the throat (O'Hara et al., 2021). Advice seeks to identify

and reduce contributing lifestyle factors alongside implementing strategies such as sleep positioning and stress management (NHS, 2023). Recent evidence has demonstrated that commonly prescribed proton pump inhibitor medications do not benefit people with persistent throat symptoms (O'Hara et al., 2021) and further study is ongoing into the potential benefit of alginate medications.

2.4.4.ii. Counselling and Behaviour change interventions

Voice disorders are frequently linked to psychological stressors or mental health issues, with a study of North American patients finding 47% of people with voice disorders also presented with a mental health diagnosis (Jordan et al., 2021). Most commonly this presents as anxiety and mood disorders (Ravi et al., 2023). Where a voice disorder is accompanied by or arising from psychological symptoms, voice therapy alone may not be effective, whereas voice therapy in combination with psychological therapy is more effective (Reiter, Rommel and Brosch, 2013). SLT practice should therefore seek to treat the voice disorder, whilst signposting to relevant psychological services to ensure professional boundaries are maintained and appropriate support is provided.

Voice therapy requires individuals to adapt voice use patterns, modify voice-related behaviours and adhere to voice therapy advice. This may be challenging for the individual and require the support of a behaviour change intervention. Interventions such as Motivational Interviewing (Miller and Rollnick, 2013) have been applied effectively to voice therapy (Behrman, 2006). In other areas of SLT practice, Solution-Focussed Brief Therapy (de Shazer et al., 2021) and positive psychology approaches have been applied, however, this has not yet been investigated in relation to voice therapy.

2.5. PRINCIPLES OF DOSAGE AND EXERCISE PHYSIOLOGY

For therapy to be effective, the underlying principles of exercise physiology should be considered alongside the content, to guide the implementation of an optimal regime. This encompasses prescription factors of dosage such as frequency, intensity, specificity and duration; and understanding whether interventions seek to target strength or skill training. Despite the importance of optimising dosage, there is an absence of established dosage recommendations across clinical areas of SLT practice (Baker, 2012). Furthermore, evaluation of dosage is complex as effectiveness is influenced by additional factors such as task complexity and therapy goals (Manes and Robin, 2012).

Several studies have examined intervention intensity in other areas of SLT practice; and suggest higher treatment intensity is favoured (childhood apraxia of speech - Kaipa and Peterson, 2016; Aphasia – RELEASE collaboration, 2022; cleft palate – Alighieri et al., 2021). However, dosage regimens will depend on what type of skill or impairment is being targeted. Hence, the distinction between whether the target behaviour is predominantly a cognitive-linguistic or motor skill should be considered (Baker, 2012). For example, whilst higher intensity intervention is advocated for in aphasia rehabilitation, the underlying mechanism of a voice impairment is different and higher intensity may not be beneficial. In the context of direct voice therapy, which predominantly targets motor skills, optimal dosage is pertinent as exercises increase vocal load. Therefore, high intensity intervention may be damaging to the vocal tract mucosa, whereas insufficient intensity is unlikely to produce benefit (Roy, 2012). Few examples of evidence-based dosage exist in voice related interventions, with notable examples being Lee Silverman Voice Treatment (Sapir, Ramig and Fox, 2011) and EMST (Laciuga et al., 2014) where dosage is clearly prescribed in a set regime. However, overwhelmingly optimal dosage of interventions is an area of need for further research.

Voice production is a complex interaction of airflow and muscle activity which requires balanced strength, flexibility and skill. It therefore follows that interventions should seek to effect change in these areas. Voice therapy approaches typically incorporate training of skill to modify voice production, however, limited knowledge of exercise physiology has

presented a barrier to the inclusion of training principles (Johnson and Sandage, 2021), such as specificity. Exercises should be progressive and specific to the activity being targeted to engage the relevant motor control systems and activate muscle fibres (Clark, 2008) therefore voice therapy interventions should involve naturalistic voice production. However, few therapy techniques exist which consider specificity and so skill or strength is targeted without linkage to a specific functional activity. This is consistent with current practices in dysphagia rehabilitation, where strength is commonly prioritised (Di Pede et al., 2016) and the assumption is that gains in strength will transfer to the act of swallowing (Langmore and Pisegna, 2015).

The fields of sports science and physiotherapy give insight into the principles of exercise physiology through a strong evidence base for rehabilitation programmes, which could provide a theoretical foundation for voice therapy interventions. Strength is a foundation component of rehabilitation which enables gain in power and speed of movement (Lorenz and Morrison, 2015). Flexibility and stretching aims to increase range of movement in joints, elongate soft tissues and extend muscle length to enhance muscular performance (Micheo, Baerga and Miranda, 2012).

To adhere to principles of strength training, interventions also require optimal repetitions, sets, progressive muscle loading and recovery phases to produce adaptations (Lorenz and Morrison, 2015). However, few studies exist that clearly apply these training principles to voice or wider SLT interventions (Speech sound disorders - Clark, 2008; EMST - Laciuga et al., 2014), therefore further research is required to understand training principles as applied to voice production and to identify optimal levels.

2.6. APPLICABILITY TO TRACHEOESOPHAGEAL VOICE

Whilst laryngeal voice therapy approaches inform and contribute to the intervention development of this study, most notably in the co-design work of Chapter Six, the study did not specifically focus on the efficacy of directly transferring an existing approach to PWL. Two

key reasons underpinned this decision. Firstly the priorities and expectations of PWL in relation to voice therapy are not yet known, therefore it has not been established that laryngeal voice therapy approaches are relevant and appropriate for PWL. These considerations are addressed in the focus group study reported in Chapter Five and the co-design study reported in Chapter Six. Secondly, the evidence for drawing on existing approaches is limited and requires further research, notwithstanding that evidence for laryngeal voice therapy as applied to laryngeal voice is not consistently robust. Therefore, this was an additional driver for the intervention development work of this study.

Few studies have questioned if laryngeal voice therapy approaches are applicable to PWL, with mostly hypothetical consideration of how tracheoesophageal voice might be modified by approaches that target the subsystems of voice production remaining intact following laryngectomy. Systematic review of the effect on voice of chemoradiotherapy for head and neck cancer found that laryngeal voice and speech deteriorated during treatment and did not improve until one-two months post treatment (Jacobi et al., 2010). Whilst the review participants were not PWL, the review considered the underlying mechanisms of the dysphonia to be treatment effects such as radiation induced fibrosis, atrophy and oedema of vocal tract musculature and tissues. It could be hypothesised that radiotherapy would equally affect the structures of the reconstructed or neopharynx in PWL.

A later review and meta-analysis of voice rehabilitation post-radiotherapy for laryngeal cancer (non laryngectomy) found that, across three randomised controlled trials, voice rehabilitation did not improve QOL, acoustic, perceptual measures or participant reported outcomes (Taito et al., 2019). This suggests that the key elements of an effective voice intervention and mechanisms of change require identification.

2.6.1. POWER

Significant changes to breathing arise following laryngectomy. Higher lung volumes are required to initiate voicing via a voice prosthesis, which results in shorter spoken phrase length (Bohnenkamp, 2008) and reduced speaking rate, contributing to lower ratings of voice

quality (Lundstrom, 2011). Improvement in pulmonary physiology had a positive impact on alaryngeal voice quality (Pawar et al., 2008; Onofre et al., 2013). Targeting respiratory support could therefore be seen as an important factor in voice therapy for people with laryngectomy.

A more recent focus of the respiratory evidence base is on the use of EMST (Sapienza et al., 2011; Reyes, Ziman and Nosaka, 2013; Templeman and Roberts, 2020; Zhuang and Jia, 2022), which is explored via a feasibility study in Chapter Seven. EMST involves breathing into a hand-held device against resistance with the aim of increasing maximum expiratory pressure. EMST has been shown to be an effective treatment in people with disorders of cough, voice and swallowing in Head and Neck cancer rehabilitation and other populations (Hutcheson et al., 2018; Laciuga et al., 2014; Tsai, 2016; Chiara et al., 2006). It is hypothesised that EMST could improve voice quality in tracheoesophageal speakers by increasing breath support and optimising secretion clearance through increased cough strength. The targeting of secretion clearance and cough is salient as these functions are disrupted after laryngectomy. Due to the anatomical changes arising from laryngectomy, humidification of the airway is reduced, which results in increased secretions (Hilgers et al., 1990). There is also a reduction in cough efficiency due to the loss of the vocal folds hence the increased secretions cannot be cleared effectively (Yue et al., 2021). The presence of secretions negatively impacts voice quality (Búa et al., 2017, therefore it is pertinent to consider secretion management and cough in the context of communication. Chapter Seven elaborates upon the changes to cough and secretions after laryngectomy. One pilot study has been completed on the use of EMST in laryngectomy (van Sluis et al., 2020). It found that EMST improved maximum expiratory pressure and loudness in PWL. However, the study did not investigate secretion management or perceptual assessment of voice.

2.6.2. FILTER

Other studies advocate for research into the effect of vocal tract movements on alaryngeal voice (Hinni and Crujido, 2013), therefore targeting the filter component of the voice production model. Baijens et al. (2011) reported on a case study where digital manoeuvres

improved alaryngeal voice. Arifin et al. (2014) demonstrated that neck muscle activity, as measured by electromyography, correlated with volume in laryngeal voice. The authors suggest investigating whether alaryngeal speakers could modify their loudness through targeting neck muscle control; the application to rehabilitation and the underlying mechanism by which the modification of loudness could occur are not elaborated on, however. The idea of targeting subsections of the vocal tract is commonplace in laryngeal voice therapy. As described above, Estill Voice Training (Estill, 2005) uses this approach to elicit change in voice production by teaching the speaker to finely control movements of vocal tract structures. These approaches have potential to enable tracheoesophageal speakers to modify the remaining vocal tract structures and effect changes in voice quality.

2.6.3. MUSCULOSKELETAL

Muscle tension is a common cause of laryngeal voice disorders, treated with soft tissue therapies such as massage and myofascial release techniques (Mathieson, 2011). Upper body movement is restricted by myofascial changes following head and neck surgery (Terrell et al., 2000) therefore it would be prudent to investigate whether soft tissue therapies could improve voice production in people with laryngectomy. Myofascial release techniques have been applied to PWL, resulting in decreased oesophageal pressure with the aim that it would facilitate oesophageal speech (Marszałek et al., 2008). This presents a direction of research for the potential transference to tracheoesophageal speakers.

2.6.4. EDUCATION AND VOCAL HYGIENE

In relation to education and vocal hygiene the rationale for transferring laryngeal voice therapy approaches to PWL is less clear. Laryngeal vocal hygiene recommendations typically focus on reducing vocal load to minimise mucosal trauma, increasing systemic and surface hydration of the vocal folds, and reducing irritants that may cause laryngeal oedema. However, in tracheoesophageal voice production, air is not inhaled through the vibratory segment therefore the impact of inhaled irritants is not comparable; furthermore, the impact

of hydration and vocal load is not understood in tracheoesophageal voice. As such consideration is needed as to what vocal hygiene comprises for PWL, in the sense of vocal hygiene as a foundation to optimal voice production. Additionally, approaches to counselling and behaviour change may be insufficient for direct transference to PWL. Given the impact and implications of cancer diagnosis and treatment on mental health and wellbeing, enhanced approaches are likely to be required to effectively support these challenges alongside the impact on self-image and identity of the altered voice.

2.7. CONCLUSION

This chapter has set out the mechanisms of laryngeal and tracheoesophageal voice production, highlighting the anatomical and physiological differences between these processes. Common approaches to laryngeal voice therapy have been identified, with consideration of how these approaches could be applied to the development of a tracheoesophageal voice therapy if appropriate to PWL, and where modification or novel solutions may be required. Additionally, the role of vocal tract health and voice education as applied to laryngectomy, was highlighted as an area for further consideration as a foundation of a novel tracheoesophageal voice therapy.

The concepts of this chapter are taken forward to the co-design study, reported in Chapter Six, where they are discussed and trialled by stakeholders as potential components of an intervention. In Chapter Three, tracheoesophageal voice therapy is explored further through a systematic review of the literature, to identify any existing interventions aimed at optimising tracheoesophageal voice.

CHAPTER 3 | A SYSTEMATIC REVIEW OF TRACHEOESOPHAGEAL VOICE THERAPY IN POST LARYNGECTOMY REHABILITATION

This chapter has been peer-reviewed and an abridged version published:

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Patient Advisory Group input:

During the planning of this systematic review the PAG were consulted regarding the aims of the review and the role of the review in informing the intervention development. The PAG also reviewed the search strategy, including search terms. The PAG were provided with information on systematic review process with specific reference to the PRISMA framework. The PAG did not advise for any changes.

3.1. INTRODUCTION

This systematic review centres on behavioural interventions for voice rehabilitation following total laryngectomy with tracheoesophageal voice prosthesis. The national multidisciplinary guideline for head and neck cancer rehabilitation (Homer and Winter, 2024) stipulates that surgical voice restoration should be offered to all patients undergoing a total laryngectomy, following which long-term SLT intervention is essential. To support this provision, it is the recommendation of the British Association of Head and Neck Oncologists (BAHNO) that a named SLT with specialist surgical voice restoration skills is present in all cancer units, and access to SLT interventions is advised at all treatment stages (Schache et al., 2021).

Whilst existing guidelines highlight the importance of the SLT role in laryngectomy rehabilitation, detail on the recommended content of SLT intervention is insufficient. In keeping with the national multidisciplinary guideline (Homer and Winter, 2024), the scope of the BAHNO standards (Schache et al., 2021) does not elaborate on the recommended content of SLT intervention. Furthermore, there is no existing professional consensus or systematic review addressing the specific question of how to improve tracheoesophageal voice quality after total laryngectomy through behavioural interventions.

Clinical knowledge is therefore limited on what therapy approaches should be used to improve tracheoesophageal voice quality and maximise functional communication. Similarly, the Royal College of Speech and Language Therapists (RCSLT) policy statement on the management of surgical voice restoration (Evans et al., 2010) centres on the insertion and maintenance of a voice prosthesis. The statement makes minimal reference to rehabilitation of tracheoesophageal voice, stipulating only that SLTs should have competency in identifying and remediating causes of failure to produce sound and excessive vocal effort (Evans et al., 2010, p21). How this should be achieved or implemented is not elaborated on, nor is there recognition that voice problems extend beyond difficulty establishing voice or sub-optimal vocal effort. Instead, the policy statement centres on remediation of structural and mechanical causes such as voice prosthesis failure or anatomical concerns.

Laryngectomy is normally offered with curative intent, with only case report level evidence of laryngectomy as a palliative procedure (Cinamon et al., 2006; McCammon, 2019). Over 30% of people with advanced laryngeal cancer survive for five-years or more (Cancer Research UK, 2022). As a greater number of people are cured of cancer and enter survivorship (Macmillan, 2017), the need for lifelong rehabilitation is essential.

In terms of related literature, Sharpe et al. (2019) completed a narrative review of the impact of post-laryngectomy communication changes on quality of life. They identified that patient reported QOL was affected by changes to communication after total laryngectomy and suggested that linking communication to quality of life is a useful approach in post-laryngectomy management. Mental health disorders such as depression and anxiety (Perry et al., 2015; Kemps et al., 2020) affect around 22% of people after laryngectomy (Keszte et al.,

2013), and their presence has been linked to the outcome of voice restoration (Keszte et al., 2013). People with head and neck cancer have a three-fold increase in incidence of suicide compared to the general population in North America. Within head and neck cancer, laryngeal cancer is among the highest incidence (Kam et al., 2015). It could therefore be interpreted that rehabilitation aimed at improving communication is a salient contributor to improving QOL and supporting mental health after laryngectomy.

PWL who had received SLT intervention reported lower self-rated communication difficulties than those who had not (Pereira da Silva et al., 2015); as measured by the Self-Evaluation of Communication Experiences after Laryngectomy (SECEL) questionnaire (Blood, 1993). The nature of the SLT intervention was not reported, however.

Several systematic reviews have been completed within the area of post-laryngectomy voice rehabilitation. These reviews have not focussed on behavioural interventions, however, and instead there is a tendency to compare the success or evaluate the outcomes of different surgical or post-laryngectomy communication methods (Luu, 2018; Mahalingam, 2016; Pawar, 2008).

Shuxin (2010) undertook a systematic review of the effectiveness of voice rehabilitation in post-laryngectomy patients. Whilst this review produced informative findings on the impact and success rate of different methods of communication post-laryngectomy, in terms of QOL, intelligibility, satisfaction and cost, it did not evaluate behavioural interventions to support use of these methods. The term voice rehabilitation, instead, was used to describe the method of communication such as electrolarynx, oesophageal speech or tracheoesophageal voice prosthesis. The review found that electrolarynx and tracheoesophageal voice have a higher success rate than oesophageal speech; whilst tracheoesophageal voice produced the highest speech quality and intelligibility.

A later systematic review by Van Sluis et al. (2018) examined the literature relating to acoustic, perceptual and patient-reported outcomes. Healthy laryngeal speakers were compared with those using oesophageal speech, electrolarynx and tracheoesophageal speech. The review demonstrated that tracheoesophageal speech was superior to

oesophageal speech on the acoustic measures of fundamental frequency, maximum phonation time and intensity. Additionally tracheoesophageal speech was rated highest on perceptual measures of voice quality and intelligibility compared with the other communication methods. This latter finding was in keeping with the Shuxin (2010) review. Patient reported outcomes did not favour one communication method over another. However, regarding the robustness of the evidence, Van Sluis et al. (2018) found that existing studies presented methodological issues, risk of inclusion bias and were typically of low quality. The authors therefore concluded that the overall level of evidence was weak for studies reporting post-laryngectomy speech outcomes.

The psychosocial factors which influence voice rehabilitation outcomes were evaluated in a systematic review by Singer et al. (2007). This review sought to identify the factors associated with the success of voice rehabilitation after laryngectomy, noting that 'there is no overall accepted criterion for success in gaining a new voice after laryngectomy' (Singer et al., 2007, p.408). Twenty-five possible factors of influence were identified and employment status, physical condition, communication method and behaviour were associated with rehabilitation outcomes. However, the authors noted that study results were inconsistent and the lack of standardised, validated measures and criteria for success presented a challenge in comparing studies and drawing conclusions. These areas were therefore recommended for further study. Whilst it was not the main focus of the review, tracheoesophageal speech was again found to be superior on perceptual and acoustic measures when compared to oesophageal speech and electrolarynx.

The effect of different prostheses on voice quality has been evaluated, based on expert raters and patient experience (Coffey et al., 2018). This study did not find a specific optimal prosthesis based on expert rating; however, individual patient preference was identified as a salient factor and thus patient involvement in decision-making was advised. Tawfik et al. (2021) conducted a large systematic review and meta-analysis of the outcome of voice rehabilitation by voice prosthesis. The aim of this review was to compare different voice prostheses and to identify which type of prosthesis was superior across various parameters. The review therefore centred on voice restoration, rather than therapeutic rehabilitative approaches. The review assessed data from 11,918 patients and concluded that the Provox-2

was the best voice prosthesis in terms of airflow, sizing, patient preference and complications.

In summary, the focus of the literature on communication rehabilitation with surgical voice restoration has been towards placement of prostheses, prosthesis selection, and management of complications, rather than on improving the quality of tracheoesophageal voice. There is therefore a gap in knowledge around the evidence for rehabilitation and optimisation of tracheoesophageal voice quality.

The aim of this systematic review is, therefore, to critically appraise and synthesise existing evidence pertaining to behavioural interventions that target improvement in tracheoesophageal voice quality. The findings of the review will inform clinical practice and the development of a new therapy approach for tracheoesophageal voice users. The undertaking of this review is in accordance with the MRC guidance for developing and evaluating complex interventions (Skivington et al., 2021) which advocates systematic literature review as the initial step towards developing an intervention.

3.1.1. OBJECTIVES

This systematic review aims to:

1. Identify and describe the evidence pertaining to rehabilitation of tracheoesophageal voice after total laryngectomy
2. Critically appraise any existing therapeutic interventions, evaluate their effectiveness and the quality of the reported evidence

3.2. METHODOLOGY

The review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline (Page et al., 2021). The PRISMA checklist is listed in Appendix 3.1. The protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) under registration reference: CRD42021265095 (Appendix 3.2).

3.2.1. ELIGIBILITY

The systematic review question was developed within the Population, Intervention, Comparison and Outcome (PICO) framework (Richardson et al., 1995), as summarised in Table 3.1.

Question	What therapy approaches are used to improve tracheoesophageal voice production in people with laryngectomy and what is their effectiveness?	Inclusion criteria in hierarchical order	Exclusion criteria
Population	Adults with total laryngectomy that use a tracheoesophageal voice prosthesis	1. Adult 2. Total laryngectomy 3. Voice prosthesis	Partial or subtotal laryngectomy Tracheostomy
Intervention	Behavioural interventions of any design that target rehabilitation of tracheoesophageal voice after total laryngectomy	4. Intervention study 5. Intervention targets tracheoesophageal voice 6. Intervention is behavioural	Surgical or instrumental intervention
Comparison	Any type of comparator or control group e.g. experimental control or comparison over time, group or task		
Outcome	Change in communicative function, activity or participation, or quality of life related to communication		

Table 3.1: PICO question, inclusion and exclusion criteria

The population of interest, and therefore primary inclusion criterion, was adults with total laryngectomy and tracheoesophageal voice prosthesis. Communication is comparably impacted irrespective of the cause for total laryngectomy. Studies were therefore included regardless of the precipitating aetiology i.e., cancer, benign airway disease or trauma. Studies were excluded if they related to sub-total laryngectomy procedures such as partial laryngectomy, hemi-laryngectomy or tracheostomy. Studies relating to outdated surgical procedures practiced during the evolution of tracheoesophageal fistula surgery were excluded. Studies that recruited mixed populations were included if the findings for the total laryngectomy with tracheoesophageal prosthesis group were reported separately, or if they formed more than 25% of the sample.

Rehabilitation to optimise functional voice after total laryngectomy is an emerging area with a limited evidence base. To identify as much evidence as possible, a broad criterion was applied to inclusion. Published, peer-reviewed intervention studies of any design with a comparator or control group were included. Interventions delivered in any setting were included. The search was not restricted by language or date of publication.

To be eligible for inclusion study interventions were required to target behavioural rehabilitation of tracheoesophageal voice after total laryngectomy. To clarify the definition of a behavioural intervention, the Van Stan Taxonomy of Voice Therapy was used (Van Stan et al., 2015). Studies were included if the intervention could be categorised according to the direct and indirect interventions listed within the taxonomy (Figure 2.7, Chapter Two). For example, direct interventions comprised working on respiratory function, vocal function, musculoskeletal aspects such as postural alignment, or auditory and somatosensory features. Indirect interventions comprised of enhancing knowledge and addressing psychosocial factors.

As this is an under-researched area with scarce validated measures, outcomes across different areas were included. Studies were eligible if their reported outcomes related to voice, speech, communication and their impact across International Classification of Function domains, QOL or well-being. Non-behavioural interventions were excluded, such as surgery

or instrumental interventions as these would not inform what SLTs, specifically, can carry out within the scope of their practice.

3.2.2. INFORMATION SOURCES

Eight databases were searched via Ovid and EbscoHost platforms in July 2021 (updated February 2023): CINAHL, Medline, Health Policy Reference Centre, APA PsychInfo, Embase, AMED, Cochrane, Ovid Emcare.

3.2.3. SEARCH STRATEGY

Search terms were identified within three groupings for title and abstract search. Terms pertaining to laryngectomy and tracheoesophageal speech; voice and communication; and terms for rehabilitative behavioural interventions were used. Subject headings were also incorporated, with slight variation in terms between databases. Truncation ensured the search was efficient in identifying variance in word endings. Table 3.2 below illustrates the search strategy. Preliminary searches using full text search yielded high results (n= 10,512), of which many were not relevant to the review question. The search was therefore restricted to title and abstract only, which improved the relevance of the reports found.

Search	Terms
1	Laryngectom* OR tracheoesophag* OR alaryngeal OR 'surgical voice restoration'
2	Subject headings: EBSCO: Laryngectomy OR Tracheoesophageal voice prosthesis OR Speech, Alaryngeal OVID: Laryngectomy OR Larynx prosthesis OR Voice prosthesis OR Alaryngeal speech
3	S1 OR S2
4	voice OR communicat* OR speech OR phonat*
5	Subject headings: EBSCO: Voice OR Voice Quality OR Voice disorders OR Communication OR Speech OR Phonation OVID: Voice OR Voice disorder OR Speech OR Phonation
6	S4 OR S5
7	Therap* OR intervention OR treat* OR strateg* OR rehabilitat* OR training OR program*
8	Subject headings: EBSCO: Rehabilitation OR Rehabilitation, Speech & Language OR Voice Therapy OVID: Therapy OR Rehabilitation OR Speech & Language rehabilitation OR Voice Training
9	S7 OR S8
10	S6 AND S9
11	S3 AND S10

Table 3.2: Search strategy for systematic review

3.2.4. SELECTION PROCESS

Search results were exported into EndNote for de-duplication, following which a manual deduplication was carried out to identify any remaining duplicates missed by the software. Deduplicated results were uploaded to Covidence software to support management of the process. An additional deduplication was run in Covidence. The PRISMA flowchart was used as a framework to document each stage of the review.

First, title and abstract screening was completed by the research student (FS) against the primary inclusion criterion of adult population with total laryngectomy with voice prosthesis. 10% of papers were checked by a second reviewer (SM) for consistency.

The two reviewers then independently screened titles and abstracts of the included papers against the full inclusion and exclusion criteria to identify studies to include for full text review. Disagreement on inclusion was resolved via consensus between the reviewers. A third senior reviewer was to make a final decision on any unresolved disagreement. At this stage, 12 studies were discussed by the reviewers (FS and SM) to reach consensus on inclusion for full text review, senior review was not required.

The reference lists and citations of included papers were screened by FS for any studies that may have been missed in the initial search. Following the initial search in July 2021, the search was re-run in February 2023 prior to data synthesis to identify any new papers.

3.2.5. DATA COLLECTION PROCESS

A data extraction tool was created within Excel to capture relevant information from included studies. Full text review was completed by the research student using the data extraction tool. The second reviewer carried out data extraction on a randomly selected 30% sample of included papers to ensure consistency.

3.2.6. DATA ITEMS

The data extraction tool included the following items:

- Date of publication, authorship and reference
- Source of funding
- Country
- Study design and type
- Study setting
- Sample size
- Participant characteristics (clinical population, health-related and demographics)
- Details of the intervention
- Targeted outcomes
- Outcome measures used
- Reported outcomes and efficacy of the intervention

3.2.7. RISK OF BIAS ASSESSMENT

The quality of included studies was rated independently by two of the review team.

Disagreements in rating were resolved by consensus, with a third senior reviewer making the final decision where consensus could not be reached. Assessment of quality was undertaken at study level. This included, as applicable, review of the randomisation method, allocation generation and concealment, blinding, reporting of compliance and treatment of incomplete data. The following quality assessment tools were used according to study design:

- For before and after studies with no control group, the National Heart, Lung and Blood Institute of the National Institute for Health quality assessment tool for Before-After (Pre-Post) Studies with No Control Group was used (NHLBI, 2021)
- For randomised and non-randomised control trials, the Physiotherapy Evidence Database (PEDro) scale (Maher et al., 2003) was used

- For single case studies, the Risk of Bias in N-of-1 Trials (ROBiN-T) scale (Tate et al., 2013) was used

The Template for Intervention Description and Replication (TIDieR) checklist (Hoffman et al., 2014) was used to assess the overall quality of the intervention reporting, specifically if the intervention reporting was sufficiently detailed to allow replication.

3.2.8. EFFECT MEASURES

Effect sizes on primary outcome measures were calculated where data was appropriate using Cohen's *d* (Cohen, 1977) Where studies did not specify primary outcome measures, effect sizes were calculated for the overall score of measures used. Cohen's *d* effect sizes were calculated using Psychometrica online calculator (Lenhard and Lenhard, 2022). Effect sizes were interpreted using the following values: small ($d = 0.2$), medium ($d = 0.5$), large ($d = 0.8$) according to values advised by Cohen (1977). A heterogeneity assessment was planned using the I^2 measure to ascertain if it was possible to perform a meta-analysis on relevant group studies; however, this was not performed as no two studies explored the same or very similar interventions. Single case studies were reported separately.

3.2.9. SYNTHESIS METHODS

Studies of adequate quality, as defined by the quality assessment tools listed above, were included for data synthesis. Descriptive statistics were used to report participant characteristics and other variables. Due to the heterogeneity in the interventions evaluated and outcome measures used, a narrative synthesis approach was implemented to describe and combine data obtained from included studies. The synthesis included the data items listed above and was informed by the four elements of the Economic and Social Research Council (ESRC) guidance on the conduct of narrative synthesis (Popay et al., 2006): (1)

development of theory of how the intervention works, (2) preliminary synthesis of findings, (3) exploration of relationships within the data, (4) assessment of the robustness of synthesis.

3.2.10. REPORTING BIAS ASSESSMENT

In order to assess outcome reporting bias, the outcomes specified in study protocols were compared with the outcomes reported in the corresponding study publication. If the protocol was unavailable, the outcomes reported in the methods and results sections of the study publication were compared.

3.2.11. CERTAINTY ASSESSMENT

Certainty assessment was planned using GRADE criteria, however, the outcome data presented within included papers was not compatible with criteria for certainty assessment.

3.3. RESULTS

3.3.1. STUDY SELECTION

6344 records were found in database searching. Following removal of duplicates ($n = 3021$), 3323 records were screened by title and abstract. 3285 records were excluded at this stage and 38 remained for full-text review. 32 studies were excluded at full text review leading to the inclusion of six studies for data extraction. Citation checking of included studies found no additional studies that met the inclusion criteria. The PRISMA flow chart in Figure 3.1 illustrates the process of study identification.

3.3.2. TRANSLATION OF NON-ENGLISH PAPERS

Three papers required translation of title and abstract, which was completed by native speaker healthcare professionals known to the research student (n = 2 German, n = 1 Polish). Six papers eligible for full text review provided an abstract in English but full text in another language (n = 2 German, n = 1 Polish, n = 1 Portuguese, n = 1 Japanese, n = 1 Chinese). These papers were informally translated using automated software (Google Translate), with the exception of the Portuguese paper which was translated by a native speaker SLT known to the research student. Of these six papers, two (n = 1 Polish, n = 1 Chinese) were deemed to potentially meet criteria for inclusion and therefore formal translation was sought using a medical specialist translation agency.

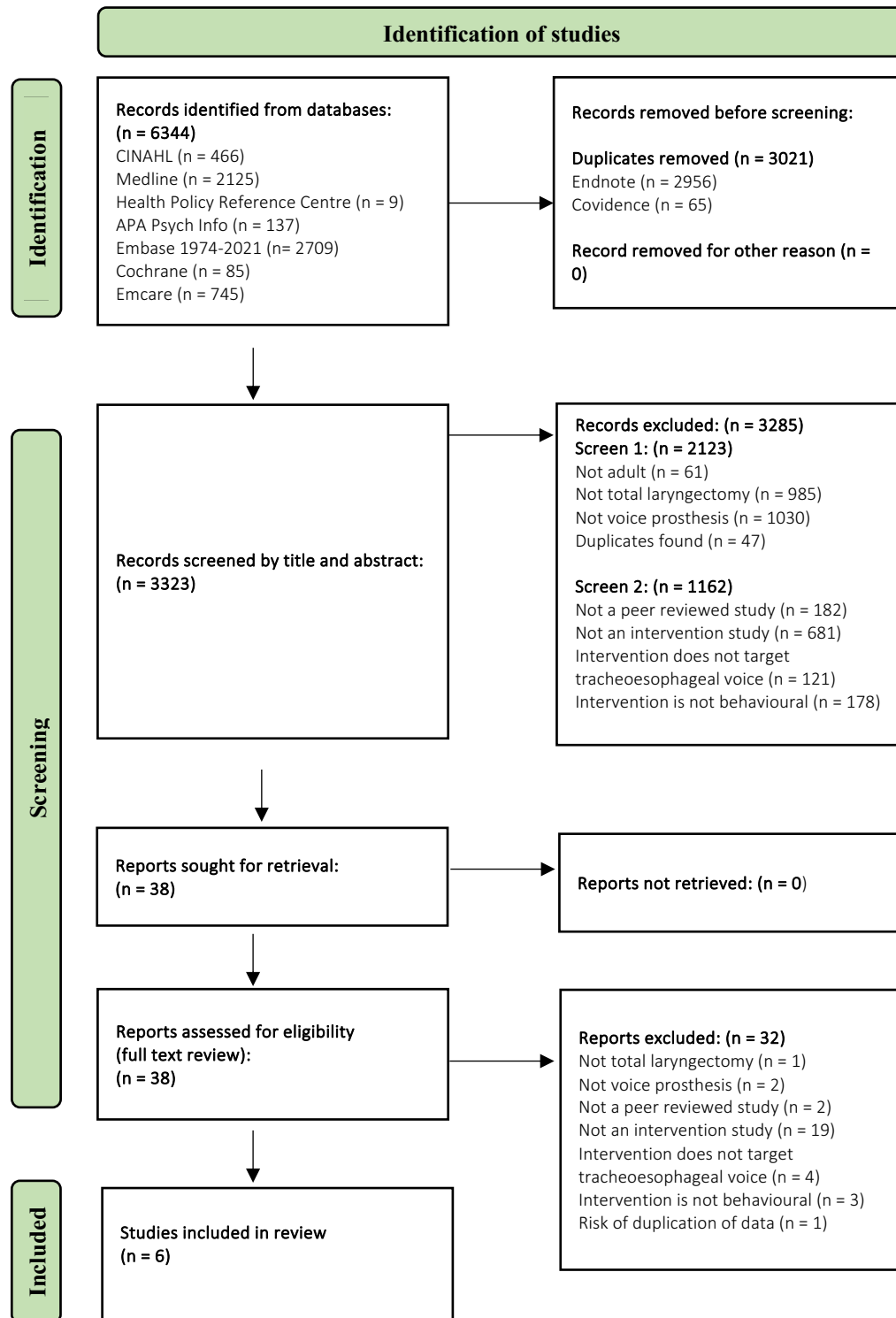


Figure 3.1: Identification of studies. PRISMA 2020 Flow diagram adapted from Page et al., 2021.

3.3.3. EXCLUDED STUDIES

Thirty-two studies were excluded following full text review. In accordance with PRISMA reporting standards the citations and reasons for exclusion are listed in Table 3.3. Three studies (Pretsfelder, 1985; Benazzo, 2001; Moors, 2020) met the majority of the inclusion criteria, and described a behavioural intervention, however, they were not eligible for inclusion due to a lack of control group or other comparator.

One paper (Costa et al., 2001) was excluded from the review due to significant similarities to De Oliveira et al. (2005) in regard to location, participant characteristics, intervention and authorship. Attempts were made to contact the research teams of both papers to confirm whether the two papers reported on the same study. Unfortunately, contact was not achieved after several attempts, therefore following discussion with the supervision team, Costa et al. (2001) was excluded at full text review due to risk of over-representing the data. The decision to exclude Costa et al. (2001) was taken as less detail was provided on the intervention and participant characteristics, in comparison to De Oliveira et al. (2005).

Study	Reason for exclusion	Additional details
Agarwal, 2006	Intervention is not behavioural	Study reports voice acquisition and problems associated with prosthesis placement, not therapeutic intervention
Ainlay, 1997	Intervention does not target tracheoesophageal voice	Study explores art therapy as a therapeutic adjunct
Allegra, 2019	Not an intervention study	Study compares subjective and objective outcomes of tracheoesophageal vs oesophageal voice
Antin, 2021	Not an intervention study	Study reports outcomes for quality of life and voice according to communication modality
Baugh, 1988	Intervention is not behavioural	Study reports on surgical treatment of pharyngoesophageal spasm
Benazzo, 2001	Not an intervention study	Study reports tracheoesophageal voice outcomes of secondary prosthesis placement and describes speech therapy following pharyngolaryngectomy with jejunum free flap. Excluded due to lack of control group or comparator
Burks, 2018	Not a peer reviewed study	Record of unpublished MSc dissertation
Caty, 2009	Not an intervention study	Study examines use of reflective practice in clinical decision-making related to tracheoesophageal voice rehabilitation
Cnossen, 2015	Not an intervention study	Study of service user focus group to inform development of a self-care program
Costa, 2001	Risk of data duplication	Study seems to report same data as De Oliveira et al (2005)
D'Alatri, 2012	Not an intervention study	Study investigates relationship between objective and subjective measures of tracheoesophageal voice and intelligibility
DeMaddalena, 1993	Intervention does not target tracheoesophageal voice	Study reports on a psychological intervention which targets participation
Graham, 2004	Not an intervention study	Study describes indications for group therapy
Hilgers, 2003	Intervention is not behavioural	Study reports on use of heat moisture exchanger for rehabilitation after laryngectomy
Ho, 2006	Not an intervention study	Study investigates the cognitive domains that influence tracheoesophageal speech rehabilitation
Jansen, 2021	Not an intervention study	Study reports on cost-effectiveness of a self-help exercise program for people with laryngectomy
McConnel, 1986	Not an intervention study	Report of surgical technique and complications

Study	Reason for exclusion	Additional details
Mendenhall, 2002	Not a peer reviewed study	Conference abstract reporting uptake of alaryngeal communication modalities
Mignano, 1993	Population is not voice prosthesis	Study describes oesophageal voice
Moors, 2020	Not an intervention study	Study describes a behavioural intervention for tracheoesophageal voice. Excluded due to lack of control group or comparator
Papadas, 2002	Not an intervention study	Provides practice guidance on care needs after laryngectomy
Peto, 2000	Not an intervention study	Describes use of dance therapy after laryngectomy
Pretsfelder, 1985	Not an intervention study	Study reports intelligibility after voice prosthesis placement and speech therapy. Excluded due to lack of control group or comparator
Qinghua, 1995	Not an intervention study	Study describes outcomes following prosthesis placement and speech therapy. Excluded due to lack of outcome measures, control group or comparator
Röhrs, 1989	Population is not voice prosthesis	Study population is oesophageal and electrolarynx users
Samlan, 2002	Population is not total laryngectomy	Study describes effect of laryngeal cancer treatment on voice and swallow
Seinsch, 1993	Not an intervention study	Study describes uptake of voice prosthesis as a communication modality
Singer, 2013	Not an intervention study	Study describes speech rehabilitation in first year post laryngectomy. Rehabilitation approach is not described, no control group or comparator
Singer, 2019	Not an intervention study	Study describes the uptake and outcome of attending rehabilitation on intelligibility. Content of rehabilitation is not described
Sokal, 2011	Intervention does not target tracheoesophageal voice	Intervention targets oesophageal voice
Terada, 2012	Not an intervention study	Describes complications following placement of voice prosthesis
Vatanasapt, 2014	Intervention does not target tracheoesophageal voice	Study population is oesophageal voice users

Table 3.3: Studies excluded following full text review

Six studies were therefore included in the review. Table 3.4 details the data extracted from included studies.

Study	Longobardi et al., 2019	Baijens et al., 2010	Van Sluis, 2020	De Oliveira, 2005	Jansen, 2020	Onofre, 2013
Title	Integrated rehabilitation after total laryngectomy: a pilot trial study	Rehabilitation program for prosthetic tracheojejunal voice production and swallowing function following circumferential pharyngolaryngectomy and neopharyngeal reconstruction with a jejunal free flap	Expiratory Muscle Strength Training in patients After Total Laryngectomy; A Feasibility Pilot Study	Oral communication of laryngectomized patients with tracheoesophageal prosthesis: pre and post-treatment comparative analysis	Effectiveness of a guided self-help exercises program tailored to patients treated with total laryngectomy: Results of a multi-center randomized controlled trial	Effect of singing training on total laryngectomees wearing a tracheoesophageal voice prosthesis
Year of publication	2019	2010	2020	2005	2020	2013
Journal	Supportive Care in Cancer	Dysphagia	Annals of Otology, Rhinology and Laryngology	Pró-Fono Revista de Atualização Científica	Oral Oncology	Acta Cirúrgica Brasileira
Location of study	Italy	The Netherlands	The Netherlands	Brazil	The Netherlands	Brazil
Declared conflicts	None	Not stated	None	Not stated	None	None
Ethical approval	Yes	Not stated	Yes	Not stated	Yes	Yes
Funding source	Not stated	Not stated	Atos Medical, Aspire products	Not stated	Michel Keijzer Fund	None
Language of publication	English	English	English	Brazilian Portuguese / English	English	English

Study	Longobardi et al., 2019	Baijens et al., 2010	Van Sluis, 2020	De Oliveira, 2005	Jansen, 2020	Onofre, 2013
Study design	Pilot randomised controlled study	Single case report	Before and after study	Before and after study	Multi-centre randomised controlled trial	Before and after study
Setting	Outpatient	Outpatient	Home / Outpatient	Not stated	Home	Not stated
Aim	To verify if targeting emotional and psychological needs alongside SLT rehabilitation influences acceptance of alaryngeal voice and quality of life	To assess if tailored rehabilitation can improve voice and swallow function after pharyngolaryngectomy	To examine feasibility, safety and compliance of EMST in total laryngectomy and its effects on pulmonary function, physical exertion, fatigue and vocal functioning	To compare the quality of tracheoesophageal communication before and after speech and voice training	To investigate effectiveness of a guided self-help exercises program for swallow, speech and shoulder problems after total laryngectomy	To assess the effect of singing training on tracheoesophageal voice
Participants N=	32 Experimental: 17 Control: 15	1	10 (1 did not continue)	17	92 Experimental: 46 Control: 46	5
Age	Experimental group: Mean: 65.64 years ± 5.83 SD	68 years	Mean/SD not stated Range: 50-73 years	Mean: 56 years / SD not stated Range: 40-81 years	Experimental group: Mean: 65 years ± 7 SD	Mean: 49.8 years / SD not stated Range: Not stated

Study	Longobardi et al., 2019	Baijens et al., 2010	Van Sluis, 2020	De Oliveira, 2005	Jansen, 2020	Onofre, 2013
	Control group: Mean: 64.53 years ± 7.42 SD Range (across groups): 54 – 80 years				Control group: Mean: 64 years ± 9 SD Range: Not stated	
Sex	Male: 29 Female: 3 Not specified by group	Female	Male	Male: 16 Female: 1	Experimental group: Male: 36, Female: 10 Control group: Male: 41, Female: 5	Male: 3 Female: 2
Communication modality*	Experimental group: Tracheoesophageal: 12 Oesophageal: 5 Control group: Tracheoesophageal: 12 Oesophageal: 3	Tracheoesophageal	Tracheoesophageal	Tracheoesophageal	Experimental group: Tracheoesophageal: 42 Oesophageal: 1 Other: 3 Control group: Tracheoesophageal: 45 Oesophageal: 1 Electrolarynx: 2	Tracheoesophageal

Study	Longobardi et al., 2019	Baijens et al., 2010	Van Sluis, 2020	De Oliveira, 2005	Jansen, 2020	Onofre, 2013
Reconstruction type**	Total laryngectomy	Pharyngolaryngectomy with jejunal free flap	Total laryngectomy: 7 Total laryngectomy with pectoralis major flap: 1 Unknown: 2	Total laryngectomy	Total laryngectomy: 92	Total laryngectomy: 1 Total laryngectomy with neck dissection: 4
Adjuvant treatment***	Experimental group: Salvage laryngectomy: 4 Adjuvant radiotherapy or chemoradiotherapy : 8 Control group: Salvage laryngectomy: 0 Adjuvant Radiotherapy or Chemoradiotherapy : 9	Adjuvant radioactive iodine	Salvage laryngectomy: 7 Adjuvant Radiotherapy: 3	Not stated	Experimental group: Salvage laryngectomy: 24 Adjuvant Radiotherapy: 16 Control group: Salvage laryngectomy: 25 Adjuvant Radiotherapy: 13	Adjuvant Radiotherapy: 2

Study	Longobardi et al., 2019	Baijens et al., 2010	Van Sluis, 2020	De Oliveira, 2005	Jansen, 2020	Onofre, 2013
Intervention	Individual intervention to establish voice and then group intervention (3-6 participants per group) Experimental group: SLT and Psychology intervention Control group: SLT intervention only <u>Experimental group intervention content:</u> Psychological support addressing issues and experiences related to illness Prosthesis care Breath co-ordination	SLT intervention content: Optimisation of head and body positioning Digital pressure on jejunal graft	Group 1 (n = 5): Four weeks of EMST home practice Group 2 (n = 4): Four weeks of EMST home practice. Then, four additional weeks of EMST home practice at reduced dosage NB: EMST device adapted to fit tracheostoma, plug inserted into voice prosthesis during practice	Speech training: Intervention content: Breathing to occlusion co-ordination Articulation training Prosody exercises Internalization	Experimental group: Individual self-help exercise program: Flexibility exercises Range of motion exercises Lymphoedema exercises 30min instructive session with healthcare professional Visual or written instructions Weekly coaching with healthcare professional Self-care education program Control group: Individual self-care education program: Booklet/DVD or Online information and advice on	Singing Singing therapy content: Respiratory muscle strengthening exercises Musical vocalisation exercises

Study	Longobardi et al., 2019	Baijens et al., 2010	Van Sluis, 2020	De Oliveira, 2005	Jansen, 2020	Onofre, 2013
	Occlusion co-ordination Speech production Communication skills Interpersonal skills Prosody exercises <u>Control group</u> <u>intervention</u> <u>content:</u> Prosthesis care Breath co-ordination Occlusion co-ordination Speech production Communication skills Interpersonal skills Prosody exercises				stoma care, voice prosthesis care, speech, smelling, nutrition and mobility NB data extracted relating to speech and quality of life only	
Control or comparator	Group: Experimental vs control Time:	Time: Pre / post intervention outcome measures	Time: Pre / post intervention outcome measures	Time: Pre /post intervention outcome measures	Group: Experimental vs control Time:	Time: Pre / post intervention outcome measures

Study	Longobardi et al., 2019	Baijens et al., 2010	Van Sluis, 2020	De Oliveira, 2005	Jansen, 2020	Onofre, 2013
	Pre / post intervention outcome measures		NB: Max expiratory pressure (MEP) and peak expiratory flow (PEF) measures taken weekly during intervention		Pre / post intervention outcome measures	
Dosage (No. of sessions)	Five individual sessions followed by 16 group sessions	Individual sessions for seven months. Total no. not stated	Group 1: 100 sessions (sets) Group 2: 140 sessions (sets)	4-5 sessions	Experimental group: 252 sessions Control group: Not stated	12 sessions
Intensity (time per session)	Not stated	30 minutes	Not stated. Duration as required for participant to complete set (five repetitions)	30 minutes	Not stated	30 minutes
Frequency	Once per week	Three sessions per week	<u>Group 1:</u> Five sets per day, five days per week for four weeks	Not stated	Experimental group: 3 practice sessions per day x 12 weeks	Once per week

Study	Longobardi et al., 2019	Baijens et al., 2010	Van Sluis, 2020	De Oliveira, 2005	Jansen, 2020	Onofre, 2013
			<u>Group 2:</u> Five sets per day, five days per week for four weeks, then five sets per day, two days per week for four weeks		Control group: Not stated	
Targeted outcomes	1. Psychological distress 2. Quality of life 3. Adjustment to new voice 4. Clinician perceptual evaluation of new voice 5. Intelligibility	1. Improvement of quality and comfort of alaryngeal voice 2. Improvement in swallow function NB data extracted for voice outcomes only	1. Pulmonary function 2. Physical exertion 3. Fatigue 4. Vocal functioning 5. Feasibility and compliance	1. Improvement in tracheoesophageal voice quality	1. Speech 2. Health related quality of life (HRQOL) 3. Self-management 4. Communication 5. Shoulder function NB data not extracted for shoulder outcome	1. Improvement in tracheoesophageal voice quality 2. Improvement in singing range
Outcome measures	1. SCL-90-R 2. WHOQOL-B 3. I-SECEL 4. INFVO 5. Mean % of correctly perceived words	1a. Voice Handicap Index (VHI) 1b. Videofluoroscopy of phonation (subjective rating) 1c. High speed endoscopy of	1. MEP, PEF, Vital Capacity (VC), Forced expiratory volume (FEV1), COPD questionnaire 2. Cardio Pulmonary Exercise	1. Perceptual analysis of 23 voice and speech parameters across four tasks, using 3-point Likert scales:	1. Speech Handicap Index (SHI) 2a. EORTC QLQ-C30 2b. EORTC QLQ-H&N35 3a. Diary of adherence 3b.	1. Perceptual analysis of voice recording (vowel production) using: 1a. GRBAS scale 1b. Likert scale of pitch characterisation

Study	Longobardi et al., 2019	Baijens et al., 2010	Van Sluis, 2020	De Oliveira, 2005	Jansen, 2020	Onofre, 2013
		vibratory segment (subjective rating post intervention only) 2. Data not extracted	Test (CPET), Borg exertion scale 3. Short fatigue questionnaire (SFQ) 4. Voice Handicap Index-10 (VHI-10), Maximum phonation time (MPT), Hz, Decibels (dB) 5. Practice log, reflective diary, questionnaire	1a. Sentence melody 1b. Sentence intelligibility 1c. Spontaneous speech intelligibility 1d. Singing voice pitch and vocal quality	Patient Activation Measure (PAM) 4. SWAL-QOL communication sub score 5. Data not extracted	2. Perceptual analysis of singing range using: 2a. Semi-tone scale, and 2b. Likert scale rating of musicality
Assessment timepoints	Pre-intervention: After five individual sessions of SLT to establish voice Post intervention: At end of intervention	Pre intervention Post intervention: At end of intervention	Pre intervention Post intervention: Group 1: Week 4 Group 2: Week 4 and 8	Pre intervention Post intervention: At end of intervention	Pre intervention Post intervention: At end of intervention At six months	Pre intervention Post intervention: At end of intervention
Results	Two-way ANOVA <u>1. SCL-90:</u> Significant difference between groups ($p < 0.05$) on	No statistical tests performed <u>1a. VHI:</u> Pre-treatment score: 80/120; post	No statistical tests reported <u>1. Pulmonary function</u> Increase in	Binomial tests performed based on those who improved versus those who did not improve	Two-way mixed ANOVA. <u>1. SHI</u>	No statistical tests performed <u>1a. GRBAS</u> Improvement in general degree of

Study	Longobardi et al., 2019	Baijens et al., 2010	Van Sluis, 2020	De Oliveira, 2005	Jansen, 2020	Onofre, 2013
	5/10 subsections: O-C, DEP and PARA. Significant difference between time for 2/10 subsections: ANX (p <0.038) and HOS (p = 0.021) Interaction effects not reported <u>2. WHO-QOL:</u> Significant difference between groups (p = 0.017) in REL domain; and time (p <0.004) in PHY domain. Interaction effects not reported <u>3. I-SECEL:</u> Significant difference between groups (p = 0.04) and time (p <	treatment score: 59/120 <u>1b. Videofluoroscopy:</u> Pre-treatment: hypotonicity, no constriction of vibratory segment, severe dilatation. Post treatment: increased tonicity and constriction of vibratory segment, more so with digital pressure <u>1c. High speed endoscopy:</u> Post treatment comparison of vibration with and without digital pressure showed improved mucosal wave during application of digital pressure	mean MEP score at week 4 vs baseline: (mean/SD): Baseline: 125.5 / (19.6) Week 4: 174.8 / (28.6) No change in PEF, VC, FEV1 or COPD questionnaire <u>2. CPET</u> No difference in physical exertion outcomes for CPET and Borg scales <u>3. Short Fatigue Questionnaire</u> No change over time in fatigue <u>4. VHI-10 and Vocal Function</u> No change over time in VHI-10 score, MPT or Hz. dB increased at	Significant difference reported in the number of speech and voice parameters (23 in total) that improved (n=18) compared to those that declined (n=5) (p=0.012) 11/17 participants improved in at least one area but there was no significant difference in means <u>1a. Sentence melody</u> No significant difference in mean <u>1b. Sentence intelligibility</u> No significant difference in mean	No significant group or time or interaction effects <u>2a. EORTC QLQ-C30</u> No significant group, time or interaction effects <u>2b. EORTC QLQ-H&N35</u> No significant group, time or interaction effects <u>3a. Adherence in experimental group</u> High in 49% Moderate in 10% Low in 41% <u>3b. PAM</u> No significant group, time or interaction effects <u>4. SWAL-QOL</u>	dysphonia, roughness and breathiness. Worsening in strain on vowel /i/ <u>1b. Likert scale of pitch</u> Pitch shifted in three participants post intervention <u>2a. Semi-tone range</u> Extended semi-tone range reported post intervention, however, baseline data is not provided <u>2b. Likert scale of musicality</u> Presence of tuning and legato increased post intervention

Study	Longobardi et al., 2019	Baijens et al., 2010	Van Sluis, 2020	De Oliveira, 2005	Jansen, 2020	Onofre, 2013
	0.001) on total scores. Interaction effects not reported <u>4. INFVO</u> All subscales showed a significant difference between groups (all P values below 0.005) and time (all P values below 0.022) for all participants. Interaction effects not reported <u>5. Intelligibility</u> No significant difference between groups. Significant difference in mean percentage of correctly perceived		week 4 but returned to baseline at week 8 follow up: Mean / SD: Baseline: 26.4dB / (5.6) Week 4: 31.9 / (3.7) Week 8: 27.6 / (5.4) <u>5. Feasibility and compliance</u> One participant withdrew for unrelated reasons 95.5% compliance with training program was achieved. Participants reported staying motivated during intervention. 4/9 participants reported air leakage under baseplate, 2/9 participants experienced	<u>1c. Spontaneous speech intelligibility</u> No significant difference in mean <u>1d. Singing voice pitch and vocal quality</u> No significant difference in mean	The experimental group performed better with significant interaction effect for overall score (p = 0.013) and communication sub-score (p=0.004)	

Study	Longobardi et al., 2019	Baijens et al., 2010	Van Sluis, 2020	De Oliveira, 2005	Jansen, 2020	Onofre, 2013
	words over time (p<0.001)		dizziness during and after training. Participants were unable to plug their voice prosthesis or found this problematic One event of voice prosthesis dislodgement during training			
Effect size of primary outcome measure or all measures if primary outcome not specified, Cohen's d (95% confidence intervals)	Primary outcome measure not specified SCL-90: Experimental group subsection scores pre/post intervention: O-C: d: -1.14 (-2.16 - -0.11) DEP:	No statistical tests reported	Primary outcome measure not specified Effect sizes calculated for MEP and dB MEP baseline/week 4: d: 2.01 (0.41 - 3.61) MEP baseline/week 8: d: 1.56 (0.06 - 3.05)	No statistical tests reported	SWAL-QOL: Overall score post intervention between groups: d: -0.18 (-0.62 - 0.26) Overall score at six months between groups: d: -0.53 (-0.97 - -0.07)	No statistical tests reported

Study	Longobardi et al., 2019	Baijens et al., 2010	Van Sluis, 2020	De Oliveira, 2005	Jansen, 2020	Onofre, 2013
	d: -1.22 (-2.26 - -0.19) PARA: d: -0.88 (-1.87 - 0.12) WHO-QOL: Social relationship domain score post intervention between groups: d: -1.14 (-1.88 - -0.39) I-SECEL: Overall score post intervention between groups: d: 1.61 (0.81 – 2.41) INFVo Domain scores post intervention between groups: I domain:		dB range baseline/week 4: d: 1.16 (-0.25 - 2.57) dB range baseline/week 8: d: 0.22 (-1.09 - 1.53)			

Study	Longobardi et al., 2019	Baijens et al., 2010	Van Sluis, 2020	De Oliveira, 2005	Jansen, 2020	Onofre, 2013
	d: -5.80 (-7.38 - -4.22) N domain: d: -5.08 (-6.5 - -3.65) F domain: d: -1.33 (-2.09 - -0.560) Vo domain: d: -4.49 (-5.79 - -3.19) Intelligibility: Mean/SD not given, unable to calculate					
Outcome summary	<u>1. SCL-90</u> Experimental group showed significant improvement in SCL-90 domains over time, whereas Control group scores worsened in	Improved score on VHI indicated reduction in self-reported voice related handicap. Subjective rating of Videofluoroscopy and endoscopy	Increased maximum expiratory pressure, and dynamic range in dB was found after four weeks, however, increase in dB was not sustained.	Based on composite score there was a significant difference between the number of parameters that improved compared to those that declined	No significant difference between control and intervention group on speech, HRQOL and self-management. Experimental group showed improved	There was a subjective perceptual improvement in degree of dysphonia, roughness, breathiness, legato voice and pitch

Study	Longobardi et al., 2019	Baijens et al., 2010	Van Sluis, 2020	De Oliveira, 2005	Jansen, 2020	Onofre, 2013
	QOL and depression domains. <u>2. WHO-QOL</u> Mean score in 'social relationships' domain improved over time in the experimental group, whereas the control group score worsened Both groups improved mean scores over time on I-SECEL, INFVO and Intelligibility	showed improvement in tonicity, constriction and mucosal wave	Compliance was high and EMST was feasible and safe after laryngectomy. No changes over time to measures of physical exertion, fatigue or other measures of vocal function	(p=0.012), however, no significant differences were found in individual parameters of voice quality post intervention	swallow function and communication sub-score	range. However, this was not statistically tested

Table 3.4: Data extracted from included studies

Abbreviations: SCL-90 – Symptom Checklist-90-Revised; O-C – obsession-compulsion; DEP – depression; PARA - paranoia; ANX - anxiety; HOS - Hostility
WHO-QOL – World Health Organisation Quality of Life Scale; REL – social relationships; PHY – physical health
I-SECEL – Italian version of Self-Evaluation of Communication Experiences after Laryngeal Cancer
INFVo – I – overall impression; N – additive noise; F – fluency; Vo – voicing. VHI – Voice Handicap Index. SHI – Speech Handicap Index
MEP – maximum expiratory pressure; PEF – peak expiratory flow; VC – vital capacity; FEV1 – forced expiratory volume in 1 second; COPD – chronic obstructive pulmonary disease; CPET – cardio-pulmonary exercise testing; MPT – maximum phonation time; dB – decibels
EORTC-QLQ – European organisation for research and treatment of cancer quality of life questionnaire; PAM – patient activation measure; Swal-QOL – swallowing quality of life questionnaire

3.3.4. STUDY CHARACTERISTICS

3.3.4.i. Study design

Of the included studies, two were randomised controlled trials using a two-armed design with intervention versus control groups (Longobardi et al., 2019; Jansen et al., 2020). Three studies (Onofre et al., 2013; De Oliveira et al., 2005; van Sluis et al., 2020) used a prospective before and after design, without control group, where timepoint was used as the comparator. These studies did not use multiple baseline data collection points, and only one study (van Sluis et al., 2020) used two post intervention data collection points. One study (Baijens et al., 2010) used a single case report design with pre and post intervention outcome measures.

3.3.4.ii. Country and setting

The studies took place outside of the United Kingdom, in three different countries. Three studies took place in The Netherlands (Baijens et al., 2010; van Sluis et al., 2020; Jansen et al., 2020). Two studies were carried out in Brazil (De Oliveira et al., 2005 and Onofre et al., 2013) and one study was undertaken in Italy (Longobardi et al., 2019).

Two studies reported that participants carried out the intervention at home (van Sluis et al., 2020; Jansen et al., 2020). Other studies did not give precise detail on the setting of the intervention but were indicative of an outpatient setting. One study reported that participants attended Speech and Language Therapy but did not give a specific setting for this (Baijens et al., 2010). Two studies did not provide any detail on setting in which the study was carried out (Onofre et al., 2013; De Oliveira et al., 2005). One study lacked clarity (Longobardi et al., 2009) stating that 'patients living offsite were excluded' (p3538) but subsequently stated that participants started to receive SLT 'immediately after hospital discharge' (p3538).

3.3.4.iii. Participants

All studies centred on participants with total laryngectomy and either exclusively, or the majority, of participants were voice prosthesis users. Information was provided on extended surgeries or reconstruction and all studies reported neoadjuvant or adjuvant oncological treatments; with the exception of De Oliveira et al. (2005) which did not provide this information. The studies reported on 157 participants, of whom 96 had intervention and 61 were in control groups. Across studies the age of participants ranged from 40 – 81 years (where reported) and the mean age ranged from 49.8 – 68 years (where reported). With the exception of the single case report (female), all studies included a higher percentage of male participants, which reflects the increased incidence of head and neck cancer in males. Van Sluis et al. (2020) included only male participants.

All studies targeted alaryngeal voice produced by a prosthesis, however, the single case study participant in Baijens et al. (2010) used tracheojejunal voice in place of tracheoesophageal voice.

3.3.5. INTERVENTION CHARACTERISTICS

3.3.5.i. Intervention description

All studies reported following a set protocol of intervention, however, in most studies this was not provided and interventions were not described in sufficient detail for replication. Reports lacked information on the specifics of intervention, such as the exact nature of an exercise, the number of repetitions or the rationale for the exercise. More detail was provided in a separate protocol paper by Jansen (2020) which described the intervention (Jansen et al., 2016). Baijens et al. (2010) provided photographs of therapeutic exercises to support written description, whereas Van Sluis et al. (2020) also used photographs to enhance description of the standard EMST device protocol. The TIDieR checklist (Hoffman et al., 2014) was used to describe the characteristics of the interventions, as detailed in Table 3.5.

TIDieR Item	Longobardi et al., 2019	Baijens et al., 2010	Van Sluis, 2020	De Oliveira, 2005	Jansen, 2020	Onofre, 2013
Brief Name	Integrated psychology and speech therapy	Rehabilitation of prosthetic tracheojejunal voice	Expiratory muscle strength training (EMST)	Speech and voice training for tracheoesophageal prosthesis users	In Tune Without Cords (self-help program)	Singing training
Why	To investigate if psychological approaches targeting emotional and psychological needs influence acceptance of alaryngeal voice and quality of life	Aims to improve voice quality by: 1. Improving vibration capacity by constricting the jejunal graft with digital pressure 2. Improving airflow through respiratory exercises	To examine the effects of EMST on pulmonary function, physical exertion, fatigue and vocal functioning in the laryngectomy population	Rationale that training can improve speech patterns, melody and singing	Following feasibility testing, to target speech, swallowing, shoulder problems and self-care education.	To investigate if strengthening respiratory muscles and vocalisation
What	Detailed description not provided. SLT intervention: Instruction on cleaning and managing prosthesis Practice of coordinating occlusion, breathing and speech	1. Digital pressure applied to the jejunal graft at the level of the fifth cervical vertebrae during phonation. Photograph of correct procedure included. 2. Respiratory exercises involving optimisation of head and body	Use of an EMST device according to set protocol. Completion of a practice diary.	Practice of coordinating occlusion and breathing. Articulation training to improve prosody using plosive initial words, sentences, singing and speech. Assessment and training protocols provided.	Protocol paper published previously. Seven flexibility exercises for head, neck, shoulders. Eight range of motion exercises for articulators.	1. Respiratory exercises: Inhaling and exhaling at varying speeds with pauses. 2. singing exercises – singing do, re, mi notes with musical accompaniment.

TIDieR Item	Longobardi et al., 2019	Baijens et al., 2010	Van Sluis, 2020	De Oliveira, 2005	Jansen, 2020	Onofre, 2013
	Prosody exercises Communication and interpersonal skill activities Psychology intervention: Management of emotional reactions, loss Acceptance of new voice Processing of feelings; Improving self-esteem	positioning. Detailed description not provided.			Five lymphoedema exercises. Participants were provided with written instructions, images and videos via online application or booklet and DVD. Completion of a practice diary	
Who provided	Speech and Language Therapist and Psychologist	Speech and Language Therapist	Researcher – profession not stated	Speech and Language Therapist	Speech and Language Therapist, Physiotherapist or Nurse practitioner	Singing teacher and Speech and Language Therapist
How	Face to face Individual sessions then group setting	Face to face individual sessions	Face to face individual session, plus home practice	Face to face individual session	One 30 minute individual face to face session. Email or telephone contact with researcher weekly, plus home practice	Face to face individual session

TIDieR Item	Longobardi et al., 2019	Baijens et al., 2010	Van Sluis, 2020	De Oliveira, 2005	Jansen, 2020	Onofre, 2013
Where	Outpatient department	Outpatient department	Outpatient department / home	Not stated	Home	Not stated
When and how much	Five individual sessions followed by 16 weekly group sessions	30-minute session three times per week, for seven months	Five sets of five repetitions, five days per week for four or eight weeks dependent on allocated group.	One 30-minute session per week for 4-5 weeks	Practice of exercises three times per day for 12 weeks.	30-minute session once per week for 12 sessions.
Tailoring	None stated	Single case study therefore the intervention was tailored to the individual following pre-intervention assessment	Adaptor was developed to connect the EMST device to the tracheostoma and to plug voice prosthesis	Participants received a fifth session to complete the training content, if required	None stated	None stated
Modifications	None stated	None stated	None stated	Not stated	None stated	None stated
Planned fidelity assessment	Not stated	Not stated	Researchers' provided participants with a training diary to log sessions and report experiences. A short feasibility questionnaire was	Not stated	Training diary to log exercises performed. Weekly follow up phone call / email	Not stated

TIDieR Item	Longobardi et al., 2019	Baijens et al., 2010	Van Sluis, 2020	De Oliveira, 2005	Jansen, 2020	Onofre, 2013
			completed post intervention.			
Actual fidelity	Not stated	Not stated	1 participant withdrew for unrelated medical reasons. Remaining participants completed the training with 95.5% compliance. Minor problems reported with occasional dizziness during and after training, and air leakage around stoma. Participants found plugging the voice prosthesis problematic.	Not stated	Adherence reported as high in 49% of participants, moderate in 10% and low in 41%	Not stated

Table 3.5: TIDieR checklist

3.3.5.ii. Intervention type

All the interventions described could be categorised within the Van Stan Taxonomy of Voice Therapy (2015). The two RCTs used indirect interventions further categorised as pedagogy and counselling. This was in the form of self-care education programmes focussed on prosthesis and stoma care; and psychological support (Longobardi et al., 2019 only).

Within direct interventions, there was a degree of homogeneity between studies in the class of direct intervention used, with respiratory, musculoskeletal and vocal function interventions being used most frequently. However, approaches differed, and a lack of detailed description prevented identification of specific similarities in therapeutic activities.

Respiratory interventions were used by Longobardi et al. (2019) and De Oliveira et al. (2005) in the form of breathing-to-stoma occlusion coordination. Whereas Van Sluis et al. (2020) and Onofre et al. (2013) used different approaches to respiratory muscle strength training.

Musculoskeletal interventions were described by Baijens et al. (2010) using digital modification and postural optimisation. Additionally, Jansen et al. (2020) described the use of flexibility, range of motion and lymphoedema exercises. However, these activities were aimed at addressing shoulder problems and were not specifically targeted towards voice rehabilitation.

Differing interventions targeting vocal function were used across studies with the exception of Baijens et al. (2010) and Van Sluis et al. (2020) which did not use this approach. Interventions focussed on articulation, prosody and pitch modulation. Onofre et al. (2013) used singing activities with the aim of improving auditory-perceptual voice quality.

3.3.5.iii. Intervention delivery

All interventions were delivered via face-to-face sessions. In Van Sluis et al. (2020) and Jansen et al. (2020), the majority of sessions were home practice following an initial face to face

session to introduce the intervention. The latter study also incorporated weekly remote check-ins using telephone or email. All studies used individual sessions with the exception of Longobardi et al. (2019) where group sessions were used after an initial block of individual sessions.

3.3.5.iv. Fidelity

Adherence was the only measure of fidelity reported, however, only two of the five studies reported measures of adherence. Where this was undertaken (Van Sluis et al., 2020; Jansen et al., 2020) a practice tracking diary was used alongside informal qualitative measures such as a questionnaire or weekly check-up conversation. Jansen et al. (2020) reported percentages across high, medium and low adherence rather than the more commonly reported percent adherence.

3.3.5.v. Attrition

No attrition was reported in three studies. One participant withdrew from Van Sluis et al. (2020) due to unrelated medical reasons and one participant died of unrelated causes during the intervention period in Jansen et al., 2020. Onofre et al. (2013) reported that two participants were excluded due to a lack of adherence to the intervention.

3.3.5.vi. Adverse effects

Adverse effects were reported by Van Sluis et al. (2020) only. There was one event of a voice prosthesis found to be dislodged after a training session. Additionally minor complaints of dizziness and poor stoma seal around the EMST device were reported. Participants did not like the instruction to plug their voice prosthesis during EMST practice, however, this was not seen as an essential component of the intervention.

3.3.5.vii. Outcome measures

There was very low homogeneity between outcome measures used. No two studies used the same intervention outcome measures with the exception of a practice tracking diary used for adherence in Van Sluis et al. (2020) and Jansen et al. (2020). Three studies assessed aspects of perceptual voice quality as an outcome, however, different outcome measures were used. For example, Longobardi et al. (2019) and De Oliveira et al. (2005) both measured intelligibility; however, this was done using a mean percentage of correctly identified words, and a Likert scale respectively.

Several studies used voice quality outcome measures borrowed from laryngeal voice therapy, which are not validated on the laryngectomy population, such as the GRBAS scale (Hirano, 1981), VHI (Jacobsen et al., 1997) and Speech Handicap Index (SHI), (Rinkel et al., 2008).

Table 3.6 details the outcome measures used.

Outcome measure	Type of measure	Longobardi 2019	Baijens, 2010	Van Sluis 2020	De Oliveira, 2005	Jansen, 2020	Onofre, 2013
Symptom checklist 90-revised (SCL-90-R)	Self-reported measure of somatic and psychological distress	X					
World Health Organisation Quality of life scale (WHO-QOL 100)	Self-reported quality of life questionnaire	X					
Self-Evaluation of Communication Experiences after Laryngeal Cancer (SECEL)	Self-reported measure of perceived adjustment to communication experiences	X					
Intelligibility, Noise, Fluency, Voice (INFVo) scale	Clinical rated scale of perceptual voice quality	X					
Intelligibility	Clinician rated perceptual measure	X - mean % of correctly perceived words			X - 3-point Likert scale		
Instrumental assessment – videofluoroscopy	Clinician rated physiological assessment		X				
Instrumental assessment – endoscopy	Clinician rated physiological assessment		X				
Voice Handicap Index (VHI)	Self-reported measure of voice-related impairment		X				
Voice Handicap Index-10 (VHI-10)	Self-reported measure of voice-related impairment.			X			

Outcome measure	Type of measure	Longobardi 2019	Baijens, 2010	Van Sluis 2020	De Oliveira, 2005	Jansen, 2020	Onofre, 2013
	Short form of VHI						
Pulmonary function tests	Subjective measures of respiratory performance			X			
Cardiopulmonary Exercise Testing (CPET)	Objective measure of cardiopulmonary function			X			
Borg Exertion Scale	Self-reported measure of exertion and dyspnoea			X			
Short fatigue questionnaire (SFQ)	Self-reported measure of fatigue			X			
Acoustic measures of voice quality (maximum phonation time, decibels and pitch)	Objective acoustic measures of voice			X			
Practice diary	Self-reported logs of practice and qualitative information			X		X	
Likert scale of voice parameters	Perceptual clinician rated Likert scales				X sentence melody, singing melody, pitch and vocal quality		X pitch and musicality

Outcome measure	Type of measure	Longobardi 2019	Baijens, 2010	Van Sluis 2020	De Oliveira, 2005	Jansen, 2020	Onofre, 2013
Grade, Roughness, Breathiness, Aesthenia, Strain (GRBAS) scale	Clinician rated perceptual measure of voice quality						X
European Organisation for Research and Treatment of Cancer (EORTC) QLQ-C30 and H&N35	Self-reported quality of life measures specific to head and neck cancer					X	
Speech Handicap Index (SHI)	Self-reported questionnaire of speech problems in daily life					X	
Patient Activation Measure (PAM)	Self-reported knowledge, skills and confidence in managing own health issue					X	
Swallowing Quality of Life questionnaire (SWAL-QOL)	Self-reported measure of quality of life related to swallowing					X	

Table 3.6: Outcome measures used in included studies

3.3.6. RISK OF BIAS WITHIN STUDIES

Risk of bias was assessed within studies using the tools stated below. Outcomes are provided in the following tables 3.7-3.9 by study design.

3.3.6.i. Randomised controlled trials (Longobardi et al, 2019; Jansen et al, 2020)

In the PEDro scale (Maher et al., 2003) a score of one is awarded where the criterion is clearly met for items 2-11 below. Grading of overall score is reported according to published guidance (Cashin and McAuley, 2019). Results are presented in Table 3.7.

PEDro scale criteria	Longobardi 2019	Jansen 2020
1. Eligibility criteria were specified	No	Yes
2. Subjects randomly allocated to groups	Yes	Yes
3. Allocation was concealed	No	Yes
4. Groups similar at baseline in most important prognostic indicators	No	Yes
5. Blinding of all subjects	No	No
6. Blinding of therapists who administered therapy	No	No
7. Blinding of all assessors who measured at least one key outcome	Yes	No
8. Measures of at least one key outcome obtained from more than 85% of subjects initially allocated to groups	Yes	Yes
9. All subjects received treatment or control as allocated, or if not, data for at least one key outcome was analysed by 'intention to treat'	Yes	Yes
10. Results of between-group statistical comparisons are reported for at least one key outcome	Yes	Yes
11. Study provides point measures and measures of variability for at least one key outcome	Yes	Yes
Score	6/10 Good	7/10 Good

Table 3.7: Risk of bias in randomised controlled trials

3.3.6.i.a. External validity

Relating to the generalisability and replicability of the results, one study (Longobardi et al., 2019) did not specify eligibility criteria and reported a single exclusion criterion for participants who did not live on the hospital site. Based on participant demographics data, both studies did not include participants with extended surgeries.

3.3.6.i.b. Internal validity

Jansen et al. (2020) used concealed allocation, reporting that participants were randomised to the intervention or control group by an independent person using an automatically created randomisation list. Longobardi et al. (2019) did not use concealed allocation, reporting that participants were randomly allocated to groups, without further information on the method used to achieve this. Both studies reported differences in the groups at baseline. Jansen et al. (2020) identified statistically significant baseline differences in HRQOL sub-scores for the domains of function, fatigue, pain, dyspnea, loss of appetite, constipation, saliva, insomnia; and the sleep domain of the SWAL-QOL. These differences favoured the intervention group. Baseline differences were identified in Longobardi et al. (2019) where all participants with neoadjuvant radiotherapy treatment were randomised to the experimental group.

Both studies presented risk of performance bias due to lack of blinding of subjects and the therapists delivering the interventions. Due to the content of the interventions, participants could not be blinded to their allocated group, however, neither study reported whether the delivering therapist was independent to the study. Potential for confounding bias was identified in Jansen et al. (2020) as participants in the intervention group received additional weekly coaching versus no weekly contact in the control group.

Both randomised controlled trials used patient reported outcome measures in the majority. Due to the lack of blinding of participants, risk of performance bias was again identified in

relation to outcome measures. Where clinician rated perceptual assessment of voice quality was used (Longobardi et al., 2019), this was rated by students blinded to the condition.

Attrition bias was not identified as a risk within the studies. Longobardi et al. (2019) did not report any attrition whereas Jansen et al. (2020) reported two withdrawals in the intervention group. Reason for attrition was documented and was unrelated to the intervention (co-morbidity prior to starting the intervention and one death during the intervention period)

3.3.6.ii. Before and after studies with no control group (Onofre et al., 2013; De Oliveira et al., 2005; Van Sluis et al., 2020)

The NHLBI Quality Assessment Tool for Before-After (Pre-Post) Studies with No Control Group was used (NHLBI, 2021), with results presented in Table 3.8.

NHLBI scale criteria (yes, no, cannot determine, not reported or not applicable)	Onofre, 2013	De Oliveira, 2005	Van Sluis, 2020
1. Was the study question or objective clearly stated?	Yes	Yes	Yes
2. Were eligibility criteria for the study population prespecified and clearly described?	No	No	Yes
3. Were participants representative of those who would be eligible for the intervention in the clinical population of interest?	Yes	Yes *Predominantly male participants	No
4. Were eligible participants that met the prespecified entry criteria enrolled?	Cannot determine	Cannot determine	Cannot determine
5. Was the sample size sufficiently large to provide confidence in the findings?	No	No	Yes
6. Was the intervention clearly described and delivered consistently across the study population?	No	No	Yes
7. Were outcome measures prespecified, clearly defined, valid, reliable and assessed consistently across all participants?	No	No	Yes
8. Were the people assessing the outcomes blinded to the participants' interventions?	Not reported	Yes	Not reported
9. Was the loss to follow-up after baseline 20% or less. Were those lost to follow-up accounted for in the analysis?	No	Yes	Yes
10. Did the statistical methods examine changes in outcome measures before/after intervention? Were statistical tests done that provided p values for pre/post change?	No	Yes	No
11. Were outcome measures of interest taken multiple times before and after intervention	No	No	No
12. If intervention was conducted at group level did the statistical analysis take into account the use of individual level data to determine effects at the group level?	Not applicable	Not applicable	Not applicable
Overall quality rating	POOR	FAIR	FAIR

Table 3.8: Risk of bias in before and after studies with no control group

3.3.6.ii.a. External validity

Objectives were clearly stated in all studies. Eligibility criteria was not defined in two studies (Onofre et al., 2013; De Oliveira et al., 2005). Detail was not provided on the protocol for recruiting participants and therefore there was deemed to be high risk of selection bias in these studies.

From a review of 67 Speech and Language Therapy cases, 14 subjects were invited to participate in Onofre et al. (2013), of which seven commenced the intervention. The remaining studies did not detail how many people were invited to take part. No studies provided information on the reasons invited participants declined to take part.

Participants were broadly representative of the laryngectomy population in terms of age however, the mean average age was towards the lower range of the clinical population at 49.8 years and 56 years in two studies (Onofre et al., 2013; De Oliveira et al., 2005 respectively). Sample sizes within the before and after studies were small, however, with only Van Sluis et al. (2020) reporting the study as a pilot. The majority of subjects in De Oliveira et al. (2005) were male (16/17 participants) whereas all participants in Van Sluis et al. (2020) were male. Across studies all subjects had undergone total laryngectomy with primary closure, with the exception of one participant with a pectoralis major flap in Van Sluis et al. (2020). Therefore, the generalisability of the studies to clinical populations with extended surgery or females is uncertain.

3.3.6.ii.b. Internal validity

Internal and external validity of one study was affected by the small sample size of five participants who completed the intervention (Onofre et al., 2013). No detail was given on rationale for or calculation of the sample size across studies.

Description of the intervention was lacking in detail in two studies (Onofre et al., 2013; De Oliveira et al., 2005) which could inhibit consistent application, leading to unclear risk of bias.

De Oliveira et al. (2005) reported that the treating therapists followed the same procedures, however, participants did not all receive the same number of sessions, with an unspecified number of participants receiving one additional session.

Outcome measures were not clearly described in two studies. Onofre et al. (2013) and De Oliveira et al. (2005) presented high risk of performance bias due to reliance on subjective perceptual Likert scales. The GRBAS scale (Hirano, 1981) was additionally used to rate tracheoesophageal voice quality in one study (Onofre et al., 2013), however, this scale is not validated on alaryngeal voices. Furthermore, there was no clear evidence that raters were blinded to the timepoint in this study. Confidence in outcome measures was low due to a lack of multiple baseline and follow up timepoints. Two studies did not include statistical analysis (Onofre et al., 2013; Van Sluis et al., 2020).

High risk of attrition bias was identified in one study (Onofre et al., 2013) which reported 28% attrition where participants were excluded due to poor adherence. Information was not provided on how missing data was treated.

3.3.6.iii. Single case study (Baijens et al, 2010)

The ROBiN-T scale (Tate et al., 2013) was used for quality assessment of the single case study. The ROBiN-T comprises internal and external validity subscales of seven and eight items respectively. Each item is given a score of 0-2 based on specified criteria, where a higher score represents greater quality. Results are presented in Table 3.9.

ROBiN-T scale criteria	Baijens, 2010
1. Design	0
2. Randomisation	0
3. Sampling behaviour during all phases	0
4. Blinding of participant and practitioner delivering the intervention	0
5. Blinding of the assessor	2
6. Inter-rater agreement	0
7. Treatment adherence	0
Internal validity sub-score	2 / 7
8. Baseline characteristics of participants	1
9. Setting	0
10. Dependent variable – target behaviour	1
11. Independent variable – intervention	2
12. Raw data record	0
13. Data analysis	1
14. Replication	0
15. Generalisation	0
External validity sub-score	5 / 16
Total score	7 / 30

Table 3.9: Risk of bias in single case study

3.3.6.iii.a. External validity

The study included one female participant with extended surgery and tracheojejunal voice, therefore generalisability to the wider laryngectomy population is limited beyond people with jejunal flap reconstruction. Information was not provided on the recruitment process to the study.

Intervention was described and supplemented with photographs of the target practice, however, detail was omitted on frequency of specific exercises, which would impair replicability. Furthermore, the intervention was provided at a high dosage of three sessions per week for seven months, which threatens generalisability to NHS healthcare settings whereby resourcing is unlikely to support high intensity and dosage of therapy. Detail was not provided on the setting of the intervention.

3.3.6.iii.b. Internal validity

Study design presented risk of bias due to the absence of multiple baselines. The study report states that the participant showed no improvement in voice quality during the first two months of prosthesis placement (prior to the intervention), however, outcome data is not provided for comparison with baseline and post intervention timepoints.

The study used the VHI (Jacobsen et al., 1997) to measure patient reported QOL related to voice impairment. A clinically significant improvement was observed on this scale, however, confidence in this finding cannot be determined as the scale has not been validated within the laryngectomy population. Furthermore, due to the study design, the participant was not blinded to the condition leading to high risk of performance bias. Functional outcomes were measured independently pre and post intervention through visual-perceptual scoring of instrumental assessments by blinded raters. Inter-rater agreement was not described and statistical tests were not used. Data on adherence to the intervention was not reported.

3.3.7. RISK OF BIAS ACROSS STUDIES

Risk of bias was moderate to high with limitations identified in all studies. Across studies sample sizes were relatively small with higher overall proportion of male participants. Few studies incorporated participants with extended surgery. No studies reported ethnicity or socioeconomic status of participants.

Selection bias was identified in several studies due to lack of stated eligibility criteria and absence of concealed allocation in one randomised controlled trial. Blinding of participants and / or researchers was not consistently applied across studies leading to risk of performance bias. Potential for attrition bias was seen in one study.

Intervention description was inconsistent in several studies, impacting on replicability, and one study presented risk of confounding bias due to the intervention design. Outcome measures were heterogenous with reliance on perceptual ratings, informal measures or measures that were not validated within the laryngectomy population.

3.3.8. DATA SYNTHESIS

Due to the heterogeneity of the studies, interventions tested and outcome measures used, meta-analysis was not carried out. The preceding section discussed risk of bias and participant information. A narrative synthesis approach was applied, informed by ESRC guidance (Popay et al., 2006), to describe the interventions and the outcomes. Two studies were excluded from the data synthesis as they were of insufficient quality for inclusion (Onofre et al., 2013; Baijens et al., 2010). The four included studies totalled 151 participants, of which 132 were male and 19 female, further participant characteristics are described in table 3.4.

3.3.8.i. Intervention description and theory

Studies were heterogenous in their interventions, stated aims and use of outcome measures. There were, however, common elements targeting voice production between studies. Three studies included breathing exercises (Longobardi et al., 2019; Van Sluis et al., 2020 and De Oliveira et al., 2005). Two provided practice of coordinating stoma occlusion (Longobardi et al., 2019; De Oliveira et al., 2005); and three included speech related elements such as articulation or prosody exercises (Longobardi et al., 2019; De Oliveira et al., 2005; Jansen et al., 2020). Jansen et al., 2020 was the only study to include upper body flexibility and lymphoedema exercises. All included studies varied in the dosage and intensity of intervention.

Two studies did not provide a rationale for the trialled interventions (Jansen et al., 2020; De Oliveira et al., 2005). Longobardi et al. (2019) provided rationale for the investigation of psychological approaches, which was the main focus of the study, whereas rationale was not provided for the included voice production approaches. Similarly, Van Sluis et al. (2020) described clearly the rationale for targeting expiratory pressures through EMST, however, the potential impact of EMST on alaryngeal voice was not elaborated.

Whilst the theoretical basis of the interventions was not illustrated in the studies, all interventions could be mapped onto the Van Stan Taxonomy of Voice Therapy (Van Stan et al., 2015). However, it has not yet been established that the theoretical principles underpinning interventions for laryngeal voice can be transferred to alaryngeal voice therapy without modification, therefore it is uncertain whether targeted outcomes could be influenced by the interventions.

3.3.8.ii. Synthesis of findings and exploration of relationships within the data

The heterogeneity of outcome measures prevented combined analysis of findings, therefore different intervention targets are described narratively. In some studies outcome measures used did not directly align to the intervention. For example, breathwork was reported in

Longobardi et al. (2019) and De Oliveira et al. (2005), however, potential change was assessed using a measure of vocal function, rather than a specific breathing outcome measure.

3.3.8.iii. Self-reported voice impact

The SECEL, VHI-10 and SHI were used to assess self-reported voice impairment (Longobardi et al., 2019; Van Sluis et al., 2020 and Jansen et al., 2020 respectively). Jansen et al. (2020) also used the SWAL-QOL, which includes a sub-section score for communication. SECEL scores improved over time with significant difference in pre-post intervention mean scores ($p < 0.001$), representing reduced self-reported voice impairment following intervention in Longobardi et al. (2019). SECEL scores improved in both control and experimental groups. This was consistent with both groups receiving the same communication-related interventions, as the independent variable of the study was psychological support. Interaction effect was not reported, however. Jansen et al. (2020) reported significant improvement in the communication sub-score of the SWAL-QOL ($P = 0.004$) in the experimental group.

In contrast no significant differences were found on the VHI-10 and SHI measures. This difference may be accounted for by variation in outcome measures. Significant change was demonstrated on the SECEL, which is a measure designed specifically for laryngeal cancer and validated within the laryngectomy population, whereas the VHI-10 is not designed for oncological populations. The SHI was developed and validated within an oropharyngeal cancer population, however, the focus of the scale is on speech problems, rather than voice quality, therefore it may not be the optimal assessment to measure alaryngeal voice change. Studies which demonstrated significant change did not focus primarily on voice interventions. Jansen et al. (2020) and Longobardi et al. (2019) investigated the use of a self-help programme and psychological support respectively.

3.3.8.iv. Vocal and pulmonary function

Longobardi et al. (2019) used the INFVo scale for perceptual evaluation of voice quality. Significant improvement in pre-post scores was reported in both experimental and control groups ($p < 0.022$), and groups were significantly different ($p < 0.0005$), however, the interaction effect was not reported to enable interpretation of the finding. De Oliveira et al. (2005) did not find any significant differences post intervention in vocal quality, pitch or sentence melody, based on Likert scale perceptual ratings. Validated outcome measures were not used within the study.

Van Sluis et al. (2020) reported an increase in mean decibels (dB) post intervention (week four), which was not sustained at second follow up (week eight). This aligned to increase in mean maximum expiratory pressure (MEP) at week four and slight mean decrease at week eight. Intensity, as measured in decibels, is proportional to expiratory pressure (Huber et al., 2009) therefore the pattern of change in mean MEP and dB scores over time is consistent. Statistical tests were not used to determine significance, as the authors reported lack of sufficient data on the laryngectomy population to perform sample size calculations. There was no change in mean maximum phonation time or pitch, which are not anticipated to be impacted by expiratory pressure changes. There was no change over time in other measures of pulmonary function, physical exertion or fatigue.

3.3.8.v. Intelligibility

Intelligibility was measured within two studies using perceptual rating (Longobardi et al., 2019; De Oliveira et al., 2005). Whilst both studies included speech production or articulation exercises in their intervention programmes, only Longobardi et al. (2019) reported a significant improvement in intelligibility over time ($p < 0.001$) based on mean percentage of correctly perceived words.

Whilst detail on the specific exercises was limited, this difference in outcome was unexpected as the speech intervention described in De Oliveira et al. (2005) targeted speech production

more directly through articulation exercises. This finding could be attributed to a difference in the measurement of intelligibility where Longobardi et al. (2019) used mean percentage of correctly perceived words, whereas De Oliveira et al. (2019) used a perceptual Likert scale which may be less robust.

3.3.8.vi. Psychological distress and quality of life

The two randomised control trials included measures of psychological distress, well-being, and quality of life. Quality of life measures and outcomes differed between studies. Jansen et al. (2020) used the EORTC QLQ-C30 and H&N35 measures which did not find any significant group, time or interaction effects. These measures are specific to the general cancer and the head and neck cancer populations. Longobardi et al. (2019) assessed quality of life using the WHO-QOL, which is a generic measure of quality of life, not specific to cancer populations. The study reported a different pattern of change in the social relationships domain where QOL improved in the experimental group and declined in the control group ($p = 0.017$); and over time only ($p < 0.004$) in the psychological health domain. Longobardi et al. (2019) additionally measured self-reported psychological distress. The measurement of self-reported psychological distress demonstrated a significant effect of group on depression ($p=0.017$), paranoid ideation ($p=0.038$) and obsessive-compulsiveness ($p=0.013$) subscores; where experimental group scores decreased and control group scores increased (indicative of more severe symptoms). The difference in outcomes between the two studies could be attributed to the inclusion of psychological intervention within Longobardi et al. (2019). Whilst the experimental group in Jansen et al. (2020) received additional weekly coaching from a healthcare professional, this was not targeting psychological support.

3.3.8.vii. Robustness of synthesis

PRISMA guidance was followed to ensure that the review process adhered to an established framework, with a search strategy designed to source all available evidence. A small number of studies were available leading to limited data for synthesis. Two studies were excluded

from synthesis due to high risk of bias. Included studies presented with quality limitations impacting on the certainty of the outcomes described. These related to allocation, blinding, poor description of interventions and fidelity, variability in interventions and outcome measures. Confounding bias was identified in one study (Jansen et al., 2020) which could have influenced a positive finding in relation to communication.

3.4. DISCUSSION

This systematic review sought to identify behavioural interventions for voice rehabilitation following total laryngectomy with tracheoesophageal voice prosthesis. The review searched eight healthcare databases and followed PRISMA guidance (Page et al., 2021). Six studies were identified which met criteria for inclusion. These included two randomised control trials, one single case study and three before and after studies. All studies presented quality issues with two studies excluded from data synthesis due to high risk of bias. The included studies explored voice rehabilitation after total laryngectomy, however, this was not the primary focus of the intervention in the majority of studies. Interventions varied between studies with inadequate description for replication. Evidence for the effectiveness of the interventions was limited with few significant findings and inconsistent outcomes between studies. The majority of studies contained small sample sizes and male participants were over-represented, therefore the generalisability of the outcomes should be interpreted with caution. Furthermore, few participants had received extended surgical reconstructions therefore the results may not be generalised to participants outside of the total laryngectomy with primary closure population.

3.4.1. INTERVENTIONS FOR TRACHEOESOPHAGEAL VOICE

The TIDieR checklist (Hoffman et al., 2014) was used to assess intervention reporting. This demonstrated that interventions were not well described with insufficient detail for replication in some studies. There was limited information on how specific exercises were

carried out by participants and an absence of theoretical rationale for some approaches. Where reported, studies varied in the number of sessions provided, and in the intensity and frequency of intervention. There was significant heterogeneity in choice of outcome measures with some reliance on measures designed outside of the laryngectomy population or informal measures such as Likert scales. This accords with systematic reviews of laryngeal voice therapy (Desjardins et al., 2016; Speyer, 2006), which found heterogeneity and methodological issue with the laryngeal voice evidence base. In the laryngectomy context, variation between studies and scarce theoretical basis may point towards a lack of consensus or awareness of which interventions or outcome measures could be of benefit to voice prosthesis users.

All studies included interventions that could be categorised within the Van Stan Taxonomy of Voice Therapy (Van Stan et al., 2015), however, differing approaches were used and voice quality was not the primary outcome in all studies. Within direct interventions, studies predominantly focussed on respiratory function such as EMST or breath to occlusion coordination. Only one study (Jansen et al., 2020) included a musculoskeletal approach aimed at increasing upper body flexibility and articulator range of motion. Vocal function was targeted via expiratory pressure to increase loudness (Van Sluis et al., 2020) and via singing pitch exercises in two studies (De Oliveira et al., 2005; Onofre et al., 2013). The latter was of insufficient quality to include in synthesis, however. Indirect interventions were incorporated into the randomised controlled trials, which used pedagogical approaches such as education on prosthesis care, and psychological intervention to support acceptance of alaryngeal voice.

Whilst interventions could be mapped onto the laryngeal voice therapy categorisations, there was an absence of direct 'borrowing' from established laryngeal voice therapy methods and certain aspects of voice were not addressed within the included studies. For example, studies did not include approaches for resonance, and pitch was incorporated only via singing exercises rather than speech. This contrasts with the established use of semi-occluded vocal tract exercises (Titze, 2006) and Vocal Function Exercises (Stemple, 1994) to target resonance and pitch in laryngeal voice therapy.

Functional approaches to voice use were not seen in identified studies, yet this approach is well established in laryngeal voice therapy, for example via Lee Silverman Voice Treatment (Pannbacker, 1998), which focusses on impairment-based drills plus functional tasks to transfer therapy gains to real world environments. This may suggest uncertainty about the effectiveness of these approaches within the laryngectomy population.

3.4.2. QUALITY OF EVIDENCE AND EFFECTIVENESS OF VOICE INTERVENTIONS

Two studies were excluded from analysis due to high risk of bias, whilst quality issues were present in all studies. Quality issues were characterised by unclear eligibility criteria, lack of allocation concealment, insufficient blinding, baseline differences between groups, confounding bias, attrition bias in one study and use of informal outcome measures. Studies included small sample sizes and male participants were overrepresented compared with incidence data, with ratio of 6.13:1 male to female.

A small number of positive findings were reported across studies, however, there was inconsistency in outcomes and a lack of commonalities relating to outcome measures and intervention details, which reduced the robustness of positive findings. Consequently, the existing evidence base is not sufficient to inform therapeutic intervention. This points toward the need to develop clinical population specific voice measures, which has similarly been highlighted within the non-laryngectomy head and neck cancer population (Jacobi et al., 2010) and other emerging fields of voice-related SLT practice, such as subglottic stenosis (Clunie et al., 2020) and above-cuff vocalisation (Mills et al., 2022). The necessity for further research to enhance transferrable evidence is identified across areas of voice therapy (White et al., 2021; Desjardins et al., 2016; Ramachandran et al., 2022).

3.4.3. LIMITATIONS

Few studies were available for inclusion into the review due to the small evidence base in this clinical area. The generalisability of the included studies is uncertain due to inconsistency

between studies in terms of interventions provided and reported results. Furthermore, the incomplete detail in intervention descriptions impacts upon the potential to replicate the interventions for wider testing. Studies did not explore all aspects of voice production therefore evidence on multidimensional elements of voice is incomplete.

Across studies male participants were over-represented. As predetermined, studies were only included if they recruited tracheoesophageal speakers, or the majority of participants were tracheoesophageal speakers. Therefore, the outcomes of this review could not be generalised to other forms of alaryngeal communication without caution. Within included studies, only one participant was reported as having extended surgery, therefore further caution is advised if generalising findings to people with extended surgical procedures such as flap reconstructions.

Outcome measures differed between studies with reliance on self-designed measures in some studies; and there was limited use of statistical testing, which prevented a meta-analysis. Quality issues were identified in all studies with two excluded from data synthesis due to high risk of bias. Consideration is also given to the potential for unconscious researcher bias at points within the review where subjective decisions were required. This was minimised through adherence to an established guideline, quality assessment tool protocols and the inclusion of a second reviewer.

3.5. CONCLUSION

This review aimed to identify evidence for behavioural rehabilitation of tracheoesophageal voice and to critically appraise the quality of the evidence and the effectiveness of interventions. The review demonstrated that there is a very small evidence base to guide behavioural rehabilitation of tracheoesophageal voice, finding only six studies, which were insufficient to inform clinical practice. Existing studies presented with methodological issues which led to risk of bias; whilst inconsistency in findings and outcome measures lead to uncertainty in study outcomes.

The review sought to find evidence which could inform clinical practice; however, this was lacking and robust evidence was not found. This has implications for future research and highlights the clear need for more studies on the development and testing of behavioural interventions to improve tracheoesophageal voice.

In acknowledging the requirement for further research, it is recommended that studies adhere to reporting guidelines such as TIDieR and methodological issues are considered to enhance quality. Consistent use of outcome measures that are designed and validated for the laryngectomy or head and neck cancer populations is advocated, to allow for comparison of findings across studies and to improve robustness of outcomes. Further studies are required which explore multidimensional aspects of alaryngeal voice production such as pitch, resonance and functional voice use; alongside wider investigation of the effectiveness of breathing and articulation approaches seen in the included studies. No studies considered the views of service users in detail within study design or intervention content and this is identified as an area of research importance.

CHAPTER 4 | APPROACHES TO TRACHEOESOPHAGEAL VOICE REHABILITATION: A SURVEY OF UK AND IRISH SPEECH AND LANGUAGE THERAPISTS' CURRENT PRACTICE

This chapter has been peer-reviewed and an abridged version published:

Sparks, F. Dipper, L. Coffey, M. Hilari, K. (2023). Approaches to tracheoesophageal voice rehabilitation: A survey of the UK and Irish Speech and Language Therapists' current practice and beliefs. *International Journal of Language and Communication Disorders*, 58(5), 1481-1495. DOI: 10.1111/1460-6984.12873

Patient Advisory Group input:

The PAG were consulted on the rationale for the clinician survey. The group agreed that it was important to understand the perspectives of SLTs and to investigate current practice. The group were satisfied with the survey methodology and framework. Further meetings were held to discuss the results of the survey; PAG members were particularly keen to emphasise the need for SLT training and increased resourcing as key dissemination points.

4.1. INTRODUCTION

This chapter reports on the use of survey methodology to explore UK and Republic of Ireland (ROI) based SLTs' current practice of tracheoesophageal voice rehabilitation. We aimed to gain novel understanding of clinical practice within this area through investigation of the experiences and views of SLTs.

Given the paucity of evidence exemplified in the systematic review of Chapter Three, it was pertinent to establish the nature of current clinical practice beyond voice prosthesis

insertion, management and care. The survey explored what rehabilitative approaches are being implemented in clinical practice across the UK and ROI and investigated the barriers and facilitators to provision of tracheoesophageal voice therapy. This was in the context of tracheoesophageal voice therapy as a rehabilitative behavioural intervention to improve voice quality, such as by transference of clinical skills commonly applied to laryngeal voice therapy.

No existing surveys or studies have investigated the specific question of what SLTs should do, or currently do in voice therapy to optimise tracheoesophageal voice quality. Hence there is a disconnect between guidelines, knowledge and clinical practice, whereby clinical guidelines stipulate the requirement for SLT intervention, but do not detail what this entails in the rehabilitation context. Furthermore, there is no established protocol within head and neck SLT practice which could provide professional consensus. Gaining a picture of current UK and ROI practice is therefore an essential foundation for development of an intervention.

4.1.1. OBJECTIVES

The objectives of this survey were:

- To investigate UK and ROI SLTs' current tracheoesophageal voice rehabilitation practices
- To identify the rehabilitative approaches implemented in clinical practice
- To explore SLTs' views, barriers and facilitators to provision of tracheoesophageal voice therapy

4.2. BACKGROUND LITERATURE

4.2.1. PREVIOUS SURVEYS

To date the evidence base for communication rehabilitation after laryngectomy has focussed on the surgical voice restoration method; and the impact of surgical interventions on voice quality, such as secondary myotomy (Lavertu, 1989) or Botox (Persaud et al., 2013; Spector et al., 2013). These interventions are used to treat muscle spasm and hypertonicity in cases where tracheoesophageal voice has not been achieved, often due to sub-optimal surgical technique in the initial laryngectomy procedure. However, Botox and myotomy only enable the acquisition of tracheoesophageal voice, and SLT support remains necessary to optimise it. Additionally secondary myotomy carries risk of significant surgical complications (Scott et al., 1993; Huo et al., 1995).

Existing surveys of SLT practice have tended to reflect the predominant focus of the evidence base for laryngectomy rehabilitation. That is, to investigate SLT training, intervention at a service provision level or in relation to voice prosthesis insertion and care. This results in a lack of information on the content of behavioural therapeutic rehabilitation or SLT perceptions about carrying out this work. This survey addresses the information gap by identifying current SLT clinical practice and by exploring the barriers and facilitators that SLTs encounter when undertaking this work.

Culton and Gerwin (1998) surveyed North American Speech Language Pathologists (SLP) with experience of alaryngeal voice production, gaining 151 responses. They investigated SLP preference for alaryngeal voice rehabilitation method from oesophageal speech, electrolarynx or tracheoesophageal voice prosthesis. Tracheoesophageal voice was preferred by 69% of respondents, with note made that choice would vary depending on patient factors and local uptake of the tracheoesophageal puncture procedure by Otolaryngologists. This survey can be interpreted in the context of an era where tracheoesophageal voice prosthesis use was increasing and gaining popularity over other alaryngeal voice methods, capturing the changing landscape of rehabilitative techniques. It concluded that successful implementation

of tracheoesophageal voice should incorporate pre-assessment, patient selection, team decision making and treatment. Whilst they did not explore the therapeutic content of SLP interventions, Culton and Gerwin (1998) did, however, provide insight on the scope of SLP involvement in surgical voice restoration. This information remains pertinent as a motivational factor in SLT practice.

A survey of similar focus was undertaken by Ryan et al. (2004) within the UK. Head and Neck surgeons (n=77) were surveyed on their current practice of laryngectomy voice rehabilitation. Tracheoesophageal voice restoration was the preferred method of 92% of respondents. All respondents reported having an SLT affiliated to their team, however, the survey did not seek SLT views on post laryngectomy voice rehabilitation.

A later survey of UK SLTs (n=72) investigated provision of surgical voice restoration in England (Bradley et al., 2013). The survey was devised in response to concerns from the National Association of Laryngectomy Clubs (NALC) regarding provision of surgical voice restoration services in some regions of England. They found that surgical voice restoration services were provided by SLTs within working hours in almost half of units; whilst the pathways for urgent out of hours services (outside of 09:00-17:00 and weekends) varied between units from advice to contact the ENT ward, contact a specific trained person, or attend the Accident and Emergency department. Service provision varied across the English Cancer Networks, however, and some units did not confirm a specific out of hours pathway was in place. Provision of out of hours services is important as PWL may experience a problem with their voice prosthesis or tracheoesophageal puncture at any time. As this may require prompt attention, it is not always safe or feasible to wait for intervention should the issue arise outside of standard SLT working hours. Bradley et al. (2013) advocated for equity and uniformity of laryngectomy patient rehabilitation within and across cancer networks; noting that education of multidisciplinary staff and increased SLT staffing levels were required to do this; in addition to the need to create nationally agreed management protocols. Given that the focus of this survey was to investigate service provision, SLT rehabilitation approaches were not discussed.

In response to this survey, Hancock et al. (2018a) investigated clinical consistency in voice prosthesis management within an Australian setting, surveying 34 clinical sites across the country. This survey reported a similar picture of variability in some aspects of SLT practice. It provided detailed information on the practical elements of SLT management, for example, voice prosthesis insertion, type of prosthesis, cleaning and anti-fungal regimens and funding provision. However, the survey did not incorporate questions on whether rehabilitative SLT interventions were implemented beyond voice prosthesis insertion and care. A second 16 item online survey by the same research group investigated Australian SLTs' clinical preparedness and availability of training for tracheoesophageal voice work (Hancock et al., 2018b). Responses from 35 centres revealed that training incorporated a combination of mentoring, informal and formal on-site training, competency programmes and external courses and workshops. Whilst 68% of respondents felt that training programmes were adequate, experienced participants working in tertiary settings were more likely to raise a desire for more advanced training opportunities.

Later studies by Hancock, Ward and Hill (2020a, 2020b) continued to build a picture of SLT perceptions towards tracheoesophageal voice work. Focus groups were used to explore further Australian SLTs' views on clinical training, skill development and confidence in providing tracheoesophageal voice rehabilitation. Several themes and challenges were identified in training for tracheoesophageal voice rehabilitation such as opportunity for hands-on practice, adequate exposure, access to learning within networks and access to formal training (Hancock, Ward and Hill, 2020b). Similarly, training opportunities, exposure and support, in addition to leadership opportunities, were identified as factors in maintenance of confidence in provision of tracheoesophageal voice interventions (Hancock, Ward and Hill, 2020a).

Earlier work by Melvin, Frank and Robinson (2001) had examined the same question of clinical knowledge and preparedness amongst SLPs in North America. This survey found that the majority of SLPs did not feel prepared to work with tracheoesophageal prosthesis users following university training programmes. The authors advocated for consideration of continuing education and training.

Alongside provision of additional training, exposure and educational modalities, the role of reflective practice has been considered. Caty, Kinsella and Doyle (2009), report a case study in which a reflective practice framework was applied to clinical decision making and development of knowledge in a post-laryngectomy voice rehabilitation setting. Whilst the single case study design presents a low level of evidence, the authors concluded that the process of reflection was important for advancing knowledge.

4.2.2. GUIDELINES FOR SLT INTERVENTION

BAHNO standards state that all head and neck cancer units should have a named SLT with specialist surgical voice restoration skills (Schache, 2021) to support patients throughout their pre and post treatment cancer journey. Similarly National Institute for Clinical Excellence (NICE) guidance advises that an SLT specialising in head and neck cancer should be available for all patients with impairment to communication or swallowing (NICE, 2004)

The clinical guidelines of the RCSLT contain a subsection on Head and Neck Cancer (section 5.13) which sets out the appropriate management of this patient group (RCSLT, 2005). The guidelines state that the SLT will 'select and teach the most appropriate method of laryngeal [sic] voice...to achieve optimum function voice' and additionally that the SLT should 'be involved in decision-making regarding the choice of prosthesis, sizing, fitting and ongoing management' (RCSLT, 2005 p114). The guidelines are therefore limited in their scope of guiding management of head and neck cancer patients and rehabilitative interventions are not stated. This contrasts with the guidance provided for management of Clinical Voice Disorders (section 5.6 of the RCSLT clinical guidelines) whereby detailed guidance is provided on the necessary steps in assessment and specific therapeutic approaches for voice care and rehabilitation are given. A later RCSLT policy statement for surgical voice restoration (Evans et al., 2010) elaborates on the required knowledge and skills the SLT should obtain to manage and troubleshoot tracheoesophageal voice prostheses, however, no further detail is provided on rehabilitation.

4.3. METHODOLOGY

4.3.1. SURVEY FRAMEWORK

To achieve the aim of exploring SLTs' views, barriers and facilitators to implementing tracheoesophageal voice therapy, the Behaviour Change Wheel (Michie et al., 2011) was applied to develop the survey. The Behaviour Change Wheel is an established model of behaviour change theory which can be used to identify factors contributing to implementation of practice and behaviour change in the healthcare setting.

The Behaviour Change Wheel consists of three integrated layers (Figure 4.1). The initial layer of the Behaviour Change Wheel seeks to understand the sources of behaviour and to identify what factors need to change at an individual or environmental level for a behaviour to happen. Subsequently, intervention types that could support change are identified, in addition to the type of policy that would support the required interventions.

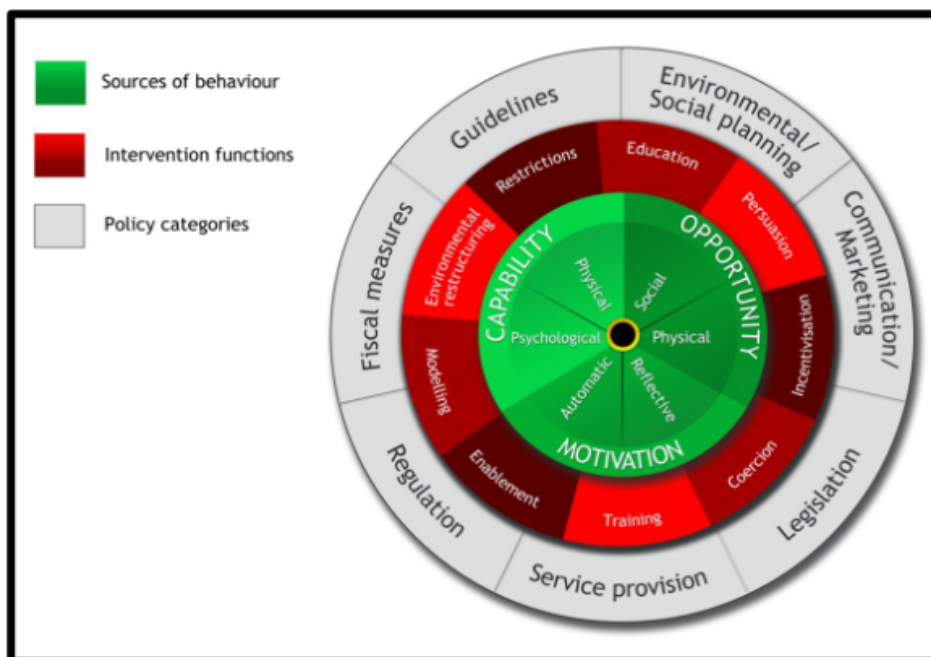


Figure 4.1: The Behaviour Change Wheel (Michie, van Stralen and West, 2011)

Michie et al. (2011) state that, for a behaviour to happen, the individual or group must have the capability, opportunity and motivation to achieve the behaviour. The initial layer of the Behaviour Change Wheel is therefore referred to as the COM-B model (Figure 4.2). Whilst the Behaviour Change Wheel identifies how to implement change, the COM-B identifies what factors need to change.

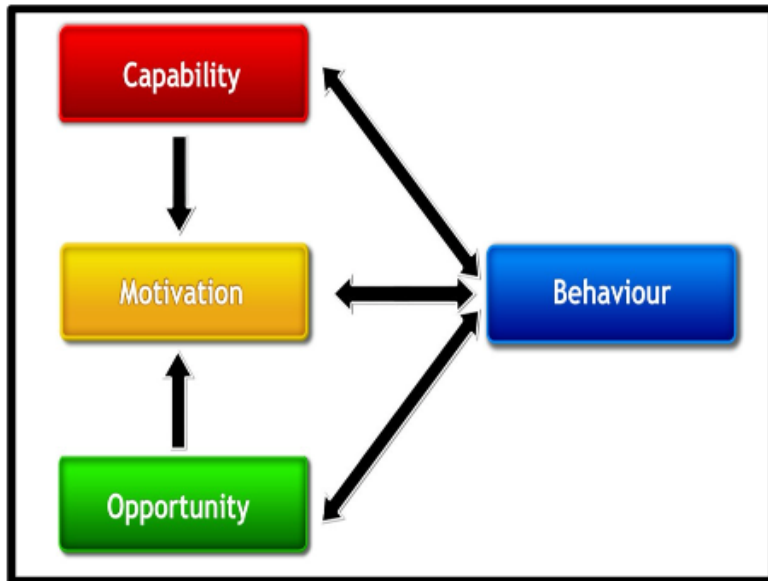


Figure 4.2: The COM-B model (Michie, van Stralen and West, 2011)

The components of capability, motivation and opportunity each include two sub-components which explore different aspects. Table 4.1 below illustrates this.

Component	Sub-component	Definition
Capability	Physical capability	Physical skill, strength or stamina
	Psychological capability	Knowledge or psychological skills, strength or stamina to engage in the necessary mental processes
Opportunity	Physical opportunity	Opportunity afforded by the environment involving time, resources, locations, cues, physical 'affordance'
	Social opportunity	Opportunity afforded by interpersonal influences, social cues and social norms that influence the way we think about things
Motivation	Reflective motivation	Reflective processes involving plans (self-conscious intentions) and evaluations (beliefs about what is good and bad)
	Automatic motivation	Automatic processes involving emotional reactions, desires, impulses, inhibitions, drive states and reflex responses

Table 4.1: The COM-B components (adapted from Michie, Atkins and West, 2014)

The Behaviour Change Wheel can be further divided into the Theoretical Domains Framework. The Theoretical Domains Framework, in its most current validated format (Cane, O'Connor and Michie, 2012), explores factors across 14 domains which influence behaviour for example, knowledge, social influences, belief about consequences. Each domain of the Theoretical Domains Framework maps on to a component of the COM-B.

It has been noted that the large number of domains within the Theoretical Domains Framework are a limitation when applying the framework to questionnaire development

(Huijg et al., 2014). Following a systematic review of qualitative studies which used the Theoretical Domains Framework, McGowan, Powell and French (2020) proposed that the framework be applied in a flexible format to ensure its use is optimised in qualitative research.

Within the confines of this survey it was not possible to include multiple questions targeting each specific domain of the Theoretical Domains Framework for individual analysis, as this would have resulted in an overly lengthy and burdensome survey. Instead, questions were aligned to the 14 domains and were analysed by their overarching components of capability, opportunity and motivation, with only supporting information relating to specific domains.

4.3.2. SURVEY DESIGN

A 35 item (of which seven were demographic questions) self-administered online survey was designed using the Qualtrics XM survey platform, accessible via mobile devices or computer. Guidance on reporting of survey research is limited (Bennett et al., 2011) however, the Checklist for Reporting Results of Internet E-Surveys (CHERRIES) (Eysenbach, 2004) provides recommendations for the reporting of online surveys. The checklist was followed to ensure transparent reporting of the survey.

4.3.3. SURVEY DEVELOPMENT

The survey items were developed to explore the areas of theoretical knowledge (n= 3 items), clinical training, (n= 2 items) clinical practice (n= 10 items), barriers (n= 2 items), facilitators (n= 3 items) and motivators (n= 7 items) plus one open question prompting any further comments. Questions were informed by the domains of the Theoretical Domains Framework and designed to align to the framework and COM-B model. For example, the question ‘do you have sufficient clinical resources to provide tracheoesophageal voice therapy?’ explored barriers to provision of therapy. This question was aligned to the opportunity component of the COM-B, and specifically to the Theoretical Domains Framework domain of environmental

context and resources. Participant demographics questions were taken from a previous survey of UK SLTs' clinical practice (Behn et al., 2020) and adapted to laryngectomy specific working. Three questions from Culton and Gerwin's 1998 survey were included within the present survey. These questions were:

- Is your role in the speech rehabilitation of laryngectomy patients that of a decision-making team member?
- Are you involved in evaluating patient suitability for tracheoesophageal puncture? (e.g., insufflation testing, motivation)
- Are you involved in 'troubleshooting' the inevitable problems encountered by tracheoesophageal puncture patients?

Questions were developed by the researcher, a Clinical Lead SLT in Head and Neck cancer and reviewed by KH and LD (a Professor of Acquired Communication Disorders and Professor of Clinical Linguistics with experience of survey methodology with people with communication disorders) and MC an expert clinician in Head and Neck Cancer. Questions were reviewed within the team and content and phrasing were discussed in a three-round iterative process, until the survey items were finalised.

Six questions were open response:

- What knowledge and skills are required to provide tracheoesophageal voice therapy compared to standard voice therapy?
- What challenges have you encountered in delivering tracheoesophageal voice therapy?
- What would help you?
- How do you feel about providing tracheoesophageal voice therapy?
- What factors help you decide whether to work on tracheoesophageal voice therapy?
- Are there any comments you would like to add about tracheoesophageal voice rehabilitation?

The remainder were closed questions in varied formats, e.g., multiple choice, Likert scale or yes/no response. A balance of closed versus open questions was used to support data capture, but also to increase the richness of participant responses in key areas (Boynton and Greenhalgh, 2004). Adaptive questioning was used on six closed questions whereby a follow up question or free text box was displayed on condition that 'yes' was selected. This format further enabled participants to expand on closed question responses whilst not adding to the overall complexity of the survey (Gillham, 2008, pp30-33). All multiple-choice questions gave an option to select 'other – please describe' to allow participants to add additional choices and information. Survey questions were not forced response; however, a prompt was provided for any questions left unanswered before the participant moved to the next screen. Back and forward buttons were incorporated to allow participants to review or amend their answers before submitting. The full survey is presented in Appendix 4.1.

4.3.4. PILOTING

The survey was piloted with seven SLTs identified through purposive sampling. The SLTs had varying levels of experience with laryngectomy, between one year to over ten years' experience. SLTs worked across inpatient and outpatient settings, with major cancer centres and district general hospitals represented (Table 4.2). Feedback was sought on the content, clarity of questions, accessibility and functionality, user experience and time to completion.

SLT	Gender	Age range	Years of experience	Work setting
1	Female	41-50	11-15	District general: Outpatients
2	Female	41-50	11-15	Major centre: Inpatient and outpatient
3	Female	31-40	6-10	Major centre: Inpatient and outpatient
4	Female	31-40	6-10	Major centre: Inpatient and outpatient
5	Female	41-50	11-15	Domiciliary / Community
6	Female	20-30	2 or less	Major centre: Inpatient
7	Female	20-30	2 or less	Major centre: Inpatient

Table 4.2: Characteristics of survey pilot participants

Feedback was positive with SLTs reporting easy access to the survey, valid content, clear questions and acceptable time to completion. Two minor amendments were made to the survey following feedback. One typing error was identified; secondly two SLTs reported that one question could be made clearer:

‘What factors help you decide how to prioritise improving quality of tracheoesophageal voice’ was amended to ‘What factors help you decide whether to work on tracheoesophageal voice therapy?’

Following feedback from the piloting SLTs, the updated wording was found to be clearer and acceptable. The average time to completion was 9.5 minutes, therefore the survey was advertised as a 10-minute survey on dissemination.

4.3.5. ETHICAL APPROVAL AND CONSENT

The survey received ethical approval from the City, University of London, School of Health Sciences Research Ethics Committee (approval no. ETH2021-2096), Appendix 4.2. A second ethical approval was granted at a later stage from the same committee to include the participation of ROI SLTs (approval no. ETH2122-0292) (Appendix 4.3).

Participants were required to give their informed consent to take part in the survey. On entering the survey, potential participants were provided with information on the background and aims of the survey. A link was provided to the Participant Information Sheet which gave detailed information on the research team, purpose of the survey, risks and benefits of taking part and data privacy. If participants did not consent, or did not respond to the question, they were unable to proceed to the survey. A second consent was requested for the use of anonymised quotations. Response to this consent was mandatory, however, provision of consent was optional and participants were able to complete the survey regardless of whether they consented to use of their quotations or not. Participants were informed that they could leave the survey prior to completing, however, answers could not be withdrawn once provided. No incentives were offered for participating in the survey.

4.3.6. PARTICIPANTS

The target population was UK and ROI based SLTs. To be eligible to take part, participants were required to confirm that they had at least one year of post-qualification experience and experience of working with laryngectomees within the last five years. Participants were also required to confirm they had current Health and Care Professions Council (HCPC) or Coru registration.

4.3.7. SAMPLE SIZE

The survey aimed to recruit 100 participants. There is no definitive list of UK and ROI SLTs that work with laryngectomy. The recruitment target was therefore based on the following considerations. The combined membership of North and South UK Clinical Excellence Networks for Head and Neck Cancer is 265 SLTs (personal communication, K. Behenna, 14/07/2021). However, no data is kept on how many members work with laryngectomy and it is noted that only a proportion of the membership would carry out this work. A 2016 study by ASHA (ASHA, 2016) looked at the percentage of ASHA certified SLPs with expertise in voice disorders and post-laryngectomy rehabilitation. This found that 5% of SLPs indicate expertise in treating people with voice disorders, 2% in treating laryngectomy, 1% have expertise in both. In the UK currently there are approximately 17,000 practicing SLTs (RCSLT, 2022), of which 1% would equal 170 SLTs. A 2013 survey of UK SLTs gained 72 participants (Bradley et al., 2013) and therefore the target of 100 participants reflects a high proportion of SLTs in the UK likely to work in laryngectomy and voice disorders; and an increased numbers of head and neck SLTs since 2013, and additionally the recruitment of ROI SLTs.

4.3.8. RECRUITMENT

The survey was open between 09/07/2021 – 07/11/2021 in order to recruit as many participants as possible after typical annual leave windows. ROI SLTs were able to participate in the survey from 15/10/2021 – 07/11/2021 following the additional ethical approval. The

survey was advertised on social media, via X and disseminated via the Head and Neck South, Head and Neck North and Voice Clinical Excellence Networks. The initial X advert was followed up with periodic tweets which encouraged recruitment from regions that were showing lower participation. The survey was again disseminated via the Clinical Excellence Networks one week prior to closing with simultaneous advertising via X. The survey was also promoted shortly prior to opening at a joint meeting of the Head and Neck North and South Clinical Excellence Networks on 18/06/2021.

4.4. RESULTS

4.4.1. PARTICIPANT CHARACTERISTICS

The initial survey advertisement received 16,809 impressions on X with 324 direct engagements. 147 SLTs took part in the survey. This comprised of 69 complete responses (47%) and 71 incomplete responses (48%). Six SLTs did not meet the criteria to take part and one did not consent following access to the Participant Information Sheet. (4.4% and 0.6% of sample respectively).

Participants were representative of the SLT workforce as evidenced by gender (93% Female, n = 114), distribution across working age (Figure 4.3) and years of experience working with laryngectomy (Figure 4.5). The majority of participants (87%, n = 105) were 31 – 66 years of age. This is indicative of head and neck cancer as a specialist area of SLT practice, which is seldom entered immediately post registration. Responses were received from all UK regions and ROI. Responses by region reflected the concentration of head and neck cancer centres with the highest percentage of responses from the London area (27.9%, n = 34), (Figure 4.4).

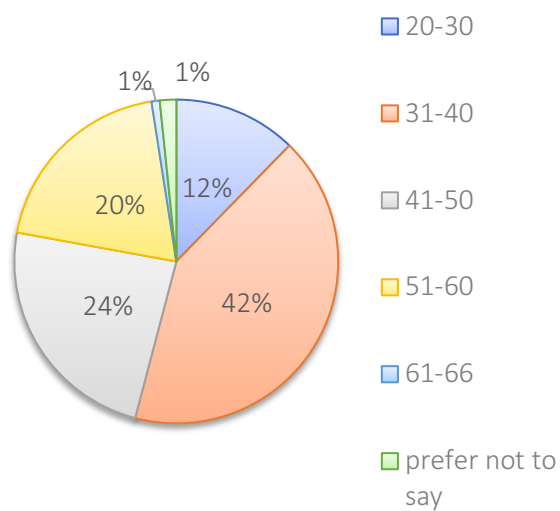


Figure 4.3:
Percentage of participants by age / years (n = 122)

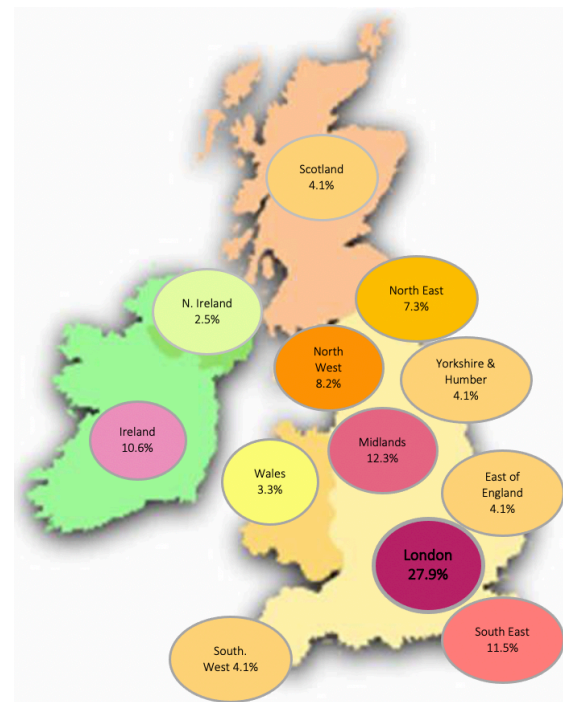


Figure 4.4:
Percentage of participants by region (n = 122)

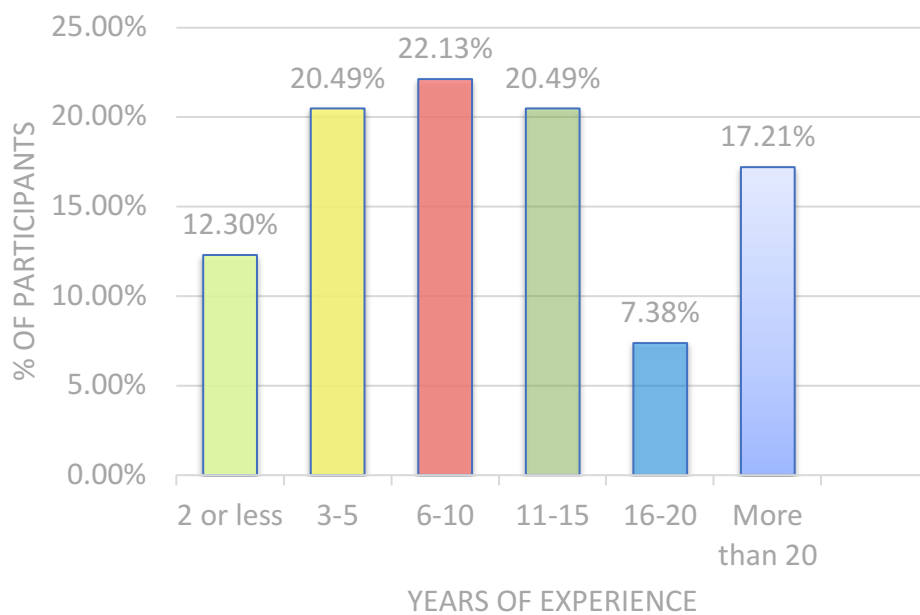


Figure 4.5: Years of experience working with laryngectomy (n = 122)

Of 122 participants, 68.8% (n = 84) reported that their typical caseload comprised of 11% or higher of PWL. Most SLTs worked in the public sector (95.08%, n = 116) versus independent practice or private sector (2.7%, n = 3) and a small proportion worked across multiple sectors (2.7%, n = 3). Participants tended to work in multiple settings (74.6%, n = 91) reflecting the usual configuration of inpatient and outpatient services within the same Head and Neck Cancer centre (Figure 4.6).

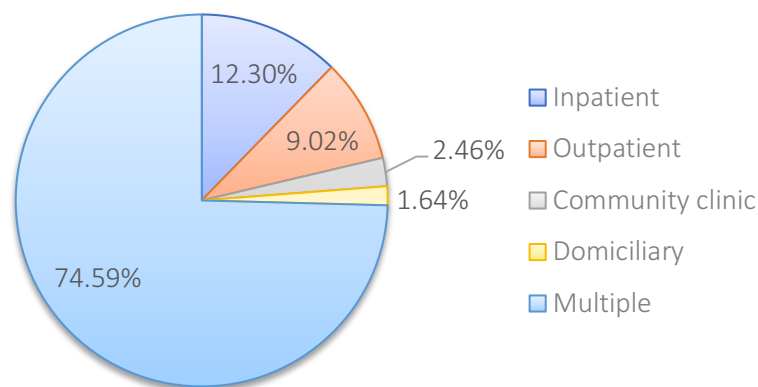


Figure 4.6: Work setting (n = 122)

4.4.2. CAPABILITY

4.4.2.i. Knowledge

Of the 94 participants who answered this question 73.4% (n = 69) were not aware of any therapy approaches for improving tracheoesophageal voice production. Of the 26.6% who were aware (n = 25), therapy approaches were described (n = 21) under the following categories: direct and indirect interventions, which aligned to the Van Stan taxonomy (Van Stan et al., 2015); and instrumental approaches (Table 4.3). No participants named an approach specifically designed for tracheoesophageal voice.

Type of approach	Examples provided by participants
Direct Interventions	Breathwork: diaphragm breathing, breath support, pacing, Accent Postural alignment Deconstriction of muscle tension and relaxation Articulation, beatboxing Volume and projection techniques Semi-occluded vocal tract therapies, flow phonation Stemple's vocal function exercises Manual manipulation Strapping or manual pressure
Indirect interventions	Scaffolding of therapy tasks Reflux management Review of voice prosthesis / baseplate / heat moisture exchanger (HME) Promoting voice prosthesis care
Instrumental	Biofeedback through videofluoroscopy, manometry, audio recording or aerodynamic assessment Expiratory or inspiratory muscle strength training Assessment of stricture Botox

Table 4.3: Therapy approaches stated by participants (n = 21)

A similar proportion (71.2%, n = 79 of 111 respondents) did not know of any guidelines relating to tracheoesophageal voice therapy. This question was asked to understand the theoretical knowledge that may influence clinical practice. Where guidelines were known, Table 4.4 shows the guidelines stated (n = 26) in descending order of frequency:

Guideline stated (descending order of frequency)
RCSLT (no specific guideline stated)
RCSLT Clinical Guidelines (containing subsection on Head and Neck Cancer)
RCSLT Surgical voice restoration Policy Statement / competency
American Speech-Hearing Association (ASHA) guidelines
Local guidelines
RCSLT Covid-19 Laryngectomy guidance
Allied organisations: BAHNO, ENT-UK and NICE guidelines
Speech Pathology Australia guidelines

Table 4.4: Guidelines relating to tracheoesophageal voice therapy (n = 26)

SLTs were asked what knowledge and skills they felt were required to carry out tracheoesophageal voice therapy compared to laryngeal voice therapy. Responses (n = 81) were detailed leading to the identification of themes as illustrated in Table 4.5. Dominant themes centred on anatomical, physiological, oncological and equipment knowledge specific to laryngectomy; approaches to therapy and assessment and allied psychological factors. Less frequent themes were knowledge of the risks of voice prosthesis management, cancer red flags, understanding MDT working and knowledge of swallow function. In addition to themes pertaining to required knowledge and skill, a minor theme was identified which expressed the belief that this a specialist area of clinical practice which requires skills, and particularly anatomical knowledge, beyond those used for voice therapy. The following quote provides an example of this view. In contrast a small sub-group reported uncertainty, stating that they did not have experience of laryngeal voice therapy and therefore did not know what knowledge and skills were required.

“This should be an advanced clinical area in my opinion – routine voice therapy is insufficient to support this cohort of patients and is potentially detrimental to a vulnerable patient who may end up not using their prosthesis due to a failure to acquire optimal voice”

Dominant themes	Knowledge and skills required
Anatomy	Understanding of altered anatomy including limitations of function arising Knowledge of surgical approaches e.g. different flap reconstruction types, impact of flap bulk, importance of myotomy and how it is performed, extent of resection Understanding impact and difference between anatomical features such as stricture, spasm, fistula and oedema
Physiology	Understanding tonicity, pharyngoesophageal / vibratory segment properties Understanding of pressures in reconstructed tract, airflow and breathing mechanics after laryngectomy Awareness of how Botox and dilatation affect function
Equipment	Knowledge of different types of voice prosthesis, HME and baseplate systems, including hands-free systems Understanding pros and cons of different prosthesis diameter Understanding how above impacts on voice quality Acquiring skill to use manometry or other pressure gauge
Wider oncological factors	Knowledge of cancer treatment timelines Understanding trajectory of radiotherapy side effects and potential impact, e.g., trismus, xerostomia, oedema Awareness of requirement to manage factors which may contribute to voice difficulty e.g., reflux and mucus Understanding of the psychological impact of cancer

Patient factors	Ability to identify patient motivation and acceptance Understanding how anxiety and confidence level will impact therapy Ability to set and manage patient expectations Ability to recognise patient's potential
Therapy and assessment approaches	Perceptual voice assessment and rating skills Knowledge of relevant outcome measures Competency in interpreting videofluoroscopy and air insufflation Knowledge of counselling approaches Ability to provide therapy targeting: - breath support - muscle tension and deconstriction - occlusion work – timing, pressure, minimising air escape - resonant voice work - positioning and postural alignment - articulation and prosody - provision of patient education and information - environmental modifications - communication partner training
Minor themes	Knowledge and skills required
Risks	Knowledge of compromised party wall management Ability to identify prosthesis issues requiring urgent management Troubleshooting skills for voice prosthesis problems Ability to identify 'red flag' cancer signs
Multidisciplinary teamwork	Close working with ENT colleagues and sharing of knowledge
Swallow function	Understanding impact of swallow function on voice Understanding impact of residue / pooled saliva on voice prosthesis

Table 4.5: Knowledge/skills required to provide tracheoesophageal voice therapy compared to laryngeal voice therapy (n = 81)

4.4.2.ii. Clinical training (skills)

Whilst participants were able to describe the knowledge and skills they felt were required for this clinical area, only 68.3% (n = 82 of 120 respondents) stated that they had received training in providing tracheoesophageal voice therapy. Training was largely provided through informal in-house training and supervision, established external courses or via stakeholders such as equipment manufacturers (Atos Medical, Blom Singer) or charitable organisations such as Macmillan. Most participants did not provide further detail on the content of in-house training; of the small group that did, responses were split between training focussed on voice prosthesis management and that which referenced voice specific training. For external courses, the Imperial Healthcare basic and advanced laryngectomy courses were most frequently stated, however, participants did acknowledge that the content of the courses is focussed on swallowing and voice prosthesis management. This is also applicable to equipment manufacturer led courses, which tend to focus on educating clinicians about new products.

By contrast, a higher proportion of participants (86.3%, n = 103 of 120 respondents) had received training in common psychological approaches used to support clinical practice (Figure 4.7). Advanced Communication Skills training was the most accessed training, consistent with this being a funded training which is regularly offered to cancer healthcare professionals. This training targets interpersonal communication in difficult clinical situations, use of communication strategies and reflection on own communication style in patient facing situations. Training reported as 'other' was categorised most frequently as cognitive behavioural therapy, in addition to lesser report of MSc modules and training through joint work with Psychology colleagues.

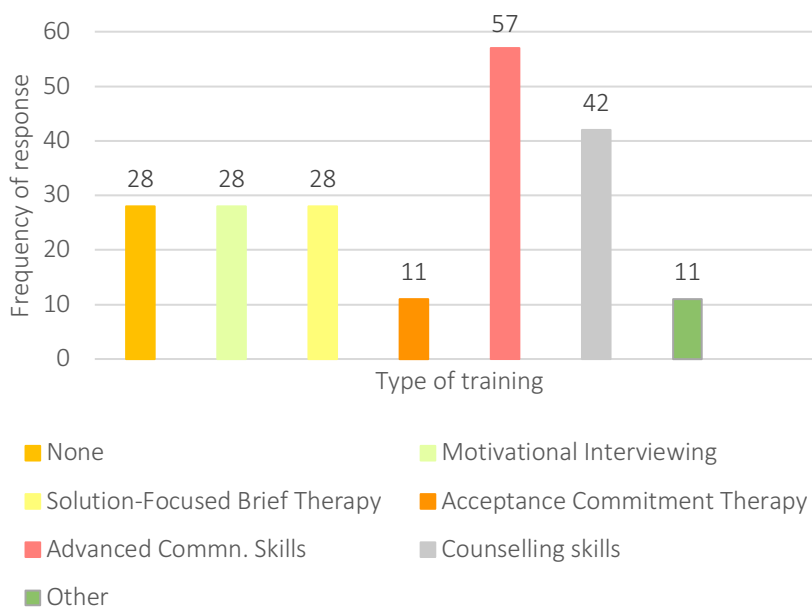


Figure 4.7: Training received in psychological approaches (by frequency of response)

4.4.2.iii. Clinical practice (skills; memory, attention and decision processes)

To understand how SLTs approach assessment of tracheoesophageal voice, SLTs were asked what clinical tools they use when assessing tracheoesophageal voice quality. To ascertain the memory, attention and decision-making processes behind clinical practice, SLTs were also asked how often they used each tool. Figure 4.8 illustrates the responses received. The majority of the participants who responded (n=90-93) never used the voice assessment tools or outcome measures which are commonly used in laryngeal voice assessment (Voice Handicap Index: 54.4%, n=50; GRBAS: 72.5%, n=66). Similarly, the majority of participants, never (44.1%, n=41), or only occasionally (32.3%, n=30), used the Sunderland Tracheoesophageal Voice Perceptual Scale (SToPs), (Hurren, Miller and Carding, 2019) to assess tracheoesophageal voice, despite this being specifically designed and validated for tracheoesophageal voice. A small number of participants (10.1%, n = 9) reported use of other assessments not listed; specifically, assessment of maximum phonation time and assessing response to digital pressure. Use of videofluoroscopy and manometry were also stated, however, it is noted that whilst these assessments provide important contributing information, they do not directly assess voice quality.

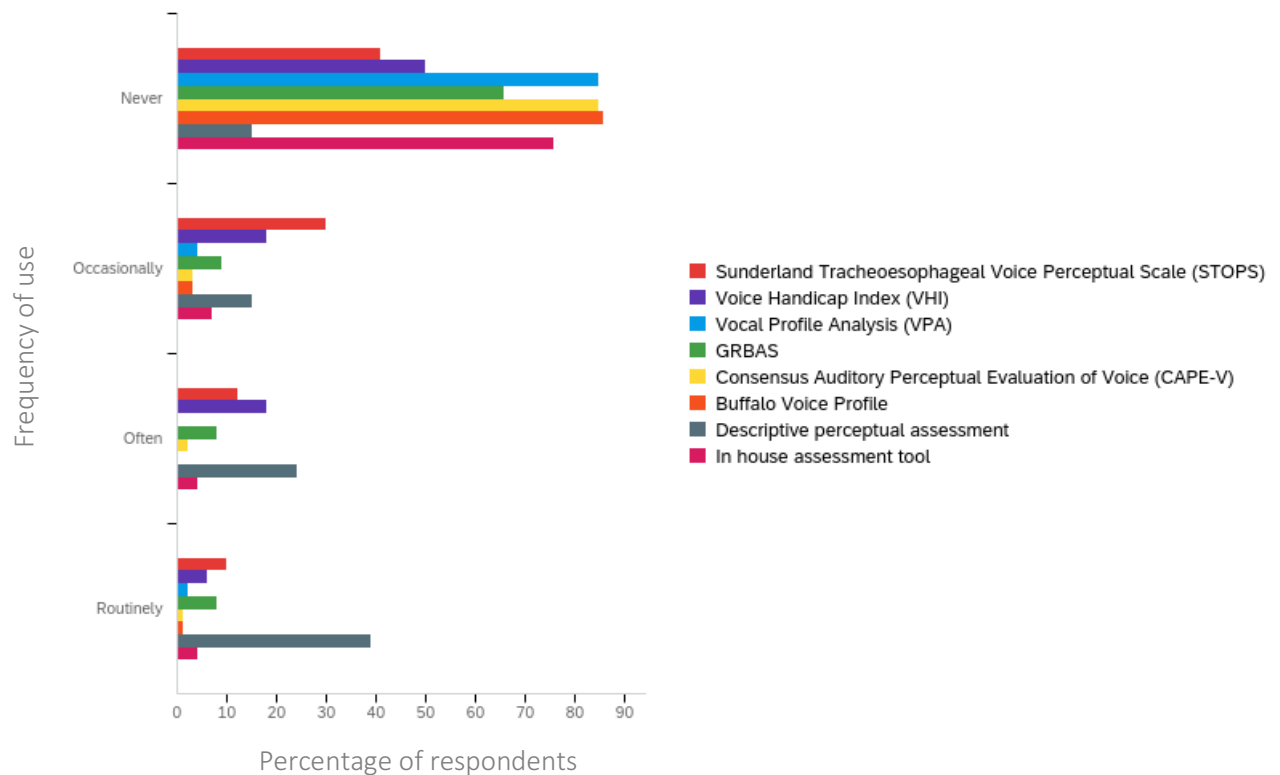


Figure 4.8: Assessment tools used by SLTs to assess tracheoesophageal voice quality, and frequency of use (n=90-93)

4.4.2.iv. Assessment

To explore tracheoesophageal voice assessment further SLTs were asked what other factors they assess alongside the quality of the voice. Here, there was a strong indicator of a routine practice to assess factors contributing to voice quality (Figure 4.9). This was favoured towards factors that could be assessed subjectively or through discussion with the service user. For example, breath support (60.2% assess routinely, n = 56) or hand dexterity (68.5% assess routinely, n = 63). This contrasted with factors requiring assessment with instrumentation such as aerodynamic assessment (9.78% assess routinely, n = 9) or tracheal manometry (5.6% assess routinely, n = 5).

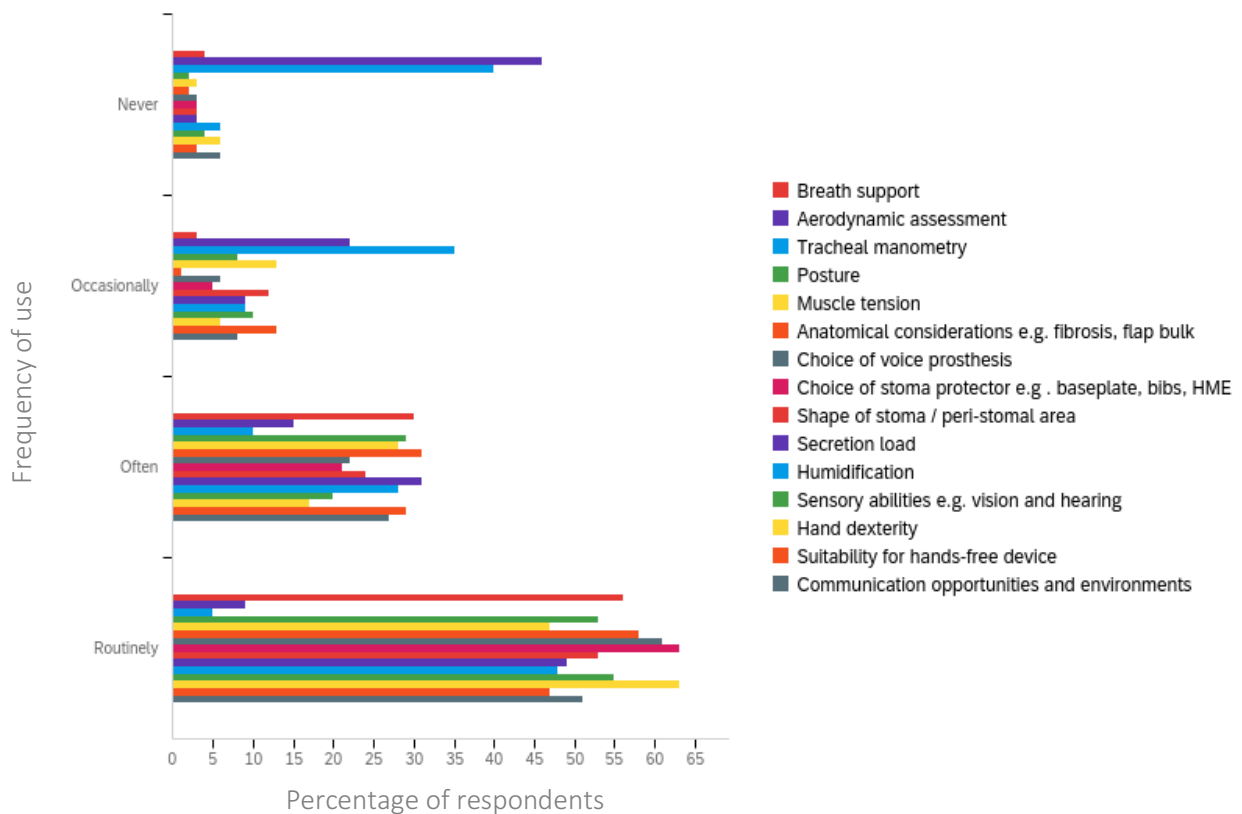


Figure 4.9: Factors assessed in addition to voice quality, and frequency of use

Participants were given the opportunity to list any other factors that they would assess. Here factors were described under the areas listed in Table 4.6. Responses ($n = 21$) broadly related to wider factors contributing to overall care, such as oncology treatment, or assessment of ability to communicate with emergency services. A small number of participants (23.80%, $n = 5$) stated that they would assess factors which form part of the SToPs assessment (Hurren, Miller and Carding, 2019). Participants did not elaborate on whether the use of sub-sections in isolation was intentional, or whether they were unfamiliar with the content of the assessment.

Theme	Factors considered in assessment
Instrumental assessment	Results of: Videofluoroscopy Air insufflation Fibreoptic endoscopic evaluation of swallowing (FEES)
Patient factors	Motivation Mood Acceptance of new voice / Psychological adjustment Self-care ability Social support Cognition Involving partner in assessment Self-assessment
Wider oncological factors	Plans for adjuvant treatment and impact on rehab progress Impact of treatment interventions e.g. previous chemoradiotherapy
Communication	Digital pressure and seal around stoma Open tract voicing versus voicing via prosthesis Indication for AAC or dual forms of communication
Risk	Task specific assessment of safety – using voice on the telephone, ability to contact emergency services
Sub-sections of SToPs	Assessment of: Articulation Intelligibility Tonicity
Other	Myofunctional release Expiratory muscle strength training* *not detailed how this would be used for assessment

Table 4.6: Additional factors considered during tracheoesophageal voice assessment (n = 21)

As a final question on assessment practices, participants were asked if they routinely recorded voice samples during assessment (Figure 4.10). Of 94 participants who responded to this question, the majority did not do this (84.0%, n = 79). Where recordings were made, a standard reading passage such as The Rainbow Passage (Fairbanks, 1960, p124) was the most used (30.9%, n = 13) which is frequently used in laryngeal voice therapy. Under the selection

of other, one participant reported recording maximum phonation time and increasing length of utterance.

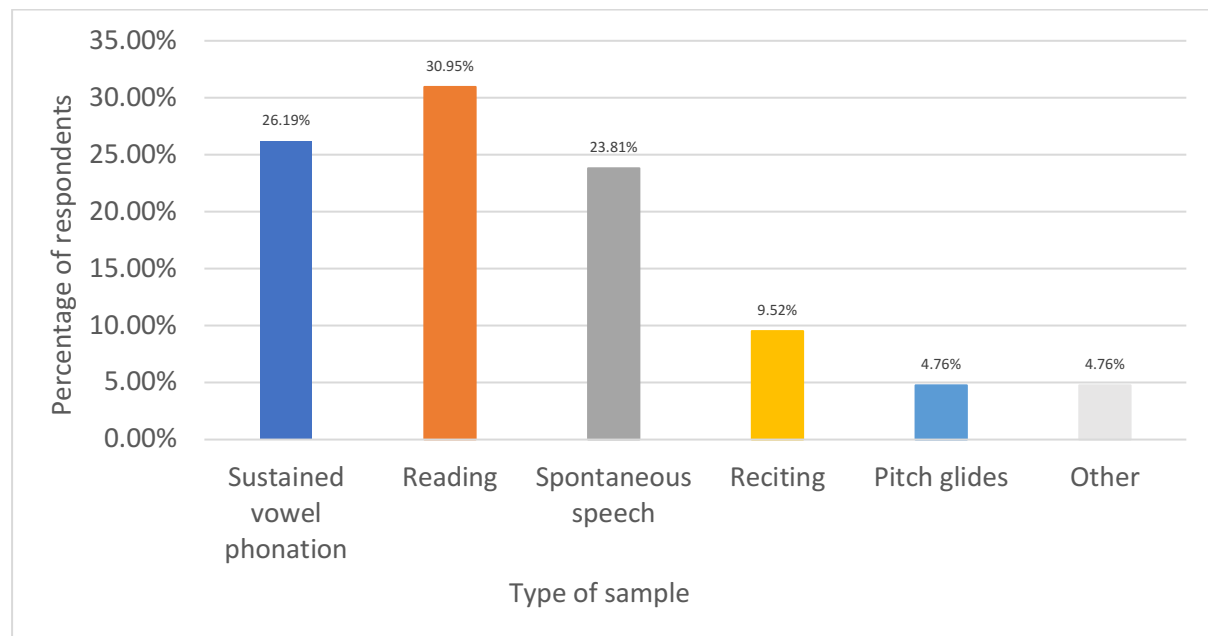


Figure 4.10: Voice samples recorded during assessment

4.4.2.v. Therapy approaches

Following on from questions on assessment, participants were asked what voice therapy approaches or strategies they used in their clinical practice with tracheoesophageal speakers (Figure 4.11). Here, multiple answer responses showed breathing exercises (27.2%, $n = 78$), articulation (20.2%, $n = 58$), deconstriction work (19.9%, $n = 57$), and projection or volume approaches (16.4%, $n = 47$) were most frequently used in intervention. A small proportion of participants (7.7%, $n = 22$) described other approaches. Fifteen participants elaborated on these approaches, which are detailed in Table 4.7; or stated that they do not carry out any therapy ($n = 4$).

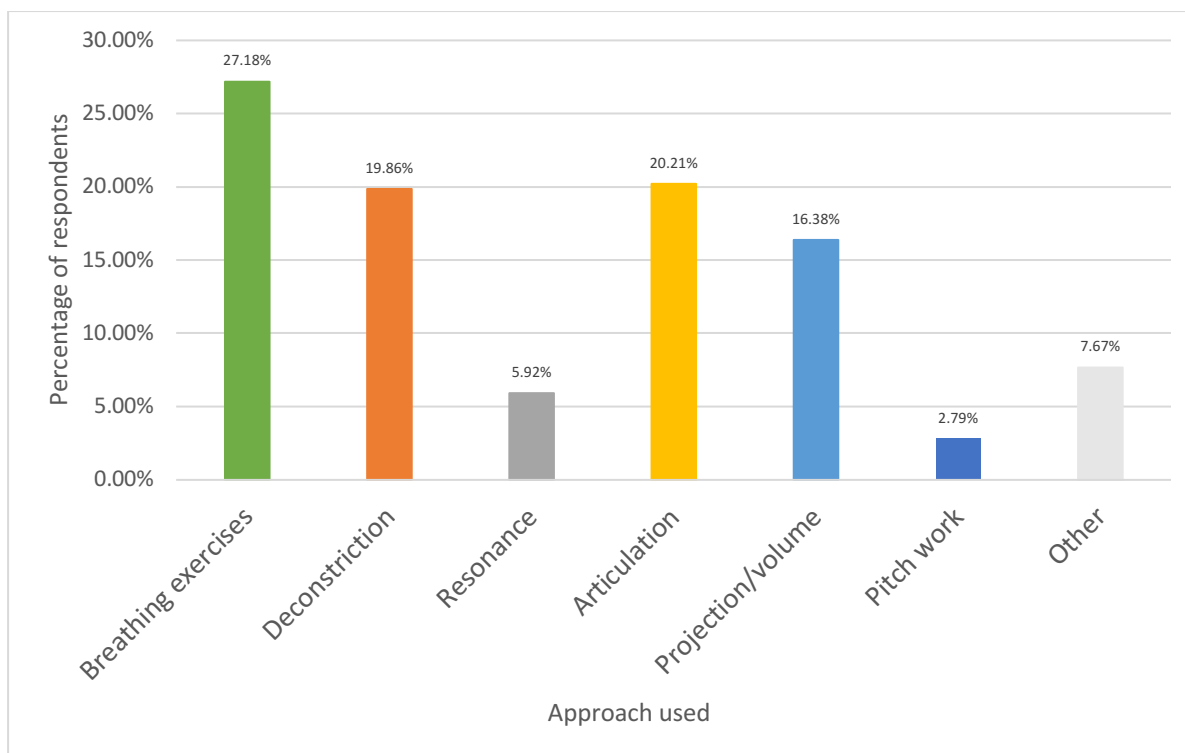


Figure 4.11: Approaches that SLTs use in clinical practice

Approach used	
Practice of digital occlusion of stoma	Group conversation practice
Use of pressure bands or manual pressure	Breath - voice onset coordination
Posture	Individualised exercises led by patient assessment
Rate of speech Phrasing	Functional tasks to improve confidence e.g. speaking on telephone with SLT for five minutes

Table 4.7: Other approaches used in tracheoesophageal voice therapy by SLTs (n = 15 responses)

4.4.3. OPPORTUNITY

4.4.3.i. Environmental context and resources

To understand how the environmental context and resources affect provision of tracheoesophageal voice therapy, participants were asked a series of questions relating to local factors that could influence their opportunities to carry out this work. The majority of 90 participants reported that they did not have sufficient clinical resources to carry out tracheoesophageal voice therapy (63.3%, n = 57). Detail on the content of clinical resources pointed to insufficient environmental, time and staffing resources.

The vast majority, 95.7% (n = 89) of 93 respondents, stated that they did not offer a standard number of sessions for tracheoesophageal voice therapy in their setting. Of the small group that did, number of sessions offered ranged from two to eight, with a mean average of 5.3 sessions. In regard to local policies, resources or guidelines which could inform practice overall, 91.0% (n = 81) of 89 participants reported that none existed within their service. Where such documents did exist (n = 7 responses), participants tended to name sources that were at a national level, rather than local documentation. For example, RCSLT guidelines, Irish Cancer Society handbooks and National Cancer Action Team guidelines. Three participants stated that local guidelines did exist, which specified voice therapy; and one example (quoted below) was provided of a collaborative resource based on MDT experience.

“Local collaborations with... Physio colleagues, resources from evidence and prior training in voice therapy for those with a larynx, access to experts and mentors from SLT and ENT whose problem-solving knowledge base includes recognition that TE voice therapy is beneficial”

4.4.3.ii. Social influences

To further understand the role of influences within the work environment, participants were asked whether SLTs within their department routinely offered voice therapy to tracheoesophageal speakers. Of the 94 participants who answered this question, 63.8% (n = 60) stated that this did occur in their department. In contrast, 27.4% (n = 26) of 95 participants stated that they personally offered voice therapy routinely (Figure 4.12).

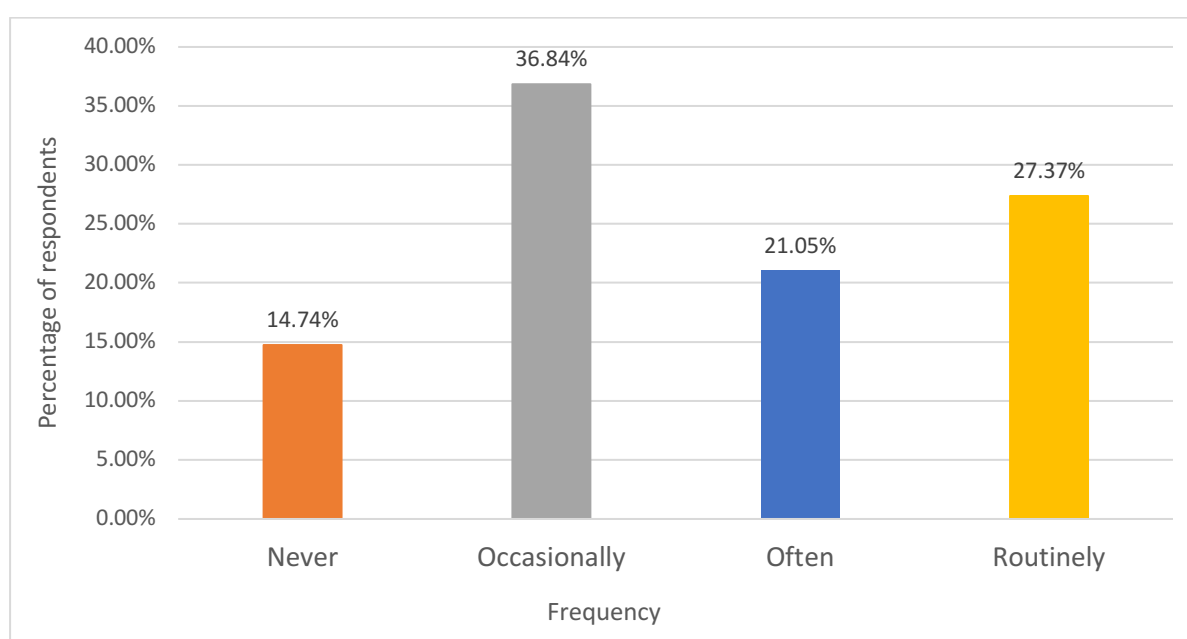


Figure 4.12: Do you personally offer voice therapy to tracheoesophageal speakers? (n = 95)

The influence of external groups (such as the Clinical Excellence Network or Service user groups) appeared to be a stronger factor with 79.3% (n = 69) of 87 participants reporting that they were influenced by other groups. Specified responses (n = 65) were captured within the categories listed in Table 4.8. Participants habitually reported multiple influences in their response.

Influencing group	Frequency stated
Clinical Excellence Network / Irish SLT Forum	49
Multidisciplinary team peers	22
Local SLT networks or access to Clinical Lead / experienced SLT	21
Social media	15
Service user groups	10
Courses / Conferences / Journals	6
Webinars or visits from product representatives	5
International SLT community	2
Negative influence 'culture of not offering'	1

Table 4.8: Groups that influence practice with tracheoesophageal speakers

4.4.4. MOTIVATION

4.4.4.i. Intentions

In regard to intentions to provide tracheoesophageal voice therapy, participants were asked how likely they were to provide this to the next voice prosthesis user that they work with. Over two-thirds of the 95 respondents were somewhat likely (27.4%, n = 26) or very likely (42.1%, n = 40) to provide this, indicating the intention is present to carry out this clinical work (Figure 4.13).

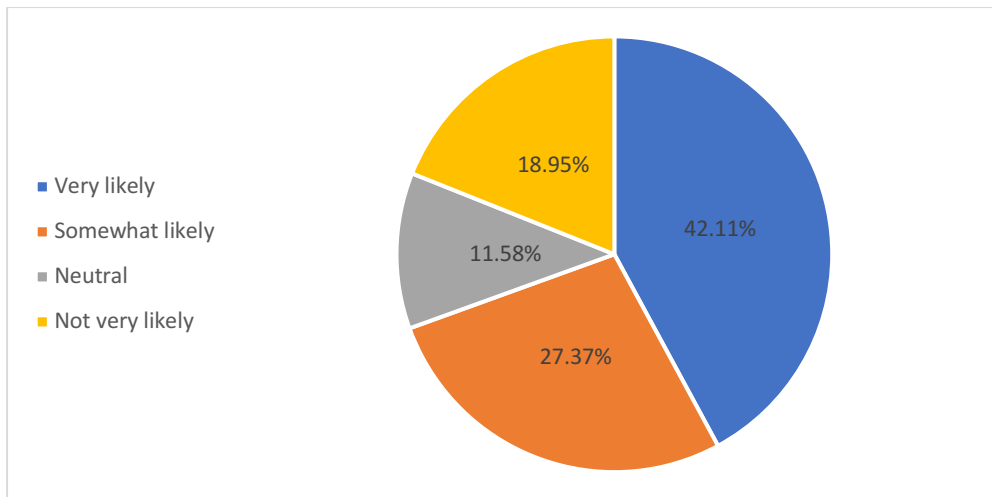


Figure 4.13: How likely are you to provide tracheoesophageal voice therapy to the next voice prosthesis user you work with? (n = 95)

4.4.4.ii. Belief about consequences and capability

To explore belief about the consequences of providing or not providing this therapy, participants were asked whether they believed that the approaches or strategies they used resulted in improved communication. Ninety-two participants responded to this question and overall appeared to express a lack of confidence in the outcomes of therapy, with only 23.9% (n = 22) stating their intervention resulted in improved communication (Figure 4.14).

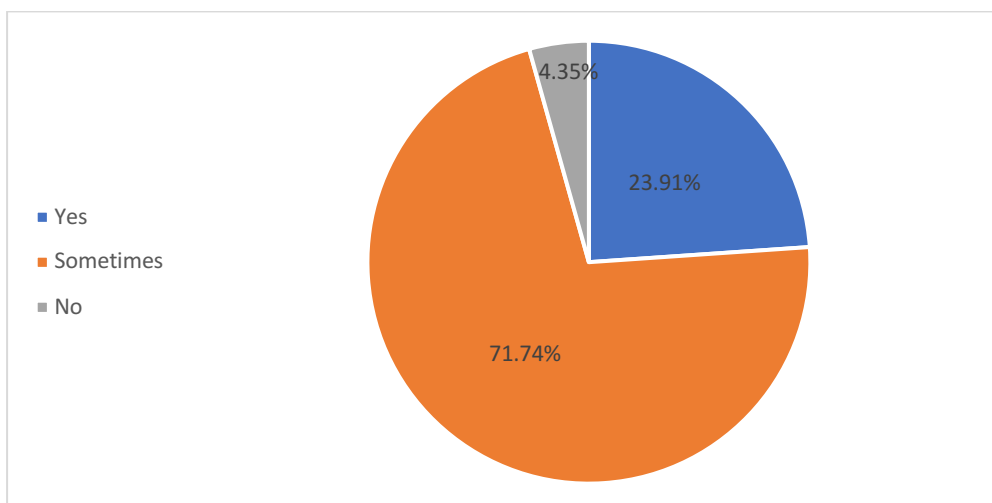


Figure 4.14: Do the approaches or strategies you use result in improved communication? (n = 92)

Despite apparent uncertainty about the outcomes of tracheoesophageal voice therapy, 82.0% (n = 73) of 89 respondents strongly agreed or agreed that it is important in overall SLT management of laryngectomy rehabilitation (Figure 4.15). Similarly, 85.4% (n = 76) of 89 respondents felt that it was very important or important to improve the quality of tracheoesophageal voice once functional voice has been established (Figure 4.16). A small but notable proportion of participants strongly disagreed that tracheoesophageal voice therapy was an important component of SLT rehabilitation (16.9%, n = 15); or did not think it was very important to optimise tracheoesophageal voice once established (13.5%, n = 12).

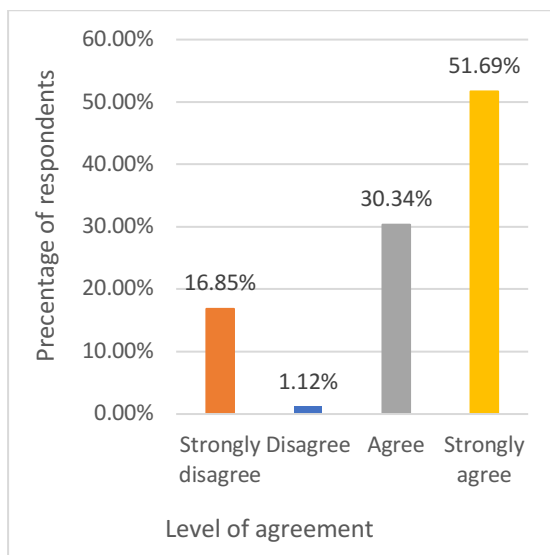


Figure 4.15: Tracheoesophageal voice therapy is Important in overall SLT rehabilitation

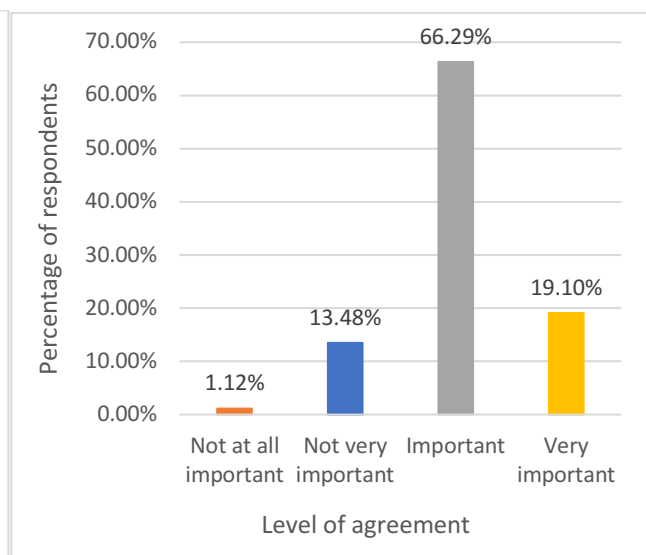


Figure 4.16: Once functional tracheoesophageal voice is established, how much of a priority is it to improve the quality? (n = 89)

4.4.4.iii. Goals

Whilst few participants (9.5%, n = 9 of 95 respondents) routinely set goals relating to tracheoesophageal voice therapy (Figure 4.17); participants were able to identify the factors which help them to decide whether to work on improving the quality of tracheoesophageal voice (n = 74). Table 4.9 describes the emergent themes, with quotes used to further illustrate the stated influences. The dominant positive influences were patient factors relating to motivation, goals and priorities; and severity of impairment with participants

expressing more likelihood of providing voice therapy when function did not meet the requirements of the individuals' voice. However, one participant noted that relying on patient factors to guide the decision to provide therapy was problematic, as patients may not be aware of how therapy could help.

"This is usually driven by patient request, but I do not feel this is necessarily a good way to do it. Patients don't always understand what can be achieved with their voice, what is realistic or what we can do to help so will not raise concerns. We should be routinely offering and assessing this."

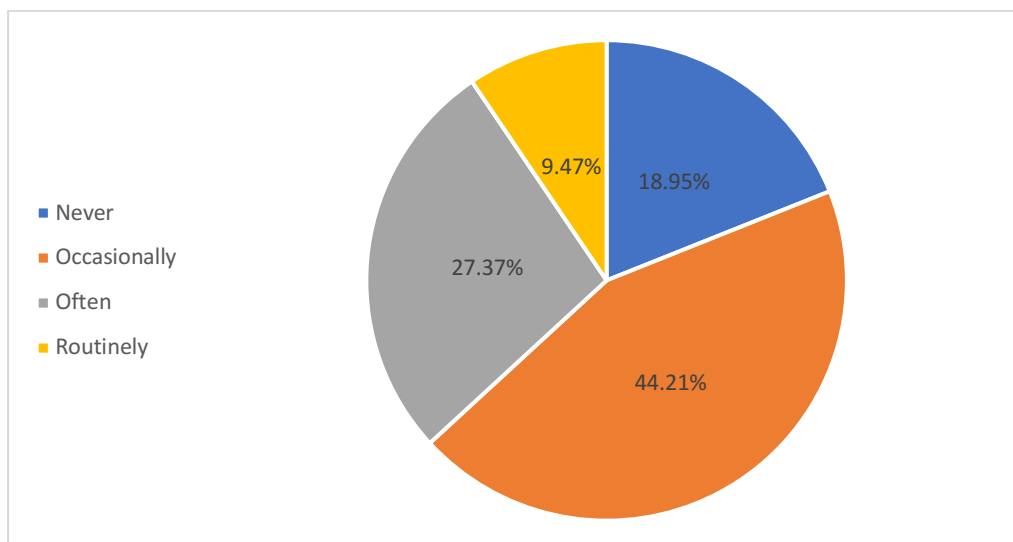


Figure 4.17: Do you set specific goals relating to tracheoesophageal voice therapy? (n = 95)

Motivating factors	
Patient factors:	Self-report of satisfaction with voice (desire to improve) Patient choice, motivation, priorities or goals supports therapy Engagement Risk of isolation Socio-economic situation, return to work Mental health concern due to voice <i>"Patient factors – isolation, social, economic, mental health...that have potential for improvement if communication is optimised"</i> Quality of life affected by voice Existing support network Positive motivation of communication partner Ability to attend face-to-face
Therapists' belief in skills	Presence of experience, knowledge or skills <i>"My knowledge/skills i.e., if there are things I think I can easily help"</i>
Severity of impairment	Level of function compared to individual voice requirements Intelligibility and voice quality <i>"the worse it is, the more I want to work on it"</i> Psychological distress / burden Perceptual evaluation <i>"We have not been doing this routinely, only with people who are struggling to get consistently functional voice"</i>
Multidisciplinary team	<i>"Buy in of surgical colleagues to deliver interventions e.g. lidocaine/Botox, stomaplasty, dilatation"</i>
Negative factors	
Resourcing / pathway issues	Time <i>"We just don't get the time to do it if I'm honest"</i> Caseload pressures

	Availability of resources Availability of staff
Belief in potential	Anatomical and physiological changes Opinion that patient has reached optimal function Potential for improvement Overall prognosis Patient readiness for voice therapy during acute inpatient phase
Therapists' belief in skills	Lack of experience, knowledge or skills
Other risks	Prioritising against other risks for specific patient
Patient factors	Low commitment to therapy Lack of patient motivation <i>"patient's feedback and motivation; some are very keen to achieve optimum voice whilst others do not wish for the burden of multiple outpatient appointments"</i>

Table 4.9: What factors help you to decide whether to work on improving tracheoesophageal voice? (n = 74)

4.4.4.iv. Emotion

To understand barriers related to emotional motivation, participants were asked how they felt about providing tracheoesophageal voice therapy. Here, responses (n = 72) demonstrated that a duality exists for many SLTs, in which they expressed positive feelings towards carrying out therapy alongside a negative descriptor, such as apprehension related to clinical skills or capacity. Table 4.10 illustrates this with descriptors listed hierarchically in descending order. Overall positive descriptors were used more frequently than negative or neutral descriptors. 'Interested' was the most frequently used positive descriptor (n = 35). Several participants elaborated to explain that they were interested in future developments, to learn more about the clinical practice, or extend skills. For example:

“Very interested and motivated, I feel that this is a much under-researched area of practice that has the potential to significantly improve the quality of life for laryngectomees”

Frustration was the most frequently stated negative descriptor (n = 5). Here participants reported frustration around resource barriers or the perception that voice work was less valued than prosthesis care. For example:

“Anxious and frustrated about capacity within a stretched clinical team... Concerned that ability to produce functional SVR [surgical voice restoration] voice is not appreciated and valued as equally and perhaps more important than competency in prosthesis placement.”

A small sub-group of participants did not report a particular feeling towards tracheoesophageal voice work; instead, they described seeing it as an essential part of the SLT role. Two participants reported feeling unmotivated due to belief that voice quality is unlikely to change, or due to lack of gains with previous patients.

Positive descriptors	Neutral	Negative descriptors
Descending order of mention, = equal mention		
Interested Motivated Excited Enjoyable Keen to learn = Rewarding = Comfortable = Essential = Enthusiastic = Intrigued = Committed = Opportunity = Love it	Unsure No strong feelings Routine	Frustrated = Anxious = Unmotivated = Aware of resource limits Nervous Under educated / skilled Apprehensive = Lacking in time = Lacking in confidence = Difficult = Unprepared = Unappreciated = Disheartened by lack of support

Table 4.10: How do you feel about providing tracheoesophageal voice therapy? (n = 72)

Participants were asked to describe the challenges that they had encountered when providing tracheoesophageal voice therapy (n = 73). Table 4.11 illustrates the themes arising in responses. Dominant themes were again, patient factors plus lack of clinical knowledge and insufficient resources and staffing issues. A small number of participants reported challenges arising from the negative influence of colleagues, where the culture within the department was to not offer tracheoesophageal voice therapy. A minor theme was present relating to challenges presented as a result of the Covid-19 pandemic.

Dominant themes	Challenges
Patient factors:	Reduced motivation or compliance Pre-morbid mental health status Psychosocial barriers to accessing services Inability to travel long distance to therapy Inability to access teletherapy Readiness to engage in therapy, anxiety about cancer treatment or diagnosis Vision / dexterity / hearing / ability to carry out tasks Alcoholism Patient or partner's acceptance of new voice Family support Attending without equipment Well-being after radiotherapy Commencement of radiotherapy before voice is established Delayed stoma healing Clinician and patient rapport Length of stay prior to discharge Other life events Lack of opportunities to practice
Clinical knowledge:	Lack of knowledge / uncertainty on what to do Lack of experience to use equipment or new approaches Lack of guidance / standardised practice / evidence base Lack of formal training

	Lack of objective measures Factors outside of SLT control Access to resources/courses Lack of development opportunities due to pandemic
Staffing	Lack of experienced supervisors Retention of skilled staff Persuading peers to deliver voice therapy Opinion in department that patients don't require help to start voicing
Resourcing	Limited availability of clinical sessions Availability of instrumental assessment Lack of clinical staff time and equipment Long waiting lists Retention of skilled staff Lack of physical clinic space
Minor themes	Challenges
Prioritisation	Deprioritised if capacity issues Deprioritised if patient has a functional voice Deprioritising to focus on safety or other rehabilitation need Balancing demand across clinical pathways
Anatomy / clinical practice	Anatomical issues affecting tonicity or use of voice Poor seal or occlusion Troubleshooting problems, secretion Frequent prosthesis failure Individual nature of patient – less ability to generalise Inability to elicit voice
Working with ENT	Post-surgical issues requiring ENT intervention e.g., short myotomy, pseudoepiglottis Consultant agreement with SLT opinion Need for close working with surgical colleagues ENT consultant not on site / less experienced local ENT teams
Other	Information governance Covid-19 – basic service provision only

Table 4.11: Challenges encountered when providing tracheoesophageal voice therapy (n = 73)

“It is often low on my patients’ agenda. This may be a demographic issue as most of my patients don’t work, live alone, already struggle with all their cancer appointments, have financial difficulties...”

Participants were then asked what would help them to address the challenges they had faced. Responses (n= 66) are detailed in Table 4.12.

Theme	Support required
Clinical knowledge	- Understanding of how to optimise therapy - Training opportunities - Specialist courses - Consistent / structured training programme - Shadowing opportunities - Instructional videos - Peer support / clinical skill sharing - More awareness and discussion about voice therapy in laryngectomy population
Resources	- Increased staff - Increased funding - Specialist SLT time / dedicated clinical posts - Physical clinic space - Spreading resources – training local voice services to accept referrals
Clinical resources	- Evidence based, standardised voice therapy approach - Best practice guide - Decision making tool or protocol - Robust guidelines - Validated assessment and descriptive tools specific to laryngectomy - Toolkit resource of therapy ideas and exercises - Resource of tracheoesophageal voice recordings - Framework of psychological techniques and strategies - Review of pathways

Theme	Support required
Evidence and audit	More research within clinical area Stronger evidence base of what is effective Audit of multicentre outcomes Access to research
Multidisciplinary team	Clear surgical notes MDT education Improved engagement with Radiologists regarding videofluoroscopy Better MDT awareness of therapy approaches
Acknowledgement	Acknowledgement of SLT expertise and due allocation of funding Acknowledgement at national level that specialist posts are required Acknowledgement of resourcing needs

Table 4.12: What would help you to address the challenges? (n = 66)

4.4.4.v. Social/professional role and identity

A series of questions were asked about aspects of the professional role and how these may impact on SLT identity. Of 90 participants, 70.0% (n = 63) stated that they were involved in evaluating suitability for tracheoesophageal puncture, and 92.2% (n = 83) were involved in troubleshooting problems experienced by tracheoesophageal speakers, indicating a key role of SLTs within laryngectomy care. The majority of participants 86.7% (n = 78) often or always felt valued by their MDT. Figures 4.18 - 4.20 illustrate these findings.

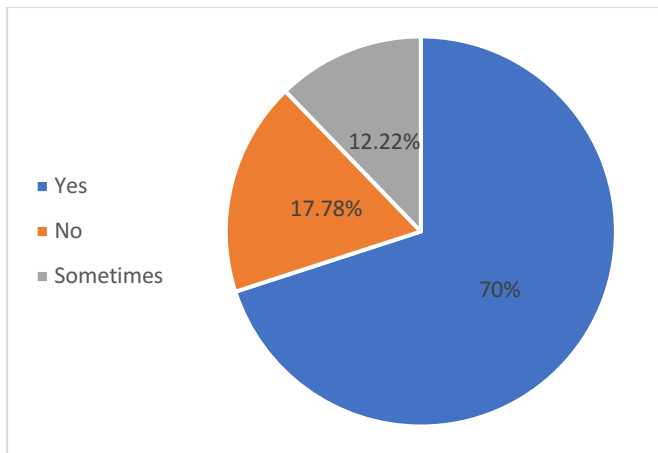


Figure 4.18: Are you involved in assessing suitability for tracheoesophageal puncture? (n = 90)

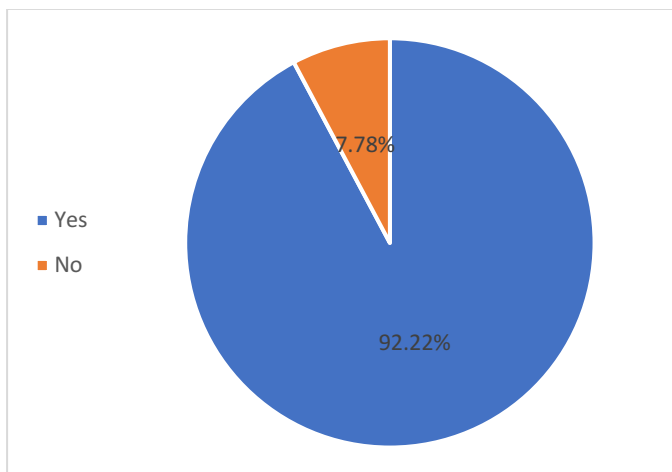


Figure 4.19: Are you involved in troubleshooting problems encountered by tracheoesophageal speakers? (n = 90)

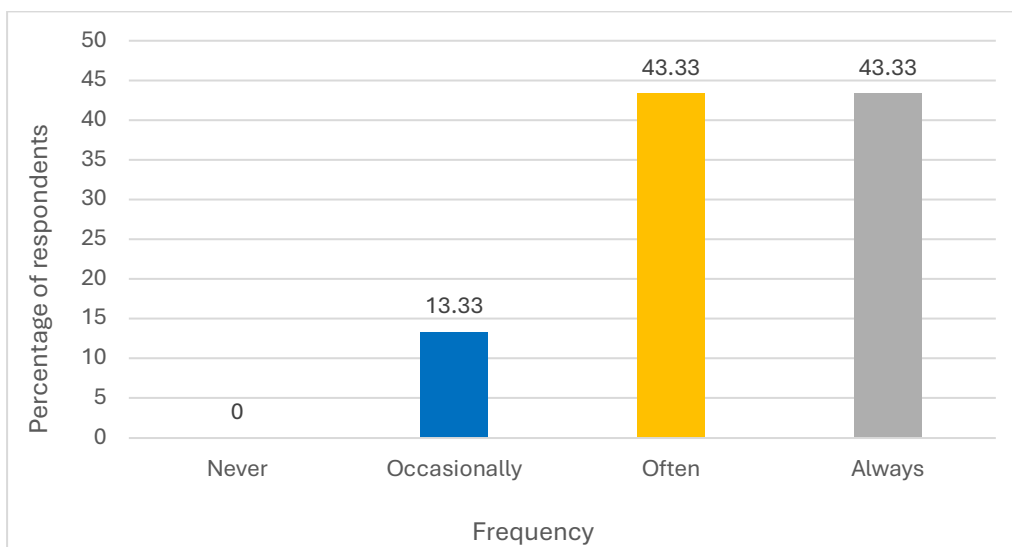


Figure 4.20: Thinking about the work you do with laryngectomees do you feel valued by your multidisciplinary team? (n = 90)

4.4.5. RESULTS SUMMARY

Table 4.13 summarises the survey results in relation to their corresponding COM-B component and theoretical domain.

COM-B component	Domain linking to component	Identified outcomes
Physical capability	Physical skills	Insufficient training provision
Psychological capability	Knowledge	- No existing specific therapy approaches - Low awareness of existing guidelines - Guidelines do not provide detail on what rehabilitation should entail - Lack of specific training courses for tracheoesophageal voice
	Cognitive skill	Belief that specialist skills and knowledge are required
	Memory, attention and decision processes	- Infrequent use of outcome measures - Infrequent use of objective assessments - No routine practice of voice recording - Routine practice of perceptual assessment
Physical opportunity	Environmental context and resources	- Insufficient clinical resources - Insufficient staffing - Insufficient experienced SLTs - Lack of local policy or guidelines
Social opportunity	Social influences	- No standard number of sessions offered - Strong influence of external groups - Negative influences 'culture of not offering therapy'
Reflective motivation	Social/professional role and identity	- SLTs hold key role in laryngectomy care decisions - SLTs feel valued by their multidisciplinary team
	Belief about capabilities	Uncertainty about the outcomes of therapy

	Intentions	• Intention to carry out tracheoesophageal voice therapy is present • Intention to carry out voice therapy is influenced by patient factors
	Goals	• Lack of routine goal setting
	Beliefs about consequences	• Belief that tracheoesophageal voice therapy is important • Uncertainty about potential for therapy gains
Automatic motivation	Emotion	• Motivation and interest are present • Frustration about resourcing or how voice therapy is prioritised • Anxiety related to clinical skills
	Reinforcement	• Feeling that SLT skills are not always fully valued • Desire for more acknowledgement of skills

Table 4.13: Summary of results by COM-B component and domain

4.5. DISCUSSION

This survey explored the current picture of tracheoesophageal voice therapy within UK and ROI clinical practice; and the barriers and facilitators that SLTs report encountering when undertaking this rehabilitative work. In keeping with the COM-B framework, the survey findings will be discussed in terms of their relationship to capability, opportunity and motivational factors.

The survey results show that the sample of participants was representative in terms of gender, age and range of experience. Responses were received from all UK and ROI regions. The sample size of 147 participants was greater than that reached in a previous UK survey of SLTs working with tracheoesophageal voice ($n = 72$), (Bradley et al., 2013). Therefore, the results of the survey are likely generalisable to the head and neck cancer SLT workforce. The potential risk of bias is acknowledged within the survey results, given that SLTs may be considered unlikely to view their input as unnecessary or unimportant. However, there is

evidence to suggest that SLTs were willing to convey such views, notably with over 16% of respondents citing that tracheoesophageal voice therapy was not important in overall laryngectomy rehabilitation; and over 13% of respondents believing that tracheoesophageal voice optimisation was not important.

4.5.1. CAPABILITY

Exploration of capability demonstrated several barriers to practice, which centred on insufficient training, lack of clinical guidelines and evidence and the absence of a specific tracheoesophageal voice rehabilitation approach. As such, responses were not reflective of poor knowledge amongst SLTs, but rather of a gap in knowledge, which was expected in the context of the current scarce evidence base. The requirement for more research to guide clinical management has been reported in surveys of SLTs working in other clinical areas (progressive dysarthria - Collins and Bloch, 2012; paediatric cerebral palsy - Watson and Pennington, 2015; primary progressive aphasia - Volkmer et al., 2019; non-progressive dysarthria - Conway and Walshe, 2015). A previous survey of UK AHPs (Metcalf et al., 2001) found that 97% of participants believed research outcomes are important to develop professional practice, but that existing literature is incomplete. This finding could be generalised to understanding of how the lack of evidence base for tracheoesophageal voice therapy influences clinical practice.

Capability barriers reflect factors identified in previous surveys of SLTs practice (Behn et al., 2020; Cruice et al., 2020), where lack of skills, knowledge and training were identified among barriers to therapy implementation. SLTs did express a clear view of what knowledge and skills they believed were required for tracheoesophageal voice rehabilitation. Clinical knowledge of laryngeal voice therapy was seen as a basis to tracheoesophageal voice work, and transference of laryngeal approaches could be a facilitating influence alongside additional knowledge. However, SLTs also identified the additional oncological and patient factor knowledge that was required to enhance their laryngeal voice therapy experience. This finding was consistent with the survey by Hancock et al. (2018b) in which participants expressed a desire for a more advanced level training to support tracheoesophageal voice

work. The lack of structured and specific training courses is problematic and, if implemented, could support consensus in clinical practice.

In terms of decision processes, the majority of participants did not routinely use outcome measures. This differs from practice in other SLT clinical areas (Volkmer et al., 2019; Conway and Walshe, 2015) and may reflect the few measures available specifically for the laryngectomy population. Measures that are available may be less known within UK and ROI clinical practice, e.g., the SECEL (Blood, 1993). Few participants reported using the SToPs despite this being a validated assessment specifically designed for tracheoesophageal voice. This could reflect the long completion time of the SToPs, where time has been demonstrated as a barrier to use of outcome measures in other areas of clinical practice (Worrall and Egan, 2013).

In the absence of suitable measures, participants did not routinely use in house assessment tools or outcome measures designed for laryngeal voice therapy as an alternative. This may be due to the lack of validation of these measures with the laryngectomy population. Descriptive perceptual assessment was the most routinely used approach for assessment of tracheoesophageal voice quality, however, further exploration is required to understand how SLTs describe features of voice quality in the absence of a consensus perceptual measure such as the GRBAS scale (Hirano, 1981) and tracheoesophageal specific voice norms. The scarcity of clinically applicable outcome measures or auditory-perceptual norms is a challenge to consistent assessment and practice and therefore presents a direction for future research.

In order to link assessment practices to therapeutic intervention, participants were asked what approaches they use in clinical practice. Here responses were aligned to common areas of laryngeal voice therapy such as breathwork, reducing muscle tension, articulation and volume. A notable difference was the absence of work on resonance and pitch (respectively 5.92% and 2.79% of participants targeted these areas). Further investigation is required to understand this difference, which may suggest that participants do not believe there is potential to modify these aspects of tracheoesophageal voice. There is, however, a small body of evidence pertaining to the ability of tonal language tracheoesophageal speakers to

modify pitch (Yan, 2012). In most areas there was consistency between the areas assessed and the approaches used in practice. However, there was a slight disparity seen in relation to patient factors. For example, participants reported that they would assess motivation and mood yet approaches to address this in clinical practice were not reported. This accords with Northcott et al. (2016), which showed a lack of confidence amongst SLTs in addressing psychological needs in the aphasia population, despite the belief that it was part of their role.

4.5.2. OPPORTUNITY

Questions within the opportunity domain explored whether participants had adequate resourcing to carry out clinical practice and how cultural or social influences afforded the opportunity to do so. Nearly two-thirds of participants reported that they did not have sufficient resources to undertake tracheoesophageal voice work, citing lack of time, experienced staffing and environmental resources. This is reflective of previous surveys of SLT practice (Behn et al., 2020; Cruice et al., 2020; Conway and Walshe, 2015) and of the NHS Long Term Plan finding (NHS, 2019) that SLTs are in short supply nationally. Furthermore, evidence submitted by the RCSLT to the Health and Social Care committee highlights that this shortage is particularly prevalent in Head and Neck / ENT specialising SLTs and has been exacerbated by the post Covid pandemic backlog (RCSLT, 2021). The RCSLT data showed that half of the head and neck cancer multidisciplinary teams surveyed did not meet BAHNO staffing standards. The RCSLT report specifically highlights the multiple clinical competencies that Head and Neck SLTs must achieve to be independent practitioners, noting that ‘substantial investment in post-graduate training and supervision’ is required (RCSLT, 2021, p6.)

Exploration of social and cultural influences indicated challenges arising from this domain. Participants (91.07%) typically reported that no local guidelines or protocols existed within their services to shape clinical practice with tracheoesophageal speakers. In a similar finding, Bradley et al. (2013) advocated for improved education and nationally agreed management protocols, albeit this was in relation to voice prosthesis management. Additionally for a similar proportion of participants there was no set number of sessions offered for this work.

It was unclear from responses whether that was related to a resource issue or a culture of not formalising this work.

There was a reported incongruence between the percentage of SLTs who personally provided routine tracheoesophageal voice therapy and whether this occurred routinely within their department. Here the percentage of departments offering therapy routinely was higher than that reported in personal practice. This may indicate that SLTs are not being strongly influenced by the cultural norms within their departments, or that the opportunities they do have are insufficient to shape clinical practice. In contrast, social and cultural influences external to the department were a more significant factor. Over two-thirds of participants stated that their practice was influenced by groups such as Clinical Excellence Networks, wider MDT peers and networks or social media. This may reflect the strong presence on X of the head and neck SLT community. The role of X in healthcare education is emerging. Benefits have been highlighted in the ability to rapidly share knowledge and increase reach of new evidence without geographical barriers (Thamman et al., 2020); and as a source of free-to-access learning, notwithstanding professional and quality considerations (Van Schaijik et al., 2021).

External networks of support may be particularly relevant outside of major head and neck centres where SLTs could be the sole clinician seeing laryngectomees or working without close access to a MDT. The risk of isolation outside of major head and neck centres was previously identified in the Australian setting (Hancock et al., 2018b), where the role of external support and influence was evidenced by a high proportion of SLPs who reported that they provide support and mentoring to therapists external to their service. The positive regard of external social influences is important and could inform strategy for developing and disseminating research, clinical guidelines or training via social media, existing SLT networks and Clinical Excellence Networks.

4.5.3. MOTIVATION

Participants were motivated to undertake tracheoesophageal voice therapy and expressed their intention to provide it. However, belief about the consequences of providing therapy was unclear with over 70% of participants stating that they only sometimes felt that their intervention resulted in improved communication. This may be reflective of the lack of an evidence base to inform what effective tracheoesophageal voice therapy should look like. In spite of this uncertainty, participants still felt that it was important to provide this therapy and to continue working to improve voice quality once voice had been established. This suggests that SLTs see potential in providing support to tracheoesophageal voice users and further emphasises the need for practice guidelines to build confidence in outcomes. A small group of SLTs strongly disagreed that tracheoesophageal voice therapy is an important part of laryngectomy rehabilitation. In subsequent questions a minority of SLTs shared their experience of unsuccessful attempts to rehabilitate the voice. Whilst the lack of positive experience could contribute to the opinion, it is a limitation of the survey that these views were not explored further, this would be an area of interest for future research.

Thinking of how SLTs develop plans to support clinical practice, few participants routinely set goals for tracheoesophageal voice work. Goal setting by SLTs has been explored within the context of aphasia rehabilitation. Here, SLT practice was influenced by a lack of knowledge on therapy frameworks which include goal setting (Sherratt et al., 2011). A previous survey of goal setting in rehabilitation found that absence of consensus on goal setting methods also influenced practice (Holliday et al., 2005). Furthermore, goal setting requires skill and effort (Parry, 2004) and is seen to be more time consuming if there is active involvement of the patient (Schoeb, 2009). This survey has highlighted lack of therapy frameworks, consensus in practice and insufficient time to carry out tracheoesophageal voice therapy, which are consistent with the evidence base as barriers to goal setting.

In the absence of goal setting, alternative motivational factors may play a bigger role in deciding whether to carry out tracheoesophageal voice work. Here positive motivators were identified as patient factors pertaining to readiness or patient's own motivation; the therapist's belief in their own skills or the potential for change; and the influence of the

multidisciplinary team. This supports findings related to capability where low knowledge of therapy approaches was a barrier to practice, and the social influence of the multidisciplinary team.

Lack of patient motivation as a barrier to practice has been previously identified (Conway and Walshe, 2014). Whilst the influence of patient priority is important, this raises the risk of SLTs only providing voice therapy to patients who express their own motivation for it, which could present a barrier to accessing support; particularly if the patient is not aware of the function that they could achieve with their tracheoesophageal voice. Furthermore, it has been demonstrated that patient motivation is not a strong predictor of intelligibility at one year post laryngectomy (Singer et al., 2013), therefore the decision to act on patient motivation alone is not supported. Demotivating factors mirrored positive factors whereby participants stated a lack of belief in their skills or in patient's therapeutic potential as negative indicators to offer therapy.

Participants were asked how they felt about doing tracheoesophageal voice therapy to understand if they felt sufficient motivation for the clinical practice. Motivation to provide therapy was expressed, coincident with uncertainty about how to undertake the work. This was seen as a duality in participants' responses with interest being expressed alongside anxiety or frustration. A small number of participants expressed demotivating feelings, with the belief that the tracheoesophageal voice is unlikely to be amenable to change. Clinicians are more likely to implement interventions that they believe will work, based upon their evidence and validity (Lipworth, Taylor and Braithwaite, 2013). Moreover, low workforce morale impacts negatively on patient care (Day, Minichiello and Madison, 2006). Attending to the causal factor of uncertainty on how to carry out tracheoesophageal voice therapy and improving the evidence, is therefore pertinent.

Participants demonstrated that their wider professional role was integral to laryngectomy care, through the high percentage who were involved in assessing and managing problems encountered by tracheoesophageal speakers. This was a more positive finding, compared with survey of SLTs working within tracheostomy (Ward et al., 2012), where only half of participants expressed a defined role in their tracheostomy dysphagia practice. The majority

of participants felt valued by their MDT, which can be interpreted as a positive motivating factor. However, there were some (13.33%) who only occasionally felt valued. This is in keeping with the small sub-group of respondents who expressed, throughout the survey, the feeling that their skills and the requirement for specialist posts was insufficiently acknowledged by colleagues.

Overall challenges to tracheoesophageal voice work were highly consistent with responses to previous questions. Dominant themes were again expressed as the lack of clinical knowledge and uncertainty on what to do in therapy, insufficient resourcing in terms of time, equipment and staffing, and patient factors. The theme of staffing was expressed both as the need for experienced staff; and the negative influence of staff who believed that tracheoesophageal voice therapy was not indicated.

In summary, participants were motivated to carry out tracheoesophageal voice therapy despite uncertainty about the results they may achieve. Participants were more motivated by belief in the skills that they do have, the potential for change and patient's motivation, rather than influences relating to routine aspects of practice. This suggests that reflective motivation is a more significant factor.

Participants had a clear sense of what would support them to overcome these challenges. Key areas were identified as the need for more training, specialist courses and robust clinical guidelines to inform practice, in keeping with previous surveys of SLT practice (Cruice et al., 2020; Collins and Bloch, 2012; Hancock, Ward and Hill, 2020b). Participants wanted increased resourcing to ensure there was sufficient time and staffing to carry out tracheoesophageal work and there was a call for a stronger evidence base and multicentre audit of clinical outcomes.

4.6. CONCLUSION

This survey captured the views of UK and ROI SLTs who work with tracheoesophageal speakers. The key findings of the survey were that SLTs were motivated to provide tracheoesophageal voice rehabilitation. They believed that it is an important part of laryngectomy rehabilitation and additionally that it is important to optimise voice quality once tracheoesophageal voice is established. There was, however, an absence of sufficient training and of clinical guidelines to support clinical practice and acquisition of knowledge. This leads to uncertainty amongst SLTs about how best to approach tracheoesophageal voice rehabilitation and what approaches might be effective.

The survey findings point towards the need for a robust training approach and detailed clinical guidelines or protocols to promote consistent practice across the profession, drawing upon the positive influence of the head and neck SLT community to create impact. The evidence base within this clinical area is emergent hence there is a need for increased research and clinical audit to inform what best practice should look like.

At a service level SLTs expressed significant under-resourcing and the belief that the depth of their skills was not always acknowledged or sufficiently valued. This should be considered in service planning to ensure that resourcing is not a barrier to tracheoesophageal speakers receiving the support they require, and that they are able to maximise their function in the face of a significant challenge to their communication.

CHAPTER 5 | EXPLORING THE VIEWS OF TRACHEOESOPHAGEAL SPEAKERS AND EXPERIENCES OF VOICE REHABILITATION

Patient Advisory Group input:

The PAG were consulted during the planning of this focus group study. The PAG provided advice on the timing and location of the focus groups, giving insight into times of day that may be less compatible with daily laryngectomy care regimens. The PAG felt that the offering of in-person and online modalities was acceptable, noting that individual PWL would have individual priorities and accessibility. The PAG advised on the draft topic guide and recommended that prompt questions were added on what wider support PWL had received. This recommendation was taken forward.

5.1. INTRODUCTION

The previous chapter explored the practices and beliefs of SLTs in relation to tracheoesophageal voice therapy. This chapter now investigates the experiences and views of PWL who use tracheoesophageal voice to communicate, through qualitative study. Focus groups aimed to explore how PWL experience learning to speak with a voice prosthesis, to identify what has helped in the process of acquiring tracheoesophageal voice and to establish service user priorities and opinions on what voice rehabilitation should entail. The timing and prioritisation of voice rehabilitation within post laryngectomy care was also explored.

Focus groups were chosen over other qualitative methods, such as individual interviews, to allow exchange of ideas and information among participants and gain insights across the group of participants. PWL are not homogenous as a patient group and have differing experiences and challenges arising from their oncology treatments. The ability for participants to reflect, share and compare where individual experiences concur or diverge was considered an important aspect for the validity of the qualitative study. There is the potential within a group setting that participants may not disclose personal or sensitive

information. However, in a study of 365 males, which compared focus group to individual interview disclosures, Guest et al. (2017) found that personal or sensitive disclosures were more likely to occur in a group setting.

After laryngectomy, communication and QOL are negatively impacted (Sharpe et al., 2018; Pereira da Silva et al., 2013). Whilst QOL recovers in some areas during the year post surgery, deterioration in speech, social contact, social and role functioning persist (Singer et al., 2013). Surgical voice restoration is consistently shown to give the most favourable outcomes for QOL and patient satisfaction when compared with other methods of communication post-laryngectomy (Maniaci et al., 2023); and to reduce symptoms of anxiety and depression (Polat et al., 2014). However, using and maintaining a voice prosthesis is a learning process which may be challenging to adjust to.

Summers et al. (2017) highlight the absence of participation-centred interventions for PWL. As demonstrated in the earlier chapters of this project, there is limited literature on post-laryngectomy communication to guide SLT practice or to contribute to the development of communication interventions. This focus group study therefore aims to enhance understanding of service user experiences, priorities and perspectives of voice rehabilitation after laryngectomy, ensuring that the subsequent intervention development places the views of PWL at the centre of the process.

5.1.1. OBJECTIVES

- to understand service user experience of being a person that uses a voice prosthesis
- to explore the views of service users on what voice rehabilitation should look like after laryngectomy
- to investigate service user opinions on how voice rehabilitation should be prioritised within wider post-laryngectomy rehabilitation

5.2. METHODOLOGY

5.2.1. ETHICAL APPROVAL

Ethical approval was granted from the City, University of London Language and Communication Science proportionate review committee (reference: ETH2122-2113), (Appendix 5.1).

Sim and Waterfield (2019) identify the key ethical issues of focus groups as consent, confidentiality and anonymity, and risk of harm. Participants were consented before taking part, as detailed below. Risk of harm was considered as the possibility that participants could experience mild psychological distress when reflecting on their views and experiences, however, it was anticipated that the level of distress would be no greater than that experienced in everyday reflections and discussions. To minimise this risk the facilitators moderated the discussion and post group debriefing was offered to any participant that wished to discuss any concerns raised or noted. Debriefing was not requested by any participant, however. Data was stored securely on the University OneDrive. To maintain confidentiality, data was de-identified prior to analysis and no participant identifiable data was included in the analysis or direct quotations. Pseudonyms were allocated to participants for direct quotations used in the reporting of the study.

The study was reported in accordance with the Standards for Reporting Qualitative Research (SRQR) checklist (O'Brien et al., 2014), listed in Appendix 5.2.

5.2.2. ELIGIBILITY

Inclusion criteria were broad, in order to elicit a diverse range of experiences and views. PWL were eligible to take part if they currently used a voice prosthesis or had used one previously. Participants were required to be at least four months post insertion of their first voice prosthesis to ensure they had experience of using the prosthesis. PWL were excluded if they

had never used a voice prosthesis or if they were based outside of the UK. The groups were conducted in English and therefore a level of spoken English was required sufficient for group discussion.

5.2.3. RECRUITMENT AND CONSENT

Participants were recruited via X and information disseminated through professional networks and patient support groups, for example: The Swallows, Head and Neck Cancer UK (HANCUK), Young Tongues, NALC. Purposive sampling was used to achieve a representative group of participants. Interested participants who were eligible were mapped onto a sampling framework comprising sex, age, ethnicity, employment status and U.K. location to ensure a diverse sample.

Interested people were invited to contact the researcher (FS) via university telephone or email to obtain information about the project, to receive the Participant Information Sheet, ask questions; and for the researcher to assess eligibility according to inclusion and exclusion criteria. The Participant Information Sheet provided detailed information to allow potential participants to make an informed decision about participating. Informed written consent was then taken at least one week after information giving to ensure participants had time to reflect and make their decision. Participants received a £25 gift voucher as a thank you for their attendance at the group.

5.2.4. SAMPLE SIZE

The study aimed to recruit 16-20 participants in total, allocated across four separate focus groups. Litosseliti (2003) recommends that a focus group should include six to ten participants to ensure that the group can be effectively moderated and for there to be sufficient space for individual views to be heard and explored. However, due to the communication difficulties of PWL, e.g., additional time required for tracheoesophageal

speech and possible limitations on intelligibility, smaller group sizes of four to seven participants were planned.

5.2.5. TOPIC GUIDE

A topic guide (Appendix 5.3) was created as a framework for the focus group discussions to meet the objectives of understanding the experience of being a voice prosthesis user, exploring what participants felt voice rehabilitation should include and how rehabilitation should be prioritised along with other post-surgical needs. These key areas for discussion were identified based on the limitations of existing literature on the lived experience and priorities of tracheoesophageal speakers and voice rehabilitation approaches. During development, the doctoral project's PAG was consulted on draft versions of the topic guide, with their suggestions incorporated on probing questions that may lead to informative areas of discussion.

5.2.6. DATA COLLECTION

Participants were free to choose their preferred type of attendance, between online via Zoom videoconferencing or in person, in a meeting room at the University. All groups were audio and video recorded to facilitate transcription.

The groups were facilitated by the Researcher and a Co-facilitator, who were both SLTs experienced in laryngectomy rehabilitation. The topic guide was used to structure the areas of discussion for the focus groups, but it was used flexibly, and specific questions were not determined in advance. Discussion was enabled to flow organically with further probes and prompts from the facilitators where relevant to elaborate on points raised or to support return to the topic. The Co-facilitator took field notes during the discussion using a whiteboard or Padlet for virtual groups. These notes were presented to the participants in stages during the groups to summarise the discussion in progress and to check with participants whether they wished to add any further points to the discussion.

5.2.7. DATA ANALYSIS

The groups were transcribed verbatim by the Researcher. Thematic analysis was chosen as an approach to data analysis due to its focus on the construction of meaning from data (Finlay, 2021), applied to generating understanding of the lived experiences of participants.

Specifically Reflexive Thematic Analysis (Braun and Clarke, 2006, 2022) was used to guide data analysis and theme development. Within Reflexive Thematic Analysis, themes are defined as ‘patterns of shared meaning underpinned by a central organising concept’ (Braun and Clarke, 2006, 2022). An experiential approach was applied to the analysis with the aim of representing the experiences and perspectives as expressed by the participants. As such, an inductive orientation was used, ensuring that themes were derived from the dataset, rather than interpreting themes through the lens of pre-existing theories. Meaning was coded at a predominantly semantic level with the aim of capturing the meaning descriptively, as expressed by the participant.

Whilst an inductive view of the dataset supports the avoidance of a preconceived analysis, the influence of the researcher cannot be fully excluded. The subjectivity of the researcher is a core concept of Reflexive Thematic Analysis where the values, experiences and skills of the researcher are implicit in the interpretation of the data. Reflexivity is therefore essential to reflect on how development of themes is an active process influenced by the researcher’s positionality (Braun and Clarke, 2020) and therefore cannot fully exclude bias. For this reason, Reflexive Thematic Analysis advises that the data is coded by one researcher and does not advocate for multiple coders or for consensus to be reached on the analysis.

Following the approach of Braun and Clarke (2006), data analysis was conducted using the six-phase process of Reflexive Thematic Analysis detailed below.

5.2.7.i. Phase one: Dataset familiarisation

During this phase, the Researcher read through the transcripts and listened back to recordings of the focus groups repeatedly to ensure a deep familiarity with the data. To avoid

pre-emptive application of ideas, the transcripts were re-read in a different order each time. This phase was completed over time to allow reflection and space to develop understanding of the data. Reflections were noted in a journal throughout all phases to capture working thoughts on the dataset.

5.2.7.ii. Phase two: Coding

Data was coded with NVIVO software. This involved working methodically through the transcripts to identify threads of data which could be pertinent to the research aims. Threads were highlighted and grouped where there was consistent meaning in the data. Groups were then coded with subsequent threads added to an existing code or ascribed to a new code as required. During this phase codes were reflected on and refined, renamed or expanded as the transcripts were worked through. Again, the transcripts were reviewed multiple times in differing order to ensure that coding was consistent across the separate group datasets. As the coding process developed, clarity was gained on which codes were frequently represented in the data versus those that were less prominent.

5.2.7.iii. Phase three: Generating initial themes

During phase three, the dataset and codes were reviewed to develop initial concepts and ideas. This process incorporated consideration and reflection on potential themes, or candidate themes, and identification of patterns within the dataset. This phase was influenced by the Researcher's experiences of working with PWL and therefore this was acknowledged to ensure theme development remained true to the dataset and was not overly shaped by Researcher experience.

5.2.7.iv. Phase four: Developing and reviewing themes

In this phase, candidate themes generated in phase three were viewed in relation to both the dataset as a whole and to specific coded data extracts. This phase involved a deeper questioning of coalescences between candidate themes, their composite codes and consideration of the key message being expressed. Here, candidate themes were revised through several iterations until the central organising concept was defined and deemed congruous with the dataset.

5.2.7.v. Phase five: Refining, defining and naming themes

In phase five, the development of themes worked on in stage four were further developed and considered in relation to the overall dataset. Themes were examined to define the concepts at the core of the theme and named to reflect these core concepts. As the theme development continued several iterations of theme names were worked with and refined until a final name was generated.

5.2.7.vi. Phase six: Writing up

The analytic process was carried into the process of writing the outcomes of the study. The writing required a deeper engagement with the dataset to interpret the themes as they fitted together into the overall narrative, and in turn how this was contextualised within the existing literature and researcher experience.

5.2.8. REFLEXIVITY STATEMENT

[Written in first person as a reflexivity statement]

I, the primary researcher am a White-British female of Irish-Scottish decent. I was born in East London within a working-class family; and am a first-generation university student. I am 16 years post-qualification as an SLT and am experienced in laryngectomy rehabilitation and laryngeal voice therapy. I arrived to the data within the context of having completed the earlier studies reported in this thesis and with extensive experience of working both with PWL and in laryngeal voice therapy. My subjectivity is influenced by my perception that tracheoesophageal voice quality can be optimised through behavioural therapeutic interventions, and through my belief that communication post-laryngectomy is an under served area of rehabilitation. My positionality as a researcher was acknowledged as being other to the participants, as a person *without* laryngectomy. Furthermore, the participants' awareness that I, and the co-facilitator, are SLTs was acknowledged in terms of the influence on power dynamics of the focus group, and the potential for positive-regard bias in participants' discussion.

5.3. RESULTS

5.3.1. PARTICIPANTS

Twenty people took part in the study, all participants had undergone total laryngectomy for treatment of head and neck cancer. Participant characteristics are presented in Table 5.1 followed by presentation of the findings of the study.

Two focus groups took place online via Zoom videoconferencing (n = nine participants) and two were held in a university meeting room (n = 11 participants). For practical reasons, most participants outside of Greater London attended virtually (n = eight participants of 11 participants outside of Greater London). Following discussion with participants, several female participants expressed a preference for a female-only group therefore the groups

were separated by gender with two male groups and two female groups held. For male and female groups, one meeting was in-person and one virtual.

Participants communicated predominantly by tracheoesophageal voice, supplemented by writing or use of the Zoom chat function to support communication. One participant chose to use an electrolarynx by preference and two participants used silent articulation due to difficulties producing tracheoesophageal voice on the day of the focus group. On average the focus groups lasted about two hours [mean time: 118 minutes (range 112-125 minutes)] including one or two short breaks per group.

Pseudonyms are used throughout the results section for participants' names and a code is given to indicate which group the participant took part in (FG1 – 4), and their age in years.

Participant characteristics	Mean (SD) and range, or count (%)
Age:	Mean (SD): 65.45 (11.85) years Range: 41 – 82 years
Gender:	Female: 8 (40%) Male: 12 (60%)
Ethnicity:	White British: 15 (75%) White European: 2 (10%) Black British: 1 (5%) African: 1 (5%) Asian British: 1 (5%)
Time post laryngectomy:	Mean (SD): 121.15 (98.40) months Range: 7 - 336 months
UK region:	London and South-East: 10 (50%) Midlands: 4 (20%) Scotland: 3 (15%) North-West: 1 (5%) North-East: 1 (5%) Yorkshire and the Humber: 1 (5%)

Table 5.1: Participant characteristics (n=20)

5.3.2. CODES AND THEMES

Initially 52 codes were identified from the dataset. After review and refinement, some codes were deemed not relevant to the study objectives and other codes were combined or further refined. For example, the initial codes ‘Support groups have changed’, and ‘The role of support groups’ were combined into a code named ‘Support systems – the good and bad’; whereas the initial code ‘Opinions of electrolaryngeal speech’ was scarcely applied and deemed not relevant.

This led to a revised list of 28 codes, which were then grouped together to form themes, as illustrated in Table 5.2. Across the dataset, six main themes were generated, which are described in the context of the key areas the focus groups explored: The unseen, Impact on work and social roles, Adjustment, The patient as expert, What I want is...; and It all depends (prioritisation). An overarching theme of Everyone is different was identified, in relation to main themes of What I want is... and It all depends (prioritisation). Figure 5.1 illustrates the thematic structure including sub-themes, which is described below and evidenced with quotations from participants.

Theme	Codes
The unseen	Covid changed things Fear and confidence The female experience Hidden disability Impact of radiotherapy People’s reactions to me
Impact on work and social roles	Impact of voice on work Impact on social roles and relationships Experiences of voicing
Adjustment	Initial difficulty using a prosthesis Mental health, withdrawal and isolation Moments of joy Shock You just get on with it

The patient as expert	Involve us to help others My role in my recovery This helped my voice
What I want is	Articulation practice Equipment Breathing and lungs Negative experience of healthcare professionals Opinions of SLT Information Support systems, the good and bad What I want
It all depends	Everyone is different Function is variable My priorities

Table 5.2: List of codes and main themes

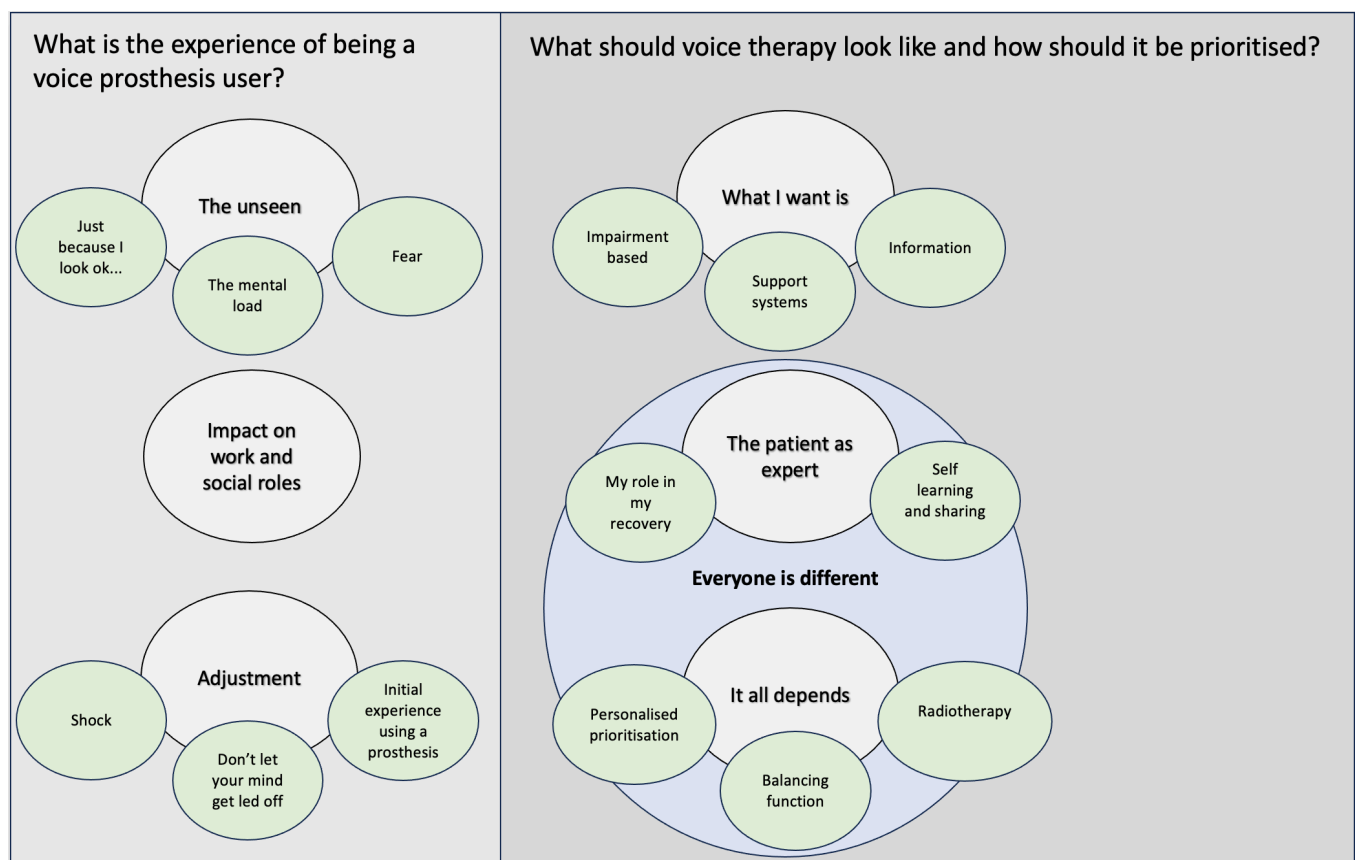


Figure 5.1: Thematic structure

5.3.3. THE EXPERIENCE OF BEING A VOICE PROSTHESIS USER

5.3.3.i. Theme one: The unseen

Participants described how many aspects of living as a voice prosthesis user, and more widely as a PWL were unseen or internalised. This incorporated the impact on daily activities, the mental load of voice loss and maintaining a prosthesis, and confronting fear and confidence issues. These unseen aspects of life after laryngectomy presented as a multifaceted hidden disability.

5.3.3.i.a. Sub-theme: Just because I look ok...

Participants recounted how the unseen impact was at times expressed in the context of appearance. Participants described a sense of presenteeism, where their daily challenges were unseen, as long as they seemingly looked well or spoke with an intelligible tracheoesophageal voice.

“I think there’s a perception that everything’s fine because I am able to voice quite well. I’m young and fit...that actually this isn’t that bad really and obviously I’m living my life and enjoying my life but I think people don’t realise...unless it’s happened to them, the daily things you deal with that you don’t tell anybody.” (Liz, 41, FG3)

“Initially when you’ve first had an operation people are sympathetic and will concentrate and listen... but as you look better and the months go by you just become part of the scenery... and you gradually find you’re being talked over and around.” (John, 78, FG2)

5.3.3.i.b. Sub-theme: The mental load

The extent to which being a prosthesis user affects all aspects of life was expressed frequently by participants. This was reported not only in terms of communication barriers but also how the practicalities of maintaining a voice prosthesis influenced daily activities and required advance planning. This suggested an unseen mental load carried by voice prosthesis users.

“You don’t realise how much you spend your time trying to work out the routes by toilets... you get the train, ok there’s a toilet there, now the tube and there’s some there. You plan your trips by where you can stop off and maintain stuff. You don’t think about it before.” (Jack, 42, FG2)

The sense of mental load and whole life impact of prosthesis use was exacerbated by variability in function. This was strongly expressed by participants whereby it became the norm to live with a degree of uncertainty about how the voice would function or when there would be an unexpected need to change the prosthesis and disrupt plans.

“Some days pitch and volume and intonation is better and some days I feel like it’s just monotone. I feel like I haven’t got that much control. There are days when I think, oh my voice is really great today and there are days when it just feels like it’s a struggle.” (Liz, 41, FG3)

Issues of service provision presented an additional mental load regarding the uncertainty of communication with a voice prosthesis. As few centres provide services for voice prosthesis problems out of hours or at weekends. The impact of a voice prosthesis problem was far greater if it occurred outside of standard SLT working hours, leading to frustration and anxiety.

“I do find it quite strange that, you know, if your valve comes out there isn’t anybody there at the weekend. I would have thought that they’d have like an emergency one for weekends but...” (Andrew, 65, FG1)

“Not even in an ideal world, just for the ordinary world. I mean there’s a facility for every other bloody.... I mean, why should we be nine to five?” (Helen, 65, FG4)

At times, participants found it difficult to speak definitively about their experience of voice use as the variability in function meant that they were unable to draw general conclusions. There was, however, a clear link between fatigue and variability of voice, which interconnected with the following theme of Impact on work and social roles.

“When you talk about the quality of the voice it’s a strange thing. Some days I can’t talk at all. Some days my speech is good and you’re chuffed with that... seven out of ten [days] my speech is worse. So here... you’re talking about quality of voice... it’s a difficult thing.” (James, 60, FG1)

“All depends on how my voice is going on that day. Some days my voice just goes, others my voice is stronger, so it depends on that as well.” (Peter, 73, FG2)

5.3.3.i.c. Sub-theme: Fear

Unseen mental load was also expressed as fears and confidence issues. Participants described how previously straightforward daily activities, such as going to the supermarket, became significant events after laryngectomy which required support or were initially approached through a staged return.

“Going out for the first time, this was a major project. Going to the supermarket...that was something to be ticked off... you’ve got to take one stage at a time” (Fiona, 78, FG3)

‘People see me and go, ‘oh you’re amazing, you’ve dealt with this so well’ and I think well yeah but... you don’t tell everybody you’re seeing a counsellor each week to go through your inner fears... it’s hugely life changing.” (Liz, 41, FG3)

Fears often centred on other peoples' reactions to understanding the altered voice, which could limit the ability to carry out a daily activity due to communication breakdown. There was also concern that the speaker's mood could be misunderstood due to limitations on modifying intonation or vocal effort, which affect expression of language. A shared experience for participants was the assumption that, because they were unable to speak, they must be hearing impaired. This common listener reaction to the absence of laryngeal voice was recounted with amusement by many participants.

"I had this person say to me, so bizarrely, why don't you learn the sign language? And I said, so do you know how to use sign language? She said no. I said, well nor does everybody else... what a stupid question!" (Helen, 65, FG4)

"When you speak it comes out as one tone, there's no ups and downs in the tone so you've got to watch what you say. A lot of speech is the way you say things, with this it all comes out as one tone." (Steve, 62, FG2)

Female participants spoke of their communication with children, an experience that was not expressed by male participants. Female participants observed that negative reactions of others were typically confined to interactions with adults, whereas children tended to show an openness and curiosity.

"The biggest barrier is other people's attitude when you speak. Children are fine with it, they accept you. But adults either get frightened and walk away or stare at you. And that's what you put up with your whole life." (Fiona, 78, FG3)

In relation to children, one female participant spoke of how the altered voice had impacted her confidence in being in public spaces with her children.

"I was too nervous to go to the park on my own with my kids because I felt I couldn't keep them safe... you need your voice to keep your children safe when you're out in public." (Liz, 41, FG3)

A shared concern for participants was a lack of understanding not only about voice, but also the potential urgent care needs related to the altered airway, and the low awareness of laryngectomy amongst healthcare professionals (HCPs). This pointed to the need for greater training and awareness building among HCPs. Participants spoke of their inner fears and concerns about receiving the right care, particularly if they were not able to explain themselves due to voice impairment. This was recounted by one participant in relation to an incident which required an ambulance:

“I couldn’t breathe I was in so much pain. When they come in the ambulance and they go to give you gas, they put it on my mouth. I said, I don’t breathe out of there! They didn’t have a clue”. (June, 68, FG4)

“My biggest fear is... a fire happened, something... is this [stoma] enough to know that I am a laryngectomy? It’s a big worry, if an accident happened, if they would know.” (Farida, 55, FG4)

5.3.3.ii. Theme two: Impact on work and social roles

Participants experienced changes to their work activities after laryngectomy, which typically manifested as a detrimental change in role or early retirement. Whilst there were some examples of supported return to work, for the majority of participants who remained in work, tracheoesophageal speech led to difficulty accessing virtual work environments or when speaking via telephone. This was often expressed as an unseen barrier to participating as before laryngectomy.

“A lot of Zoom calls filter me out. If you put the automatic background filtering on, my voice disappears... because you don’t get that pitch change, the computer just thinks you’re background noise. You end up turning the background filter off but then all that people can hear is the background noise because my voice isn’t as loud. So you’re fighting against all those.” (Jack, 42, FG2)

For many participants the inability to return to work was emotionally distressing and impacted beyond the practical barriers of fulfilling their role.

“My voice was not enough... two, three times I went there and I was trying. I came back as a volunteer but it was unsuccessful. And then every time I would go there, I would come back...tears and... oh my god, something happened to me. Once I went back and she [manager] took my picture off the board and that was the worst day. There is no hope because this voice...” (Farida, 55, FG4)

“I am a journalist... I used to give political comments on [television channel]. And so, with this, I knew that I would lose my role and I can’t support my people in [country name redacted]. I can’t support the revolution. Oh it was painful, so painful.”
(Nasir, 67, FG2)

The impact of tracheoesophageal speech on social roles and participation was experienced by all participants to the extent that many activities were modified or required additional thought. This impact was not confined to the ability to produce an intelligible voice but more widely participants described factors such as contending with the need to use a hand to occlude the stoma for speech or managing the fatigue of voicing. Conversely, one participant described how living alone with less occasion to speak can leave the voice out of practice or deconditioned, suggesting that balance is required to maintain vocal function. As with work activities, using the telephone was challenging for most participants regardless of their self-perceived voice quality. One participant explained this as a technological issue due to the compression and reduced frequency range of sound transmitted by telephone. Participants did not share examples of other people adapting their interaction or offering support, which suggested that the challenges of social interaction were an unseen burden carried only by the person using a voice prosthesis.

“It’s more effort to speak. Means sometimes you don’t speak as well because... if you’ve been out socially you can feel quite tired afterward because of the effort you put in to speak.” (Richard, 75, FG1)

“I don’t know if you know anything about country dancing but there are occasions when you are holding two people’s hands... and you can tell people, you go that way or that way, but I can’t often do that. I can sometimes gesture but erm, I don’t know...how do you communicate without speaking just like that?” (John, 78, FG2)

Participants spoke frequently of the relationship between speech volume and social isolation, where the difficulty of producing a loud tracheoesophageal voice was a significant barrier to participation. This was often expressed as an internalised experience without any clear solution. Participants rarely spoke about discontinuing their pre-laryngectomy social activities, which gave a picture that activities were still attended but that isolation or exclusion now occurred within the experience, particularly in groups or noisy environments.

“If I want to interject into the conversation, by the time I have got myself together, get my finger up there, the conversation has moved on half an hour ago. Slowly you get left behind. People won’t bother even talking to you because they can’t be bothered, you know? In a noisy environment it becomes more difficult, so I’ve taken to speaking one-to-one... fighting to get a word in” (Arthur, 79, FG1)

“If you go to another environment, which is noisy, you could close down, because nobody can hear you and mentally you can’t accept that. And you tend to start to notice that... slowly people accept that and it’s almost as if you’re not there.” (James, 60, FG1)

5.3.3.iii. Theme three: Adjustment

A main theme of Adjustment to life after laryngectomy was identified from the data. This centred on participants describing their process of experiencing and coming to terms with a new way of communicating. The adjustment journey required participants to overcome shock, manage the uncertainty of variable tracheoesophageal voice quality; and to actively navigate the impact of laryngectomy on mental health. This process incorporated positive and negative aspects of finding acceptance and was often expressed as the need to ‘just get

on with it' in the absence of an alternative. This interlinked with the theme of Impact on work and social roles, where for many, adjustment to life as a voice prosthesis user meant accepting it may not be possible to continue roles in the same way post-operatively. At times participants shared their experiences with humour; and few examples were offered where a positive life change was attributed to the event of having a laryngectomy.

5.3.3.iii.a. Sub-theme: Shock

Before navigating adjustment, participants described the moment of shock that arose on hearing that a laryngectomy was necessary for curative treatment. Whilst some participants felt they had emotionally prepared for the first voiceless moments post-surgery, for others the sense of shock was revisited.

"When you initially get told this is going to happen, you're in complete shock. And I mean complete shock, it just doesn't even dawn on you. And then they're telling you things but you're not listening because you're in shock." (James, 60, FG1)

"When I was in the hospital the first thing when I woke up... I was trying to say and then, I don't remember what happened. The doctor came quickly with a whiteboard. Oh my god. My voice is not there, no more voice. That was shocking."
(Farida, 55, FG4)

5.3.3.iii.b. Sub-theme: Initial experience of using a voice prosthesis

As a first step in adjustment, participants spoke of their initial experiences of learning to use a voice prosthesis. How this phase of recovery was experienced differed for participants depending on the timing of prosthesis insertion and their emotional response to hearing tracheoesophageal voice for the first time. For some participants this was a distressing experience, whereas for others the restoration of the ability to make sound was a positive

moment of relief, particularly if producing tracheoesophageal voice was easier than expected.

“The speech and language therapist came and told me to try and make a sound. And so I tried to learn to speak by going ‘aaahh’. That one note was wonderful, wonderful feeling. Because you knew you would be able to make some noise.” (Fiona, 78, FG3)

“For two years I couldn’t speak at all... me throat tightened up and no matter how... the more voice I put in the less came out. I just thought it were never going to happen.” (James, 60, FG1)

5.3.3.iii.c. Sub-theme: Don’t let your mind get led off

Participants were aware of the risk of mental health deterioration after laryngectomy and referenced the high incidence of suicide within head and neck cancer. The need to monitor and manage one’s own mental health was often presented as responsibility borne by the person with laryngectomy. Few examples were shared of support from psychological or counselling services, suggesting a lack of service provision.

“You might have better days, you might have days when it’s worse, but there’s a huge part of the mental side of things, all the mental and emotional... and just the acceptance that you need to find within yourself about what’s happened”
(Jack, 42, FG2)

“Everything centres on what you feel up here [taps head]. I just had to accept it knowing that I was on my own, frightened for anyone to say ‘oh I can’t hear you’. I had to step up and look after myself. It made me independent.” (Fiona, 78, FG3)

Isolation through communication impairment was a key factor in mental health impact. Participants described the active role that they took in continuing to pursue spoken

communication, even when the barriers to doing so presented an alternative of withdrawing from social situations.

"I focused you know, I didn't let my mind get led off. Some people they get scared and they shut down and they don't want to talk. They don't want to get through it, they just say that's it I'm done, and then they just shut down" (James, 60, FG1)

"There is a need to talk to be able to communicate, to fit in with society. And it's actually very easy to stop doing that. To shrink into a corner and just live on your own. But that's not fair to you and it's not fair to other people either. But it's quite tempting to do sometimes." (Arthur, 79, FG1)

Overcoming the pull towards social withdrawal was supported by the notion of just having to get on with life post-laryngectomy and seeking acceptance of the changes that have occurred. To reach a place of acceptance, participants presented examples where they had drawn on inner strength or focussed on what remains, rather than what has been lost.

"You are told before the operation that this will change your life. But you've got to be strong enough to not let it change you too much. If you go out into the world and you say it's not me that's different, it's everybody else and make yourself go out there as if there is nothing different, it's a lot easier." (Carol, 72, FG3)

"What he [Surgeon] said to me probably will stick with me forever. He said to me that you need to remember that you haven't just had a life-changing operation you've had a life-continuing operation. He said, what I have done has given you the ability to continue your life as best as you can." (Jack, 42, FG2)

At times participants drew on humour to support the adjustment process, acknowledging the need to carry on with life, in spite of communicative challenges. Positive experiences that have shaped life following laryngectomy were also shared.

“Prior to my operation I wouldn’t say my life was sparkling but it was alright. After my operation I decided I would do what I wanted to do, and I’ve travelled the world since then. I was determined to see as much of the world as I could instead of being focussed on one wee area.” (Fiona, 78, FG3)

“It’s hopeless me going up to a bar to order drinks, but that works to your advantage. You just tell everybody ‘I can’t order the drinks, they won’t hear me! [laughs]. You’ve just got to use what advantages you get.” (Arthur, 79, FG1)

5.3.4. WHAT SHOULD VOICE THERAPY LOOK LIKE?

5.3.4.i. Theme Four: The Patient as expert

The conceptualisation of The patient as expert was identified as a main theme, which included sub-themes of My role in my recovery and Self-learning and sharing. Participants understood that their knowledge of laryngectomy, as a relatively uncommon surgery, was unique and described the contribution they had made to their own rehabilitation, and the value they could bring to service provision. In discussing what voice therapy should include, PWL centred their role as active within the therapy process, not only as a recipient of therapy but as someone who could help SLTs to learn and share their knowledge with other service users.

5.3.4.i.a. Sub-theme: My role in my recovery

Participants shared examples of proactive solutions they had implemented to overcome barriers in daily situations, highlighting their role in their recovery. In some cases, this could be interpreted as a practical response to managing fears. Whereas for others the acquisition of knowledge occurred through necessity as there was no one else to support care. In many examples, participants also took an active role in raising awareness of laryngectomy, again indicating that HCP understanding of the surgery was low.

“A lot of A&E and ambulance people, if you fainted they wouldn’t necessarily know... I carry with me a description of what’s happened in colour because some people want to know a bit more.” (Helen, 65, FG4)

“When I was in the hospital, they showed you once how to clean your stoma and then you just had to do it, and because I was on my own, I did just have to do it. I didn’t have anybody to say, can you help me?” (Jackie, 49, FG3)

Connection to the sub-theme of Don’t let your mind get led off was evident, where participants recounted their role in their rehabilitation as an action without a viable alternative. This recounting gave the sense that if participants did not take ownership of communication challenges and try to overcome them, they would find themselves in a psychologically negative situation. Here, a notion of otherness was suggested in the data with participants contrasting themselves as other to people who had not persevered and were less active in their recovery. Many participants also expressed otherness through the belief that they were fortunate to be in a better situation than other PWL. This may reflect that those opting to taking part in the focus groups were likely to have greater levels of motivation.

“I think it’s just practice and the longer you have it. I think back and I think, my god, suppose I hadn’t have tried. I’d be there with the [writing] and the amount of people you realise can’t read.” (June, 68, FG4)

“I’ve met people who just give up. This is the end of their life. They just give up completely, they don’t try to talk, they don’t want to talk. They don’t want to mix with other people. It’s psychological. To feel close to other people, being able to communicate with them, it’s very necessary.” (Andrew, 65, FG1)

5.3.4.i.b. Sub-theme: Self-learning and sharing

The path towards The patient as expert was one of self-learning and perseverance. Whilst participants positively acknowledged the support of their SLTs, they spoke in greater detail about the self-directed practice and trial-and-error that had helped their own voices beyond what was offered by SLTs.

“The biggest thing I found was just forming the letters and words that relied on the airflow. Things like ‘h’ and letters that weren’t formed from your teeth. And I took a lot of time just practicing to form those letters as best I could.” (Liz, 41, FG3)

“I read quite a few bits and pieces... books to do with speaking consonants and that sort of stuff. I was speaking with my SLT team and they explained, you know, we can’t teach you how to talk again you’ve already done that when you were three or four so you’ve got to use that same mechanics.” (Jack, 42, FG2)

The process of self-learning was interpreted as central to the process of becoming experts in their own condition, where participants’ unique perspective as a tracheoesophageal speaker also enabled them to make a valid contribution to HCP and laryngectomy education. There was an understanding that SLTs and other HCPs do not have lived experience and may not have all the solutions to post-laryngectomy challenges; whereas those who had acquired tracheoesophageal voice could share their process with newer tracheoesophageal speakers.

“I don’t think they use us enough. I think we would be a lot more beneficial to train other people how to voice better. And I think coming from ourselves we probably have a better understanding than people who haven’t had a laryngectomy.”

(Helen, 65, FG4)

“They’ve told me the stuff I share with them has helped them become better speech therapists.” (James, 60, FG1)

In discussing these issues, participants typically expressed openness and a keenness for collaboration with HCPs to improve care, despite having experienced rehabilitation that had not always met their needs. However, some participants described encounters where their autonomy and understanding of their condition was not respected by HCPs, which led to feelings of disempowerment.

“I think the staff don’t give you enough credit for your own capabilities. We need to be empowered. Losing the voice is a disempowerment in itself, so we need to feel we are being empowered you know, and if that means knocking on doors and saying, Oi! You’re not being rude you’re just being assertive.” (Helen, 65, FG4)

“Sometimes where clinicians are coming from is their rule book so to speak. And they spill that out and don’t necessarily satisfy the needs of a particular patient.”
(Arthur, 79, FG1)

5.3.4.ii. Overarching theme to themes five and six: Everyone is different

In discussing what voice therapy should include, a higher-level theme of Everyone is different was evidenced in relation to the content, support needs and prioritisation of therapy. This theme was overarching to themes five and six and provided a conceptual framework for the development of a tracheoesophageal voice therapy. This overarching theme recurred frequently throughout focus group discourse and foregrounded participants’ opinions of a personalised novel therapy. However, some participants expressed uncertainty about how realistic it would be to individualise therapy, questioning to what extent this would be possible.

“They [healthcare professionals] treat everybody the same and there lies the problem. I think every individual person has a different progression. So it’s not one fits all because that’s not how it is.” (Carol, 72, FG3)

“It would be very difficult to adapt an exercise protocol based on every individual’s progress and where they are. It would be very difficult to do that.” (Helen, 65, FG4)

The rationale for tailoring therapy to a personalised approach was often related to the understanding that function is highly variable between individuals after laryngectomy. Participants referenced factors such as surgery type, reconstruction, requirement for adjuvant treatment alongside pre-existing physical differences.

“ Everyone is different. Everyone’s lung capacity is different, everyone’s airway is different, everyone’s new throat is different so if you can advise on the starting points, it would be helpful to understand where things might not be so easy. I found that was the key for me to help get my voice back.” (Jack, 42, FG2)

“The thing is that it [voice quality] is entirely a result of what they take out and what they don’t. And my surgery has left me with the ability to use this very well.”
(Andrew, 65, FG1)

5.3.4.iii. Theme Five: What I want is...

Whilst participants universally agreed that each PWL will have different function and rehabilitation needs, there was consensus on what the components of a novel voice therapy could be. This included impairment-based work targeting specific aspects of voice quality, improved equipment options, consideration of support systems and better provision of information. These components are elaborated in the following sub-themes of Impairment-based therapy, Support systems and Information.

5.3.4.iii.a. Sub-theme: Impairment-based therapy

Participants identified the aspects of voice quality that should be incorporated within voice therapy, namely articulation, breathwork, loudness and pitch. In most examples reported,

this was based on the participant's own experimentation through a trial-and-error process, whereas examples of impairment-based activities completed within speech therapy were less commonly shared. The lack of impairment-based activities within speech therapy contrasted with discussion on equipment, where examples showed that equipment issues were focussed on in speech therapy sessions.

The importance of articulation work was highlighted, in which the recommendation was to start with individual sounds and short words, using regular repetitive practice. Several participants noted that aspirated or voiceless sounds were particularly challenging, with the phoneme /h/ being referred to as an example.

"What you should do is start with the letters of the alphabet or one, two. And start with those wee words all the time, drilling. A couple of words and getting them out."

(Helen, 65, FG4)

"I realised that I couldn't pronounce any letter that relied on the air, where I was struggling. So I started to sound like a cockney, in most places all the h's were dropped off." (Jack, 42, FG2)

Breathwork was seen as a key component of voice therapy, and participants shared the view that optimised breathing was important for tracheoesophageal voice. Experiences of breathing for voice differed, however. Some participants found that adjusting to breath support for tracheoesophageal voice occurred quite naturally whereas for others this took time.

"I'm certain there is some people whose speech could be improved by thinking about things like breathing, breath control and using the whole of the lungs."

(Peter, 73, FG2)

"I just remember at the beginning feeling really, really tired because it's obviously different with the breathing but it [voice] seemed to come quite naturally."

(Liz, 41, FG3)

Breathwork was typically described in conjunction with articulation exercises or voicing practice. No examples were shared of breathing exercises completed in isolation, instead importance was placed on breathwork aimed at optimising airflow for voice and phrase length.

“Well, you do practice taking breaths to be able to say a word and then stringing it into a sentence.” (Fiona, 78, FG3)

“So you have to remember that deep breathing. Even if it is four or five words and then you can’t carry on. Over time you learn to be able to speak.” (June, 68, FG4)

“Learning to whistle is a good one! Yeah, learning to whistle...quite good for the airflow. But again, everyone is different” (Derek, 82, FG1)

To a lesser extent, participants discussed stoma occlusion and hands-free HMEs. In the context of breathwork. Stoma occlusion was raised as a component of breathwork, and therefore a potential therapy target, where coordination of breathing, occluding and voicing was required.

“Learning to take a deep breath, talk... take your finger off quick. Take a breath and talk again. It is learning how to be able to do that.” (Farida, 55, FG4)

Hands-free devices were only used by two participants during the focus groups who explained that effective usage could be challenging and required time to adjust to the optimal breath control. For this reason, the majority of participants had not pursued hands-free speech. The challenge of breath control for hands-free speech was recounted with amusement in an interchange between participants, where use of excessive breath support on speaking or coughing had resulted in the HME detaching.

“It took me a lot of time to get used to it because with your valve you breathe around here but with this one you breathe through the front. And sometimes when I cough it...! [gestures to HME detaching], [laughs].” (Mauro, 62, FG2)

"I think my best is 10 or 12 feet in one go! If you are sitting in the train and something suddenly whistles past you... I think we could have a competition, me and him!"

(John, 78, FG2)

Discussion of breathwork extended to consideration of lung health. Whilst perceptions of lung health varied, participants saw breathwork as a necessary activity for lung health in addition to optimised voicing. Some participants found that breathing was easier after laryngectomy or unchanged, whereas others needed time to adjust to breath support or queried the impact of surgery on their current and future lung health.

"My voice has got weaker over time and I think that's more to do with the lung capacity because we don't use our lungs as much as people who are breathing normally. Whether that's a deterioration that continues... I don't know but I've noticed it being weaker and unable to project as much." (Arthur, 79, FG1)

"It's quite funny when you breathe, it feels like you've got more air coming in"

(Aidan, 57, FG2)

Loss of speech volume and projection was frequently experienced after laryngectomy and was both a communication barrier and a factor in social isolation. Participants agreed that working on volume was an important component of a novel voice therapy, however, no examples were shared of exercises targeting volume. This suggested that volume work was not currently being experienced in speech therapy or self-learning. Where ideas for volume were prompted by the facilitators, participants pointed to the potential of equipment solutions rather than suggesting a behavioural therapeutic activity.

"It would be nice if they invented one [prosthesis] that would give you a bit more volume because the more you try to speak loud you get all this stuff coming up and then you have to go to clean it." (Aidan, 57, FG2)

Researcher: I'm interested to hear what you think might help? [to increase volume]

"A microphone!" [laughs at Researcher] (Carol, 72, FG3)

Similarly, there was a keenness for voice therapy to target increased pitch range, with the aim of improving the expressiveness of the voice, reducing monotone and misgendering. Few participants could share examples of pitch modification exercises; however, one example was demonstrated of using diaphragmatic breathing to control pitch.

"Do you ever answer the phone and get called Mrs? Because I do... Initially you get offended by that but you soon get used to it." (Steve, 62, FG2)

"It's very difficult but again, it's from the diaphragm isn't it. You've got pitch, you've got pitch [points to other participants] and I've got pitch. La la la la la! [sings arpeggio scale]" (Helen, 65, FG4)

Within groups participants could differentiate between their own voices and other participants who had subjectively more or less pitch range, which was met with interest. Despite pitch work being seen as a component of voice therapy, there was uncertainty over whether it was possible to modify pitch, or surprise when finding it was possible.

"I was talking to a speech therapist and I asked her about pitch. I didn't realise you can actually make... you can actually sing. And if, having that sort of ability would enable people to put more expression into their speech." (Andrew, 65, FG1)

Within the sub-theme of Impairment-based therapy, equipment issues were identified as important. Specifically finding the optimal voice prosthesis, baseplate and HME was identified as the foundation to achieving voice. Participants had experienced a trial-and-error process

with different equipment and held the view that if a good foundation was not established, there will be difficulty producing voice. When discussing equipment, participants frequently referred to the support of their SLT, which contrasted with discussions on voice work where self-learning appeared more prominent. This suggested that SLT sessions may be focussed more on optimising equipment than direct voice work.

“My speech initially was very poor and few people could understand me. Erm, but over time we [participant and SLT] tried different combinations of a valve and filters and we found something that is much better than it initially was.” (John, 78, FG2)

For several participants, they had not reached a point where current equipment was meeting their needs and so improved options were called for. This was expressed by one participant who could not achieve voice due to ineffective baseplate seal, which resulted in air escape.

“I think with the air escaping [gestures to throat and shakes head]. If they could...but they’ve [SLT] tried lots of different ones. A better one... that would help.”
(Cathy, 79, FG4)

“There is need for more services, new products and we need to listen with people with laryngectomy. We need to listen to new proposals because everybody here has his own experience. This is the beginning of... to make rehabilitation better.”
(Nasir, 67, FG1)

5.3.4.iii.b. Sub-theme: Support systems

Support systems were seen as an essential part of a voice therapy approach. SLTs were seen as the core HCP for post-laryngectomy care and participants spoke positively of the support they received from their SLT services, in the context of knowing that both facilitators were SLTs.

“I think for me um, my speech therapists have been incredibly supportive throughout. I mean, one of them was there on the day I received my diagnosis. So I mean, I see them way more than I see my Consultant or anybody else and we’ve formed a really good relationship.” (Liz, 41, FG3)

Where negative aspects of SLT were discussed, this typically related to resourcing or service provision issues. Participants described how services had changed over the years and highlighted a lack of time during SLT sessions or longer waits to access an appointment. For some participants this influenced what issues they would raise within their SLT session.

“The speech therapists now don’t have the same amount of time they had when I had my valve [put] in. Imagine now a speech therapist saying “oh, you want to use the... you want to learn oesophageal speech? I’ll teach you oesophageal speech”. So that was about an hour and a half out of her day. It’s just not possible now because they are all so busy.” (Derek, 82, FG1)

“Well, I get the feeling I’m taking up their time, their unplanned time. They’ve been good enough to get me in... I feel like I’ve got to get out as soon as possible so I don’t go on for social discourse.” (Arthur, 79, FG1)

Whilst SLTs were viewed positively, participants emphasised that additional routes of support were required. The rationale for requiring additional support systems was the need to find support from people with lived experience. Participants expressed that SLTs had a vital role, yet there would be aspects of life post-laryngectomy that they could not address.

“You’re telling people how to get on with their life and I couldn’t ask somebody... I wouldn’t go and see somebody who has had a baby and tell them, because I’ve never had one. I’ve had children but I’ve never had a baby so I couldn’t do that.” (Steve, 62, FG2)

Here the role of laryngectomy clubs was identified as very important to provide the experienced based peer support that SLTs could not. Yet, many participants also welcomed

the presence of HCPs within peer support spaces, particularly SLTs and Clinical Nurse Specialists, to collaboratively provide advice on matters that might arise in peer discussions.

“At all the support groups people have been through the same as ourselves and they can give advice... so it does help as well the support groups. And it’s totally different for your speech and language, they are there to help you with these things but... the support group... they’ve had the operation as well, and that’s a help.” (Jackie, 49, FG3)

“We’ve got a really popular support group, and we’ve got great support from our speech therapists that come to every meeting that we have. So we’ve always got help there you know.” (James, 60, FG1)

However, one younger participant, found that the local group was not the right avenue of support, due to difference in age demographic. Instead, peer support was found online via proactive social media contact.

“They had like a local support group, but I...there was nothing like that available for me and... particularly for me, I wanted to meet other women who’d had the operation and... younger women. And um, a lot of that I did myself online through social media, connecting with, you know finding other women who’d had a laryngectomy.” (Liz, 41, FG3)

Given the positive view of laryngectomy groups, participants were asked their thoughts on group voice therapy, to ascertain whether a shared learning space could provide another means of peer interaction. Here the majority view was that group therapy could be beneficial and there was an openness to the idea of attending a group session. However, one individual, who was unable to produce tracheoesophageal voice, expressed a preference for individual sessions. Participants conveyed that people with less voicing ability may find it challenging to participate and experience success in a group environment. A solution was proposed by some participants where a rolling group therapy programme could be attended once a tracheoesophageal voice had been established.

“Would that benefit from having a group? Two or three patients together with the speech therapist. Erm, just seeing other people and perhaps getting encouragement, maybe it would also benefit from the NHS point of view being able to work with more than one patient at a time.” (Andrew, 65, FG1)

“I would like one-to-one therapy, feeling more confident in a one-to-one session.”
(Cathy, 79, FG4)

In the context of individual SLT sessions, views also differed on who should be present for service user support. Again, discussion indicated that individual preference was the key factor. Some participants wished for the inclusion of their partner or family in therapy, whereas for others attending SLT alone was a means to a defined place to share concerns.

“Family, or your wife... that could be quite important. They’re affected a great deal and their support has been absolutely immense. I think including them in it would be quite useful.” (Richard, 75, FG1)

“I found going on me own is better. It was sort of escaping and when I was with my speech therapist I had my escape... you know, I’m alive! You know? I found that better for me personally than going with someone that I knew.” (James, 60, FG1)

Many participants recounted speaking to a person with laryngectomy prior to their surgery, as part of the pre-surgical preparation. This became circular for some participants where they now fulfilled the role of laryngectomy visitor or laryngectomy ‘buddy’ in their local services. At times this role was undertaken during a joint session with an SLT and the person due to have surgery. There was an evident link in this regard to the theme of The Patient as Expert where people who had progressed through the adjustment process could share their experiences with those who were about to begin life with laryngectomy.

“I go to the hospital and talk to women who are getting it done now. So that I can help them cope with what it will be like once they get the operation, so I think a lary buddy is quite good as well.” (Jackie, 49, FG3)

“Having someone maybe that hasn’t had the operation but has experience to team up... you know you could have someone that’s had the operation with the help of someone that’s from the medical side as well to try to tailor that a bit because as you say there’s not one clear path so... it’s tricky” (Jack, 42, FG2)

Whilst laryngectomy visitors were established within pre-operative services, there was little evidence of continuation into a post-operative peer-befriending role. It was unclear whether this was due to lack of a central organising person, such as an SLT, to set-up of peer-befriending or whether people were directed to laryngectomy clubs without recognition that peer-befriending is a different provision. Participants were asked by the facilitators whether continuation to peer-befriending could be beneficial; this was viewed positively with some participants expressing a willingness to provide this role both for voice difficulties and wider issues.

“I think you really should promote the buddy system, pairing people up. Because... I’m sure I can help in little ways. You know, how to access things that you need that you don’t know.” (Helen, 65, FG4)

“Once you go over and speak to someone and you tell what is going to happen and what happens after as well... and er, I think you should be assisted anytime by one of us... I am looking for a job! [laughs]” (Mauro, 62, FG2)

[Researcher] “And so if someone was struggling with their voice could I call you up and say, do you want to come in and help?”

“[nods and thumbs up] Yeah. Some of them don’t want but... some want” (Mauro, 62, FG2)

Beyond the role of SLTs and peer support participants spoke of the psychological impact of altered communication, highlighting the need for psychology or counselling interventions. A shared experience here was the lack of mental health support services offered to people or

difficulty accessing services in a timely manner, which led to one participant paying for private counselling.

“I decided to move to my home to face the challenge to live my new life. There is a need to support people living alone and support people psychologically because this is a very difficult time. To lose your voice, this is something psychological. Not only by providing psychological support but also by providing care. This is very important for this period.” (Nasir, 67, FG2)

“I think the provision of psychological support slash counselling could definitely be improved. I mean, I was put on a waiting list with a Macmillan counsellor and I had to wait months and months.” (Liz, 41, FG3)

Participants were asked if SLTs should have a wider role in supporting mental health, however, it was agreed by participants that the acuity of mental health needs were beyond the scope of SLT practice; and additionally that SLT resourcing was insufficient to take on this role. Nevertheless, SLTs were seen to be in an important position to identify where people may need support and to encourage people to attend support groups.

“Speech therapists don’t have the time. They are allotted so much time to deal with the person just like the G.P. And there’s not enough speech therapists to begin with.” (Fiona, 78, FG3)

“Just go and try to get to a support group and all that. That’s amazing help really. I just think it helps everybody, but they’ve got to be encouraged to go.” (James, 60, FG1)

5.3.4.iii.c. Sub-theme: Information

Clear information provision was identified as a central component of voice therapy. Participants focussed particularly on the pre-operative information that was given in preparation for surgery and the associated functional changes. Information pertaining to

voice therapy specifically was not discussed, suggesting that participants had not received or experienced this. Overwhelmingly there was consensus that existing information was poor and did not meet the needs or expectations of participants. Information was often presented in paper format, which participants perceived as outdated and not professionally produced. In discussing pre-surgical information, participants gave examples of information being delivered at a time when it was difficult to process it, or in ways that were not accessible to them, leading to feelings of unpreparedness.

“You’ve got so much going on in your brain at this time. Your whole life is changing and it’s...they throw a pile of paperwork at you and say, here, read that. [confused expression] Well, I’ve just binned all that!” (Arthur, 79, FG1)

“You can’t imagine no matter what you tell us. They give you the paperwork but then big words mean nothing to you. You’re like, oesophagus, laryngectomy... all them big words mean nothing.” (June, 68, FG4)

This was compounded by the often short timeframe between diagnosis and surgery, which meant participants did not have time to explore information in detail or consider the implications of surgery. One participant described how the pre-operative medical focus was on other aspects and so preparation for communication change was not prioritised, leading to regret about not recording her laryngeal voice.

“In the hospital they didn’t give much information, they...they were focussing on my operation and about my diet because at that time I was losing weight. Every time Dietitian phones and this food and this... but not this skill. Voice is gonna go and then, they should have told me that if you want to record your voice, you can record it so that you can listen afterwards.” (Farida, 55, FG4)

“I didn’t really have time to take anything in. I had me appointment with the surgeon and the speech therapist on the Thursday and went in the hospital to have the operation on the Tuesday. It was just really, really quick. They told me what I were having done and that were it.” (James, 60, FG1)

There was acknowledgement again that individual needs will vary, so that information should be tailored to a specific person. This linked clearly to the overarching theme of Everyone is different where it was demonstrated that some people may wish to know more than others about their treatment.

“Everybody is different and there’s no one thing for one person. You’ve got to look at the circumstances, um, and I wonder how much contact do the speech therapists have with the surgeons after their operations? Because I think that’s quite important to know exactly what the surgeon has done so that they will be able to help this person get onto a reasonable footing.” (Derek, 82, FG1)

“I like to know about things. So, as much information as possible. But again, depends on the person. Some people don’t want to know whereas I like to know what’s going on. The Consultant actually erm drew it on the back of an envelope, that was my information!” (Arthur, 79, FG1)

Furthermore, the tailoring of information was discussed in terms of representation. This was expressed particularly by younger participants where information included images that did not feel representative. This was reported typically in the context of age, where resources often depicted older people. There was a notable absence of discussion of representation of race. In the context of a predominantly white-British group, participants did not raise the lack of diverse representation, instead the focus was towards age.

“I was given a DVD to watch... it was what to expect after surgery and how you might sound, but their DVD was so out of date and everybody was much older than me and I found it incredibly difficult to relate to any of it. And I’m just feeling horrified, this is what’s going to happen to me? So yeah, I threw it in the bin!” (Liz, 41, FG3)

“I had a phone call with a gentleman who had had the operation before and I came out of that feeling quite good, but I guess you know, everyone is different. You could have a phone call with someone who maybe hasn’t had a good experience and then you’re going into it thinking, shit... what if that happens to me.” (Jack, 42, FG2)

5.3.5. HOW SHOULD VOICE THERAPY BE PRIORITISED?

5.3.5.i. Theme Six: It all depends

In relation to prioritisation of therapy, a main theme of It all depends was interpreted from the data. Participants described how their prioritisation of voice therapy was influenced by other factors such as stage in post-surgical recovery, adjuvant treatment, and other aspects of function such as swallowing. This theme was positioned under the overarching theme of Everyone is different and was interlinked with participants' experiences of living with variable communicative function and unpredictability discussed within The Unseen.

5.3.5.i.a. Sub-theme: Personalised prioritisation

Participants expressed diverse views on when voice therapy should begin. For some, early intervention post-operation was not preferred due to the many adjustments being negotiated in the early post-operative period, whereas for others commencing voice therapy as soon as possible was favoured. This indicated that there was no optimal timepoint and instead, personalised therapy planning should be tailored to individual needs and priorities.

"When you do have your laryngectomy getting your voice as good as it can be is only one of many concerns and things pressing on you. Erm, the actual recovery from surgery, managing the stoma and then going for check-ups where you're thinking, are they going to find something? You know there's a lot going on at that time."

(Andrew, 65, FG1)

"I think the earlier the better. If you think about... you're in your bed recovering from your operation and you're writing on that whiteboard so that people understand you. Aren't you more receptive to getting back to something like normal at that stage, when you want to be normal? The earlier the better." (Peter, 73, FG2)

Factors influencing how people prioritised voice therapy were also seen to change over time. The desire to focus on optimising voice quality was often recounted in relation to work and social roles, where the need to return to work placed importance on the voice. Additionally, as people emerged from the immediate post-operative recovery and began to re-engage with social roles, voice became prioritised.

“My job needed a voice. That was my top priority, but... it’s individual...”

(Andrew, 65, FG1)

“You will be starting the first step into normal life, meeting friends and meeting family then getting back to work and you’ve got... you’ll obviously want to have dealt with... the voice will be very high on your priorities then.” (Richard, 75, FG1)

5.3.5.i.b. Sub-theme: Radiotherapy

Adjuvant radiotherapy treatment was a key factor in participants’ views on the timing of voice therapy. Participants were aware that post-operative radiotherapy could impact negatively on tracheoesophageal voice quality and therefore it was perceived as fruitless to focus on optimising voice until radiotherapy treatment was completed. Another aspect of this factor was the mental load of radiotherapy. As a typically daily treatment, radiotherapy requires an arduous schedule which could make it unfeasible to manage the additional demand of voice therapy during that time.

“If you’re going for radiotherapy or chemotherapy, you can’t even begin to think about it until after that. Then you’ve got to give yourself time to heal because some people lose their voice. Some people don’t get it back, some do.” (Carol, 72, FG3)

“And they were saying, you might lose the voice or it could come back, it might not. You know, so to be having voice treatment then would have been quite unfeasible really. It wouldn’t have made any odds” (Andrew, 65, FG1)

“So my voicing was going quite well and then when I started chemo and radiotherapy, it just kind of dropped off. Everything was so sore inside so I was barely just whispering. And I had an awful lot of issues with my valve after radiotherapy... and my voice quality was really poor for a long time.” (Jackie, 49, FG3)

5.3.5.i.c. Sub-theme: Balancing function

The third factor identified in prioritisation was the need to balance voice function with other areas of physical function, particularly swallowing. Due to the altered anatomy after laryngectomy, there is an interplay between voice and swallow function. This can result in the need for a procedure to improve swallowing, which would negatively impact voice quality. Participants described living with this careful balance management of function, which sometimes required trade-offs between having voice or prioritising the ability to swallow.

“When my swallow’s been really bad, when it’s been very tight inside has impacted on my voice. I had quite a few [dilatations] in close succession and then I was struggling to produce a decent voice afterwards... it’s a fine line between giving you enough space to swallow but making too much room so that you can’t make the vibration inside.” (Liz, 41, FG3)

“Difficult sometimes to prioritise things. I remember when I was going through a difficult patch, the consultant actually said to me, well would you prefer to eat or talk?” (Arthur, 79, FG1)

5.4. DISCUSSION

This series of focus groups centred on the lived experience of voice prosthesis users to guide the development of a novel tracheoesophageal voice therapy intervention. The groups included 20 PWL and explored the experience of being a person that uses a voice prosthesis, views on what tracheoesophageal voice rehabilitation should include and opinions on how voice rehabilitation should be prioritised. Interpretation of the dataset produced six main themes with interlinked elements; and an overarching theme of Everyone is different captured participants views on personalised care and a flexible provision of voice rehabilitation. Understanding the lived experiences of voice prosthesis users provides an essential scaffold for the development of a voice therapy intervention. Therapy is contextualised by understanding the overt and hidden challenges that voice prosthesis users encounter, and exploring how these could be overcome with support structures alongside impairment-based therapy activities.

5.4.1. THE EXPERIENCE OF BEING A VOICE PROSTHESIS USER

People in cancer survivorship experience long-term physical and emotional effects with interaction between impairments and restricted participation (Magasi et al., 2022). This was evidenced in the focus groups where participants reported significant unseen challenges associated with mental load, fear and confidence issues. The presence of hidden disability and mental load after cancer is not reported in existing literature, whereas the impact on mental health is consistently reported. Head and neck cancer patients experience significant levels of psychological distress (Hammermüller et al., 2021) and are at increased risk of suicide compared to the general population (Osazuwa-Peters et al., 2021; Kam et al., 2015). Participants expressed the shock of the immediate post-operative period, in which they first experienced voicelessness. In other areas of cancer, self-reported emotional shock was associated with low psychological wellbeing for up to two years post-surgery (Stinesen Kollberg et al., 2017 – prostate cancer), whereas the temporary voice loss associated with tracheostomy has been experienced by patients as a form of torture (Donnelly and Wiechula,

2006) causing powerlessness and fear (Foster, 2010). Participants reported isolation in social settings due to difficulty increasing speech volume and the additional time taken to occlude the stoma for speech. This is pertinent in the context of increased risk of loneliness in head and neck cancer patients (Dahill et al., 2020) and points to the need for voice therapy interventions to promote participation and support social interaction.

Participation in social contexts was also impacted by physical fatigue associated with prolonged tracheoesophageal speaking. Tracheoesophageal speech requires greater effort compared to laryngeal speech; this may be compounded by cancer-related fatigue which is higher in people with advanced staged disease or who have had multimodal treatment for head and neck cancer (Sharp et al., 2023).

Few studies have investigated the experience of return to work after head and neck cancer. Whilst this was not the primary focus of this study, participants described how return to work had been negatively impacted by laryngectomy. In an exploratory study of return to work in UK, non-laryngectomy head and neck cancer patients raised consistent issues (Miller et al., 2023). Notably greater healthcare professional support for return to work was advocated for. This was not overtly stated by our focus group participants; however, this could be due to the specific focus of the Miller study on return to work. In a meta-analysis of return to work after head and neck cancer, Yu et al. (2019) found that 67% of people employed at diagnosis returned to work. Studies specifically on return to work after laryngectomy report less favourable outcomes. In a Japanese setting, a rate of 40% employment loss due to voice loss was reported after laryngectomy (Kotake et al., 2019). Similarly, a Spanish study reported 47% of people becoming unemployed after laryngectomy; voice prosthesis users were more likely to maintain their work activity, however, (Costa et al., 2018). The high percentage of people with laryngectomy not retaining employment indicates the importance of a personalised voice therapy which supports the communicative abilities required for work.

Telephone use and virtual meetings presented a challenge for participants who returned to work. In relation to telerehabilitation, it is recommended that a caregiver is included in the telerehabilitation process to overcome communication breakdowns (Varghese et al., 2021), however, this is not a feasible approach within the workplace nor for those without caregiver

support. People with laryngectomy therefore face greater access difficulties, particularly when video is not used (Ghulam-Smith et al., 2020). Examples of successful virtual laryngectomy club meetings were reported by participants and in literature (Jonathan et al., 2022) and indeed two focus groups were completed via videoconferencing. A contrasting example was presented by one participant, however, where tracheoesophageal voice was processed as background noise and filtered out during virtual meetings. This suggests that accessibility of virtual meetings may vary between tracheoesophageal speakers and requires individual assessment.

Technologies, such as voice banking and artificial intelligence enabled voice repair and synthesis are expanding. However, technologies have not yet progressed to offer the real-time voice repair or synthesis required to support live telephone calls or virtual meetings for work or social interactions. Furthermore, many existing technologies are designed to process normal voice quality, rather than supporting alaryngeal or dysphonic voices (Zhang et al., 2023), or they require pre-laryngectomy voice data which participants may not have. One focus group participant expressed regret over not being advised to record voice prior to surgery, and many voice prosthesis users will have had surgery prior to the emergence of voice banking. Given the rapid progression of these technologies, it is recommended that people undergoing laryngectomy are encouraged to use voice banking and retain laryngeal voice samples for potential future applications.

Post-traumatic growth was evidenced in how some participants navigated the adjustment to life post-laryngectomy, working through shock towards coping with life as a PWL. Post-traumatic growth is defined as positive psychological change as a result of the struggle with trauma or highly challenging situations (Tedeschi et al., 2018). Within the study participants used humour at times to recount experiences and relayed positive events or personal growth that had occurred post laryngectomy. Post-traumatic growth emerges from the adaptation to trauma and can support the loss of an existing identity, towards the evolution of a new identity with greater adjustment and flexibility skills (Dell’Osso et al, 2022). This is pertinent for PWL who live with unpredictable and fluctuating levels of function. Sharpe et al. (2018) established that post-traumatic growth is possible in people who have survived head and neck cancer, particularly in younger people, females and people with social support;

however, the proportion of post-traumatic growth was lower than in other cancer types. Understanding where an individual is in their journey of adjustment and their potential for post-traumatic growth, is relevant for the clinical setting. This provides a context to an individual's readiness to engage with therapy and what adjustment or support may be required as a precursor.

This study did not focus specifically on exploration of female versus male PWL experience; however, it was observed that female participants spoke more of the negative reactions of other adults, and of their interactions with children. The latter were positively framed; however, one participant shared her fears of not being able to keep her children safe in public as a PWL. These findings are consistent with existing research on the female laryngectomy experience. The reduced ability to carry out caring activities has been evidenced in females post-laryngectomy (Van Sluis et al., 2020). Additionally female PWL experience frequent negative assumptions and reactions to their voice, vulnerability and self-consciousness over their appearance (Van Sluis et al., 2020). Aspects of quality of life relating to emotional and social functioning are more affected in female laryngectomees (Lee, Gibson and Hilari, 2010). These factors should be considered when planning tracheoesophageal voice assessment and intervention to ensure that the specific needs of female PWL are identified and addressed.

5.4.2. THE ELEMENTS OF A TRACHEOEOSOPHAGEAL VOICE THERAPY

In discussing what PWL want from a voice therapy intervention, there was a clear desire from participants to be more active in their rehabilitation and to work towards desired outcomes in collaboration with SLTs.

The concept of the Expert Patient undertaking active self-management of a long-term condition was an approach produced by the Department of Health (Department of Health, 2001). This was first introduced for chronic diseases with the aim of later extension to all areas of healthcare (Tattersall, 2002). Currently, Expert Patient Programmes are offered by various NHS Trusts in the form of six-week courses, which promote self-management of non-

cancerous chronic conditions, such as asthma or diabetes. Whilst an approach of this type may empower and inform PWL who are less confident in their self-management, participants in the present study envisaged a wider role of the Expert Patient in supporting not only personal rehabilitation but also for the benefit of other PWL and HCP education.

Few examples exist in literature of service users as educators; and exploration of outcomes and theoretical framework is lacking (Towle, 2009). However, the involvement of service users in medical education is positively received as necessary and complementary to standard clinical education content; furthermore, it is seen as empowering to the patient educator (Jha et al., 2009). Yet cultural change is required to view service user experience as an addition to academic and professional learning; and guidelines are required to support the practice (Donaghy et al., 2010).

A key thread which ran throughout the focus groups was the requirement for therapy to be individualised and responsive to changing functions and priorities. This accords with current models of precision, or personalised, medicine which seek to tailor healthcare to individual needs and avoid the use of 'one size fits all' approaches (NHS England, 2016) that are not feasible for the heterogenous laryngectomy population. Whilst the focus of precision medicine could be seen as centred on genomic research, targeted and personalised interventions and a participatory role for patients are stated as core concepts of precision medicine (NHS England, 2016). These concepts are transferrable to rehabilitation and aligned to the priorities of PWL participants.

The current picture suggests that patient participation is not yet well established in head and neck cancer, however. Hamilton et al. (2022) identified that head and neck cancer patients are not fully involved in decision making around their cancer treatment and may be disempowered by current models of multidisciplinary team working, whereas existing research of wider cancer teamworking advocates for better representation of patient views in decision making (Lamb et al., 2013). In the setting of lung and colorectal cancer, oncology treatment governed by physician-controlled decision making were associated with lower service user rating of the quality of care and associated communication (Kehl et al., 2015). Personalised care and active, collaborative rehabilitation were identified as overarching constructs to a tracheoesophageal voice intervention; however, participants also identified

the specific components of impairment-based activities, support systems and enhanced information.

Participants did not have extensive examples to share of voice directed interventions as this had not been offered to them in their post laryngectomy care. Nevertheless, participants highlighted targets for impairment-based therapies and considered how these might relate to activity and participation. An example of this approach is explored in Chapter Seven where the feasibility of an impairment-based respiratory intervention (EMST) is tested to explore the impact on loudness, which PWL identified as a barrier to social participation.

In a review of head and neck cancer rehabilitation studies, Parke et al. (2022) found an absence of studies that test the impact of rehabilitation interventions on activity and participation. Whilst participants did not directly link all participatory challenges to a specific impairment, it is considered that a tracheoesophageal voice intervention should situate impairment-based approaches within activity and participation-based aims, for example, identifying impairment-based approaches that would support increased telephone use or return to work. The rationale for this approach comes from studies in aphasia SLT practice where impairment-based interventions have effected functional impact (Carragher et al., 2012; Best et al., 2009).

Participants highlighted the importance of different support systems, which could be accessed alongside SLT services, such as support groups and psychological services. In affinity with the expert patient role, participants advocated for peer-befriending and active support of other PWL learning to use a prosthesis. Shared experience is a core element of peer-befriending, which SLTs cannot provide, therefore the potential for PWL to undertake a peer-support role is an avenue for future research. Peer-befriending has been demonstrated as feasible for people with aphasia (Hilari et al., 2021). Furthermore, preliminary evidence of positive impact on depression was found, which would be pertinent for PWL given the high incidence of mental health impact following head and neck cancer treatment.

Enhanced information provision was of high importance to PWL, with current resources deemed unacceptable. PWL required tailored information at all stages of the treatment pathway. Here the heterogenous nature of information requirements was identified, as

participants shared differing preferences for the timing, amount and modality of information. This accords with the identification of information as an essential component for the successful implementation of precision medicine, which should be easily accessible, understandable and reliable (Vicente, Ballensiefen and Jönsson, 2020). Satisfactory information prior to treatment is predictive of improved post-treatment outcomes in people with head and neck cancer (Fang and Heckman, 2016), therefore the need to develop acceptable information with PWL is significant.

5.4.3. LIMITATIONS AND RISK OF BIAS

This study used broad inclusion criteria and purposive sampling with the aim of convening a representative sample of PWL. Geographic representation across the UK was achieved and participants were representative in terms of male/female incidence of head and neck cancer, however, it was not possible to include non-English speakers and participants were predominantly White. It is therefore uncertain how representative the study outcomes are of non-White PWLs' experiences. Younger participants were included in the study; however, the mean age of participants was 65.4 years and of 115.65 months post laryngectomy, therefore the outcomes may be less representative of younger PWL or people that have had surgery more recently.

PWL are heterogenous as a service user group and present with diverse characteristics in relation to their cancer journey, treatment history and post laryngectomy function. Though the people recruited to this study were diverse in their characteristics and expressed a variety of views, we cannot be confident that we sampled people with opposite opinions; this is therefore a limitation of the study.

The nature of laryngectomy itself presents communication challenges for potential participants who were aware that attending the focus group would require group conversation over time. It is possible that this presented a barrier to the participation of people who were less confident to speak in a group or who felt their vocal function was not sufficient. However, two participants attended and used silent articulation in the absence of

sufficient tracheosophageal voice, whereas another participant used electrolarynx instead of tracheoesophageal voice.

Accessibility of participation was another area of potential bias. Whilst participants were offered virtual group attendance to minimise cost and travel burdens, virtual attendance necessitated participants having access to the internet, an internet-enabled device and the digital literacy to participate. This presents a potential sampling bias towards participants who could afford and use online devices.

Whilst research positionality was reflected upon, participants were aware that the group facilitators were SLTs and this gives rise to potential bias around discussion of experiences and views of SLTs and services. Furthermore, participants did not have significant experience of active therapy to optimise voice quality; the lack of therapy experience may have limited the ability to reflect upon it.

5.4.4. FUTURE DIRECTIONS

Studies on the priorities of PWL are limited and therefore continued qualitative research is required in this area. The outcomes of the focus group provide direction on several areas for future research. Firstly, there is a need to develop and test interventions with PWL that incorporate impairment-based approaches, situated within translation to activity and participation. This may include supporting return to work and social activities, or specific issues such as optimising communication for videoconferencing. Intervention development should embed the principles of precision medicine (NHS England, 2020) to ensure care is personalised and PWL are active collaborators in their rehabilitation. This could be achieved through participatory approaches such as co-production. Here, a focus on development of information that is diverse, representative and multi-modal is indicated. The role of peer-befriending and expert patient as educator have not been explored within the laryngectomy context, therefore future research would be pertinent to identify feasible approaches and frameworks of practice.

5.5. CONCLUSION

This study aimed to establish the experiences of tracheoesophageal speakers and to explore service user views on what tracheoesophageal voice rehabilitation should entail; and how it should be prioritised. This was achieved through a series of focus groups which incorporated the contributions of 20 PWL. Six main themes were interpreted from the data, which provided insight on the experiences and rehabilitation priorities of PWL. The outcomes of this study are considered in the next chapter, Chapter Six, where co-design is used to bring together the outcomes of the thesis studies for further development of the voice rehabilitation intervention.

CHAPTER 6 | CO-DESIGNING A NOVEL TRACHEOESOPHAGEAL VOICE THERAPY INTERVENTION

6.1. INTRODUCTION

This chapter reports on the use of co-design for intervention development; in collaboration with PWL and SLTs as partners. There is an absence of therapeutic interventions to optimise tracheoesophageal voice (Summers et al., 2017) and limited literature on post-laryngectomy communication to contribute to the development of communication interventions (Sparks et al., 2023). Whilst there are examples of co-design for service improvement projects in cancer care (Green et al., 2020), to date PWL have not been included in intervention development as stakeholders.

O’Cathain et al. (2019) categorise nine approaches to intervention development, which define the focus underpinning intervention development. For example, development processes may be evidence and theory based, centred on implementation, or a combination of approaches. Table 6.1 describes the nine approaches. These approaches build upon MRC guidance for intervention development (Skivington et al., 2021) and the framework of actions involved in intervention development (O’Cathain et al., 2019) described in Chapter One (Table 1.1); and provide a scaffold for the doctoral study.

The doctoral study overall combines approaches to intervention development; however, this co-design study is predominantly situated in the partnership and target-population centred intervention development approaches described by O’Cathain et al. (2019) and described in Table 6.1. Partnership approaches utilise co-production and shared, equal participation of stakeholders, whereas target-population centred development is based upon the priorities of the end users of the intervention.

Category	Definition and examples
Partnership	The people the intervention aims to help are involved in decision-making throughout the development process, with at least equal decision-making powers with the research team. Example approaches: Co-production, co-design, user driven
Target population centred	Interventions are based on the views, priorities and actions of the people who will use the intervention. Example approaches: Person-based, user centred.
Theory and evidence based	Interventions are based on the combining of published research evidence and existing theory. Example approaches: Behaviour Change Wheel, MRC framework
Implementation based	Interventions are developed with attention to ensuring it can be used in the real world if evaluated and found to be effective Example approaches: Reach, Effectiveness, Adoption, Implementation, Maintenance
Efficiency based	Experimental designs are used to test intervention components to determine the active components and make interventions more efficient. Example approaches: Multiphase Optimization Strategy
Stepped or phased	Development emphasises systematic and sequential processes. Example approaches: 6SQuID, Five actions model
Intervention specific	The intervention development approach is constructed for a specific type of intervention. Example approaches: Patient decision support aids
Combination	Published approaches to intervention are combined. Example approaches: Participatory action research based on behaviour change theories
Pragmatic	A self-selected set of actions is used to develop the intervention. Example approaches: Mixed methods or formative evaluation

Table 6.1: Approaches to intervention development (adapted from O’Cathain et al., 2019)

O’Cathain et al. (2019b) also identify seven domains which govern the overall process of intervention development (Figure 6.1). This study is situated in the domain of Designing an Intervention, specifically targeting idea generation, identification of intervention components; and considering content, format and delivery of the intervention.

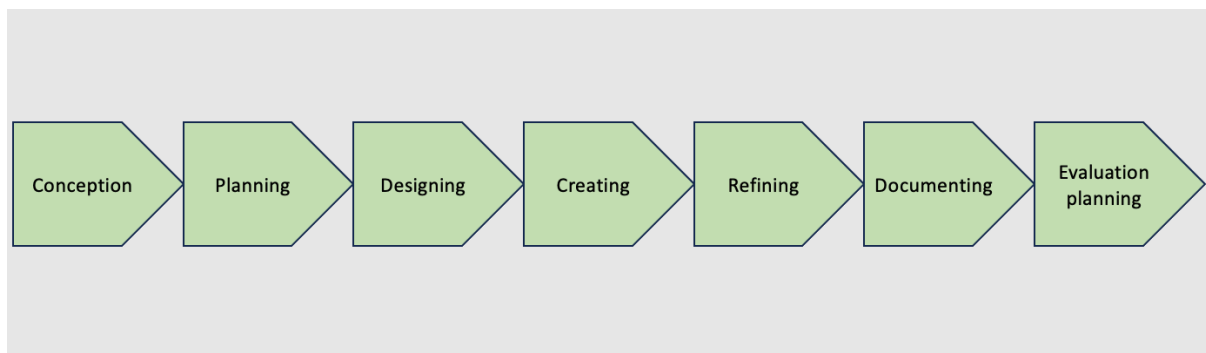


Figure 6.1: The seven domains of intervention development (adapted from O’Cathain et al., 2019b)

6.1.1. RATIONALE FOR USE OF CO-DESIGN

Participatory approaches to stakeholder collaboration are often described through the interchangeable terminology of co-creation, co-design and co-production. Distinctions exist between these specific approaches, however, and there are several models for these approaches evidenced in literature. Co-design focusses on the establishment of priorities and strategies to overcome a pre-specified problem (Vargas et al., 2022). This is differentiated from co-creation, which refers to the overarching process of problem identification, through to implementation of solutions and evaluation; and co-production, which centres on efficient implementation of the identified solutions (Vargas et al., 2022). A common principle of successful participatory approaches is the emphasis on creative design, which centres the human experience and employs power-sharing measures (Greenhalgh et al., 2016). This aligns with NIHR guidance, which advocates for co-creation processes governed by the key principles listed below. NIHR proposes these principles as an alternative to the adherence to a specific technique or framework, which could be counterintuitive to the innovation and flexibility required for co-created research (NIHR, 2018):

- Shared power
- Inclusion of all who can make a contribution
- Everyone is of equal importance
- Everybody benefits from working together
- Relationships should be built and maintained

The notion of ‘no decision about me without me’ (Department of Health, 2010) was set out to empower service users with a more active role in their care. This concept of equitable involvement extends to healthcare research where people who may benefit from the outcomes of research should be centred in research activities and decision-making (Connery and Salsberg, 2023). Service user priorities may differ from researcher priorities, leading to outputs that lack relevance and risk ineffective use of research funding (Slattery, Saeri and Bragge, 2020). Co-design describes the equal collaboration between stakeholders to identify problems and implement solutions (Singh et al., 2023), which presents a potential resolution to these challenges. Furthermore, collaboration with relevant stakeholders promotes a bridging of the research to real-world gap (Wehrens, 2014). Co-design was chosen for the design of this intervention to adhere to the above-mentioned NIHR and Department of Health guidance (NIHR, 2018; Department of Health, 2010) and to ensure that service user priorities are met. Co-design is considered an effective, inclusive methodology for generating outcomes that deliver direct and indirect benefits to the community the research aims to reach (Benz et al., 2024). In addition, existing research suggests that the use of co-design in research is also beneficial for researchers, the research process and the outcomes of the research (Slattery, Saeri and Bragge, 2020).

A notable issue in participatory approaches is the lack of diversity (Michalak et al., 2023), where White middle-class people are prominent (Shimmin et al., 2017). People from minority ethnic groups are under-represented in research due to complex socio-cultural and linguistic barriers, which are upheld by inadequate researcher engagement strategies (Farooqi et al., 2022). Furthermore, people from Black and Asian ethnic groups are less likely to report a positive experience of their cancer care compared to White service users (Martins et al., 2022) therefore under-representation of these views is problematic. In the field of head and

neck cancer, racial survival disparities exist (Liu et al., 2023; Mazul et al., 2022). This is pertinent in London, where 20% of head and neck cancers are from non-White groups (Tataru, 2017).

Within this study, engagement strategies were used to include PWL from the Bangladeshi community as a specific group, alongside a separate group of PWL from any other ethnic group; and SLT partners. The Bangladeshi community was identified as a specific group due to it being the largest ethnic group in the east London borough where the study was situated. White British residents of the borough of Tower Hamlets make up 22.9% of the borough's population, whereas Bangladeshi residents make up 34.6% (Tower Hamlets Partnership, 2023). A recent audit of a London head and neck cancer centre (Chartkul, Cook and Govender, 2024) found that 18% of service users had non-English primary languages, of which 78% required interpreting services with Bengali language being the most common; however, 24% of those requiring interpreting did not receive formal or informal interpreting. The audit found that outcomes were consistent with existing studies on under-resourcing of interpretation and highlights the negative impact on inclusive and equitable care.

6.1.2. STUDY AIMS

A co-design approach was used to synthesise themes arising from outputs of the doctoral study (the systematic review, clinician survey, service user focus groups and EMST feasibility trial) to inform intervention development. This was implemented with the objective of developing a novel tracheoesophageal voice therapy intervention for later refinement and feasibility testing. The aims of the co-design project were to:

- Work in partnership with specialist SLTs and PWL who are representative of the local communities to develop an acceptable tracheoesophageal voice therapy intervention
- Establish priorities and approaches to assessment, outcome measures and information provision
- Design and test therapy activities and resources which could form the components of an intervention

6.2. METHODOLOGY

The reporting of the study was informed by the Guidance for Reporting Involvement of Patients and the Public short form (GRIPP2 short form; Staniszewska et al., 2017), listed in Appendix 6.1.

6.2.1. ETHICAL APPROVAL

The study was approved by the City, University of London Language and Communication Science proportionate review committee (reference no. ETH-2223-1189), listed in Appendix 6.2. Ethical issues considered included the burden on partners' time for travelling to and attending workshops. Additionally, a low risk of mild psychological burden was identified for PWL when reflecting on their experiences. To reduce these risks, partners were informed of the time commitment and subject matter of the co-design process prior to participation; and the researchers moderated workshop discussions to minimise any potential distress.

6.2.2. ELIGIBILITY

The study sought partners in two categories: PWL who use a voice prosthesis to communicate and who spoke either English, Bengali or Sylheti language; and SLTs with significant experience of laryngectomy, equivalent to NHS Highly Specialist or Clinical Lead level. PWL partners who were not from the Bangladeshi community were required to have a sufficient level of spoken English, as it was not within the scope of the study to provide bilingual co-researchers across additional languages. PWL partners were required to be able to travel to the University or community locations to attend in-person workshops.

6.2.3. RECRUITMENT AND CONSENT

Partners were recruited via social media advert on X, advertisement to the SLT Clinical Excellence Networks and dissemination to patient support groups. A sampling framework was used in the recruitment process to ensure there was diverse representation. SLT partner variables included geographical location, clinical setting, care pathway type, sex and ethnicity. PWL partner variables included gender, ethnicity and employment roles. Partners were recruited to one of three groups: SLTs, PWL from any community (PWL-A), and PWL from the Bangladeshi community (PWL-B).

Potential partners were invited to contact the researcher (FS) via university email or telephone to obtain further information about the project and ask questions. During this first contact the researcher assessed eligibility and requested information to guide purposive sampling. The Participant Information Sheet and sample consent form was then sent to potential partners so they could make an informed decision about collaborating. Informed written consent was taken at least one week after contact with the researcher, and prior to the first workshops.

To support engagement and recruitment of PWL-B, the toolkit for increasing the participation of Black, Asian and minority ethnic communities in health research was followed (Farooqi et al., 2022). Table 6.2 summarises the guidelines proposed in the toolkit and the corresponding actions implemented by the researcher. Instead of direct contact with the researcher, potential PWL-B partners were highlighted to the researcher by their usual SLT. The researcher worked with the SLT to check eligibility and gain the consent of the PWL-B to provide their email or telephone details. The PWL-B was then contacted by a multilingual co-researcher/SLT assistant from the Bangladeshi community (JKA). The co-researcher informed the potential PWL-B partner of the co-design project by verbally conveying the details of the Participant Information Sheet and consent form; and answering any questions. On agreeing to collaborate, the PWL-B then provided written consent at a later date but prior to the first workshop. Written consent was supported by the co-researcher who read the consent form with translation to Bengali or Sylheti as required.

All PWL partners received a £75 gift voucher for each workshop attended in recognition of their work during and outside of the workshops. This amount was informed by NIHR rates for involvement in an activity that requires preparation and equates to approximately one half-day (NIHR, 2024). This reflected that partners were asked to consider activities or trial them at home in addition to direct workshop time. SLT partners did not receive remuneration for their time as workshops were scheduled during normal working hours.

Guideline	Descriptor	Action taken
Considering the communities which the research needs to involve	Identify who to include in the study and why their representation is important Consider potential barriers to recruitment	Researcher viewed ethnicity data from local borough and identified Bangladeshi population as majority ethnic group in study location Potential barriers identified as language, cultural beliefs, trust in healthcare systems, understanding reason for involvement in clinical research
Undertaking effective patient and public involvement in research	Use a model or approach that conducts research with or by the public rather than to or about them, involving at all stages	Working with doctoral project diversity advisor group to discuss approaches to engagement and involving PWL-B with co-design in early phases of intervention development
Conducting effective recruitment in BAME communities	Identify effective recruitment strategies and solutions to potential barriers	Co-working with multilingual HCPs from the Bangladeshi community to identify effective routes of information provision, clear messaging on the rationale for the research, appropriate location and timing of workshops
Ensuring cultural competence in the conduct of your research	Researcher self-evaluation and reflection to ensure research is conducted in harmony with cultural norms; and sub-conscious prejudices are identified and managed	Active self-reflection of researcher on positionality as a White-British female. Researcher discussion and learning with diversity advisor group to ensure practices are in keeping with cultural expectations
Providing effective feedback to research participants	Provision of relevant and accessible feedback. Explanation of how research outcomes will be disseminated and what may change	PWL-B partners updated at each workshop on the progress of the co-design process. Next steps for research dissemination and continuation discussed at final workshop

Table 6.2: Guidelines and actions to increase the participation of PWL-B. Adapted from Farooqi et al. (2022)

6.2.4. SAMPLE SIZE

The study aimed to recruit 20 participants in total, consisting of 10 SLTs and 10 PWL split across the PWL-A and PWL-B groups. Sample sizes within co-design studies vary and recommended sample sizes are not defined in literature. Co-production studies in other SLT areas, such as aphasia, have included a range of samples sizes, for example: four service users and four SLTs (Cruice et al., 2021); five service users, three family members and four SLTs (Wray et al., 2021). The aim of 10 SLTs was set to ensure diversity of work experience and demographics. Similarly, the target of 10 PWL across groups was to increase diversity whilst ensuring the groups were small enough to support communication, interpreting and enable all views to be heard.

6.2.5. DATA COLLECTION AND ANALYSIS

After consideration and discussion with the doctoral project's PAG and DAG, the decision was taken to hold separate groups for SLTs, PWL-A and PWL-B. The decision to hold separate groups reflected that SLT and PWL partners were working with different aspects of the co-design content (see workshop design below). Whilst PWL-A and PWL-B workshops followed the same content, the groups were separated to enable PWL-B workshops to be held in Bengali and Sylheti language; and to host the workshops in the preferred location of PWL-B partners.

SLT and PWL-A workshops were convened by the researcher (FS) and a White-British co-researcher/SLT experienced in laryngectomy rehabilitation and co-design (RH). PWL-B workshops were convened by the researcher and two co-researchers: a British-Bangladeshi SLT assistant (JKA) and a British-Bangladeshi Radiographer (SK). PWL-B workshops were led by JKA and SK in Bengali and Sylheti language, with live interpretation to English for the inclusion of the researcher. All PWL-B partners spoke some English to varying degrees and occasionally would speak directly to the researcher in English during the workshops.

Partners attended three workshops over an eight-week period, with typically two to three weeks between each workshop (range: 10 – 21 days). Workshop dates were alternated between SLTs and PWL to enable the researcher to facilitate the sharing of ideas and feedback across groups. Each SLT partner workshop lasted two hours with a break, whereas PWL partner workshops lasted approximately 2.5 hours with one or two breaks. SLT partners attended online workshops via Zoom videoconferencing, which were audio and video recorded. Virtual collaborative spaces were created using Padlet and Microsoft Word shared documents to capture data derived from workshop activities. Padlet (www.padlet.com) is a collaborative workspace where multiple users can create content at the same time on a virtual noticeboard.

PWL-A workshops were held in a meeting room at the university, whereas workshops with PWL-B partners were held in a meeting room at the London Muslim Centre. Workshops for PWL were audio recorded and hard copy outputs were produced on paper by drawing and writing. The researcher and co-researchers took written field notes, which were collated on paper. After each workshop the discussions were summarised into minutes and key outcomes, which were disseminated to participants via written or verbal feedback to check the accuracy of collected data. Photographs were taken of hard copy outputs. The researcher provided feedback at the start of each workshop regarding the outcomes of other groups' workshops.

6.2.6. WORKSHOP DESIGN

6.2.6.i. Workshop content

Workshop content was derived from the earlier outputs of the doctoral project and planned to meet the study aims. Figure 6.2 illustrates how earlier sub-projects informed the co-design process.

Outputs of earlier studies were shared with partners at the beginning of the co-design process to situate the co-design work and explain how workshop activities had been

formulated. For example, the systematic review and theoretical voice chapters (Chapter Two and Three) were used to provide context and set the scene of existing and potential interventions. The outcomes of the clinician survey (Chapter Four) and PWL focus groups (Chapter Five) led to the focus on assessment and outcome measures, and discussion of pathway design and prioritisation. The therapy targets highlighted in the focus groups and EMST study informed the intervention activities that SLT partners were asked to generate in the first workshop. Additionally, the outcomes of the focus group were taken forward to discussion of information provision.

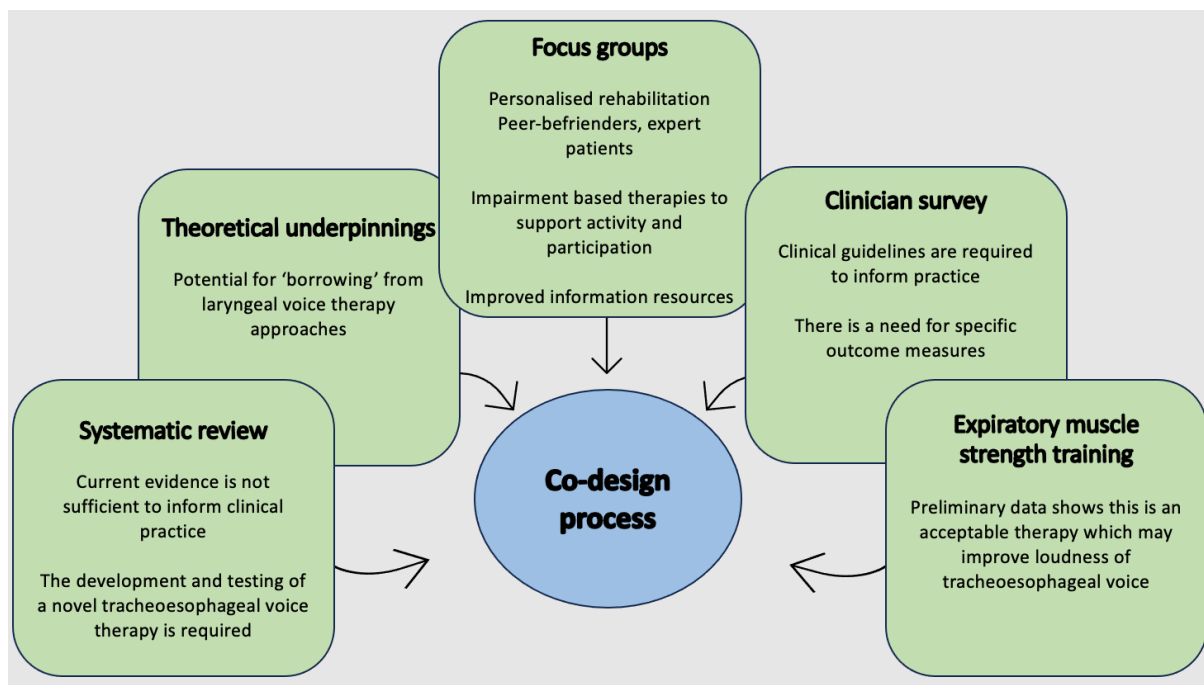


Figure 6.2: Inputs to co-design process

Tables 6.3 and 6.4 illustrate the aims and planned activities of each separate workshop for SLT and PWL partners. Whilst each workshop had specific aims, the content of the second and third workshops was iteratively refined based on the outcomes of the preceding workshops and inter-group feedback.

6.2.6.i.a. SLT partner workshop one aims

- Identify therapy ideas for volume, pitch, breath support, articulation, and for supporting activity and participation

For SLT partners, workshop one aimed to generate ideas for therapy activities, which could then be trialled by PWL. The *areas* of activity were informed by the intervention priorities cited by focus groups participants, i.e. volume, pitch, breath support, articulation, activity and participation; however, the specific approaches were generated by SLT partners within the workshop.

6.2.6.i.b. SLT partner workshop two aims

- Discuss SLT views on assessment and outcome measures
- Generate solutions to challenges raised by PWL

Workshop two focused on improving assessment and outcome measures towards a more patient-centred process, based on issues raised within the clinician survey and focus group data. This was also based upon feedback from the first PWL workshop, where outcomes of importance and experiences of assessment were discussed.

6.2.6.i.c. SLT partner workshop three aims

- Discuss feedback from PWL and consider solutions
- Discuss example voice therapy pathway

Workshop three built upon PWL feedback following trial of the voice activities generated in SLT workshop one and of their views on information and resources. Additionally, SLTs considered an ideal tracheoesophageal voice pathway and identified barriers and potential solutions.

6.2.6.i.d. PWL partner workshop one aims

- Identify what outcomes are important for voice
- To explore how outcomes should be assessed
- To understand what makes a positive experience of assessment

For PWL partners, workshop one aimed to elaborate on the themes raised by focus group participants around experiences of assessment. Partners considered what outcomes were important to them at different stages of recovery, leading to discussion of the elements that create a positive or negative experience of assessment. Partners reviewed existing SLT assessment tools to identify directions for improvement.

6.2.6.i.e. PWL partner workshop two aims

- To trial voice therapy activities as suggested by SLT partners in meeting one
- To define the role of the expert patient

Workshop two was experiential and partners were lead through active trial and experimentation with therapy activities generated by SLT partners in workshop one. Partners were guided through activities with encouragement to provide feedback and reflection of the acceptability. Partners then continued unstructured home-practice of activities between workshops.

6.2.5.i.f. PWL partner workshop three aims

- Feedback from home practice of therapy activities
- Discuss how therapy should be delivered
- Discuss information provision and resources
- Feedback on SLT partners views on assessment

Workshop three aimed to elicit PWL partners feedback following home practice and to capture views on dosage parameters. Additionally, the session focussed on brainstorming ideas to improve information provision, which was highlighted as a significant priority by focus group participants

6.2.6.ii. Workshop activities

A range of activities were implemented to elicit rich input from partners. This included group discussion supported by the principles of appreciative inquiry, flexible brainstorming, active trial and reflection on therapy activities. Appreciative inquiry (Cooperrider and Srivastva, 1987) is a positive psychology model developed within the Organisational Development field, which engages stakeholders in using affirmative approaches to create change. This is achieved by identifying existing positive aspects of a challenge to be addressed and using a positive paradigm to envision what aspects could and should be built upon to create desired change. Brainstorming is a creative problem-solving approach which emerged from the advertising industry. Brainstorming seeks to harness group level discussion and thinking to generate ideas to address a specific, clearly stated problem (Osborn, 1948).

Use of four specific techniques from the cocreation literature is outlined in more detail below.

1. A technique called *“Someone Who Isn’t Me”* or SWIM (Wilson et al., 2015) was used in PWL workshops as a method for extending the viewpoints offered. The technique asks partners to think about someone they know with the same condition, but who is different to themselves, thus creating their SWIM. Partners describe the characteristics or abilities that their SWIM may have, and then consider the needs and views of their SWIM alongside their own during workshop activities.

Liberating Structures (Lipmanowicz and McCandless, 2013) are a set of facilitation techniques to promote engagement, innovative thinking and organisational or community change. Activities, termed Liberating Structures, are used to facilitate the design of

innovations and solutions to a particular challenge. There are 33 Liberating Structures that can be selected from according to the challenge to be addressed. Three Liberating Structures techniques were used in SLT partner workshops, 1-2-4-All, Improv Prototyping and TRIZ.

2. In the *1-2-4-All activity*, partners are presented with an issue for which they are asked to propose solutions. Partners are given time for individual thought, which forms the basis for ideas generated in pairs and then discussed in groups of four, before sharing with the whole group.
3. *Improv Prototyping* requires a group of partners to present a scenario or process to an observing group of partners. The observers then discuss which elements of the process are deemed successful or unsuccessful, refining and re-presenting an improved process back to the first group. The Improv Prototyping technique was used to refine ideas proposed in the 1-2-4-All activity.
4. In the *TRIZ technique* partners list all that could be done to achieve the worst possible outcome for a particular objective. Partners then review their list to identify any existing practices or structures that resemble or could lead to the worst possible scenario. Finally, partners reflect on solutions or changes to existing practices and structures that would prevent the attainment of worst possible outcomes.

SLT partners workshop one	SLT partners workshop two	SLT partners workshop three
Aims: Identify therapy ideas for volume, pitch, breath support, articulation, and supporting activity and participation	Aims: Discuss SLT views on <u>assessment and outcome measures</u> Generate <u>solutions</u> to challenges raised by PWL	Aims: Discuss <u>feedback from PWL</u> and consider solutions Discuss example <u>voice therapy pathway</u>
Desired outcome: Generate therapy ideas to trial with PWL groups	Desired outcome: Identify components of patient centred assessment	Desired outcome: To identify challenges and next steps towards pathway implementation
Introductions: Project overview Explanation of co-design and setting group rules Discuss session aims 1-2-4-All (two groups in breakout rooms): Group 1 generates ideas for volume Group 2 generates ideas for pitch Groups exchange best ideas and capture on Padlet Improv Prototyping: Group 1 builds on group 2's best ideas for pitch, or suggests own, or modifies Group 2 builds on group 1's best ideas for volume, suggests own, or modifies Feedback to whole group for discussion Repeat 1-2-4-All and Improv Prototyping rounds: Repeat with breath support, articulation, activity and participation focus Meeting summary and close	Convene group: Matters arising from SLT partners meeting one Feedback from PWL first meetings Discuss session aims Assessment review: Individual time to look at typical voice therapy assessments and make reflections TRIZ technique round one: Partners respond to the question on Padlet: What would the worst assessment ever include? Partners respond to the question on Padlet: What do we do that gets close to this? Outcomes of clinician survey and PWL meeting one presented by researcher: 1-2-4-All activity to identify the threads of an acceptable assessment Meeting summary and close	Convene group: Matters arising from SLT partners meeting two Discuss session aims Feedback from PWL groups: Including PWL partner views on therapy exercises and home practice PWL views on group therapy and peer support, information and resources Update on PWL solutions for SLT assessment challenges The ideal pathway: Group discussion and brainstorming to create a sample pathway for voice rehabilitation Individual time for SLT partners to reflect on sample pathway, identifying barriers and potential solutions on shared document Group discussion of reflections on proposed barriers and solutions Meeting summary and close

Table 6.3: SLT partner workshops

PWL partners workshop one	PWL partners workshop two	PWL partners workshop three
Aims: Identify what outcomes are important for voice To explore how outcomes should be assessed To understand what makes a positive experience of assessment	Aims: To trial voice therapy activities as suggested by SLT partners in meeting one To define the role of the expert patient	Aims: Feedback from home practice of therapy activities Discuss how therapy should be delivered Discuss information provision and resources Feedback on SLT partners views on assessment
Desired outcome: To establish therapy priorities and acceptability of assessment To understand how assessment looks at different stages To identify any primary outcomes	Desired outcome: To obtain service user feedback on voice therapy ideas To explore how PWL partners would like to be engaged in peer befriending and supporting others	Desired outcome: To gain information on the potential content of a therapy programme, and associated information resources
Introductions: Project overview, explanation of co-design and setting of group rules, discussion of session aims Review of typical SLT assessments and discussion What does good assessment look like? 1-2-share: Post-it notes for what to keep, add or discard Summarise responses into key principles of assessment What outcomes are important at different stages? Partners draw their timeline from pre-surgery to now, deciding on how to define their own stages Process mapping: what outcomes were important at each stage? How could assessment be personalised at each stage?	Convene group: Matters arising from PWL partners meeting one Discuss session aims Active experimentation with therapy ideas: Habitual posture and grounding Body scanning and reducing tension Stretching and range of motion exercises Breathing pattern awareness Exploring breath in diaphragm, thoracic and back body Accent method Breath support pacing and stamina exercises Forward resonance, trial of lax vox and EMST Articulation exercises and exploration of speech sounds Trialling pitch glides, pitch bouncing and sirening Exploring twang resonance	Convene group: Matters arising from PWL partners meeting two Discuss session aims Feedback on therapy trials: Group discussion for partner feedback and reflections following trial of voice exercises at home Defining a therapy programme: Group discussion to identify factors such as timing of voice practice, frequency, dosage and intensity of practice, important markers of change How can information be improved? Brainstorming session on provision of information including format, modality and timing Feedback on SLT partner views of assessment:

PWL partners workshop one	PWL partners workshop two	PWL partners workshop three
Someone who isn't me: SWIM: Partners design their SWIM person and process maps their outcomes of importance Meeting summary and close	The expert patient: Group discussion and brainstorming on definitions of the role Meeting summary and close	Summary of SLT partner suggestions for group feedback Meeting summary and close

Table 6.4 PWL partner workshops

6.3. RESULTS

6.3.1. CO-DESIGN PARTNERS

Nineteen partners took part in the co-design process, comprising 10 SLTs and nine PWL. In the PWL groups there were three PWL-B and six PWL-A partners. One additional PWL-B expressed an interest but did not participate due to travel distance, as they lived outside of the study borough. Tables 7.5 and 7.6 provide information on partner characteristics.

PWL-B participants were all male with a mean (SD) of 55.67 (21.13) years and mean average of 82.66 (129.34) months post laryngectomy, the range of months post laryngectomy was wide at 6-232 months, however. All PWL-B partners had adjuvant radiotherapy and whilst none were in employment at the time of participating, all had worked prior to laryngectomy.

PWL-A partners had a mean (SD) age of 54.00 (11.40) years. Four partners were male and two female. The mean (SD) average months post laryngectomy was 46.00 (37.06) months and the majority of partners had received radiotherapy before ($n = 3$) or after ($n = 2$) laryngectomy. Most partners were working either full or part-time.

SLT partners were predominantly female ($n = 9$) and White-British. The mean (SD) average duration of clinical experience in head and neck cancer was 12.10 (5.61) years. Partners attended from diverse geographical regions and represented difference service types from community, domiciliary, inpatient and outpatient settings.

Group	Gender	Age (yrs)	Ethnicity	Months post laryngectomy	Radiotherapy	Work status	Current or last role
PWL-B	Male	45	Bangladeshi	6	Post-surgery	Not working	Chef
PWL-B	Male	80	Bangladeshi	232	Post-surgery	Retired	Food preparation
PWL-B	Male	42	Bangladeshi	10	Post-surgery	Not working	Delivery driver
PWL-A	Male	68	African	17	Post-surgery	Modified work activities	Journalist
PWL-A	Female	56	British Pakistani	98	Post-surgery	Not working	Nursery teacher
PWL-A	Male	43	White British	20	Pre-surgery	Full time	Construction
PWL-A	Male	62	White European	38	Pre-surgery	Part time	Chef
PWL-A	Female	57	White British	87	Pre-surgery	Part time	Accountant
PWL-A	Male	38	White British	16	None	Full time	Construction

Table 6.5: PWL partner characteristics

Gender	Ethnicity	Years of experience	Location	NHS service type	Pathway experiences
Female	White British	15	London	Surgical centre	Inpatient, outpatient
Female	White British	10	South-East	Surgical centre	Inpatient, outpatient, community, domiciliary
Male	White British	3	London	Community healthcare	Community, domiciliary
Female	White British	14	Wales	Surgical centre	Inpatient, outpatient
Female	White British	15	Midlands	Oncology centre	Inpatient, outpatient
Female	White British	11	North-West	Surgical and oncology centre	Inpatient, outpatient
Female	British Asian	14	North-East	Surgical centre	Inpatient, outpatient
Female	White British	11	Yorkshire	Oncology centre	Inpatient, outpatient, community
Female	White British	23	North-East	Surgical centre	Inpatient, outpatient
Female	White British	5	Midlands	Surgical and oncology centre	Inpatient, outpatient

Table 6.6: SLT partner characteristics

6.3.2. APPROACHES TO ASSESSMENT AND OUTCOME MEASUREMENT

Partners worked together to identify the potential elements of a tracheoesophageal voice therapy intervention. This included assessment and measurement of outcomes, exploration of therapy activities and approaches to support participation, peer support and the provision of information.

6.3.2.i. Outcomes of importance to PWL

In order to improve communication assessment and administration of outcome measures, it was first necessary to understand what outcomes are important to PWL and how the experience of being assessed could be optimised. PWL partners were encouraged to draw out their personal laryngectomy pathway, thinking about what voice outcomes were important to them at different stages. Specific timepoints were not proposed by the researchers so that PWL could represent their individual pathways as they wished to define them. Pathways were then shared with the intention of identifying the most important outcomes for tracheoesophageal voice rehabilitation. However, this activity demonstrated that individual pathways differed greatly and so it was not feasible to identify a core set of voice related outcomes, as priorities were informed by individual needs. Furthermore, PWL partners noted that priorities changed over time and did not necessarily follow an expected or unidirectional trajectory.

Figures 6.3 and 6.4 illustrate two differing post-laryngectomy pathways. In Figure 6.3 the PWL partner established tracheoesophageal voice relatively soon post-surgery and therefore their important outcomes centred on continued step-wise progress, returning to health and fitness and building links with the laryngectomy community. This contrasts to the pathway represented in Figure 6.4 where the focus on tracheoesophageal voice did not become prioritised until five years after laryngectomy. Given the changing needs over time, PWL felt that assessment processes should be flexible and responsive to individual needs.

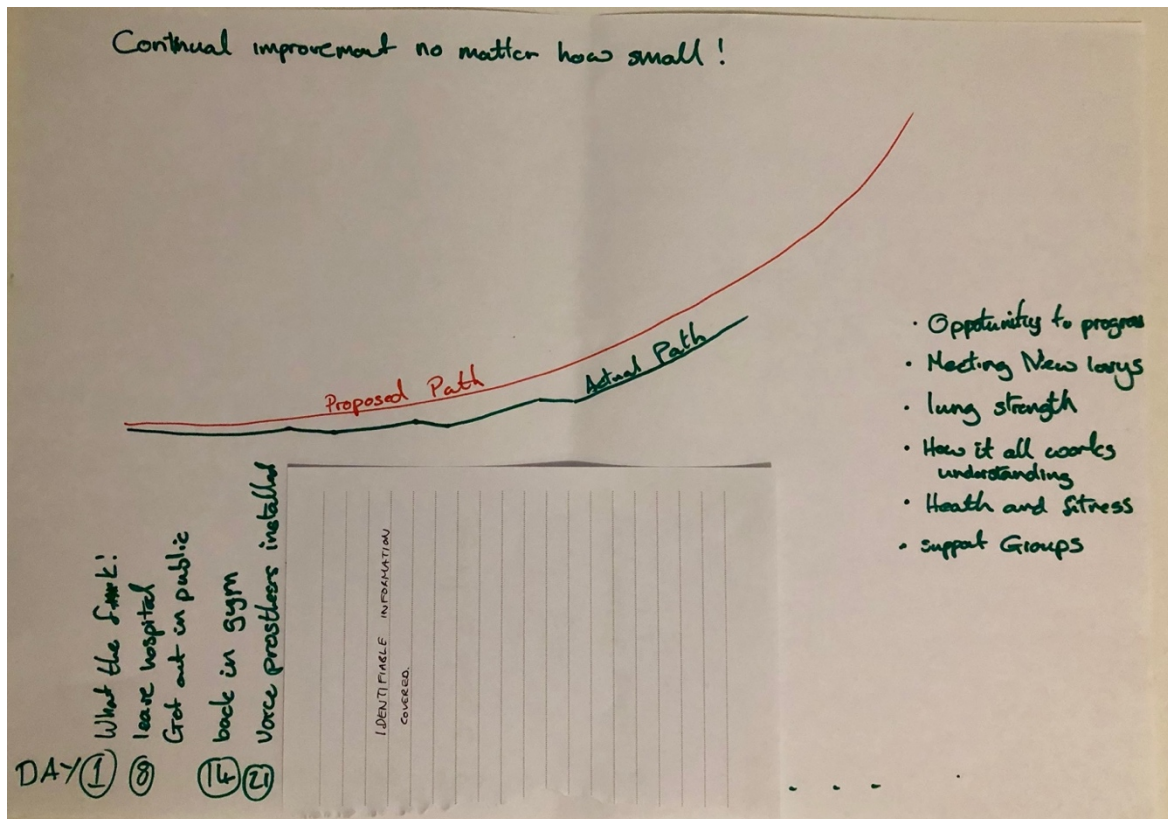


Figure 6.3: Example of PWL post-surgical pathway

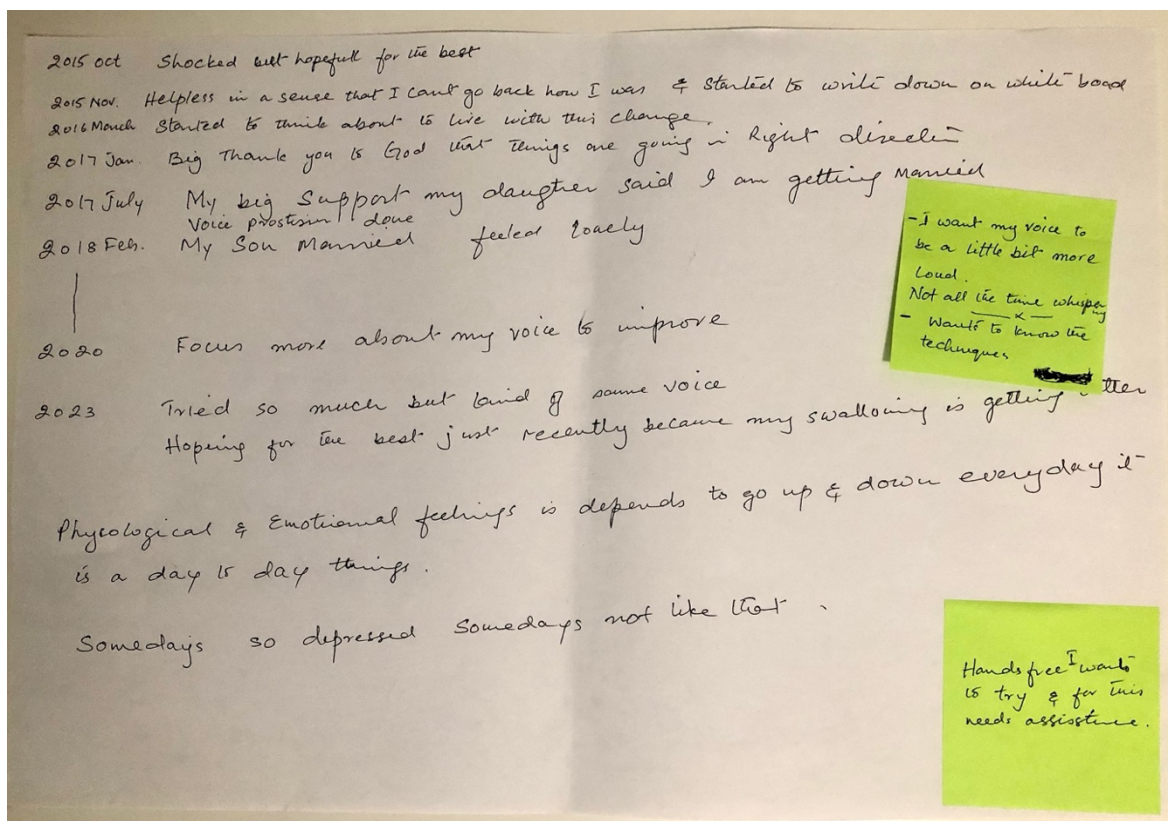


Figure 6.4: Example of PWL post-surgical pathway

6.3.2.ii. PWL experiences of assessment

PWL partners were asked to reflect on their experiences of being assessed and to provide feedback on standard voice outcome measures. Here, PWL partners described uncertainty as to what the purpose of assessments is, and whether they are for the benefit of the individual or the SLT agenda. Where the aims of assessment were unclear, the process did not feel meaningful for PWL partners and was viewed as a process to meet SLT requirements. The researchers gave context that outcome measures may also be used by SLTs to demonstrate efficacy and value of services. Whilst this was understood by PWL partners, it remained essential that assessment should be relevant and worthwhile, therefore there was a need to find balance between these elements.

PWL-B partners experienced assessment as involving many questions, which did not feel relevant to their life as an individual and did not capture a holistic picture of interests, activities, work and social domains. There was a desire for a narrative based assessment, rather than binary or closed questions. This aligned to PWL-A partners' views that assessment should be collaborative and based in meaningful conversation between the SLT and service user. PWL-B partners suggested that it could be helpful to have a laryngectomy visitor present during assessment to support goal setting. The presence of a laryngectomy visitor, described by PWL-B as a 'successful patient' was valued for showing people what voice outcomes could be possible to achieve. This was seen by PWL-B as more important than information SLT could provide on potential voice outcomes.

Focussing specifically on outcome measures, PWL felt that measures were detached from the reality of their experience and did not capture different modes of voice use such as telephone, singing or prayer. Of the outcome measure examples shared, PWL partners noted the SECEL was a comparatively better outcome measure, which is one of few measures designed specifically for PWL. Additionally, PWL partners reported that assessment omitted important factors such as psychological needs and use of hands. Given that hand-to-stoma occlusion is necessary for the majority of tracheoesophageal speakers, assessment of hand use was reported as essential. One PWL partner working in construction gave an example of how, when using both hands to hold power tools, communication ability was affected, as it

was not possible to simultaneously occlude for voicing. A key criticism of PWL partners was that outcome measures used negative and ableist language, such as describing voice quality as deviant or handicapped (Figure 6.5). Across both groups, PWL partners considered outcome measures to be negatively framed upon what an individual is unable to do, rather than focussed on maximising existing ability and function. PWL-B partners observed that linguistic translation of measures was insufficient as certain domains or questions did not translate culturally and were not meaningful to the community.

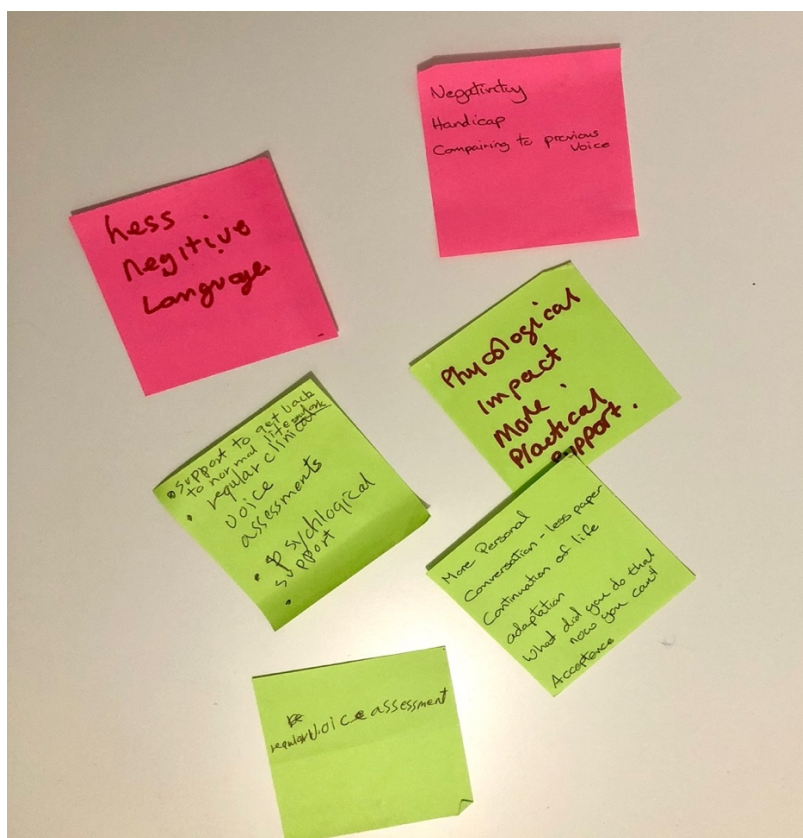


Figure 6.5: PWL partner views on elements to add or discard from assessment

6.3.3.iii. SLT views on assessment

SLT partners were presented with PWL partner feedback and frequently used outcome measures before completing the Liberating Structures TRIZ activity to identify barriers and negative practices. This was captured on Padlet, with an excerpt shown in Figure 6.6. SLT partners agreed that a sub-optimal assessment would be non-collaborative and led by the agenda of the clinician or the outcome measure used, rather than following the PWL's agenda. Other negative elements were identified as use of labelling, not providing rationale as to why the assessment is being carried out or context for the questions asked. SLT partners agreed strongly that assessment should be individualised and dynamic with a focus on function rather than perceptual elements of the voice.

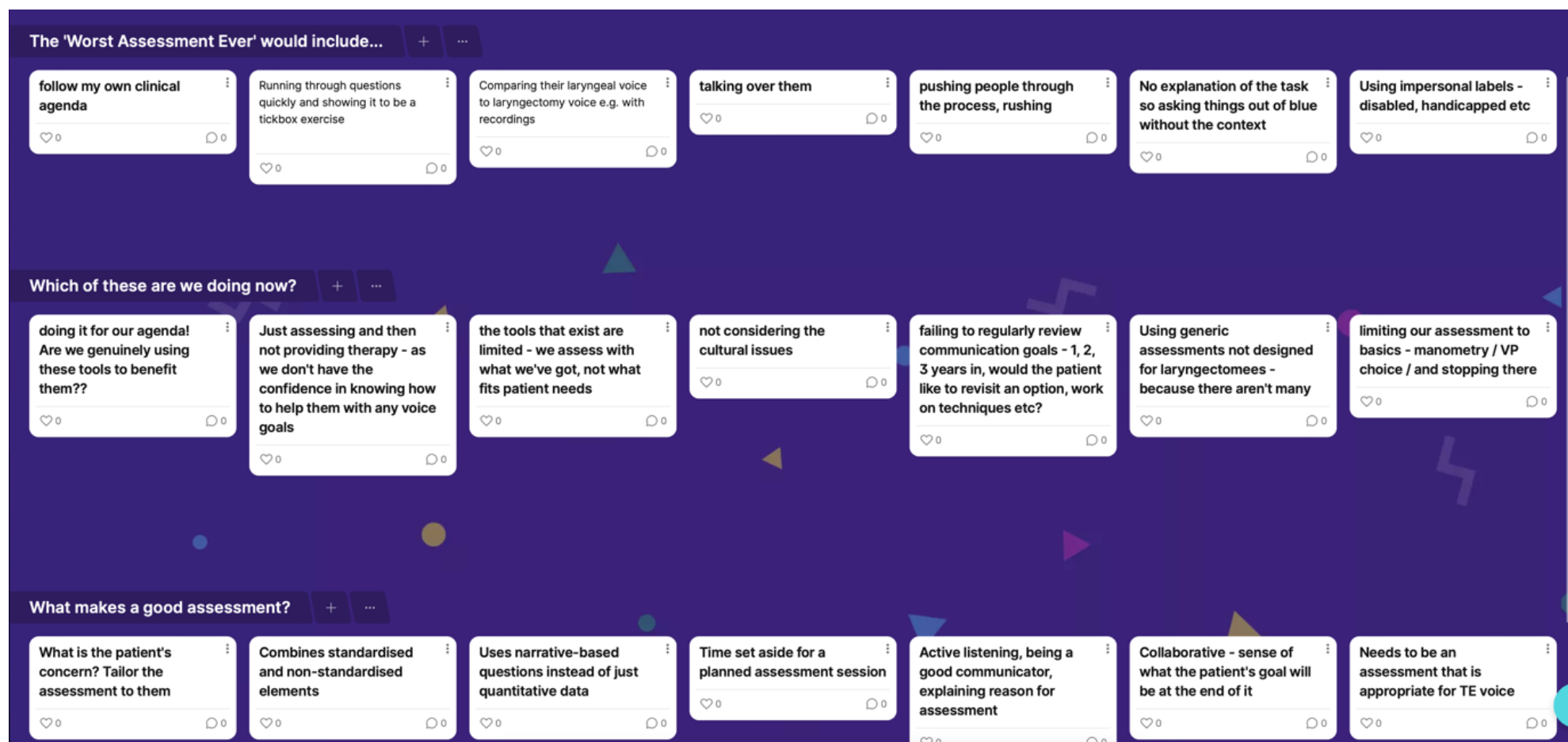


Figure 6.6: Excerpt of SLT partner responses to TRIZ activity captured on Padlet

SLT partners identified where barriers exist that could lead to negative practices within assessment. Highlighted barriers included lack of laryngectomy-specific assessment tools, insufficient clinical time and pressure to balance clinical outcomes with a meaningful service user experience. SLT partners also felt that assessment was influenced by lack of evidence base and approaches for therapy. There was uncertainty over asking detailed questions about voice where SLTs have limited confidence and knowledge about what change might be possible. Similarly, SLTs observed that discussion of tracheoesophageal voice may reveal feelings of grief or psychological support needs which go beyond the boundary of SLT practice. However, SLT partners reflected that there was a need to explore voice use in a detailed, holistic manner; and to avoid assumptions that where tracheoesophageal voice was established, it was sufficient. It was also observed that communication post-laryngectomy typically is overlooked in prioritising stoma and prosthesis maintenance. Partners noted that this contrasts with other areas of practice, such as stroke rehabilitation, where detailed communication histories and patient-centred goal setting are routine alongside dysphagia management.

6.3.3. A PATHWAY FOR TRACHEOESOPHAGEAL VOICE THERAPY

SLT partners considered solutions and worked to identify the key elements of an individualised, collaborative tracheoesophageal voice intervention. The elements proposed by PWL and SLT partners were captured into an intervention pathway mapping document (Appendix 6.3 with excerpt shown in Figure 6.7).

Sample pathway for laryngectomy voice therapy				
Stage	Activity	Barriers	Solutions	Comments/ideas
Pre op	Pre-treat session with protected time to focus in depth on voice and communication, including: Detailed communication history (think of approach used in stroke or laryngeal voice therapy, Identifying person's communicative roles – life, work, social Activities involving use of hands that may affect communication	Where to fit this in to busy pre-op pathway Time is an issue as this is an extra session	Discuss with MDT about a particular time/making this essential If it is specifically a voice case hx does it need to be an SLT that does this, could be an assistant, B5 or student following a protocol Start or end an MDT session with protected time Finding the best time Using a questionnaire for the background communication history – a communication passport like in aphasia Going out to the home to get a real idea of the person Fine tune the pathway to know who needs pre-op	Needs a dedicated session to get best out of patient Concern that we don't always know the true voice outcome for people Might not be the person's agenda Issue is that people get to post-op and they just stop doing their activities. Idea that communication history is known so SLTs can check what they have continued / stop doing. Who is this person? Getting them closer to the real you. Also using B5 and students good to <u>open up</u> workforce and engage people early.

Figure 6.7: Excerpt from intervention pathway mapping

Discussion of key elements led to priorities for further co-design work, such as the production of a narrative-based communication history protocol that is collaborative, positively framed and culturally appropriate. SLT partners considered that an individualised communication history that leads into goal setting and therapy may feel more meaningful and relevant to PWL. SLT partners were mindful that assessment and outcome measures should not compare tracheoesophageal voice to laryngeal voice as a baseline of normal voice quality. SLT partners observed that it would be important to complete a communication history prior to surgery to ensure there is a clear picture of the individual's typical activities and voice use. It was noted that this could guide therapy and goal setting post-operatively towards getting the PWL as close as possible to their pre-laryngectomy activity and participation. However, a challenge was identified as to how this could be achieved within the short pre-operative window between diagnosis and surgery when multiple MDT assessments and preparations are taking place. SLT partners working in community settings highlighted a challenge where the communication needs of PWL within the hospital differ greatly to their communication on return home. This was identified as an important factor to address in assessment.

To address the deprioritisation of voice therapy post-operatively, SLT partners suggested that a dedicated session is planned for communication assessment only. This may require reconfiguration of existing clinic resources to protect time for communication focus. SLT partners proposed that, with training, this could be undertaken by an SLT assistant or early career SLT to maximise resources. This suggestion was received positively by PWL, and it was expressed that it would be more acceptable to complete 'tick box' measures if they followed a holistic, collaborative communication session. PWL partners also advocated for a yearly communication check-in session for people who have been living for some time post-laryngectomy, to ensure that changing needs are not missed.

6.3.3.i. Content of a tracheoesophageal voice therapy intervention

SLT partners worked to generate therapy activities and refine them through collaborative discussion. This process was completed through the use of Liberating Structures techniques, which were used effectively to meet the aims. SLT partners focussed on the sub-elements of volume, pitch, breath support, articulation; and they aligned these to approaches for increasing activity and participation. Ideas were captured on Padlet, which is illustrated in Figure 6.8. This section first presents the therapy ideas presented by SLT partners, followed by PWL feedback to these ideas. SLT partners generated therapy ideas based upon the key target areas that emerged from the focus group study.

freyparks • 26d
SLT Co-design1
Voice therapy ideas

How to improve volume?

0 16

- Anonymous 26d
If Hypotonic, add digital pressure
- Anonymous 26d
Haven't seen breath work being effective (too much back pressure, blasts HMEs)
- Anonymous 26d
?EMST (a/w Freyas results!)
- Anonymous 26d
Twang?
- Anonymous 26d
Posture and relaxation
- Anonymous 26d
?improve articulation to improve clarity (ie difficulties perceived as poor volume but not nec)
- Anonymous 26d
Changing head posture to increase or decrease volume
- Anonymous 26d
Visualisation e.g. imagine distance and actively increase to reach
- Anonymous 26d
Use of manometry for biofeedback
- Anonymous 26d
Feedback with decibel meter
- Anonymous 26d
Optimisation of valve/adhesives etc.
- Anonymous 26d
Amplification devices
- Anonymous 26d
Reducing background noise - problem solving for different environments
- Anonymous 26d

How to improve pitch range/control

0 13

- Anonymous 26d
Focus on features that promote a "brighter" sound e.g. forward resonance, to create an impression of higher pitch
- Anonymous 26d
Focus on other features e.g. articulation, choice of language that impact on perception of voice
- Anonymous 26d
Is it anatomically possible to alter pitch much?
- Anonymous 26d
?any technology to alter voice pitch on phone
- Anonymous 26d
Introduce base of tongue tension
- Anonymous 26d
laronix technology
- Anonymous 26d
Singing groups
- Anonymous 26d
Limit/ adapt facial expression (changing vocal tract)
- freyparks 26d
Pharyngeal shortening
- Anonymous 26d
'ee,or'/'sirening' techniques
- Anonymous 26d
Intonation/ prosody work e.g. raising pitch end of question
- Anonymous 26d
prehab? pitch technique and awareness

How to work on articulation?

0 20

- freyparks 1mo
Oral/articulation activities to improve shaping of words
- Anonymous 26d
minimal pairs early on
- Anonymous 26d
encourage over articulation
- Anonymous 26d
consider rate of speech
- Anonymous 26d
optimise dentition
- Anonymous 26d
if secondary puncture.... encourage any talking! (out of the habit)
- Anonymous 26d
avoid excess effort/ pressure
- Anonymous 26d
period of avoiding VP use post op encourages practice of good articulation
- Anonymous 26d
demonstrate what they are doing successfully e.g. ask people to look at them etc
- Anonymous 26d
ATOS demo videos to show how to do it well
- Anonymous 26d
learning to 'fix problems' rather than carry on sentence when broken e.g. stoma blast/ valve blocked/ gurgley.
- Anonymous 26d
Biofeedback (passage recordings)
- Anonymous 26d
Silent mouthing practice (?as prehab)

How to work on breath support and coordination?

0 14

- freyparks 1mo
Target deeper diaphragmatic breathing
- Anonymous 26d
Manometry for biofeedback
- Anonymous 26d
Optimise lung health with HMEs
- Anonymous 26d
Optimise posture
- Anonymous 26d
Accent method - rhythmic breathing in time with digital occlusion of stoma
- Anonymous 26d
Flow phonation - for efficiency of breathing and coordination of voicing
- Anonymous 26d
EMST
- Anonymous 26d
Pacing and phrase length - planning when to take breaths to maintain good breath support throughout phrase
- Anonymous 26d
Joint working with physio to look at resting breathing pattern (e.g. lower vs upper thoracic)
- Anonymous 26d
?LaxVox/straw phonation - difficult to coordinate holding straw and occluding stoma
- Anonymous 26d
general deconditioning/ general fitness to support breath
- Anonymous 26d
reminders about ongoing pulmonary care eg continuing use of nebs

Activities to support participation / confidence and carry over to daily life

0 10

- Anonymous 1mo
Education re video calling to allow visualisation (family etc)
- Anonymous 26d
timing of therapy
- Anonymous 26d
voice banking
- Anonymous 26d
Supported trips to coffee shop
- Anonymous 26d
Phone call to SLT assistant
- Anonymous 26d
Buddy systems
- Anonymous 26d
lead in sentences in public
- Anonymous 26d
phone call practice/ random spot check phone calls
- Anonymous 26d
Script training
- Anonymous 26d
would patients want to have supported work in the community setting? shops etc

Other ideas for voice therapy

0 2

- freyparks 1mo
Postural changes e.g. centering head and chin tuck
- freyparks 1mo
Use of visualisation, e.g. visualising deeper tones

Figure 6.8: Excerpt of ideas generated on voice therapy content captured on Padlet

6.3.3.i.a. Volume

As a foundation to the above sub-elements, SLT partners placed importance on establishing an optimised regimen of stoma protectors and humidification; and ensuring good stoma and prosthesis care. This was seen as an essential starting point, with the belief that impairment-based therapies would not be effective without this foundation. Partners compared this to implementing good vocal hygiene as a first step of laryngeal voice therapy. As part of equipment optimisation SLT partners queried whether voice prosthesis diameter could influence volume; the rationale here was the potential for increased airflow through a larger diameter prosthesis to increase volume.

Direct therapy approaches for volume centred on optimising posture and addressing soft tissue problems such as increased muscle tension, which could inhibit vocal projection. Additionally, targeting breath support through the use of breathing exercises was viewed as important for volume. SLT partners had been informed of the outcomes of the EMST pilot study and were interested in using this approach as part of intervention targeting breath support. The role of resonance was discussed in relation to volume, where SLT partners considered the potential of twang quality, which is an element of Estill Voice Training (discussed in Chapter Two) commonly offered to increase perceptual volume in laryngeal speakers.

Furthermore, SLT partners agreed that therapy for volume should incorporate exercises for improving vocal projection. Here direct projection exercises were advised to be supported with mental strategies such as visualisation, identifying an object or person further away. Biofeedback was also cited by SLT partners to aid self-monitoring and progress during therapy sessions, such as the use of tracheal manometry and decibel meters.

In considering volume, SLT partners related this to tonicity, querying if the application of digital pressure could improve volume for PWL with hypotonic voices. The hypothesis presented was that digital pressure could approximate the walls of the vibratory segment to achieve a greater amplitude of vibration. Other postural modifications were suggested for the same reason, such as trialling head turns or positioning to increase vibratory segment

contact. Additional compensatory or augmentative approaches were proposed, such as the use of amplifiers, reducing background noise and modifying the environment to support low volume voice. SLT partners highlighted the need to check for co-existing factors, such as clarifying if speech volume was indeed the cause of communication breakdowns, or whether intelligibility and voice quality were also factors.

6.3.3.i.b. Pitch

When generating ideas for pitch activities, most SLT partners reported limited experience of pitch work and held the belief that pitch is unlikely to be amenable to change in PWL. This reflected the survey finding that few SLTs work on pitch with tracheoesophageal speakers and perhaps points to a rationale for the lack of implementation. Furthermore, SLT partners expressed the assumption that only female PWL would be likely to want to work on pitch, and that the therapy target would be to raise, not lower, modal pitch. This contrasts to the focus group data where men also expressed misgendering and modal pitch concerns.

In contrast, the researcher (FS) and co-researcher (RH) shared examples of service users who were able to modify pitch significantly, evidencing that pitch range was possible for tracheoesophageal speakers. This led to discussion on what could be modified physiologically to alter pitch, in the absence of vocal folds, and interest in exploring neopharyngeal function. Specifically, SLT partners considered whether neopharyngeal shortening could have a mechanistic role in pitch variation. Here there was consideration of whether laryngopharyngeal dysphagia and voice exercises such as the Mendelsohn, or pitch sirening exercises could influence neopharyngeal length and therefore perceived pitch.

Altering resonance through the modification of oral structures was seen as an important part of pitch work. SLT partners suggested direct therapy approaches such as forward resonance, placement of articulation and modifying tongue tension to 'lighten' perceived pitch. Other direct approaches proposed were the use of intonation and prosody exercises to target pitch variation in connected speech. Again, the use of visualisation and prompts was advised, such as cueing pitch variation by moving hand position up and down. SLT partners were interested

to explore outcomes for pitch that could be gained through singing practices, referencing the work of the Shout at Cancer laryngectomy choir as a potential source of information for this approach.

The potential for augmentative technology to support pitch was highlighted by SLT partners. Whilst partners were not aware of any existing technology, the development of applications was advocated for. Specifically, SLT partners suggested a telephone-based app that could modify pitch upwards in real time.

In regard to pitch variation, SLT partners reflected on whether pre-operative vocal function influences post-operative tracheoesophageal voice quality. SLT partners questioned whether having knowledge of how to modify pitch before laryngectomy could enable post operative control of tracheoesophageal voice. Here, the role of pre-habilitation was contemplated positively with the view that an individual's knowledge of voice production may be minimal before laryngectomy. Importance was placed on upskilling knowledge of voice production and modification before laryngectomy to support post-surgical voice therapy.

6.3.3.i.c. Breath support

SLT partners proposed several approaches to improving breath support. It was felt that before commencing these exercises, attention should be placed on optimising posture and pulmonary health, through the implementation of nebuliser regimens and review of stoma care items. SLT partners noted variability in access to Physiotherapy within Head and Neck cancer MDTs, however, working in partnership with Physiotherapists to establish adequate breathing patterns was seen as an important precursor to breath work. SLT partners also believed they had a role in promoting general lung health through encouraging walking and other physical activity after laryngectomy.

Similarly to discussions on pitch exercises, SLT partners considered the mechanisms underlying breath support in tracheoesophageal voice and expressed a lack of clarity on what could be a modifiable target. Discussion centred on the voice prosthesis, where they noted

that the dimensions of the prosthesis only allow a specific amount of airflow through to the neopharynx, hence aiming to increase amplitude of neopharyngeal vibration by increasing breath support may be ineffective. SLT partners also considered the impact of the open tracheostoma and absence of vocal folds in relation to semi-occluded vocal tract approaches (Titze, 2006). As semi-occluded vocal tract approaches increase supra-glottic pressure to promote efficient vocal fold function, it was unclear what effect they would have on the post-laryngectomy vibratory segment.

Instead, SLT partners felt that breathwork should focus on what could be responsive to change, namely respiratory stamina and breath control for speech. Suggestions included setting the foundations of postural alignment to support breath work, before exploring thoracic and diaphragmatic breathing patterns. To ensure transference to speech, SLT partners advocated for Accent Method (Thyme-Frøkjær and Frøkjær-Jensen, 2021) which aims to coordinate breathing, voice and articulation for efficient voice production. Pacing exercises were also highlighted to target efficient voice production, with the aim of optimising breath to phrase length. It was observed that tracheoesophageal voice quality should be prioritised over phrase length. SLT partners felt that semi-occluded vocal tract approaches could be adapted here for use as a breath pacing and coordination exercise. Additionally digital occlusion of the stoma was viewed as a core element of breath work, to ensure that coordination of occlusion to speech onset was effective and avoided excess pressure or stoma blast.

6.3.3.i.d. Articulation

SLT partners identified the time immediately post-surgery as a potential window to focus on articulation, as PWL will have not started to use tracheoesophageal voice due to wound healing requirements. Furthermore, PWL awaiting tracheoesophageal puncture as a secondary procedure would have a period without voicing and could benefit from articulation practice during that time. All partners acknowledged that articulation work was important to support intelligibility regardless of whether the PWL was speaking with a voice prosthesis or using an alternative method such as electrolarynx or silent articulation for lip-reading.

Precursors to articulation work included assessment of oromotor function, oral health and dentition, with signposting to services such as Restorative Dentistry as required. SLT partners observed that radiotherapy or extended surgery incorporating the oral cavity could impact on function, for example due to hypoglossal nerve damage or xerostomia. Suggested therapy exercises included drilling of minimal pairs and silent articulation to improve speech clarity, which could be achieved through dysarthria exercises and less traditional approaches such as beatboxing. Partners also considered the potential to borrow from dysphagia exercises for oral control. Audio recording of articulation practice was recommended during SLT sessions as a means of online monitoring and biofeedback.

The researchers prompted SLT partners to identify solutions for producing the /h/ phoneme, which was noted by focus group participants to be a particular challenge. SLT partners agreed that further exploration of /h/ production was required; and suggested that if individuals could not produce this, an alternative could be to substitute with a different placement. For example, substituting /h/ for a uvular fricative by raising the posterior tongue, so as to create a 'ch' sound (such as in Bach) in place of the /h/ phoneme. This led to discussion amongst SLT partners on how voice onset and offset could be achieved post-laryngectomy, and to what extent the vibratory segment was under the voluntary control of tracheoesophageal speakers. For example, where laryngeal speakers are able to close the glottis without voicing, it was unclear whether tracheoesophageal speakers were able to approximate the vibratory segment in the same way.

6.3.3.i.e. Activity and participation

SLT partners noted that activities to support participation and carry over to real-world scenarios were often impacted by insufficient time resource. SLT partners working in community and domiciliary settings felt there was more opportunity to achieve this as they were present to observe how communication occurred in the home or family environments. However, the need for additional risk assessments was a barrier to working with PWL in community environments, for example making a visit to a local shop. Specifically, this was due to the additional administrative burden of completing risk assessment and, for hospital-based

SLTs, uncertainty around processes and governance of working with PWL outside of the hospital. Instead, hospital-based SLT partners gave examples of visiting the hospital café with PWL to practice ordering: this was not routine practice, however. Additionally, goal setting was targeted at goals to translate impairment-based work into functional settings, for example, with the practice of functional phrases individualised to the PWL's day-to-day life. Practice of functional phrases within a therapy session, such as pronouncing a regular coffee order, could be used to practice articulation and phonation onset, in addition to scaffolding a carry over goal such as subsequently using the phrase in a 'real world' setting to order a drink.

SLT partners agreed that carry over activities should aim to build confidence in communication, but were uncertain how to achieve this and suggested that PWL could provide advice on appropriate strategies. SLT partners stated the importance of framing communication to PWL as a two-way process with shared burden, in which listeners are active. This was addressed in therapy by involving familiar communication partners, implementing strategies to resolve communication breakdowns and practicing what to do if the PWL could not be understood.

There was evidence of the SLT role in assisting PWL with technology, where there was consistent practice of aiding PWL to use smartphones and video-calling to support communication. This was embedded by practicing calls with the SLT or an assistant during therapy sessions.

6.3.3.ii. PWL feedback on SLT partner suggestions

PWL trialled the above voice activities in an exploratory workshop, which included exercises for posture, breath control, articulation, resonance and pitch. Following the workshop, PWL were encouraged to trial the exercises in home practice. Both PWL groups engaged positively in workshop activities which were perceived as potentially beneficial for the voice. However, a limiting factor for all PWL partners was the absence of prior experience of tracheoesophageal voice work, as this is not currently established in SLT practice. Therefore, PWL partner feedback could not be informed by extensive lived experience of therapy

activities and instead was to some extent hypothetical, based upon brief exposure to therapy activities during the workshop and home practice. Furthermore, it was evident that PWL partners did not have clear understanding of tracheoesophageal voice production, which points to the need for an educational component of tracheoesophageal voice therapy. Figures 6.9 and 6.10 illustrate the ideas and feedback captured during the workshop.

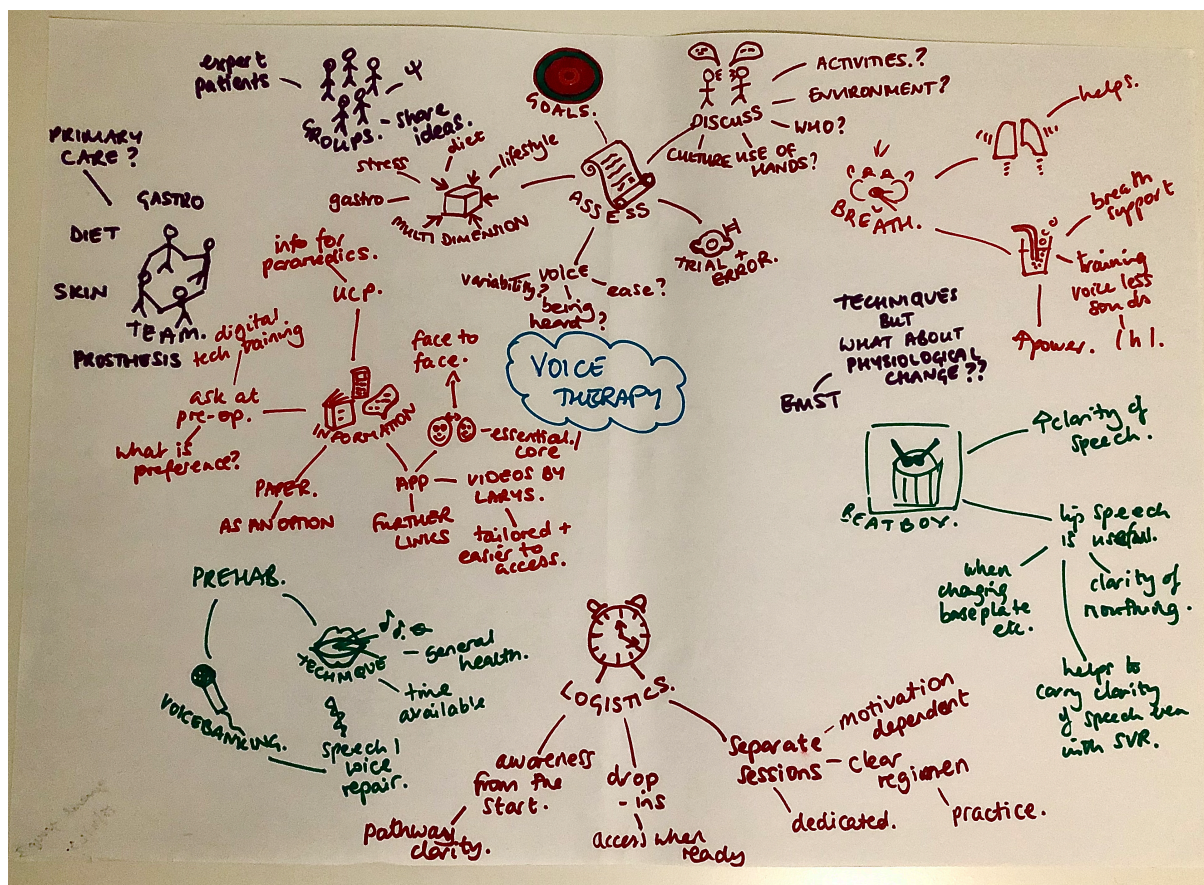


Figure 6.9: Brainstorm map of voice therapy trials in PWL-A group

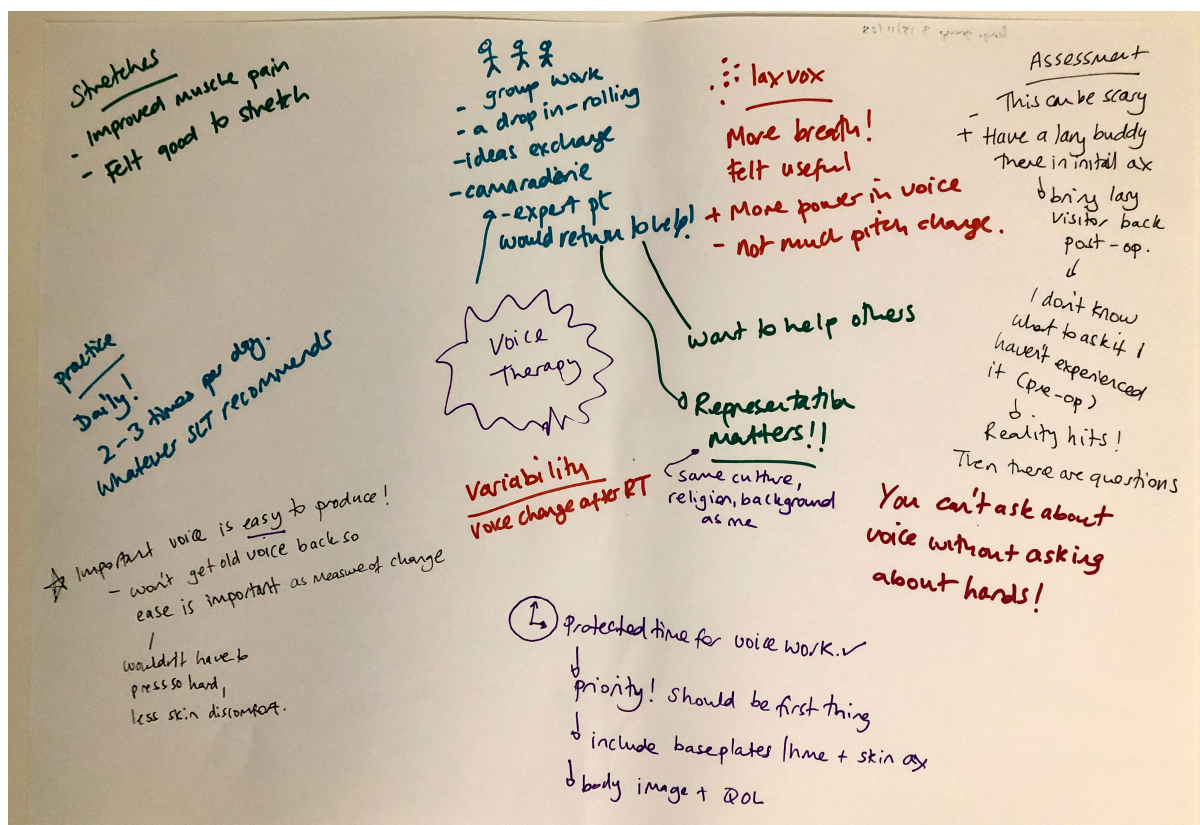


Figure 6.10: Brainstorm map of voice therapy trials in PWL-B group

PWL partners felt that the trialled exercises would be useful for the voice and were acceptable activities to carry out. Partners had not considered posture and muscle tension as part of voice therapy but believed it could be beneficial once a rationale was explained. PWL partners were aware that lung health might be affected after laryngectomy and there was good acceptance of breath work exercises. The use of semi-occluded vocal tract exercises was feasible but challenging to coordinate holding the cup/straw in one hand whilst occluding the stoma with another, however, PWL partners enjoyed the exercise and felt it would be a helpful tool to target breath flow and pacing. Twang resonance was perceived positively. Perceptually, PWL agreed it would allow the voice to cut through more clearly and were keen to practice further and explore. PWL partner feedback on articulation exercises was limited as across the groups, partners presented with clear articulation and so found it less relevant to their experience. They did not express strong views on the intensity or dosage of therapy exercises. Instead, clear rationale and potential benefit were the motivating factors with PWL

partners expressing they would be happy to follow any advised regimen if they understood the purpose and target outcome.

A common element of PWL partner feedback was the importance of personalising both the content and timing of voice therapy. Several partners observed that certain activities may have helped them at previous timepoints on their post-laryngectomy pathway; or could help someone with different needs to themselves. The researchers queried PWL views on pre-habilitation; this was viewed as potentially helpful but partners noted how short the pre-surgical window could be and highlighted the significant amount of information that was already being delivered at that time.

Regarding the delivery of therapy, PWL partners were keen to explore the option of group therapy. This was identified by PWL-B as an important route to peer learning from a successful PWL who could give hope alongside supporting voice learning. PWL-A also felt this would be beneficial, with partners motivated both to attend and to hold the role of successful PWL. On discussion, PWL partners noted that group therapy could be challenging for PWL that had not fully established tracheoesophageal voice use, therefore it was recommended that group therapy could follow initial individual sessions.

6.3.4. PROVISION OF INFORMATION AND THERAPY RESOURCES

PWL partners discussed their experiences of receiving information during the pre-operative phase and post-operative rehabilitation. Universally partners' experiences of information had been sub-optimal and had led to overwhelm and feeling insufficiently informed. To address this issue, PWL partners suggested that information provision should commence with SLTs enquiring how PWL want to receive information, for example verbally, written or by online and digital sources. Additionally, PWL felt that SLTs should assess individual needs to ensure that the appropriate balance and pacing of information is achieved without producing overwhelm or fear. In regard to pre-operative information, few PWL partners were aware of voice banking, therefore this was identified as an area of information need. PWL partners were in favour of this being a core part of pre-operative information.

PWL partners were shown example tracheoesophageal voice therapy videos, produced by Shout at Cancer and hosted online. The use of PWL in the videos to demonstrate exercises was received positively and experienced as a helpful resource. PWL partners felt that the existing videos could be expanded to cover more content; and PWL-B partners discussed using more PWL in the videos to increase diversity and representation. SLT partners also viewed video resources favourably, with potential to expand this, however, both SLT and PWL partners highlighted the risk of digital exclusion if information resources progress towards online modalities only. It was agreed that written information should continue to be provided for those that wish to access it, whilst SLTs could also encourage people to access digital literacy schemes in the community. Alternatively, SLT partners suggested using students or SLT assistants to offer a supported appointment, where people could access online information with help within the hospital environment.

In regard to post-laryngectomy information, PWL-B advocated for an additional session with their pre-operative laryngectomy visitor. PWL-B explained that, at the time of meeting the visitor pre-operatively, they did know what questions to ask or what they might want to know as they had not yet experienced life with laryngectomy. A second visit was therefore seen as an important source of information at a time when it may be more relatable to speak to someone with lived experience. Again, it was noted that representation was important when connecting people with a laryngectomy visitor. SLT partners were greatly in favour of a repeat laryngectomy visitor, however, it was noted that finding a well-matched visitor can be difficult, particularly for SLTs working in geographically smaller or more isolated locations. A potential solution offered was to build up a bank of accessible video resources of PWL talking about their experiences as a person with laryngectomy. This was positively received, however, SLT partners queried where such information could be collated and retained.

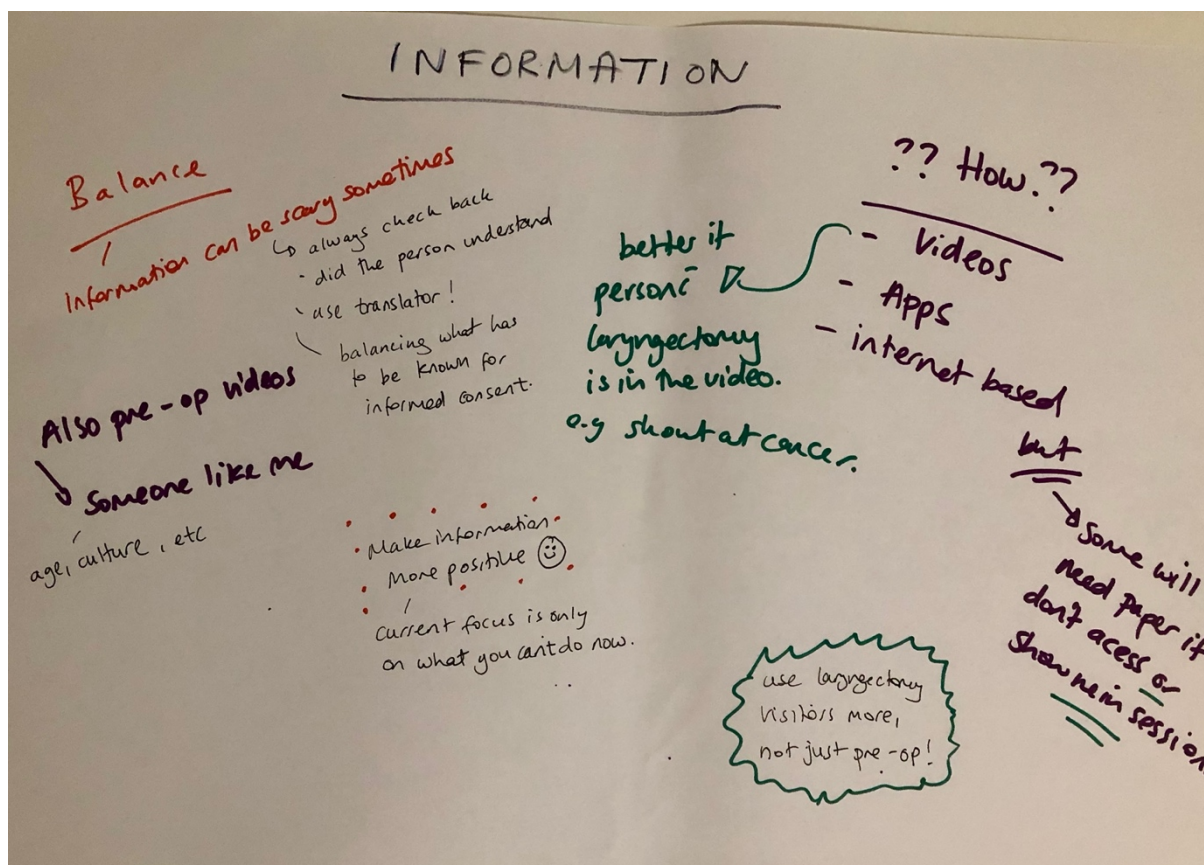


Figure 6.11: Brainstorm discussion of information

In summary, partners identified the following key intervention elements:

- Holistic assessment which considers all roles and activities an individual engages in
- Collaborative assessment processes that are based upon narrative case history
- Development of meaningful and relevant laryngectomy-specific outcome measures
- Positive laryngectomy-specific terminology that avoids ableist language or comparison to laryngeal voice norms
- Assessment that includes demands on hand use in addition to vocal demands
- Dedicated session for voice assessment and individualised priority setting
- Dynamic priority setting which is responsive to changing needs and abilities
- Intervention approaches which seek to enhance existing function, instead of deficit-focus
- Personalised interventions which link impairment-based activities to activity and participation-centred outcomes

- Implementation of group therapy models alongside individual voice therapy sessions
- Inclusion of expert patients and peer-befriending pre and post operatively
- Enhanced multimodal information which is representative and co-produced
- Enhancing pre-operative information, including specific advice on voice banking and recording
- Signposting to other support systems such as psychology and laryngectomy support groups
- Upskilling of SLTs and further research to inform and support practice
- Review of existing SLT pathways to identify optimised service provision within existing resources

6.4. CRITICAL REFLECTION

This co-design study engaged PWL and SLT partners in a collaborative process to identify priorities for assessment, outcome measurement and content of a tracheoesophageal voice therapy. The views of SLT and PWL partners were generally aligned, whilst each group provided novel ideas which enriched feedback and design thinking between groups.

Partner feedback demonstrated that current assessment processes do not meet the needs of service users or clinicians. Existing processes felt abstract and irrelevant to PWL with the observation that assessment was an activity to benefit SLTs rather than PWL. This linked to the role of assessment as a core element of personalised care. To achieve service user-centred care, patient preferences, needs and values should guide decision-making (Norcini, 2017). It is therefore pertinent that assessment processes are acceptable to PWL as a foundation to identifying needs, preferences and priorities for subsequent decision-making.

Continued co-production processes were indicated, aimed at creating holistic, narrative-based frameworks for communication case histories; alongside development and use of outcome measures that are specific to the laryngectomy population and sensitive to change. Narrative-based healthcare centers patient experience thereby moving the emphasis from

problem-solving to understanding as a basis for subsequent intervention (Zaharias, 2018). Holistic assessment is equally identified as a core component of person-centred care, and should seek to achieve connection, communication and understanding between service user and clinician (Mills, 2017). The challenge of delivering meaningful assessment within time-pressured NHS services was identified by both SLT and PWL partners, which reflects existing literature on this issue (Zuydam et al., 2023). SLT partners considered that redesign of existing clinical time could provide scope for sessions dedicated to holistic assessment and priority setting.

Significant barriers for SLT partners were the absence of evidence to link assessment outcomes to potential therapy targets, and the absence of normative data for tracheoesophageal voice. Whilst borrowing from laryngeal voice therapy approaches was viewed positively for impairment-based activities, it was seen as problematic to apply laryngeal voice assessment models to tracheoesophageal voice as this could lead to ableist views and negative labelling of voice quality. The practice of assessing tracheoesophageal speech against laryngeal voice norms has been identified previously as a flawed construct (Hurren, Miller and Carding, 2019). Therefore, these factors point towards the need to consider a specific taxonomy of tracheoesophageal voice descriptors.

Discussion of therapy activities highlighted the need to better understand the mechanisms of tracheoesophageal voice production. There was uncertainty amongst SLT partners over the potential to modify physiology within the neopharynx and to what extent modification was under speaker voluntary control. The uncertainty presented a barrier to implementation of voice therapy and to providing clear information to service users on the prognosis for voice rehabilitation. Similarly, PWL partners demonstrated low awareness of how tracheoesophageal voice was produced, which, it is hypothesised, could negatively impact their self-management and autonomy related to voice post-operatively.

Pre-laryngectomy information impacts post-surgical quality of life, and the engagement of AHPs, care-givers and use of peer-befriending is recommended to enhance pre-operative service user education (Mikhael et al., 2024). More widely, information was clearly highlighted as an area for improvement. This is consistent with previous co-design work with

head and neck cancer patients regarding the pre-treatment pathway, which highlighted enhanced, multi-modal information provision and buddy systems as key priorities for improvement (Brady, Goodrich and Roe, 2020).

In identifying therapy activities, borrowing from laryngeal voice therapy (e.g. Stemple et al., 1994; Estill et al., 2005; Titze, 2006; Thyme-Frøkjær and Frøkjær-Jensen, 2021) and dysphagia rehabilitation (e.g. Logemann et al., 2010; McCullough et al., 2012; Langmore and Pisegna, 2015) was viewed as important, with acknowledgement that feasibility and efficacy testing was required. This incorporated not only impairment-based activities but also a framework for a laryngectomy equivalent of vocal hygiene as a precursor to therapy. However, borrowing from laryngeal voice therapy was problematic when relating to elements of voice that are produced by the vocal folds, such as pitch, as this was less transferable to alaryngeal anatomy. Interestingly, there was no discussion of borrowing from trans-voice therapy, which typically incorporates pitch modification as a core element (RCSLT, 2018). Of note, SLT partners shared the view that pitch was not amenable to change and that this would be a concern affecting only female tracheoesophageal speakers, which is inconsistent with focus group outcomes where male speakers also reported misgendering and concerns about pitch.

Pre-operative laryngectomy visits are predictive of later QOL (Stam, Koopmans and Mathieson, 2008). However, PWL partners also placed importance on engaging proficient tracheoesophageal speakers in the voice therapy process and of continued peer-befriending in place of the single pre-surgical laryngectomy visitor. This was of particular importance to PWL-B who described a potential psychological benefit of ongoing meeting with a proficient speaker, alongside benefit to voice outcomes. Peer befriending and mentoring has been found to be feasible in people with advanced cancer, with early data indicating a positive effect on QOL (Walshe et al., 2020). However, consideration needs to be taken of how to implement the role of expert patients whilst managing the time and financial burdens. The positive regard of PWL partners towards group voice therapy models may also provide a route to accessing peer learning and support. Group therapy is shown to be effective and improve voice related QOL in small scale studies of laryngeal voice therapy (Simberg et al., 2006; Law et al., 2012).

6.4.1. LIMITATIONS

A notable limitation of the study was that partners did not have experience of tracheoesophageal voice therapy, as it is not currently well established in clinical practice. Whilst SLT partners were able to draw on their knowledge of laryngeal voice therapy and wider clinical practice, PWL partners did not have similar knowledge to inform their collaboration. Instead, PWL partner feedback was based upon trial of therapy exercises within the workshop and home practice. This also limited discussion on intensity and dosage of therapy, as PWL partners were uncertain what would be acceptable to them, and SLT partners did not have an evidence base to support recommendations. The project was successful in recruiting diverse participants to the PWL-A group and engaging with the Bangladeshi community through the PWL-B group, however, male partners were over-represented in the PWL group. Conversely, there was an under-representation of males and poor ethnic diversity in the SLT partner group, which was reflective of diversity issues within the SLT profession in terms of gender and ethnicity, where 94.8% of SLTs are female and 93.4% are White (Moore, Bitchell and Lord, 2020).

6.4.2. FUTURE DIRECTIONS

The co-design process identified future avenues for continued co-design and research priorities. There was a clear need to investigate mechanisms of tracheoesophageal voice therapy to understand what parameters of voice could be responsive to therapy, and to what extent it is possible to modify components of the neopharynx. This would provide a theoretical framework to guide borrowing from laryngeal voice and dysphagia rehabilitation as possible components of a tracheoesophageal voice intervention. Furthermore, development of tracheoesophageal voice outcome measures is required, which should be developed in collaboration with PWL to ensure measures are meaningful and relevant. Partners highlighted the need to optimise information resources towards the creation of accessible, multi-modality information. Production of information resources would be most effective if achieved through further co-design work that centres PWL and incorporates diverse representation.

6.5. CONCLUSION

This co-design study adds novel information on the views of PWL and SLTs on priorities for assessment, therapy content and associated information resources. This will inform the next phase of development of a novel tracheoesophageal voice therapy intervention, which is acceptable and feasible to PWL. Partnership working highlighted current challenges and desired outcomes for assessment protocols and service delivery models. Impairment based voice therapy approaches were trialled, leading to the identification of potential therapy activities and targets, supported by participation focussed interventions. Partners explored information provision, giving clarity on how information could be optimised through multi-modal delivery and greater inclusion of diverse service users. These elements will be discussed in Chapter Eight with consideration of how they can be synthesised with earlier outputs of the study towards the next stages of intervention development.

CHAPTER 7 | FEASIBILITY STUDY OF EXPIRATORY MUSCLE STRENGTH TRAINING TO IMPROVE VOICE AND RESPIRATORY OUTCOMES

Patient Advisory Group input:

The concept for the EMST study was discussed with PAG members prior to the planning of the study. The PAG was consulted on whether the use of EMST at the neck stoma appeared acceptable for the study design, and whether the time commitment of the study was an acceptable burden on participants. To support decision making, PAG members were shown the EMST device and provided with information on rationale for the study. PAG members were also given an overview of the van Sluis et al., 2020 study for further information. The PAG were satisfied that the study should proceed and no amendments to the proposed methodology were advised.

7.1 INTRODUCTION

This study investigates the feasibility and preliminary efficacy of EMST for the rehabilitation of PWL.

EMST has been demonstrated to improve MEP and cough function in healthy, elderly adults (Kim, Davenport and Sapienza, 2008), neurodegenerative diseases (Chiara et al., 2006, Laciuga et al., 2014, Tawara et al., 2018), and to increase MEP post-radiation for head and neck cancer (Hutcheson et al., 2018) and in people with laryngeal voice disorders (Tsai, 2016). A small pilot study of EMST after partial laryngectomy found it was an acceptable treatment which improved cough strength and reduced dyspnoea (Palmer et al., 2019). A systematic review and meta-analysis of EMST studies (Templeman and Roberts, 2020) found a significant increase in MEP following EMST. Improvement in other respiratory measures

was not significant, however, studies were limited in number, heterogenous and with small sample size.

EMST involves breathing into a hand-held device against resistance. The device contains a spring-controlled valve that opens on response to sufficient pressure generated from an expiratory breath. The spring within the device is adjustable which allows for increase or decrease in the valve opening pressure. On generating a forceful expiration into the device, the expiratory muscles are engaged. Targeting MEP therefore results in the ability to generate increased expiratory force, which in turn improves cough strength as a key component of the cough mechanism (Pitts et al., 2008). Where MEP is reduced, voluntary cough strength is diminished (Chiara et al., 2006).

The implication of cough strength is salient as mucociliary clearance and cough are the two components of airway clearance. In normal anatomy the cough mechanism is enacted in three phases, inspiratory, compressive and expiratory (Chang, 2005). First an inspiratory breath is taken increasing lung volume to prepare for expiratory airflow. During the compressive phase the vocal folds close and the expiratory muscles contract to build intrathoracic pressure. As the vocal folds open the expiratory airflow is released through compressed airways at high velocity (McCool, 2006). The force of the high velocity airflow aerosolises and removes material from the airway (Pitts et al., 2009), clearing material which cannot be eliminated by normal mucociliary transport (Bustamente-Marin and Ostrowski, 2017). Respiratory muscle strength is therefore a key component of an effective cough and in turn, of airway clearance.

After laryngectomy cough mechanics and respiratory function are greatly altered due to the anatomical changes arising from the surgery. With the removal of the vocal folds, the compressive phase of the cough mechanism is disrupted as there is no glottic closure to build intrathoracic pressure. Cough is therefore less efficient after laryngectomy and reliant on the inspiratory and expiratory phases, which impacts on the ability to clear secretions from the airway (Yue et al., 2021).

The difficulty of secretion clearance after laryngectomy is compounded by changes to the airway anatomy that reduce humidification. After laryngectomy air is inhaled directly via the neck stoma. The nose and mouth are bypassed preventing filtering, warming and humidifying of the inhaled air. Air entering the trachea is therefore colder and drier (Merol et al., 2012); and mucociliary clearance is negatively impacted (Kelly et al., 2021). This leads to principal complaints of increased mucus production, and the need for coughing and frequent forced expiration to effect airway clearance (Hilgers et al., 1990).

The changes to respiratory function after laryngectomy also impact the ability to produce adequate, functional tracheoesophageal voice. Reduced breath support can cause reduced words per breath (Lundstrom and Hammarberg, 2011), reduced loudness (Ng and Woo, 2021); and the presence of secretions in the pharyngoesophageal segment impacts on the perceptual quality and intelligibility of the voice (Búa et al., 2017). Respiration during speech is impacted by the double issue of air leak at the tracheostoma, and increased airflow resistance to phonation (Ward et al., 2007). Air leak occurs if there is poor seal of the baseplate or laryngectomy tube to the peristomal skin, resulting in air escape during occlusion of the tracheostoma for voicing. Increased airflow resistance arises from both the voice prosthesis and the pharyngoesophageal segment. The combined resistance to airflow from the voice prosthesis and the pharyngoesophageal segment result in a 7.5 times greater phonatory airflow resistance in laryngectomies compared with laryngeal speakers (Bohnenkamp et al., 2012). In sustained phonation, tracheoesophageal speakers therefore use expiratory breath flow less efficiently than laryngeal speakers.

Alaryngeal speech is associated with greater effort and fatigue levels when compared to laryngeal speech (Searl and Knollhoff, 2018). This may arise from the way tracheoesophageal speakers compensate for inefficiencies in speech respiration and increased airway resistance. Tracheoesophageal speakers may use more of their inspiratory reserve volume to fill the lungs prior to initiating speech and continue past their resting expiratory level, using more of their functional residual capacity (the volume of air remaining in the lungs after normal exhalation) during speech production (Bohnenkamp et al., 2011), which reduces phrase length and maximum phonation time (Ward et al., 2007). This is exemplified by the finding that tracheoesophageal speakers use higher lung volumes for speech whilst producing fewer

syllables per breath compared to laryngeal speakers (Bohnenkamp et al., 2011). Figure 7.1 illustrates these differences in speech respiration.

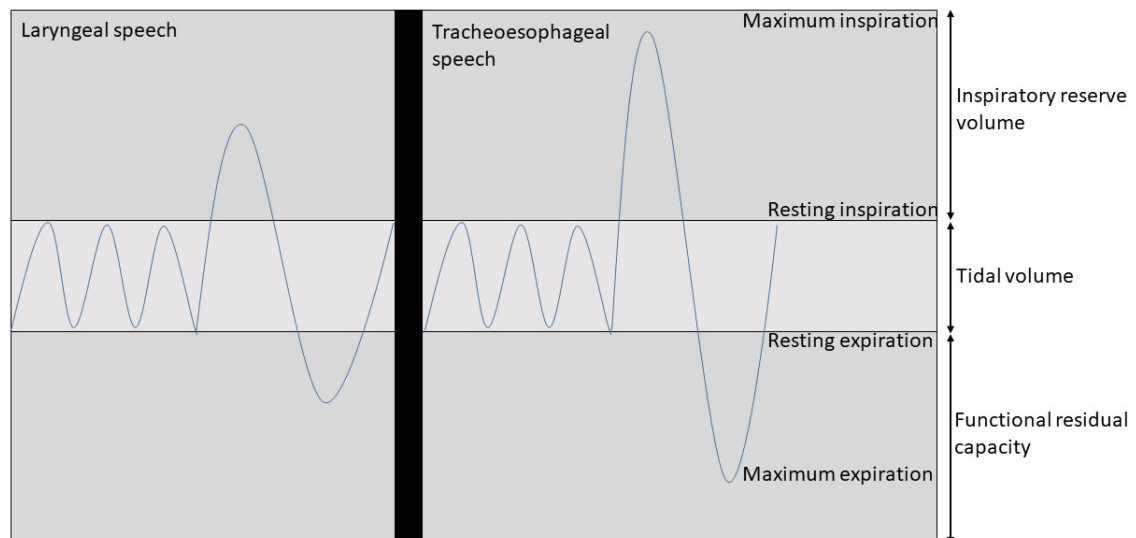


Figure 7.1: Speech respiration in tracheoesophageal speakers compared with laryngeal speakers

Whilst EMST may provide benefit to the impairments to respiration and cough, a significant challenge of the existing evidence base for EMST is that studies have been carried out on laryngeal speakers, whereas post-laryngectomy anatomy is considerably different. Therefore, it is uncertain whether study outcomes are transferrable to PWL. One pilot study has been completed on the use of EMST in laryngectomy (Van Sluis et al., 2020). This found that EMST improved MEP and loudness in laryngectomees. However, the primary focus of the study was feasibility, safety and compliance rather than cough and secretion burden or potential secondary impact on perceptual assessment of voice quality.

This feasibility study therefore aims to add to the Van Sluis et al. (2020) data and investigate these areas with the hypothesis that EMST may increase MEP after laryngectomy, which would improve cough function, secretion clearance and breath support. In turn, improvement in cough function, secretion clearance and breath support may improve perceptual features of tracheoesophageal voice and communication-related quality of life.

7.1.1. OBJECTIVES

The objectives of this study were:

- To investigate the feasibility and acceptability of an EMST program in a laryngectomy sample
- To explore the impact of EMST on:
 - instrumental measures of respiratory function using the measures of peak flow (PF), forced expiratory volume in one second (FEV1) and MEP
 - participant reported measures of cough and secretion burden, voice related QOL and communication by using the Cough and Sputum Assessment Questionnaire (CASA-Q), (Crawford et al., 2008); Voice-Related Quality of Life (V-RQOL), (Hogikyan and Sethuraman, 1999); and the Self-Evaluation of Communication Experiences after Laryngectomy (SECEL), (Blood, 1993) respectively
 - tracheoesophageal voice quality, using the STOPS, (Hurren, Miller and Carding, 2019), maximum phonation time (MPT) and maximum decibels on phonation (dB)

7.2. METHODOLOGY

7.2.1. STUDY DESIGN

This experimental feasibility study was of repeated measures design. As an early exploratory study, it did not include a control group. However, a double baseline and follow up data collection points were implemented as control aspects to increase confidence that any change on outcome measures post-EMST would be due to the intervention rather than other factors.

7.2.2. ETHICAL APPROVAL AND CONSENT

The study received ethical approval from the City, University of London Senate Research Ethics Committee (reference no. ETH2223-1307), (Appendix 7.1). Participants were required to give their informed written consent to take part in the study.

On expressing an interest in the study, potential participants were given a Participant Information Sheet and consent form which provided information on the aims of the study, risks and benefits of taking part and data privacy. Potential participants were offered the opportunity to ask questions and the researcher (FS) established eligibility for inclusion. People wishing to participate then had an in-person appointment at least one week post initial information giving to ensure they had enough time to make an informed decision and also further opportunity for discussion and questions, before written consent was obtained. Consent was also taken from participants to inform their managing Consultant or SLT of their participation in the study.

7.2.3. RECRUITMENT

Participants were recruited via an advert disseminated through social media, patient support groups and professional networks. Recruitment was open between 28/11/2022 - 20/01/2023.

7.2.4. PARTICIPANTS

The study recruited PWL who at the time of recruitment used a voice prosthesis to communicate. Participants were required to be free of active cancer and at least six months post-laryngectomy surgery and/or adjuvant treatment to ensure time for post-treatment healing. Participants were required to travel to the University on four occasions and to have sufficient dexterity to use an EMST device (or have carer support available to do this). A

handheld EMST150 device was used, produced by Aspire Respiratory Products; Sections 7.1 and 7.2.8. describe the device in further detail.

The following exclusion criteria were set, according to the EMST 150 device manufacturer's contraindications:

- Asthma
- Ruptured ear drum or other condition of the ear
- Pregnancy
- Uncontrolled gastroesophageal reflux
- Uncontrolled hypertension
- Abdominal hernia or recent abdominal surgery
- Tracheostomy tube in situ
- Acute stroke
- Complex cardiac issues
- History of pneumothorax
- Recent surgery to the upper body
- Lung transplant or recent resection
- Dental abscess or osteoradionecrosis
- Epistaxis or active haemoptysis

7.2.5. SAMPLE SIZE

The study aimed to recruit 10-12 participants. It was acknowledged that the study was underpowered to evaluate efficacy of EMST in the target population. However, this was a justifiable limitation of the study, given its exploratory nature and the primary aim of collecting feasibility and acceptability data. The existing pilot study of EMST after laryngectomy recruited nine participants (Van Sluis et al., 2020), therefore the aim of 10-12 participants was considered adequate given the early stage of research in this area.

7.2.6. SETTING

The study took place at City, University of London. Participants attended the mandatory in person appointments within a small sound-treated meeting room at the university. Other appointments were held either at the university or via virtual modalities (MS Teams, email conversation, WhatsApp chat or video call) according to participant preference.

7.2.7. OUTCOME MEASURES

Outcome measures were collected in the domains of feasibility, acceptability, respiratory function, participant reported outcome measures and tracheoesophageal voice quality.

7.2.7.i. Feasibility

Feasibility outcomes included the proportion of participants eligible from those who expressed interest in participating (number eligible/number interested), the proportion of eligible participants who consented to take part (number who consented/number eligible); and number of participants who completed the intervention.

7.2.7.ii. Acceptability

Acceptability of EMST was assessed by looking at participant adherence to the protocol and outcome measures and their experience of the intervention. Participants were provided with a practice tracking diary to record compliance with daily EMST practice (Appendix 7.2). The diary included space to write reflections on the practice which were discussed during weekly check-ins with a member of the research team to measure adherence. At the end of the study, participants completed a final discussion with a member of the research team which added to qualitative data on acceptability. The weekly check-in and final discussions were semi-structured questionnaire-led and included questions on equipment issues, intensity of

the practice, frequency of contact with the research team and participants' impressions of EMST. The discussion guide is available in Appendix 7.3.

7.2.7.iii. Adverse events

Based on existing research (Van Sluis et al., 2020) the risk of adverse events was considered to be low. Formal criteria for cessation of the study were not defined in advance, however, the progress of the study was monitored during fortnightly research supervision meetings. Any indication to stop the study early on safety grounds was to be discussed with the senior researcher (KH), however, this was not indicated.

7.2.7.iv. Respiratory function

Respiratory function was assessed using measures of peak flow (PF), forced expiratory volume in one second (FEV1) and MEP. MEP is a measurement of the maximal strength of the respiratory muscles on exhalation, specifically the maximal strength of the abdominal and intercostal muscles (Obando et al., 2012); whereas PF and FEV1 are measures of expiratory airflow (Culver, 2012, p133). PF measures the amount of air exhaled with effort, whilst FEV1 measures the amount of air that can be forcefully exhaled in one second. Participants underwent respiratory assessment at four time-points: baseline one, baseline two, post-treatment and at six-week follow up. To measure the respiratory function at each timepoint participants completed three repetitions of maximum exhalation into a peak flow meter (for PF and FEV1 measurement) and a pressure manometer (for MEP measurement) via the neck stoma. As described in Section 7.2.10., the mean average of the three trials was recorded as the outcome.

7.2.7.v. Participant reported outcome measures

Participants also completed the following self-reported outcome measures at four time-points: baseline one, baseline two, post-treatment and at six-week follow up. Few self-reported outcome measures exist that are designed specifically for post laryngectomy evaluation; therefore, some of the measures were chosen due to a precedent for their use in existing laryngectomy research.

- Cough and Sputum Assessment Questionnaire (CASA-Q), (Crawford et al., 2008)

No laryngectomy specific measure of cough and mucus impact exists; therefore, the CASA-Q UK English version was used as a participant-reported outcome measure in this domain. The CASA-Q is a 20-item questionnaire developed and validated for chronic bronchitis or chronic obstructive pulmonary disease populations. The questionnaire measures symptoms and impact of cough and sputum over the past seven days, across four domains: cough severity, cough impact, sputum severity and sputum impact. Cough severity measures the frequency of coughing using self-assessment of items such as coughing during the day, whereas cough impact measures how coughing impacts on daily life with items such as 'tiredness after coughing' and 'interruption of conversations due to coughing'. Sputum severity assesses the frequency and viscosity of sputum, whereas sputum impact measures daily life impact with items such as 'avoidance of public places' or 'difficulty breathing'.

Each domain is scored separately between 0 – 100, with a higher score representing lower symptoms and impact. Each individual item is scored on a five-point Likert scale categorised from 'never' to 'always' for frequency items and 'not at all' to 'extremely' for intensity items. Minimum clinically important differences are given for each domain. Whilst not validated with the population, the CASA-Q has been used previously in laryngectomy research to assess the effects of heat-moisture exchangers on cough and sputum (Longobardi et al., 2022; Ward et al., 2023).

- Voice-Related Quality of Life (V-RQOL), (Hogikyan and Sethuraman, 1999)

The V-RQOL is a ten-item questionnaire that assesses the impact of voice impairment in two domains: physical functioning (six questions) and social-emotional (four questions). Items are scored on a five-point Likert scale between 1-5, resulting in a score range of 10-50. A higher score indicates greater severity of impact. The V-RQOL was developed and validated on a population of laryngeal voice users (Hogikyan and Sethuraman, 1999; however, the measure has been used widely in laryngectomy voice research (Grillo et al., 2021; Cocuzza et al., 2020; Agarwal et al., 2015, Kazi et al., 2006). Construct validity of the V-RQOL in the laryngectomy population has been investigated. This identified that alaryngeal populations may require a modified scoring procedure, proposing that two physical domain questions are transferred to the social-emotional domain, to increase validity of the questionnaire in alaryngeal populations (Bornbaum, Day and Doyle, 2014). The above-mentioned laryngectomy voice studies did not use the modified V-RQOL scoring, however, therefore for comparability it was not used in this study.

- Self-Evaluation of Communication Experiences after Laryngectomy (SECEL), (Blood, 1993)

The SECEL is a self-rating measure designed specifically for people with laryngectomy, which has undergone validity and reliability testing. The SECEL consists of 35-items relating to experience of communication after laryngectomy, which are separated into General, Environment and Attitudinal subscales. General items highlight how people experience conversational situations, whereas the Environmental domain indicates how communication is experienced in different environments; the Attitudinal domain describes attitudes towards speech, self-perception and perception of others (Rodrigues et al., 2023). Each item is scored on a four-point scale with higher scores indicating greater communication difficulty. The domain scores range from: Total score 0 – 102, General score 0-15, Environmental score 0-42, Attitudinal score 0-45.

Minimally important clinical differences and cut-off scores for rehabilitation need have been established. Rehabilitation cut-off scores are given as: Total score = 20, General score = 4, Environmental score = 16 and Attitudinal score = 5; whereas minimally important clinical differences are given as improvement of -13 points or deterioration of +8 points (Tuomi et al., 2015).

7.2.7.vi. Measures of voice quality

Voice quality was measured using MPT and maximum dB on phonation. Voice recordings were taken of participants reading The Rainbow Passage (Fairbanks, 1960) for perceptual rating of voice quality. Voice recordings were anonymised and randomised using an online random number generator accessed via www.calculatorsoup.com.

Blinded perceptual assessment of voice was completed by a SLT experienced in laryngectomy rehabilitation, using the SToPS, (Hurren, Miller and Carding, 2019). The SToPS is a clinician rated 14-item scale, which assesses perceptual parameters of tracheoesophageal voice. The SToPS has established validity, intra-rater reliability (Hurren, Miller and Carding, 2019) and inter-rater reliability for the majority of items (Coffey et al., 2019); and is the only scale designed to perceptually rate tracheoesophageal voice.

The 14 individual items of the SToPS perceptually rate tracheoesophageal voice quality in domains such as 'strain', 'impairment of volume', or 'social acceptability of voice'. The full list of items is shown in Table 6.2. Rating is completed using a four-point Likert scale per item; with the exception of tonicity, which is rated on an 11-point bipolar semantic scale. The points of the Likert scale range from zero to three, where a score of zero represents no impairment and a score of three represents severe impairment. The item 'positive features of articulation' is also scored on a four-point Likert scale, however, the scoring differs from the other items with zero representing 'neutral voice' and a score of three representing 'outstanding voice'. This item assesses for aspects of tracheoesophageal speech that have a positive effect on listener perception, but that do not arise from tracheoesophageal voice quality itself; for example: phrasing, diction and intonation. Two other items, Accent and

Reading, are not intended to measure a parameter of tracheoesophageal voice. Instead, these two items serve to monitor for potential bias in the clinician-rater, for example, the possibility that poor reading may impact on perceptual assessment. It is anticipated that Accent and Reading scores would remain static and unchanged over time-points.

The SToPs only provides item scores and no aggregate scores, however, and requires further testing to establish minimally important clinical differences and sensitivity to change. Section 7.2.10. further describes the analysis of the SToPs assessment data.

7.2.8. EQUIPMENT

The study used the EMST150 device produced by Aspire Respiratory Products. The device is supplied with a round mouthpiece which was used to connect the device to a baseplate for use at the neck stoma (Figure 7.2).



Figure 7.2: EMST device sited within baseplate

All voice recordings were taken in the same small sound-insulated meeting room at the University. A Shure SM137 condenser microphone was placed in a holder at 30cm microphone to mouth distance. A Sauter SU130 sound level meter was sited directly under the microphone. Recordings were captured on a Zoom H6 digital audio recorder connected

to the microphone. A hand-held Sonmol peak flow meter was used to measure PF and FEV1 with an Intersurgical Inter-guard breathing filter fitted to the mouthpiece of the EMST device and placed into a baseplate (Figure 7.3). To record MEP, an In-Health pressure manometer was used with an In-Health manometer adaptor kit placed into the participant's normal baseplate.



Figure 7.3: Attachment of PF/FEV1 meter to baseplate

7.2.9. PROTOCOL

Following consenting, participants attended for two baseline assessments at a two-week interval (t1 and t2), a post intervention assessment five weeks later (t3) and a follow up assessment after a period of six weeks maintenance after t3 (t4). Double baseline measures were taken to support the inference that EMST is the causal factor in any improvement post intervention. At each assessment participants completed the outcome measures:

Acceptability and adherence:

- a. Practice tracker and diary for participant completion (Appendix 7.2)
- b. Questionnaire investigating acceptability (Appendix 7.3)

Patient reported outcome measures:

- a. Self-evaluation of communication experiences after laryngectomy (SECEL)
- b. Cough and Sputum Assessment Questionnaire (CASA-Q)
- c. Voice related quality of life (V-RQOL)

Voice and respiratory measures:

- d. Voice recording of Rainbow Passage
- e. Three repetitions of vowel /a/ for maximum decibels and MPT
- f. Three trials of PF, MEP and FEV1

Between t2 and t3 participants completed the EMST intervention. At the second baseline assessment visit, participants were shown how to use the EMST device and offered any support required for using the device correctly. The device was set at the participant's individual starting value of 75% of MEP. Participants were instructed on the protocol for self-delivery of the five-week EMST intervention. During the five-week intervention period participants were contacted each week by one of the research team to provide advice if required, to discuss weekly adherence to the protocol and to gain qualitative feedback. Dependent on participant preference, weekly contact occurred via a combination of video call, virtual meeting, email, text chat or face-to-face visit.

At t3 participants attended for post intervention assessment and instruction on the protocol for the subsequent six-week maintenance period. At the end of the maintenance period participants attended for the final assessment (t4). During the maintenance period participants did not have routine weekly check-ins with the research team, however, they were able to contact the team at any point if required.

7.2.9.i. Intervention Description

To complete the five-week EMST intervention, participants were required to exhale forcefully into the hand-held device, repeating for five sets of five repetitions, five times per day, for five days per week. This comprised a total dosage of 625 breaths. Participants increased the pressure threshold of the device periodically to sustain work at 75% of MEP as they became accustomed to the expiratory pressure required. Participants were not advised to plug the voice prosthesis during practice.

During the maintenance period participants were instructed to follow a reduced dosage of 25 breaths per day, for two days per week, for six weeks. This comprised a total maintenance dosage of 300 breaths. Participants continued to adjust the device as required to work at 75% of MEP during the maintenance period. Participants completed the practice tracker and diary during the intervention and maintenance periods. Appendix 6.4 describes the intervention using the TIDieR checklist.

7.2.10. DATA ANALYSIS

Descriptive statistics were used to report participant characteristics, feasibility and quantitative acceptability outcomes and scores on outcome measures. Qualitative data on acceptability obtained from practice diaries and participant reports were analysed using content analysis. Participant reported outcome measures were scored according to instructions prior to statistical analysis. For dB, MPT, PF, FEV1 and MEP values the mean average of three trials was calculated prior to statistical analysis.

The STOPs does not provide an overall score for analysis, therefore individual items were inspected descriptively, as intended, and a composite score was also calculated for inferential statistical analysis. To calculate the composite score 11/14 of the STOPs individual items were summed. Accent and Reading scores were excluded from the composite score as these items serve to identify potential bias in the rating clinician and are not expected to change over time. Tonicity was excluded from the composite score as it was not found to be as reliable as

other parameters (Coffey, 2019), furthermore tonicity is rated via an 11-point bipolar scale (negative scores indicting hypotonicity, 0 good tone, positive scores hypertonicity) that was incompatible with the scoring of the other items. Prior to inclusion in the composite score, the Positive Features item was reverse scored to be consistent with other SToPs items where higher scores indicate a greater level of impairment.

Statistical analysis on outcome measures scores across time was carried out with SPSS software analysis using one-way repeated measures ANOVA or Friedman test, depending on data type, to explore the pattern of change. Given the exploratory nature of this study, adjustments for multiple comparisons were not used, but p values are given together with effect sizes. Effect sizes were calculated by partial eta squared using interpretation values from Statology (Zach, 2021); or Kendall's W for non-parametric data, using interpretation values from Landis and Koch (1977).

7.3. RESULTS

7.3.1. PARTICIPANT CHARACTERISTICS

Ten PWL took part in the study. Participants were predominantly male and white-British with a mean age of 62.2 years (S.D. 14.94). All participants had undergone total laryngectomy with 40% of participants having total laryngectomy with pectoralis major flap. The median average time post-surgery was 29 months (IQR: 17.25-133.00) and 70% of participants had received radiotherapy before or after surgery. Table 7.1 details participant characteristics.

Participant characteristics	Mean (SD) and range
Sex	Male: 8 Female: 2
Age	Mean: 62.2 years, S.D: 14.94 Range: 37 – 80 years
Ethnicity	White British: 8 Black-Caribbean: 1 White European: 1
Employment status	Retired: 7 Part-time work: 1 Full-time work: 2
Months post-surgery	Mean: 61.1 months, S.D: 60.99 Median: 29 months, IQR: 17.25-133.00 Range: 6 – 172 months
Type of surgery	Total laryngectomy: 6 Total laryngectomy with pectoralis major flap: 4
Radiotherapy	None: 3 Pre-surgery: 4 Post-surgery: 3
Type of prosthesis	Blom-Singer Classic indwelling prosthesis: 5 Blom-Singer Increased Resistance indwelling prosthesis: 1 Blom-Singer Low Pressure exdwelling prosthesis: 1 Provox Vega indwelling prosthesis: 1 Provox NID non-indwelling prosthesis: 2

Table 7.1: Participant characteristics (n=10)

7.3.2. FEASIBILITY

During the recruitment period, 14 PWL contacted the researcher to express an interest in participating. Of the 14, two people were ineligible to take part due to contraindications (poorly controlled reflux, n=1; less than six months post-surgery, n=1). Of the 12 eligible PWL, 10 consented to take part in the study with two PWL declining due to the requirement to

travel to the University on four occasions for the assessments. Of note the travel distance for the two who declined was considerable as they lived in a different city to where data collection was taking place. The ten participants who consented to the study all completed the intervention and attended all baseline and follow-up assessments. Further detail is provided in the following section.

7.3.3. ACCEPTABILITY

7.3.3.i. Adherence

Adherence to dosage was measured using participant-reported practice tracking sheets and discussion with participants at the weekly check-in appointment. During the five-week practice period all participants reported they completed the set dosage of 625 breaths. However, adherence to the prescribed frequency of 25 breaths per day for five days per week varied in two participants. One participant completed the dosage over seven weeks due to a mild Covid-19 infection which impaired respiratory function for several days; whereas another participant sustained an unrelated rib injury which required cessation of practice for one week. Dosage was therefore completed over six weeks.

During the six-week maintenance period 80% of participants completed the set dosage of 300 breaths, however, one participant varied the frequency each week to facilitate the practice around daily commitments. Two participants did not complete the full maintenance dosage, due to uncertainty of the benefit of additional practice (n=1) and difficulty sustaining additional practice around other commitments (n=1). These participants completed 33% and 83% of maintenance dosage respectively.

7.3.3.ii. Qualitative data on acceptability

Qualitative data was captured from the weekly check-in with the research team and comments the participants had written in their practice diaries. This incorporated opinions on the benefit and intensity of the EMST practice and equipment issues.

7.3.3.iii. Opinions of the EMST intervention

Participants reported that the EMST protocol was acceptable and could be accommodated into daily routine after a short period of establishing a suitable time pattern for the practices across the day. Two participants considered their baseplate usage within the timing of practice, noting that after several hours of wear baseplate seal was less resistant to the pressure of the expiratory breath. Practice was therefore timed to accord with more recent baseplate placement, however, for one participant this resulted in reduced lifespan of baseplate seal after practice.

Nine of the ten participants stated the EMST practice had felt beneficial, with changes typically reported after two weeks of practice. Participants described increased exercise tolerance on walking or stair climbing, the sensation of greater lung expansion on inhalation and ease of mucus clearance. One participant observed easier mucus clearance with lowered nebuliser use, yet the pattern of mucus clearance altered resulting in increased expectoration during the day, which was inconvenient. Two participants queried whether EMST may benefit swallow function, due to the sensation of pharyngeal constrictor engagement during exhalation into the device. This was not investigated during the study, however.

All participants expressed satisfaction with the frequency of contact with the research team. The flexibility to have the weekly check-in via in person or virtual/online modalities was seen as beneficial.

7.3.3.iv. Equipment issues and problem solving

Participants were advised to use the nose clips or pinch the nose when practicing, if they experienced egressive airflow via the prosthesis to nose on exhalation into the device. This was reported by one participant who pinched the nose to improve air seal. Two participants reached the maximum pressure of the device during the five-week training period.

All participants used the device independently; however, minor device adaptations were necessary to enable use at the neck stoma and to increase efficiency and safety of practice. Most participants completed practice with their usual baseplate, whilst three participants found the seal was insufficient to prevent air leak between the baseplate and the skin during forceful exhalation. These participants changed to use of a strongly adhesive In-Health Accufit baseplate during practice to improve baseplate-to-skin seal.

Participants were instructed to place the device into their baseplate using the round mouthpiece connector, which has a 22mm diameter. This accords with the 22mm diameter of all Blom-Singer and some Atos baseplates. Air leak between the baseplate and the device was experienced by the majority of participants, but exacerbated for those using Provox Life baseplates, which have an increased diameter of 23mm. This issue was resolved by using elastic bands wrapped around the device mouthpiece, which enabled a complete seal between the device and the baseplate (Figure 7.4). In addition, the placement of elastic bands prevented participants from inserting the device too far into the baseplate, which could cause peristomal skin irritation.



Figure 7.4: Placement of elastic bands on device to improve seal

Participants were encouraged to experiment with the device to explore facilitatory solutions beyond the use of elastic bands. One participant used a deconstructed HME as a casing for the device mouthpiece, which was an alternative way to improve device seal with the baseplate (Figure 7.5). A second participant adapted the In-Health manometer adapter to use as an alternative casing for the device mouthpiece, as discussed in the following section.



Figure 7.5: Deconstructed HME casing for device

7.3.3.iv.a. Safety considerations

Since it is not possible to inhale with the device in situ at the neck stoma, it is necessary to remove the device promptly after exhalation in order to breathe in. This presents a potential airway safety issue for PWL that use EMST. Clinicians must ensure that they have comprehensively assessed the individual PWL's ability to consistently remove the device from the neck stoma to ensure there is no risk of airway obstruction from the device. Two participants reported reduced hand dexterity that caused a small delay in removing the device rapidly after exhalation, therefore a participant-led solution was explored to increase safety and comfort of use. An In-Health manometer adapter was modified to create a connector between the device and the baseplate, with a hole cut into the adapter to allow airflow (Figure 7.6). Participants were then able to cover the hole with a finger during exhalation into the device, and to remove the finger for inhalation with the device in situ. This technique was preferred by one participant for efficiency, rather than a dexterity issue. Where participants presented with a deep, recessed stoma, the manometer tubing could be left attached to enable inhalation through the tubing (Figure 7.7).



Figure 7.6: Device with modified In-Health manometer adapter



Figure 7.7: Device with In-Health manometer adapter tubing

7.3.3. ADVERSE EVENTS

Two participants reported a non-serious adverse event of minor peristomal skin irritation. On discussion between the researcher and respective participants, the causal factor was found to be use of excessive contact pressure to prevent air leak when connecting the device at the neck stoma. Participants were given advice on technique and the device adaptations stated above were implemented, which improved air seal and therefore reduced the contact pressure required on placing the device. Both participants opted to use elastic bands on the device, and the minor skin irritation resolved within a few days of review.

One participant reported light-headedness in the first week of practice. In discussion with the researcher the participant reported that light-headedness occurred after completing all daily breaths in one set. This resolved immediately after the participant was reminded to break the daily 25 breaths into smaller sets.

No participants reported dislodgement of the voice prosthesis during the study.

7.3.4. IMPACT OF EMST ON OUTCOMES

Table 7.2 presents group outcome measure results across timepoints. Where data was non-parametric, median scores and interquartile ranges are additionally reported in italics.

Outcome measure	Baseline 1 Mean (S.D.) <i>Median (IQR)</i>	Baseline 2 Mean (S.D.) <i>Median (IQR)</i>	Post-intervention Mean (S.D.) <i>Median (IQR)</i>	Follow up Mean (S.D.) <i>Median (IQR)</i>	Repeated measures ANOVA or Friedmans
Respiratory					
FEV1 (L/sec)	1.12 (0.32)	0.94 (0.27)	1.35 (0.28)	1.40 (0.31)	p<0.001
Peak Flow (L/min)	220.93 (64.72)	215.73 (76.13)	266.40 (67.46)	270.60 (64.09) <i>250.84 (236.83-293.59)</i>	p=0.002
Maximum expiratory pressure (cmH ₂ O)	119.40 (21.79)	120.40 (23.76)	136.03 (14.97)	134.37 (14.33)	p=0.004
Participant reported measures					
CASA-Q COUS	57.50 (13.86) <i>62.50 (54.17-66.67)</i>	63.33 (16.76)	63.33 (24.60) <i>66.67 (58.33-77.08)</i>	60.83 (17.59)	p=0.45
CASA-Q COUI	74.07 (17.86) <i>75.00 (64.85-85.16)</i>	70.32 (18.82) <i>75.00 (57.82-82.81)</i>	80.32 (22.78) <i>84.38 (77.35-92.97)</i>	76.25 (18.23) <i>79.70 (67.19-88.28)</i>	p=0.04
CASA-Q SPUS	49.17 (20.20) <i>54.17 (41.67-66.67)</i>	53.75 (20.07)	55.00 (27.83)	59.17 (23.72)	p=0.20
CASA-Q SPUI	60.41 (19.46)	59.17 (22.97) <i>70.83 (39.58-75.00)</i>	65.83 (25.29) <i>75.00 (58.33-83.33)</i>	64.58 (24.71)	p=0.05
V-RQOL	26.20 (10.52) <i>21.00 (17.75-36.00)</i>	26.00 (11.94) <i>21.00 (17.75-36.25)</i>	24.40 (10.55) <i>20.00 (16.75-30.75)</i>	24.10 (12.73) <i>18.00 (14.75-36.75)</i>	p=0.36
SECEL Total score	39.00 (21.88) <i>29.00 (22.00-61.25)</i>	38.80 (25.75) <i>26.50 (18.75-65.50)</i>	33.40 (21.22)	33.60 (28.00) <i>22.00 (12.75-53.25)</i>	p=0.05
SECEL General score	5.70 (3.43)	5.20 (4.16)	4.90 (3.41)	4.60 (3.69)	p=0.44
SECEL Environmental score	20.20 (8.47)	19.20 (10.38) <i>15.00 (11.00-29.25)</i>	16.90 (7.77)	17.10 (11.39) <i>12.50 (8.75-25.00)</i>	p=0.01
SECEL Attitudinal score	13.10 (11.19) <i>7.50 (6.00-23.00)</i>	14.20 (11.85) <i>7.50 (6.75-26.00)</i>	11.60 (10.86) <i>6.00 (3.75-23.00)</i>	11.90 (13.50) <i>6.00 (3.00-21.50)</i>	p=0.046
Objective voice measures					

Outcome measure	Baseline 1 Mean (S.D.) <i>Median (IQR)</i>	Baseline 2 Mean (S.D.) <i>Median (IQR)</i>	Post-intervention Mean (S.D.) <i>Median (IQR)</i>	Follow up Mean (S.D.) <i>Median (IQR)</i>	Repeated measures ANOVA or Friedmans
Maximum phonation time (seconds)	10.59 (5.26)	10.46 (9.44)	9.44 (6.79) <i>8.01 (3.97-14.18)</i>	8.97 (6.58) <i>7.30 (3.96-13.20)</i>	p=0.52
Decibels	74.88 (6.45)	76.15 (5.54)	79.56 (5.72)	82.05 (4.91)	p=<0.001
SToPS Perceptual scale					
Composite score	13.30 (8.42)	13.10 (7.71)	12.60 (8.75)	13.90 (9.94)	p=0.69
Overall voice quality	1.60 (0.97)	1.60 (0.97)	1.50 (0.85)	1.70 (0.95)	p=0.27
Strain	1.40 (0.97)	1.30 (1.16)	1.10 (0.99)	1.40 (1.35)	p=0.54
Wetness	0.70 (1.06) <i>0.00 (0.00-1.25)</i>	0.70 (0.95) <i>0.50 (0.00-1.00)</i>	0.70 (0.95) <i>0.50 (0.00-1.00)</i>	0.90 (1.20) <i>0.50 (0.00-1.50)</i>	p=0.87
Volume	1.10 (1.10)	1.10 (1.10)	1.10 (1.20)	1.40 (1.07)	p=0.33
Social acceptability	1.80 (1.03)	1.80 (0.92)	1.70 (0.95)	1.70 (1.06)	p=0.77
Whisper	1.30 (0.95)	1.50 (0.85)	1.40 (1.07)	1.40 (1.07)	p=0.66
Intelligibility	0.80 (1.13) <i>0.00 (0.00-2.00)</i>	0.70 (1.06) <i>0.00 (0.00-1.25)</i>	0.90 (1.20) <i>0.50 (0.00-1.50)</i>	0.80 (1.23) <i>0.00 (0.00-1.50)</i>	p=0.59
Stoma	1.10 (0.87)	0.80 (0.63)	0.60 (0.52)	0.80 (1.03) <i>1.00 (0.00-1.25)</i>	p=0.45
Fluency	0.70 (0.82)	0.70 (1.16) <i>0.00 (0.00-2.00)</i>	0.70 (1.06) <i>0.00 (0.00-1.25)</i>	1.0 (1.05)	p=0.23
Articulation	0.80 (1.14) <i>0.00 (0.00-2.00)</i>	0.80 (1.03) <i>0.50 (0.00-1.25)</i>	0.70 (0.95) <i>0.50 (0.00-1.00)</i>	0.80 (1.14) <i>0.00 (0.00-2.00)</i>	p=0.85
Positive features	2.00 (1.05)	2.10 (0.88) <i>2.00 (2.00-3.00)</i>	2.20 (0.92) <i>2.00 (2.00-3.00)</i>	2.00 (0.94)	p=0.76
Tonicity	-0.90 (2.51)	-0.90 (2.77)	-1.00 (2.49)	-0.80 (2.78)	0.70
Accent	0.90 (0.99) <i>1.00 (0.00-1.25)</i>	0.90 (0.99) <i>1.00 (0.00-1.25)</i>	0.80 (1.03) <i>0.50 (0.00-1.25)</i>	0.90 (0.99) <i>1.00 (0.00-1.25)</i>	p=0.73
Reading	0.40 (0.70) <i>0.00 (0.00-1.00)</i>	0.20 (0.42) <i>0.00 (0.00-0.25)</i>	0.20 (0.63) <i>0.00 (0.00-0.00)</i>	0.10 (0.32) <i>0.00 (0.00-0.00)</i>	p=0.22

Table 7.2: Group outcome measure results across time and statistical comparisons

Acronyms:

FEV-1: Forced expiratory volume in one second. **CASA-Q:** Cough and sputum assessment questionnaire. **COUS:** Cough severity. **COUI:** Cough impact. **SPUS:** Sputum severity. **SPUI:** Sputum impact. **V-RQOL:** Voice -related quality of life. **SECEL:** Self-evaluation of communication experiences after laryngectomy. **SToPS:** Sunderland tracheoesophageal voice perceptual scale.

7.3.4.i. Respiratory function

7.3.4.i.a. FEV1

There was a significant improvement in FEV1 values post-intervention $F(3,27) = 13.10$; $p < 0.001$, with a large effect size ($\eta_p^2 = 0.59$). There was no significant difference between baseline scores ($p=0.21$) whereas there was a significant increase in FEV1 between baseline two and post-intervention and follow up ($p=0.002$; $p=0.01$). There was no significant decrease in score between post-intervention and follow up ($p=1.00$).

7.3.4.i.b. Maximum Expiratory Pressure (MEP)

MEP values improved post-intervention $F(3,27) = 5.71$; $p=0.004$, with a large effect size ($\eta_p^2 = 0.39$). There was no significant difference in baseline mean scores ($p=1.00$), which were 119.40cmH₂O (21.79) at baseline one and 120.40cmH₂O (23.76) at baseline two. Mean MEP score increased significantly between baseline two and post intervention to 136.03cmH₂O (14.97); ($p=0.047$). Whilst there was no significant difference in MEP between post-intervention and follow up ($p=1.00$), mean score decreased slightly at follow up to 134.37 cmH₂O (14.33), which was not significantly different from baseline one and two mean scores ($p=0.23$, $p=0.33$ respectively).

7.3.4.i.c. Peak Flow

Peak flow improved from baseline to post-intervention and follow up, Friedman $\chi^2(3) = 14.52$, $p=0.002$ with a moderate effect size ($W = 0.484$). Median (IQR) scores were 224.00l/min (187.75-245.50) at baseline one, 213.67l/min (146.17-266.33) at baseline two increasing to 253.00l/min (214.75-342.99) post-intervention and 250.84l/min (236.83-293.59) at follow up. Post hoc comparisons demonstrated no significant differences between baseline one and two ($p=0.58$); or between post-intervention and follow up ($p=0.39$), but

significant increases between the two baseline scores and post-intervention and follow up scores ($p=0.03-0.01$)

7.3.4.ii. Participant reported outcome measures

7.3.4.ii.a. V-RQOL

Higher V-RQOL scores indicate a greater degree of impairment. Median V-RQOL scores showed a downward trend, however, no change across timepoints was significant, Friedman $\chi^2(3) = 3.21$, $p=0.36$ with a small effect size ($W=0.11$). Median (IQR) scores were consistent between baseline one [21 (17.75-36.00)] and two [21 (17.75-36.25)] followed by slightly lower scores post-intervention [20 (16.75-30.75)] and at follow up [18 (14.75-36.75)].

7.3.4.ii.b. CASA-Q

CASA-Q scores are reported across the domains of cough severity (COUS), cough impact (COUI), sputum impact (SPUI) and sputum severity (SPUS), where higher scores indicate less impairment. COUS scores did not change significantly following EMST, Friedman $\chi^2(3) = 2.67$, $p=0.45$ with a small effect size ($W=0.09$). Additionally, no significant change in scores was observed for SPUI (Friedman $\chi^2(3) = 7.71$, $p=0.052$) with a small effect size ($W=0.26$) or SPUS (Friedman $\chi^2(3) = 4.64$, $p=0.20$) with a small effect size ($W=0.15$). However, SPUS scores did meet minimal clinical important difference level for reduction in sputum symptoms between baseline one [median (IQR)= 54.17 (41.67-66.67)] and follow up [median (IQR)= 66.65 (33.33-77.08)]. COUI scores were significantly improved post-intervention (Friedman $\chi^2(3) = 7.86$, $p=0.049$), with a small effect size ($W=0.26$), demonstrating a reduction in cough impact between median scores at baseline two [median (IQR)= 75.00 (57.82-82.81)] and post-intervention [median (IQR)= 84.38 (77.35-92.97)], $p=0.02$. Post-intervention improvement was sustained at follow up with no significant difference in scores, $p=0.23$.

7.3.4.ii.c. SECEL

SECEL scores are reported as a total score and sub-scores within general, environmental and attitudinal domains, where lower scores indicate less impact. There were no significant differences in the total score (Friedman $\chi^2(3) = 7.61$, $p=0.05$ with a small effect size, $W=0.25$) or the general domain score ($F(3,27)=0.93$, $p=0.44$ with a medium effect size, $\eta p^2 = 0.09$) across timepoints. In the environmental domain, participants' median scores improved over time (Friedman $\chi^2(3) = 11.40$, $p=0.01$ with a small effect size, $W=0.38$). Environmental domain median (IQR) scores were significantly lower at post-intervention assessment [14.50 (11.25-25.50)] compared with baseline one [17.00 (14.75-28.50)], $p=0.008$, and baseline two [15.00 (11.00-29.25)], $p=0.04$. There were no significant differences in baseline median scores ($p=0.17$) or between post-intervention and follow up ($p=0.83$), however, median (IQR) follow up scores [12.50 (8.75-25.00)] were not significantly different to baselines one ($p=0.08$) and two ($p=0.13$). Attitudinal domain scores also improved over time (Friedman $\chi^2(3) = 8.01$, $p=0.046$ with a small effect size, $W=0.27$). Post hoc comparisons demonstrated significantly lower median (IQR) scores post-intervention [6.00 (3.75-23.00)] compared with baseline two [7.50 (6.75-26.00)]; $p=0.02$. There was no significant difference in median scores between baseline one [7.50 (6.00-23.00)] and two ($p=0.08$); or post-intervention to follow up score [6.00 (3.00-21.50)]; $p=0.89$.

7.3.4.iii. Measures of voice quality

7.3.4.iii.a. Maximum decibels on phonation

Mean maximum decibels were not significantly different ($p=1.00$) between baseline values of 74.88 (6.45) at baseline one and 76.15 (5.54) at baseline two. Participants did increase mean maximum decibels post-intervention, $F(2.05, 18.46) = 12.47$; $p<0.001$, with a large effect size ($\eta p^2 = 0.58$). Post hoc comparison indicated that participants increased their scores between baseline one and follow up (82.05, SD: 4.91), $p=0.013$; and between baseline two and post-intervention (79.56, SD: 5.72), $p=0.001$ and follow up, $p=0.015$. Decibel increase was

sustained during the maintenance period with no significant differences between post-intervention and follow up scores ($p=0.67$).

7.3.4.iii.b. Maximum phonation time

No significant changes were found in maximum phonation time in seconds across timepoints, Friedman $\chi^2(3) = 2.28$, $p=0.52$ with a small effect size ($W=0.08$). Median (IQR) values showed a trend of attenuating MPT post-intervention and at follow up: baseline one [11.29 (5.28-15.38)], baseline two [11.65 (4.35-16.07)], post-intervention [8.01 (3.97-14.18)], follow up [7.30 (3.96-13.20)], however, the reduction in MPT was not significant.

7.3.4.iii.c. Perceptual voice quality

There were no significant differences in the composite score, $F(3,27)=0.50$; $p=0.69$, overall voice quality $F(3,27)=1.39$; $p=0.27$ or individual item scores of the SToPs (see Table 6.2). Visual inspection of the data did not demonstrate any pattern of change. This indicated no change in perceptual voice quality between baselines or post intervention, as assessed by an experienced clinician.

7.4. DISCUSSION

This study investigated the feasibility and preliminary efficacy of EMST after total laryngectomy. The study found that EMST is feasible for PWL and was indicative of potential benefit in respiratory measures and voice loudness in decibels; perceptual voice quality was unchanged, however. Participants additionally reported reduced impact of cough, improved attitude towards speech and of communicating in different environments as measured by the CASA-Q and SECEL. However, as a small feasibility study, with a self-selecting group of motivated participants, outcomes should be interpreted tentatively.

7.4.1. FEASIBILITY AND ACCEPTABILITY

Ten participants completed the assessment and intervention with high adherence to the protocol, demonstrating that EMST is feasible and acceptable after laryngectomy. Two additional eligible participants did not consent to take part in the study due to long travel distances. However, as the study was recruiting participants UK-wide, this was not indicative of transference to clinical practice where PWL would typically access therapy closer to home.

Whilst all participants required device adaptations to prevent air leak, simple adaptations were effective with the use of low-cost materials, such as elastic bands, or modification to commonly used tracheostoma equipment, such as heat moisture exchangers or manometry adapters. The availability of low-cost modifications may be a pertinent factor in widening access to EMST, where funding is inconsistent within NHS services (Graley, May and McCoy, 2011) and globally outside of free healthcare systems.

Participant feedback highlighted the need for solutions if the device could not be removed promptly from the neck stoma to allow for inhalation. Whereas laryngeal users may release the device easily by opening the mouth after exhalation or inhaling via the nose, the alteration to anatomy post laryngectomy prevents this approach. Participants demonstrated self-management skills and innovative thinking in relation to device adaptation, offering solutions that they had devised from experimentation with their existing daily consumables. As described in Section 7.3.3.iv.a., it is essential that clinicians routinely assess individual PWL's ability to consistently remove the device from the neck stoma to enable prompt inhalation. This ability should be assessed for all PWL using EMST, regardless of whether a device adaptation is in use.

Shoulder mobility may be impaired after laryngectomy (Rauchenwald et al., 2021; Yeh, Sahoaler and Fung, 2017), impacting the ability to raise arm towards the neck stoma for device removal, therefore this may present risk in using the device for people with shoulder dysfunction or other impairment to dexterity. Studies on the use of EMST via other neck breather populations for comparison, such as tracheostomy, are infrequent. In existing studies, the potential issues of device removal and air leak are not reported (Clayton et al.,

2022). More widely, studies of device-based inspiratory muscle training in tracheostomy do not report on these issues (Elkins and Dentice, 2015; Santos-Pascotini et al., 2014; Martin et al., 2011). However, since these studies took place in critical care units, it may be expected that healthcare professionals were present throughout the intervention to assist with device insertion and removal. Furthermore, equipment is designed to attach more readily to a tracheostomy tube in contrast with laryngectomy products.

In terms of implications for clinical practice, it is recommended that individuals are advised on use of a highly adhesive baseplate during EMST practice, with associated peristomal skincare. Assessment of device-to-baseplate air seal is also required with use of modifications if seal is insufficient or where individuals require support to insert the device at an appropriate depth thus avoiding skin irritation. Furthermore, hand and arm dexterity should be assessed to ensure the device can be promptly removed from the neck stoma independently. Where individuals lack sufficient dexterity, a modification must be offered.

One prior pilot study of EMST use in laryngectomy exists (Van Sluis et al., 2020), which advocated for future testing without plugging of the voice prosthesis. The absence of plugging was suggested as, of the nine participants in the study, three were unable to plug the prosthesis and continued without it; of the remaining six participants, three found plugging inconvenient. The authors therefore recommended that future research should test EMST without plugging to ascertain whether improvement can still be gained. In the present study the recommendation was implemented, and participants were advised not to plug the prosthesis, with only one participant reporting a need to nose pinch to reduce airflow via the prosthesis. As participants demonstrated significant gains in respiratory parameters without plugging the prosthesis, this suggests that plugging is not necessary to derive benefit from EMST.

7.4.2. RESPIRATORY FUNCTION

A double baseline assessment was used in this study to increase confidence in attributing outcomes to the intervention. Across all outcome measures there were no differences

between baseline assessments indicating that participants' respiratory function was stable prior to commencing EMST. Normative respiratory values have not yet been established for PWL. In comparison with normative values for the laryngeal population, the (predominantly male) participants' average MEP at all timepoints was below the male lower threshold of 140cmH₂O (Ponce, Sankari and Sharma, 2023). Similarly, PF values at all timepoints were below the female and male lower threshold ranges of normal by mean age, using the EN13826 scale (Clement Clarke International, 2004).

Study outcomes demonstrated a significant increase post-intervention in MEP, albeit with a detraining effect at follow-up. The increased MEP value is consistent with existing EMST research in the laryngeal population and with Van Sluis et al. (2020) relating to the laryngectomy population. In contrast with Van Sluis et al. (2020), measures of PF and FEV1 also increased over time, and gains were maintained at follow-up. Increased PF with EMST was also observed in studies of elderly populations (Park et al., 2017) and after partial laryngectomy (Palmer et al., 2018). The differences in PF and FEV1 outcomes between this study and Van Sluis et al. may be explained by differences in participant characteristics as mean baseline values for PF, FEV1 and MEP were lower than baseline values in Van Sluis et al. (2020). Van Sluis et al. (2020) described all their participants as 'relatively fit' which may have led to a ceiling effect. A measure of performance status or exercise tolerance was not included in this study to quantify this difference, however. Gains in respiratory function post-intervention are consistent with qualitative participant reports of increased exercise tolerance in walking and stair climbing, and greater lung expansion on breathing. This finding has been reported in healthy subjects who reported reduced sensation of respiratory effort during treadmill-based exercise, following EMST (Suzuki et al., 1995).

Two participants reached the maximum pressure threshold of the device before the end of the five-week intervention, which may have curtailed the potential for further increases in respiratory outcome measures in those individuals. This was also reported in Van Sluis et al. (2020). Future research into EMST post-laryngectomy may benefit from use of devices that can reach a higher pressure threshold and exploration of this finding; such as the impact of altered anatomy and lack of laryngeal valving on expiratory force.

7.4.3. PARTICIPANT REPORTED OUTCOME MEASURES

Participant reported outcome measures were used to ascertain whether change in objective measures was reflected in functional or QOL of life experiences. No significant change was found on the V-RQOL, however, this scale has not been developed for the laryngectomy population and therefore may not be sensitive to change. Outcomes of the SECEL scale, which is specifically designed for laryngectomy, demonstrated reduced impairment in the Environmental and Attitudinal domains. Change in Environmental score expresses how participants experience their voice in different environments, whereas change in Attitudinal score expresses how participants perceive their voice and how they are perceived by others (Johanssen, Ryden and Finizia, 2008). Loudness is a frequent concern for tracheoesophageal speakers, with difficulty being understood in noisier environments. The improved Environmental and Attitudinal scores could therefore be interpreted as consistent with increased maximum decibel levels post-intervention.

In qualitative reports, participants described easier mucus clearance following EMST, which correlated with reduction in cough impact and severity of sputum as measured by the CASA-Q. In comparison with the COPD population, who experience hypersecretion of mucus, improvement in CASA-Q scores has been shown to relate closely to improved QOL (Shen et al, 2018). Amongst symptoms and concerns most closely relating to the CASA-Q cough impact domain, people with COPD reported impact on social interactions and discomfort in talking to others. Whereas the sputum severity domain was related to difficulty and exhaustion arising from mucus clearance (Patalano et al., 2022). This may provide some rationale for the consistency in improved CASA-Q and SECEL Attitudinal and Environmental scores produced by PWL in this study.

7.4.5. MEASURES OF VOICE QUALITY

A significant increase in maximum decibels was observed post intervention and was maintained at follow up. This was consistent with Van Sluis et al. (2020). In a study of laryngeal speakers, expiratory muscle tension was increased when speaking louder (Huber,

Chandrasekaran and Wolstencroft, 2005); therefore, gains in MEP may have contributed to the increase in maximum decibels found within this study. Conversely, there was a small non-significant decline in MPT across timepoints. Normative values for MPT are not established for PWL, however, a previous study which measured MPT in PWL reported a mean MPT of 7.0 seconds (Takeshita-Monaretti et al., 2014), which was shorter than the findings of this study. Increase in decibels has been demonstrated to negatively influence maximum phonation time in laryngeal populations (Schmidt, Klingholz and Martin, 1988); therefore, this finding may suggest that as participants improved vocal intensity, breath support was modified leading to slightly reduced MPT, however, decrease across timepoints was not significant.

No changes were found in perceptual voice quality after EMST intervention. Participant scores on the items of the SToPs scale were within the range of no impairment to mild impairment at baseline with low impact of reading or accent features. Similarly mean tonicity was within the range of mildly hypotonic to normal. Therefore, there is potentially little room for improvement. However, it is worth noting that the clinician perceptual ratings of no to mild impairment were inconsistent with participant reported measures; and at all timepoints participant scores met the threshold values for rehabilitation (Tuomi et al., 2015) on all domains of the SECEL.

The inconsistency of SToPs rating between participants and clinicians has been found in previous research involving auditory-perceptual assessment of tracheoesophageal voice (Coffey et al., 2018). This may reflect a limitation of the SToPs as a clinician-rated measurement tool; however, it is of note that inconsistency between service user and clinician rating has been reported in laryngeal voice research (Karnell et al., 2007; Kim and Choi, 2009) and so may point to a wider question on factors influencing service user and clinician rating of voice. This indicates the need for development and testing of perceptual voice outcome measures to establish sensitivity to change, clinically important values and correlation with participant experience of communication.

7.4.6. LIMITATIONS AND DIRECTIONS FOR FUTURE RESEARCH

Whilst this study adds to the evidence base on post-laryngectomy rehabilitation and has demonstrated the feasibility and acceptability of EMST and some improvements on outcomes following EMST, results should be interpreted with some caution due to the small sample size. Further testing is required to explore the efficacy of EMST in an appropriately powered study; and whether results gained during controlled study conditions are transferrable to routine clinical practice. A further limitation is the absence of normative respiratory, acoustic and perceptual outcomes for tracheoesophageal speakers, which limit interpretation of outcomes in the context of the wider laryngectomy population. After laryngectomy anatomical changes result in decreased dead space of the respiratory tract, however, the impact of this on respiratory function is not yet established in literature (Ackerstaff et al., 1995), additional research is required to understand how the improvements in respiratory measures might impact function post laryngectomy.

Few outcome measures exist which are specific to people with laryngectomy therefore measures developed within laryngeal or other clinical populations were used without adequate validation. This study did not include measures of exercise tolerance, general health, or performance status. This data may have been informative in exploring participant report of improved exercise tolerance. Furthermore, baseline assessment of health status could indicate which people have the greatest potential for response to EMST or identify a ceiling effect in healthier participants. This is recommended as a direction for future research. It was not within the scope of this study to investigate whether use of EMST also had an effect on training skill or technique of breathing alongside targeting strength. Additionally, this study did not explore the potential of inspiratory muscle training or combination training, which may have indications for use post laryngectomy. This would be a relevant direction for future research.

Swallowing function was not investigated during this study, however, two participants gave qualitative feedback on swallowing and considered whether the muscular engagement of EMST could assist neopharyngeal bolus transit. EMST has been found to impact positively on

swallowing in laryngeal populations therefore it would be pertinent to investigate the impact of EMST on post-laryngectomy swallow function.

7.5. CONCLUSION

EMST was found to be acceptable and feasible for PWL, however, device adaptations were required to support safe usage. Specifically, in relation to the prompt removal of the device from the neck stoma to prevent airway obstruction. This study was of small scale but provided important early data to inform a larger scale study. Improvements were demonstrated post-intervention in respiratory measures of MEP, FEV1, PF, and in voice loudness, which aligned with participant reported measures of cough, self-perception of communication and environmental and attitudinal impact. Further research is required in this area to generate greater understanding of the role of respiratory muscle training in laryngectomy rehabilitation, and to target treatments more specifically to those who may benefit from it. Additionally, there is a need to develop new and existing assessments of tracheoesophageal voice to support reliable and valid measurement of clinical outcomes.

CHAPTER 8 | DISCUSSION

This doctoral study encompassed the initial stages of development of a novel tracheoesophageal voice therapy intervention for PWL. The study applied mixed research methodologies to achieve this, guided by the first phase of the MRC framework for developing and evaluating complex interventions (Skivington et al., 2021) and further development guidance proposed by O’Cathain et al. (2019).

Several sub-projects were completed to ensure intervention development was underpinned by theory, existing evidence and centred stakeholders within the process. Published research evidence for tracheoesophageal voice rehabilitation was identified through a systematic review and was considered alongside exploration of laryngeal voice therapy approaches, which may provide translational theory and models of practice. Intervention development was informed by this evidence and shaped by stakeholder involvement, namely a survey of clinicians to establish the current landscape of tracheoesophageal voice therapy practices, and a qualitative study using focus groups to identify the experiences and priorities of PWL in relation to voice therapy. These outputs led to the feasibility testing of EMST as a potential intervention component. A co-design project followed, which gave a preliminary insight into additional intervention components, priorities and clinical barriers to implementation.

The inception and progression of the study was guided by a PAG, whereas a DAG was formed to support inclusion of minority ethnic PWL into the study. The doctoral study has culminated in the identification of key intervention components which can be taken forwards for further refinement, feasibility testing and implementation strategy. This chapter will present the main findings, synthesise outcomes and propose a preliminary programme theory to inform the next phase of intervention development. The chapter ends with consideration of strengths and limitations, and recommendations for future research.

8.1. MAIN FINDINGS

The main findings of the study are discussed in relation to the study aims, and synthesis of the study outputs is presented.

8.1.1. AIM ONE: TO ESTABLISH CURRENT KNOWLEDGE AND TO IDENTIFY EXISTING EVIDENCE FOR TRACHEOESOPHAGEAL VOICE REHABILITATION

The first aim was met through the completion of a systematic review which investigated behavioural interventions for tracheoesophageal voice rehabilitation (Chapter Three). This foundation context to intervention development was enhanced by the detailing of laryngeal and alaryngeal voice production, and exploration of existing laryngeal voice therapy models presented in Chapter Two. Together these chapters present the status of existing knowledge for tracheoesophageal voice rehabilitation and consider whether existing laryngeal therapy approaches could be transferrable to tracheoesophageal voice.

In preparation for the systematic review, preliminary searches identified that no previous systematic reviews had investigated the evidence for behavioural approaches to tracheoesophageal voice rehabilitation and existing professional guidelines were insufficient to inform SLT practice. This is in the context of a strong evidence base for other aspects of laryngectomy care, such as outcomes of surgical approaches, complication rates, comparison of post-laryngectomy communication methods and voice prosthesis selection. The focus of the literature on the wider aspects of laryngectomy and voice restoration, rather than rehabilitation, provide important contextual information in which to situate a novel tracheoesophageal voice therapy approach. However, there was a clear knowledge gap relating to tracheoesophageal voice rehabilitation, which presented a strong rationale for the systematic review.

The systematic review was carried out according to the PRISMA guideline (Page et al., 2021) and registered with PROSPERO. The review found six studies for inclusion, which were

assessed for quality and data extraction. The findings of the systematic review indicated that participants were predominantly male (87.4%), which was not reflective of the 69% male / 31% female incidence of head and neck cancer cases in the UK (Cancer Research UK, 2021). Furthermore, studies did not report on the ethnicity of participants and few participants with extended surgery were included; therefore, the generalisability of the findings is uncertain.

Studies were heterogenous in terms of the interventions assessed and outcome measures used. This highlighted the challenge of assessing tracheoesophageal voice as few laryngectomy-specific outcome measures exist, and fewer still for assessment of tracheoesophageal voice. Therefore, studies relied predominantly on laryngeal voice outcome measures (VHI, SHI, GRBAS) and informal perceptual ratings. Most reported interventions were not described in detail, however, there was a range of different direct approaches trialled comprising respiratory, musculoskeletal and vocal function approaches. Pedagogy and counselling were also included in the form of self-care training and psychological support. Direct approaches showed evidence of adaptation for the laryngectomy population. For example, two studies used breathing exercises which included practice of coordinating breath to stoma occlusion (Longobardi et al., 2019; De Oliveira et al., 2005). A challenge of the studies was that interventions often included several aspects and were assessed with outcome measures that were not specific to one aspect, therefore it was unclear which elements of an intervention were most beneficial.

Uncertainty around identifying which elements of an intervention are responsible for positive outcomes has been highlighted as an issue in laryngeal voice therapy (Roy, 2012). In addition, Roy (2012) notes that voice therapy interventions do not strongly adhere to principles of exercise physiology. This was evidenced in Chapter Two where the majority of laryngeal voice therapy interventions were found lacking in guidance on optimal dosage. Moreover, it is uncertain whether principles of exercise physiology can be directly transferred to voice training without adaptation, since they are derived from the evidence base for limb skeletal muscle function and cardiorespiratory fitness (Johnson and Sandage, 2021).

Chapter Two explored the differences between laryngeal and tracheoesophageal voice production, which revealed avenues for future research and raised key questions. Namely,

what aspects of laryngeal voice therapy could be transferable to tracheoesophageal voice. An additional question arising here was whether that is an acceptable approach without further understanding of the underlying mechanisms of tracheoesophageal voice production, the active elements of an intervention, and optimal dosage. Notwithstanding that, the evidence base and descriptions of laryngeal voice interventions, as applied as intended to laryngeal voice, are limited and require further research. The systematic review demonstrated that these questions are not answered by the existing small body of studies on tracheoesophageal voice rehabilitation. Given the lack of robust evidence, an existing laryngeal or tracheoesophageal voice intervention was not tested more widely for the purposes of this study. Whilst the use of EMST was explored in Chapter Seven, this was to gain further information about the feasibility and acceptability of EMST as a component of an intervention, rather than as an approach to be used in isolation. Given the current evidence base and the issues highlighted, a strong rationale was evidenced for the development of a novel tracheoesophageal voice intervention.

8.1.2. AIM TWO: TO UNDERSTAND WHAT APPROACHES SLTS CURRENTLY USE IN CLINICAL PRACTICE, AND TO IDENTIFY BARRIERS AND FACILITATORS TO IMPLEMENTATION OF TRACHEOESOPHAGEAL VOICE THERAPY

To achieve the second aim of the study, a survey of UK and Irish SLT practice was carried out and is reported fully in Chapter Four. In the context of the dearth of evidence for tracheoesophageal voice therapy and lack of detail in clinical guidance, it was pertinent to examine how, or indeed if, SLTs carry out voice therapy for PWL. This information contributes to intervention development in several ways. SLTs are key stakeholders in the development of an intervention, therefore an understanding of current practice was necessary to identify the existing foundation from which the intervention is developed. Secondly, it was important to establish whether SLTs perceived voice rehabilitation after laryngectomy as a central component of rehabilitation and to explore their views on undertaking this clinical work. Finally, it was essential to ascertain the barriers and facilitators to this aspect of clinical practice, to identify the factors that would require addressing for successful implementation of a novel intervention.

The survey received good engagement from the head and neck SLT community, with 147 responses from the ROI and across all regions of the UK. The survey demonstrated that the majority of SLTs were not aware of any therapy approaches specific to tracheoesophageal voice. This was in line with the outcome of the systematic review, which highlighted the absence of robust evidence to guide practice. Of the few examples of practice that were shared, approaches were based upon laryngeal voice therapies, such as diaphragmatic breathing and focus on reducing muscle tension. The finding that the majority of SLTs never use outcome measures was also reflective of the systematic review in highlighting the impact of the lack of alaryngeal voice-specific outcome measures. The need for a tracheoesophageal voice rating scale has been noted previously (Hurren, Hildreth and Carding, 2009) but has not yet been implemented. The lack of appropriate, validated outcome measures for tracheoesophageal voice is reflected in other areas of head and neck cancer such as dysphagia (Manduchi et al., 2022), dysphagia-related QOL (Clunie et al., 2023); and xerostomia (Walsh, Fagan and Davies, 2023). Additionally, the issue of inconsistent approaches to symptom measurement has been identified (Bolnykh et al., 2024 – pain in head and neck cancer survivors).

A lack of clinical knowledge and resourcing in terms of staffing and time were cited as the main barriers to delivering tracheoesophageal voice therapy, leading to feelings of frustration at these limitations. As a consequence of resourcing issues, SLTs noted that voice work was often deprioritised in favour of other rehabilitation needs that were deemed higher safety risks, or if the PWL presented with a functional, but not necessarily optimal, voice.

Whilst SLTs were attempting to provide therapy and viewed it as an important part of laryngectomy rehabilitation, only 23.9% of those surveyed agreed that their intervention resulted in improved communication. Furthermore, SLTs expressed feelings of uncertainty and a lack of confidence despite being interested and motivated to carry out tracheoesophageal voice therapy. This again points to the sequelae of the lack of evidence to guide practice, and reflects the questions raised in Chapter Two regarding the feasibility of transferring laryngeal approaches to PWL.

Additionally in Chapter Two, the notion that aspects of laryngeal voice therapy would require adaptation was considered. The survey revealed evidence of this occurring in clinical practice, for example SLTs cited optimisation of prosthesis type, baseplate and HME systems as a key component of voice therapy. This could be interpreted as comparable to a component of vocal tract care and vocal hygiene as a foundation of laryngeal voice therapy.

SLTs clearly articulated the knowledge and skills they felt were essential for tracheoesophageal voice therapy, which spanned knowledge of both laryngectomy care and therapeutic voice skills. This suggested that SLTs viewed knowledge of either laryngectomy or laryngeal voice therapy alone as insufficient, and both skillsets were required to deliver effective rehabilitation. Alongside the relevant clinical skills and knowledge, SLT respondents identified the clinical resources that would support their practice. Here the need for clinical resources encompassed a wide range of aspects and revealed the extent of the absence of clinical guidance. SLTs desired a stronger evidence base, practice guidelines, decision-making tools, validated laryngectomy-specific assessments, toolkit resources of therapy ideas and a resource of tracheoesophageal voice recordings to inform learning.

A clear implementation strategy is required to translate research findings into an effective and acceptable intervention, and to minimise risk of research waste (Klaic et al., 2022). The highlighting of the above requirements indicates that for a novel intervention to be successful, it would necessitate multiple factors including the development of supporting clinical resources, a detailed training package and to be based on evidence. The survey demonstrated the influence of external groups such as the Clinical Excellence Networks were a positive influence on practice, which could present an important route of engagement and dissemination in future intervention development work.

A notable absence in the survey responses was recognition of the potential for PWL to be stakeholders in the delivery of clinical training, the development of resources, or as an expert patient partner within the delivery of therapy. This is consistent with existing studies identified in the systematic review, where in all studies PWL were involved as research participants but were not partner stakeholders in developing the tested interventions. Expert service users can fulfil several roles to support clinical education, such as teaching, assessing

and supporting curriculum design (Dijk et al., 2020); which would be relevant for the development of clinical training resources to support implementation of a novel intervention. Furthermore, increased service user participation improves interactions between clinicians and service users (Cegala et al., 2007), and is associated with positive clinical outcomes (Omeni et al., 2014). Partnership working with service users is therefore an essential factor in the development of an intervention and the training associated with it. However, evidence from the field of medical education has indicated that a culture change is required to overcome clinical trainees' skepticism that service user-led input to clinical training can produce beneficial outcomes (Donaghy, Boylan and Loughrey, 2010). Additionally in undertaking expert patient roles, service users may encounter challenges from self-disclosure, exposure to potentially negative assumptions and the emotional burden of having to withdraw from teaching in the event of disease progression (Dijk et al., 2020). The risks to service users of their involvement therefore requires careful consideration and safeguarding.

8.1.3. AIM THREE: TO ESTABLISH THE VIEWS, EXPERIENCES AND PRIORITIES OF PWL REGARDING TRACHEOESOPHAGEAL VOICE REHABILITATION

A qualitative study was completed using focus group methodology to achieve this aim, as reported in Chapter Five. The outcomes of the focus groups also fed into the subsequent co-design study, which is discussed under Aim four.

The focus groups were attended by 20 PWL of which 40% were female, therefore there was a slight over-representation of female PWL in comparison with head and neck cancer incidence. Of the participants, three were from a minority ethnic group. The use of online videoconferencing enabled the participation of PWL from distinct English and Scottish regions, however, PWL from Wales and Northern Ireland were not represented.

The focus group found six main themes in relation to the experiences of PWL and their priorities for voice rehabilitation. The themes highlighted the breadth of the impact of laryngectomy on all aspects of daily life, including work, personal and social roles; and the extent of unseen hidden disabilities and emotional burden that PWL encounter. These

findings gave vital insights into the level of psychological readiness that PWL may bring to rehabilitation, and the hidden or overt issues that they may be dealing with alongside adjustment to the altered voice. Readiness to engage with therapy has been demonstrated to predict completion of rehabilitation programmes and improve rehabilitation outcomes in other areas of clinical practice (pain - Tkachuk et al., 2012; sports injury – Faleide and Inderhaug, 2023), therefore this is a pertinent factor to consider in intervention development. These challenges were not specifically highlighted by SLTs in the survey, beyond acknowledgement that patient motivation was a factor in whether or not to deliver voice therapy, which suggests the depth of impact may also remain hidden to SLTs. The engagement of varied stakeholder groups is advocated for within clinical research to ensure a range of unique perspectives and priorities are acquired (Maurer et al., 2022). This demonstrates the added value achieved through the inclusion of different stakeholder groups in the research, which increased the breadth of insights gained.

In terms of service provision, PWL were aware of the insufficient clinical resourcing that SLTs highlighted in the survey and had experienced this. PWL described the impact of resourcing challenges negatively. For some, the lack of weekend service provision was a significant issue when prosthesis problems arose outside of standard working hours, whereas for other participants access to services was also limited during normal weekdays. The ‘weekend-effect’ in healthcare describes the finding that people admitted to hospital on weekends are more likely to die than those admitted on weekdays (Aylin et al., 2010). Detailed research on this effect has found that the causal factor was not due to errors or fewer Consultants present in hospital care at the weekend; instead, it relates to insufficient care in community settings at the weekend, and thus patients admitted at weekends having higher acuity or end-of-life care needs (Bion et al., 2021). The absence of weekend outpatient SLT service provision for PWL can be equated to the insufficient weekend community care, which is a driver for PWL attending A&E for treatment of urgent voice prosthesis issues. However, PWLs’ needs may not be met in the A&E setting due to insufficient clinical knowledge of HCPs, which was raised as a concern by focus group participants in Chapter Five. Pilot study of simulation-based training has found that this approach is feasible for the upskilling of HCPs in urgent laryngectomy care needs (Sparks et al., 2021), however, larger-scale study is indicated.

In other aspects of service provision, there was also a consistent experience between PWL and SLTs in terms of what *is* prioritised clinically, but not necessarily what PWL *wanted* to be prioritised. PWL gave examples of SLT appointments focussing on prosthesis management rather than voice rehabilitation, and of feeling that SLTs do not have time for the latter. Participants did not give examples of discussing this with their SLT, however, which suggested that their needs were not always being recognised or met, or that they did not feel able to raise concerns during appointments. This finding reflects study of head and neck cancer teams' decision-making around treatment options (Hamilton et al., 2016), which found that service user involvement in decision-making was obstructed by existing processes that create exclusion.

Providing service users with control over their healthcare decisions is a core element of patient-centred care (Naik and Catic, 2020). In the geriatric care setting, aligning care to service user-led priorities was shown to be feasible, and to result in more referrals to community-based support services and increase in self-management tasks (Freytag et al., 2020). Within the focus group study, PWL placed importance on signposting to varied support systems and on being empowered to be more active in their care. The outcomes of Freytag et al. (2020) suggest that ensuring service user priorities inform care could be a way to achieve this. This presents a direction for further research to explore the potential misalignment of priorities between SLTs and PWL, and how this can be overcome.

An additional contrast in prioritisation was evident between the clinician survey and focus groups outcomes. PWL spoke about how their interpretation of prioritisation, and therapy goals more generally, was strongly personalised to individual needs and was variable according to fluctuating levels of function. For PWL, prioritisation of voice was also embedded in the balance between maintaining voice and swallow function. This differed with SLT views on prioritisation, where maintaining the voice prosthesis and addressing the highest clinical risks were the key drivers in what was prioritised during an SLT session. This points towards a need for priority setting which is dynamic and collaborative to ensure therapy meets the needs of PWL whilst negotiating the clinical safety concerns that SLTs may have. PWL advocated for this to be situated within an intervention which has responsive, personalised care at its core. Here, the field of dysphagia management is informative, where

intervention seeks to balance risks with quality of life and individual patient preferences (RCSLT, 2021). In reference to dysphagia, Smith and Bryant (2022) advise clinicians to identify whether their views align with the person with dysphagia and to recognise them as an expert in their condition, in order to improve management plans. Similarly in dementia care, patient-centered goal setting is advocated for to address the challenge of managing safety versus maintaining independence (Jennings et al., 2016).

In relation to impairment-based therapy, PWL stated that increased volume, articulation, breathwork and pitch were important to them. This was consistent with the therapy approaches that SLTs reported in the survey and with studies included in the systematic review. The highest priorities in laryngeal voice therapy are identified as vocal clarity, loudness, pitch range and vocal endurance (Titze et al., 2018). Whilst PWL did not discuss vocal clarity as a specific parameter, vocal endurance was highlighted in the context of fatigue and additional effort associated with tracheoesophageal voice production. PWL additionally expressed the wish to know more about different equipment and the options that may be available to them. This aligned with the SLT view that establishing the optimum prosthesis and humidification systems was an important element of voice therapy. There may, however, be a role for greater involvement of PWL in the selection process and improved level of information provision around equipment options.

Information was cited as a key component of voice therapy by PWL and overwhelmingly participants' experiences of information received, or indeed not received, were highly negative. PWL emphasised that information provision was an area for improvement, raising issues with the timing of information provision, the delivery method and the volume of information given. Patient information is highlighted as a key component of a care pathway and service user involvement in information development is a marker of quality information (Department of Health, 2019). Enhancing information provision was therefore interpreted as a strong area for future co-design work to improve service user experience and was taken forward into the subsequent co-design study. In contrast SLTs did not raise information issues within survey responses, however, this may be more reflective of a survey limitation as information provision was not an area of direct questioning.

Another aspect of optimising information was the central role of information in enabling PWL to be experts in their condition. Patient information and education improves health literacy and facilitates informed decision-making (Bhattad and Pacifico, 2022). PWL expressed the importance of being informed about laryngectomy so that they could be active in their recovery and to be increasingly self-sufficient. There was also a keenness amongst PWL to share their knowledge for the benefit of SLT learning and for peer-befriending of new laryngectomees. Peer-befriending has been shown to be feasible in people with aphasia (Hilari et al., 2021) and perceived as a positive, rewarding experience for the peer-befrienders (Northcott et al., 2022). There is therefore the potential to investigate the transferability of this approach to post-laryngectomy rehabilitation. Clinicians did not consider the potential role of experienced PWL for these purposes in survey responses, rather PWL were framed as recipients of therapy by SLTs. During the focus groups, PWL described examples of voice self-learning and ideas of how they could be engaged in delivery of support services, therefore there was evidence of the wide potential for shared learning and collaboration. This may require clinicians to consider innovative models of practice, however.

Whilst PWL viewed SLTs as the key professional in their rehabilitation, they were aware that other avenues of support were required as adjuncts to SLT intervention, such as the aforementioned peer-befriending, support groups and psychology services. PWL shared examples of the impact of laryngectomy on their mental health yet felt that it was beyond the scope of SLT practice to address this fully; however, PWL also noted that access to psychological services was limited and difficult to navigate. One randomised control trial (Longobardi et al., 2019) was included in the systematic review, which found benefit from the inclusion of counselling alongside SLT; whereas within the survey, SLTs only noted that low mood or poor engagement would influence their decision whether to pursue voice optimising therapy with an individual. Northcott et al. (2017), investigated the views of SLTs on providing psychosocial support for people with aphasia; finding that psychological care delivered collaboratively by SLTs and other HCPs could improve services, however, multiple barriers would need to be addressed to achieve this. It would therefore be pertinent to explore a model of integrated therapies further given the high impact of laryngectomy on

mental health, and the communication difficulties that may present barriers to accessing support.

The focus group study elucidated the experiences and priorities of PWL in relation to voice therapy, which added novel insights to the evidence base. Areas of alignment and contrast between SLT practice and PWL were identified, alongside indicators for further exploration, which were taken forward into the subsequent EMST and co-design studies.

8.1.4. AIM FOUR: TO EXPLORE THE POTENTIAL COMPONENTS OF A NOVEL TRACHEOESOPHAGEAL VOICE THERAPY

This aim was met principally by two studies: a feasibility study of the use of EMST as a potential component of the VITAL intervention, reported in Chapter Seven; and a co-design process in partnership with PWL and SLT stakeholders, detailed in Chapter Six. The EMST and co-design work was directly informed by the earlier outputs of the doctoral project and drew upon these outputs to generate the content of the two studies.

Two key drivers were identified for the EMST study. Firstly, within the focus group study PWL highlighted that loss of volume was a significant barrier to their communication after laryngectomy, which affected participation and created social isolation. Furthermore, PWL viewed breathwork as an important part of their rehabilitation, which aligned with the inclusion of respiratory interventions in clinicians' current practice, as detailed in the survey outcomes of Chapter Four. There is a clear relationship between volume and respiratory function, as described in Chapter Two, where exhalation provides the power source for sound-generating mucosal vibration. Volume and respiratory intervention are therefore well-aligned as an intervention target and activity; and were identified as a key intervention component. This led to consideration of interventions that could effect change in volume through respiratory intervention, which identified the work of Van Sluis et al. (2020) on the feasibility of EMST after laryngectomy. Van Sluis et al. (2020) found that EMST, a respiratory intervention, was feasible for PWL and improved loudness in tracheoesophageal speakers.

The EMST study findings were consistent with Van Sluis et al. (2020) and showed that EMST was feasible and acceptable to PWL. Device modifications were required to support usage, however, and several modifications were designed and shared by PWL participants using existing equipment. This presented a practical example of the interest of PWL in being more active in therapy and in demonstrating the potential of shared learning from the patient-as-expert persona, which was discussed by focus group participants. The study found that EMST increased volume, reduced the impact of coughing and improved measures of respiratory function, which was consistent with EMST studies in the laryngeal population (Pitts et al., 2009; Laciuga et al., 2014; Allen et al., 2020). This led to an improved attitude towards speech and of communicating in different environments, as measured by participant-reported outcome measures. Other aspects of perceptual voice quality were unchanged, however, and limitations of the perceptual voice outcome measure used were identified. EMST was therefore identified as a potential component of a tracheoesophageal voice therapy, which could be incorporated alongside other activities targeting other perceptual features of voice quality.

To explore other potential components of the intervention, a co-design study was convened in partnership with nine PWL and ten experienced SLTs. This study aimed to bring earlier outcomes together and to refine them towards identification of preliminary intervention components. The co-design content (detailed in Tables 6.3 and 6.4) was iterative over the course of the co-design meetings and was informed by earlier outcomes of the study, as detailed in Chapter Six (Figure 6.2), in addition to therapy activity ideas generated by SLT stakeholders during the co-design process.

The key findings of the co-design were that, as a core value, PWL required an intervention based upon personalised care and responsive to changing priorities and function. This was strongly aligned to the views of focus group participants, where personalised care was a key priority for intervention design. Throughout the focus group and co-design studies, PWL were aware that individual experience and function varied greatly between individuals after laryngectomy. The NHS Long Term Plan for Cancer (NHS England, 2019) states that people with cancer should have access to personalised care and support interventions from diagnosis onwards, therefore it is pertinent to identify solutions to personalising care within

the context of the variable function and heterogenous clinical presentations of PWL. Wade-McBane et al. (2023) propose a model of personalised prehabilitation for people with lung cancer which applies a tiered approach to rehabilitation, tailored to personal needs.

Rehabilitation approaches and information are tiered as universal, targeted or specialist and offered to service users according to the complexity of their needs. This presents a model of practice which could be adapted to meet the diverse and changing rehabilitation needs of PWL.

PWL were critical of existing assessment and outcomes tools and felt that their individualised needs or priorities were not fully met, which reflected the challenge of outcome measurement identified in the systematic review and clinician survey work. This may also point to an explanation for the mismatches in prioritisation between SLTs and PWL, if current assessment processes are clinician-centred and not meaningful or active for PWL. A novel insight of the co-design was the view of PWL that the language of assessment tools was ableist, negatively framed and not relevant to PWL. In general, the use of outcome measures and assessment tools were not fully acceptable to PWL, rather a collaborative narrative-based assessment process and case history was preferred. Furthermore, Bangladeshi PWL partners observed that existing assessment processes were not culturally sensitive. This points to the need to consider several factors in intervention development, firstly whether a specific taxonomy of tracheoesophageal voice descriptors is required, to avoid the benchmarking of tracheoesophageal voice against laryngeal norms. Additionally, further co-design work is required to create an assessment process which is collaborative, personalised to individual need and culturally appropriate.

A key aim of the co-design was to generate therapy activities based upon the priorities raised by PWL in the focus group study. SLT partners worked to identify activities targeting volume, pitch, breath support and articulation; that could sit within a framework of increasing activity and participation. Chapter Six describes these activities in detail. SLT partners drew strongly on laryngeal voice therapy approaches here, noting where modification would be required for alaryngeal function. This led SLT partners to identify gaps in knowledge about the underlying mechanisms of tracheoesophageal voice and potential for functional gains, which aligned with the issues raised in Chapter Two. Through the co-design process, SLT partners

mapped a sample pathway for tracheoesophageal voice therapy, identifying possible solutions to barriers raised in the survey and noting where further work was required to address challenges.

PWL partners trialled therapy activities during the co-design process. Feedback was positive and PWL partners felt that the activities suggested by SLT partners were acceptable and feasible for them. However, a challenge of the study was that PWL did not have experience of prior voice therapy to contribute to therapy activities, therefore PWL feedback was based upon trial of activities suggested by SLT partners and lived experience of adapting to their altered voice use. In alignment with focus group participants, PWL emphasised that whilst direct therapy activities were acceptable, the intervention as a whole should be holistic and incorporate wider use of peer-befriending and learning with expert patients, which could be achieved in part through group voice therapy. Signposting to other services such as support groups and psychological services was also important. Intervention should also be complemented by improved information provision.

8.2. IMPLICATIONS

The doctoral study has provided novel insights into the status of the evidence base for tracheoesophageal voice therapy, the experiences and views of PWL and SLT stakeholders; and has established key intervention components based upon co-design and feasibility study. Furthermore, future directions for the next phase of intervention development have been identified to address remaining uncertainties and refine a prototype intervention protocol. Table 8.1 summarises these findings.

Study	Main findings	Implication for key components	Uncertainties
Voice production and theory	There are differences between tracheoesophageal and laryngeal voice production Understanding of the mechanisms of tracheoesophageal voice optimisation is limited The evidence base for laryngeal voice therapy is insufficient in some areas	More research is required to understand the mechanisms of tracheoesophageal voice therapy Some laryngeal voice therapy approaches could be transferrable to PWL with modification and further research	What aspects of tracheoesophageal voice are amenable to modification? Are modified laryngeal voice therapy approaches acceptable to PWL?
Systematic review	Tracheoesophageal voice therapy is an under-researched area of clinical practice Existing evidence is not sufficient to inform clinical practice There is a lack of laryngectomy specific outcome measures	More research is required to develop and test behavioural interventions to optimise tracheoesophageal voice Stakeholders should be engaged in intervention development	What are the active elements of the intervention? What is the optimal dosage of the intervention? Is the intervention feasible and acceptable to PWL and SLTs?
Clinician survey	There are no existing approaches to guide clinical practice Insufficient clinical resources Lack of voice specific training Uncertainty about how to optimise tracheoesophageal voice	Evidenced based clinical guidelines for tracheoesophageal voice therapy are required A robust training programme and associated clinical resources are required	What are the key elements of the intervention to inform clinical guidelines? What are the key elements of a training programme and how should this be developed? How can pathways be redesigned within existing resourcing?
Focus groups	Personalised care and prioritisation of therapy is important Peer-befriending, support groups and psychological support are all necessary	The intervention should be collaborative, dynamic and enable PWL to be active in their rehabilitation	How can assessment processes and intervention content meet the aims of personalised care at the right time?

Study	Main findings	Implication for key components	Uncertainties
	alongside SLT intervention Laryngectomy causes hidden disability Main impairment-based targets are volume, articulation, breathwork, pitch Current information provision is not acceptable	The intervention should be holistic and embedded in wider support systems Further intervention development is required Improved information resources should be developed	How could PWL and other support systems be integrated into a tracheoesophageal voice intervention? What impairment-based activities are feasible and effective? How can information content and delivery be better tailored to individual preferences?
Co-design	Agreement with focus group study that intervention should be personalised, responsive to changing priorities and PWL should have an active role in participation and support of others Improved assessment processes, outcome measures and information are required Direct therapy approaches were acceptable to PWL PWL were uncertain about acceptable dosage of therapy SLT pathways require redesign to support implementation of tracheoesophageal voice therapy	Co-design study demonstrates consensus with earlier study findings Modified laryngeal voice therapy approaches are acceptable, with modifications to the needs of PWL Further co-design work is required to progress aspects of intervention design and development of assessment resources and information Additional co-design work is required to consider model pathways of tracheoesophageal voice therapy provision in greater detail	Unknown aspects following the co-design study were consistent with future development directions highlighted in the earlier studies: What are the active elements of the intervention? What is the optimal dosage of the intervention? What impairment-based activities are feasible and effective? How can information content and delivery be better tailored to individual preferences? How can pathways be redesigned within existing resourcing?
EMST Feasibility	EMST is feasible for PWL with device modifications	EMST could be incorporated as a component of a	Which groups of PWL benefit most from EMST?

Study	Main findings	Implication for key components	Uncertainties
	EMST improved measures of respiratory function, volume and reduced impact of cough EMST improved attitude to communication in different environments	tracheoesophageal voice therapy intervention Larger scale study is required to reinforce findings	Is there a role for other respiratory approaches such as inspiratory muscle strength training?

Table 8.1: Summary of main findings and key intervention components

The practical application of the synthesised doctoral study findings is to identify that an acceptable intervention will incorporate the following elements. These are listed in this section and will be organised further down in this chapter:

- Collaborative assessment and goal setting based upon narrative case history
- Use of validated laryngectomy specific outcome measures
- Timing of voice therapy requires dynamic prioritisation which is revisited regularly
- Therapy is accompanied by multimodal information, centring representation of PWL
- Culturally specific and personalised clinical resources and information
- Voice therapy should take place within a focussed clinical session
- A personalised voice therapy plan which is tailored to individual requirements
- Voice therapy incorporates empowering service user education
- Equipment is optimised and laryngectomy-specific vocal hygiene is implemented as a foundation of voice therapy
- Direct therapy activities target optimisation of volume, pitch, articulation and breath support according to individual goals
- Therapy supports increased activity and participation in relevant areas, such as return to work or social activities
- Group voice therapy should be offered to practice voice skills in a supportive environment with peer support, following individual sessions to establish voice
- Services should seek to set up models of peer-befriending and shared learning from experienced PWL

- Signposting to additional avenues of support such as laryngectomy support groups and psychology services
- Creation of a best practice clinical guideline to inform clinical practice
- Specialist SLT training to upskill SLTs in tracheoesophageal voice therapy

The above elements are underpinned by the following intervention principles:

- SLT training improves skill, confidence and effectiveness of therapy provision (McAllister, 2009)
- Evidence-based clinical guidelines support best practice (Dodd, 2007)
- Education and improved information empower service users (Bhattad and Pacifico, 2022)
- The assumption that tracheoesophageal voice therapy which targets impairment, activity and participation will lead to optimised voice quality and increased voice use

8.3. PROGRAMME THEORY CONSIDERATIONS

MRC guidance (O’Cathain et al., 2019) provides a clear framework of actions to support intervention development. The guidance has been followed in this study (as detailed in Chapter One, Table 1.1) leading to the identification of the above intervention elements and principles. The next step is to bring these components together within a theoretical framework to demonstrate how they are integrated. A programme theory can be developed to achieve this.

Programme theory provides a conceptual foundation for an intervention, illustrating the change mechanisms of the intervention and the process by which the included components produce the intended benefits (Chen et al., 2024). Programme theory demonstrates how an intervention is expected to lead to its effects; enabling exploration of the different contexts and levels at which an intervention needs to function, to ensure the intervention is feasible and incorporates all relevant aspects (Pearson et al, 2015). For example, within this study the intervention requires development at PWL stakeholder and SLT stakeholder level, and also

within the context of the existing organisational and service frameworks into which it will be implemented.

No definitive framework of programme theory exists and there is not yet consensus on how programme theories should be articulated (Pearson et al., 2015). Rossi et al. (2019) state that an effective programme theory should clearly conceptualise its objectives and demonstrate how the objectives are achieved, based upon underlying theory and explicit description of the assumptions being made. For example, to achieve this, Rossi et al. (2019) propose a programme theory framework that incorporates a service utilisation plan to describe how interventions are expected to reach the target population; an organisational plan which centres on the required resources, personnel and facilities required to deliver a service; and an impact theory model that describes the cause-and-effect theory of included activities. An impact theory model is presented by Chen et al. (2024), as a component of an alternative wider, layered programme theory relating to the development of a hospital admission avoidance service. The model presents the interconnected components of the intervention and the anticipated outcomes for delivery of care, leading to the impact on patients, carers and the care system.

The approach by Chen et al. (2024) of identifying components and linkage to anticipated outcomes is relevant for the theoretical underpinning of the Vital intervention, however, further work is required to understand mechanisms of change and the detail of the Vital intervention components. At this stage, therefore, it is premature to articulate a complete programme theory for the Vital intervention. Further refinement of the intervention components described in Section 8.2 and Table 8.1, is required. The following Section 8.4 describes the preliminary programme theory of the Vital intervention.

8.4. PRELIMINARY VITAL INTERVENTION

This study has culminated in establishing the existing research context of tracheoesophageal voice rehabilitation, the views of PWL and SLT stakeholders and exploration of potential

intervention components through feasibility study and co-design. Whilst there is minimal theoretical evidence for tracheoesophageal voice rehabilitation to guide intervention development, the outputs of this study provide a theoretical direction situated strongly upon stakeholder views. However, further intervention development is required to design and refine a prototype intervention, therefore at this stage only a preliminary programme theory can be considered. The key components of the preliminary programme theory, derived from the main findings of this study, are listed above (pp. 361-362). Assumptions are made about the processes of change that the intervention activities could produce, therefore further intervention development work and later testing are required to assess and refine the feasibility of the theory; and to establish mechanisms of change.

8.4.1. OVERALL VITAL INTERVENTION DESCRIPTION

Across healthcare disciplines and diagnoses, rehabilitative interventions present a challenge in that treatments are not described systematically, therefore the active ingredients of the treatment cannot be identified and replicated in clinical practice (Hart et al., 2019). Furthermore, inadequate reporting of rehabilitation research impedes assessment of quality and identification of potentially effective interventions (Dijkers, 2021). Two resources are highlighted that seek to address this issue by describing intervention elements in detail. The Template for Intervention Description and Replication (TIDieR), (Hoffman et al., 2014); and the Rehabilitation Treatment Specification System (RTSS), (Van Stan et al., 2019). The TIDieR presents a checklist of 12 items by which an intervention should be reported. The inclusion of these items aims to improve the completeness of intervention reporting, to provide sufficient detail for an intervention to be replicated. Table 8.2 demonstrates how the identified components of the VITAL intervention could be described under the TIDieR framework, and where further development is required to detail the intervention sufficiently for it to be implementable and replicable (indicated in italic font in Table 8.2). Hoffman et al. (2014) advise that the TIDieR items do not need to be presented in a specific order and items may be combined in a single piece of information, if appropriate.

Item no.	Item	VITAL component
1.	BRIEF NAME: Provide the name that describes the intervention	Voice Therapy After Laryngectomy (VITAL). An intervention to optimise tracheoesophageal voice quality.
2.	WHY: Describe any rationale, theory or goal of the elements essential to the intervention	Intervention targets components of voice production identified as a priority by PWL: volume, breathwork, articulation and pitch. <i>Further research is required to identify mechanisms of action and theoretical basis.</i>
3.	WHAT: Materials: describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or training of intervention providers	Intervention is supported by optimised information available in multiple modalities according to service user preference. Intervention may include the use of devices such as EMST trainer or straws for respiratory activities. <i>Development of an intervention manual for SLTs is required.</i>
4.	WHAT: Procedures: describe each of the procedures, activities and/or processes used in the intervention including enabling or support activities	Intervention includes collaborative, narrative based case history and personalised goal-setting. Laryngectomy equipment (baseplates, HMEs, voice prosthesis) and humidification are optimised as a foundation to voice therapy. Service user is provided with education and explanation of tracheoesophageal voice production. Activities are introduced according to individual needs and linked to functional outcomes that increase activity and participation. <i>Further development is required to detail specific activities.</i>
5.	WHO PROVIDED: Describe expertise, background and any specific training given	SLTs with specialism in laryngectomy rehabilitation and voice therapy; or expert patients as a therapy partner. <i>Development of a training programme is required to support implementation</i>

Item no.	Item	VITAL component
6.	HOW: Describe the modes of delivery and whether provided individually or as a group	Individual face-to-face therapy sessions to establish voice initially followed by group therapy
7.	WHERE: Describe the type of locations where the intervention occurred	Outpatient SLT department or community healthcare location
8.	WHEN AND HOW MUCH: Describe the number of times the intervention was delivered, over what time period including number of sessions, schedule, duration, intensity or dose	<i>Further development is required to establish optimal duration, number and frequency of sessions.</i>
9.	TAILORING: If the intervention was personalised, titrated or adapted; describe what, why, when, how	Intervention is personalised and tailored to individual needs and priorities. Timing of intervention differs between individuals and is dependent on service user prioritisation and readiness for therapy. <i>Further development is required to determine how to personalise intervention</i>
10.	MODIFICATIONS: If the intervention was modified describe the changes	<i>To be determined following further intervention development and feasibility testing.</i>
11.	HOW WELL: Planned: if intervention adherence or fidelity were assessed, describe how and by whom, and with what strategies	<i>Development of a feasibility protocol is required, including fidelity processes and checklists</i>
12.	HOW WELL: Actual: If intervention adherence or fidelity were assessed, describe the extent to which the intervention was delivered as planned	<i>To be determined following further intervention development and feasibility testing.</i>

Table 8.2: Components of the VITAL intervention described using TIDieR

8.4.2. VITAL INTERVENTION COMPONENTS

Hoffman et al. (2014) state that the TIDieR checklist items are a minimum recommendation for intervention description and researchers should include further detail where necessary for an intervention to be replicated. This accords with the RTSS (Van Stan et al., 2019), which advocates for rehabilitative interventions to be specified to a greater degree than that of reporting guidelines such as the TIDieR; on the principle that the aspects of treatment that lead to change are not explicitly described within reporting guidelines.

The RTSS provides a framework in which the underlying theories of an intervention are reported through clear detailing of the elements of a rehabilitative activity that are hypothesised to be the active agents of the intervention (Van Stan et al., 2019). The RTSS therefore characterises a treatment theory through the factors of components, targets, ingredients, and mechanisms of action, of which the latter may be hypothesised (Hart et al., 2019). Additionally, a glossary of specific definitions and a systematic method of intervention description are incorporated in the RTSS to support homogeneity in reporting. The RTSS can be used to design an intervention at the early stages of development (Van Stan et al., 2019) and has been applied to descriptions of laryngeal voice therapy (Van Stan et al., 2021; White et al., 2024; Saccente-Kennedy et al., 2024). It is therefore highlighted as a relevant framework in which to describe a tracheoesophageal voice therapy intervention. Table 8.3 illustrates the layered structure of the RTSS and how the different elements are connected to produce a detailed description and theory of intervention.

RTSS item	Description
Treatment	The intervention, which may comprise of multiple components from the overarching treatment component groups
Treatment component groups	Organ functions: Components concerned with changes in the efficiency, function or replacement of an organ or system through exercises, habituation or prosthetics Skills and habits: Components involving modification of mental or behavioural skills through practice, repetition and feedback Representations: Components that aim to alter mental representations relating to cognition, affect, motivation and volitional behaviour
Component structure	Target: The precise aspect of function that is to be changed by the ingredients Ingredient(s): What the therapist specifically does to achieve the target Mechanism of action: The causal process through which the intervention is hypothesised or known to work, demonstrating how the ingredients affect the target
Treatment aims	The effects of the treatment that may result from one or multiple targets being achieved
Volition	An additional factor within the intervention relating to the voluntary actions elicited by clinician actions, and the effort expended by the treatment recipient, which may influence treatment success or failure of volitional treatments in the following ways: 1. The degree to which the chosen ingredients affect the treatment target 2. The degree to which the ingredients result in the treatment recipient performing the therapy activity as directed

Table 8.3: Structure of the RTSS, adapted from Van Stan et al., 2019

The inclusion of volitional behaviour within the RTSS is pertinent and considers how clinician actions may influence the volitional behaviour of the service user, which in turn may affect the treatment outcome. For example, if insufficient explanation and rationale is given for a specific activity, the service user may not carry out the activity as intended or have insufficient motivation to do so, which could negatively impact treatment aims and effects. This is relevant to the findings of this study, where clinicians reported uncertainty about the outcomes and content of tracheoesophageal voice therapy; and to the focus group and co-design studies, in which PWL highlighted insufficient information as a key issue. Furthermore, it has been highlighted within this chapter where additional research is required to establish mechanisms of change and intervention details such as specific content and dosage. Therefore, the ability to provide a hypothesised rationale for treatment components, in the absence of established mechanisms of change, supports the use of the RTSS to describe the current and ongoing development of the VITAL intervention.

Additionally, the RTSS can be aligned to the COM-B model (Michie et al., 2011) and behaviour change technique taxonomy (Michie et al., 2013) to demonstrate the factors that influence patient adherence to treatment targets and ingredients (Van Stan et al., 2024). Table 8.4 exemplifies how the RTSS could be applied to the Vital intervention. Further intervention development research is required to refine the Vital intervention, triangulate outputs of the studies and reach consensus on intervention components towards a complete programme theory. However, preliminary information gained within the course of the doctoral study can be used to propose the so far identified essential intervention components (according to RTSS terminology) of VITAL, as illustrated in Table 8.4. The corresponding behaviour change techniques are also stated.

Treatment	VITAL intervention			
Treatment aims	Optimise perceptual tracheoesophageal voice quality Implement effective care of the neopharynx and respiratory tract Increase participation in social and work communication activities			
Components	Target	Ingredient(s)	Mechanism of action	Example of relation to BCT
Representations	Increase knowledge of changes to anatomy and the mechanism of tracheoesophageal voice production	Clinician provides multimodal information which is tailored to individual needs and culturally specific	Increased knowledge will empower PWL and influence positive volitional behaviours	2.4 – Self-monitoring of outcomes of behaviour 5.1 – Information about health consequences
Skills and Habits	Improve adherence to vocal hygiene, including a daily care regimen and equipment optimisation	Clinician provides verbal and written information regarding the benefits of nebuliser and humidification systems on secretions and lung health Clinician and PWL identify acceptable prosthesis, baseplate and HME system and implement staged protocol to habituate PWL to usage	Increased knowledge will empower PWL and influence positive volitional behaviours Regular use of baseplate and HME is demonstrated to optimise humidification and reduce secretions	2.4 – Self-monitoring of outcomes of behaviour 1.3 - Goal setting (outcome) 7.1 - Prompts/cues 8.3 – Habit formation

Components	Target	Ingredient(s)	Mechanism of action	Example of relation to BCT
Representations	Improve adherence to personalised voice therapy plan for home practice	Clinician provides information on voice therapy tasks and rationale for use specific to individual need	Increased knowledge will empower PWL and influence positive volitional behaviours Acquisition of skill supported by information will facilitate regular practice, which will positively impact tracheoesophageal voice production	1.8 – Behavioural contract 1.9 – Commitment 2.3 – Self-monitoring of behaviour 4.1 – Instruction on how to perform the behaviour 6.1 – Demonstration of the behaviour
Organ functions	Increase breath support and improve ease and coordination of occlusion for phonation.	Clinician describes the task and provides rationale and feedback. Provide opportunities to practice breath support and coordination activities	Acquisition of skill supported by information will facilitate regular practice, which will positively impact breath support and coordination	2.3 – Self-monitoring of behaviour 4.1 – Instruction on how to perform the behaviour 6.1 – Demonstration of the behaviour
Organ functions	Increase maximum volume achievable during conversation	Clinician describes the task and provides rationale and feedback. Provide opportunities to practice volume techniques	Acquisition of skill supported by information will facilitate regular practice, which will positively impact attempts to increase volume of voice	2.3 – Self-monitoring of behaviour 4.1 – Instruction on how to perform the behaviour 6.1 – Demonstration of the behaviour
Organ functions	Improve pitch range used during conversation	Clinician describes the task and provides rationale and feedback. Provide opportunities to practice pitch ranging exercises	Acquisition of skill supported by information will facilitate regular practice, which will positively impact extension of pitch range in conversational speech	2.3 – Self-monitoring of behaviour 4.1 – Instruction on how to perform the behaviour 6.1 – Demonstration of the behaviour

Components	Target	Ingredient(s)	Mechanism of action	Example of relation to BCT
Organ functions	Increase precision of articulatory targets during conversation	Clinician describes the task and provides rationale and feedback. Provide opportunities to practice articulation	Acquisition of skill supported by information will facilitate regular practice, which will positively impact accuracy of articulation	2.3 – Self-monitoring of behaviour 4.1 – Instruction on how to perform the behaviour 6.1 – Demonstration of the behaviour
Representations	Increase participation in social and work activities appropriate to individual aims	Clinician and PWL identify opportunities to participate in activities. Clinician and PWL identify and implement stepped activities to habituate to participation. Clinician applies appropriate behaviour change techniques to support participation.	Identification of barriers and facilitators to participation will empower PWL to participate in social and work activities Implementation of stepped activities will influence positive volitional behaviours at a pace appropriate to individual needs	1.3 – Goal setting 13.2 – Framing/reframing 15.1 – Verbal persuasion about capability
Representations	Increase participation in peer-befriending or group shared learning	Clinician provides opportunities to participate in peer befriending and learning. Clinician applies appropriate behaviour change techniques to support participation	Regular interaction with peers will empower PWL, lead to use of communication strategies and increase positive attitude towards communication Use of techniques will support behavioural changes which will impact positively on participation	1.3 – Goal setting 1.8 – Behavioural contract 13.2 – Framing/reframing 15.1 – Verbal persuasion about capability

Table 8.4: Proposed example of essential intervention components using RTSS terminology

Tables 8.2 and 8.4 have demonstrated how the TIDieR and RTSS could support the description and ongoing development of the VITAL intervention. They provide a framework outlining the potential components of the intervention required to achieve the desired outcomes of a tracheoesophageal voice therapy, which is effective and acceptable to PWL, feasible for implementation into existing services; and with embedded SLT and expert patient training to ensure its delivery is safe and efficient. In order to achieve this, it is necessary to consider the future directions of the study.

8.5. FUTURE DIRECTIONS

Several avenues of future research are proposed. The study has identified the key components of the intervention, however, much is still to be established in regard to the physiological mechanisms of change in tracheoesophageal voice. This would provide understanding of how specific impairment-based therapy activities may lead to desired voice outcomes and knowledge of functional potential, based upon reconstruction type and other salient factors.

Roy (2012) notes that complex interventions require investigation to ascertain what are the active components of an intervention. Future exploration of individual components would be pertinent to refine the intervention. Additionally, optimal dose was not established during this study through review of existing evidence or stakeholder feedback. PWL were not able to draw upon prior experience of therapy, however, the acceptability of EMST as an intensive intervention suggested that high intensity therapy would be acceptable.

There was a strong indication for further co-design work. Specifically, this should focus on development of assessment tools and outcome measures designed for tracheoesophageal speakers, which avoid comparison with laryngeal voice norms. This points to consideration of a novel taxonomy to describe and discuss tracheoesophageal voice quality, which has previously been identified as an area of need (Hurren, Hildreth and Carding, 2009). Furthermore, assessment tools and processes require co-design to ensure cultural relevance.

The current service user experience of information provision is sub-optimal. PWL generated improvement ideas during the co-design study, which require continued partnership working to refine and implement improvement ideas leading to acceptable and meaningful information.

Following further development work, a feasibility trial is required to test the feasibility, acceptability and preliminary efficacy of the intervention, and define important parameters for a definitive trial. This would require an implementation strategy based upon behaviour change theory and accompanying clinical training and best practice guidelines.

In summary, the following are identified as the next steps in development of the intervention:

- Creation of a taxonomy to describe tracheoesophageal voice quality
- Development of a perceptual outcome measure specific to tracheoesophageal voice
- Development of a holistic assessment tool for communication needs
- Partnership approaches with PWL to refine the intervention components and to co-produce enhanced information provision
- An e-delphi study with SLT partners to reach consensus on intervention components
- Development of a programme theory for the intervention
- Development of an SLT training package to support trial implementation
- Implementation of a feasibility trial for preliminary intervention and efficacy testing

8.6. STRENGTHS

Voice therapy is a complex intervention (White and Carding, 2022). The study was guided by the MRC framework for developing and evaluating complex interventions (Skivington et al., 2021) and was informed by mixed research methodologies. This provided a multidimensional understanding of the current status of tracheoesophageal voice rehabilitation and identified the core components of an intervention.

No previous studies have investigated the development of a tracheoesophageal voice intervention that places key stakeholders at its core. It is a strength of this study that the intervention development work has established the views of both PWL and SLTs as a foundation of intervention development. Whilst transference of some aspects of laryngeal voice therapy approaches may be relevant, it was not indicated to implement an existing laryngeal voice therapy approach in isolation and to test the feasibility of the approach with PWL. This would have negated PWL's experiences, priorities and requirements of a voice therapy intervention; and relied on untested assumptions about the transference of laryngeal voice therapy approaches. Instead the study was strongly embedded in stakeholder involvement, from inception of the doctoral proposal through to the culmination of outcomes in the co-design study. This ensured that outcomes were meaningful and the direction of the study was relevant to both PWL and SLTs. PWL are a minority group within the UK and ROI and incidence of head and neck cancer is linked to poorer socio-economic status and deprivation (Cancer Research UK, 2019). PWL could therefore be considered a hard-to-reach population for research; however, in all studies of the doctoral project, recruitment targets were met which indicated that recruitment strategies were effective.

Importance was placed on engaging a diverse range of participants therefore recruitment strategies aimed at widening the geographical spread of participants; and strategies were used to facilitate the participation of minority ethnic PWL. Recruitment was also effective in gaining the participation of PWL and SLTs from a range of UK and ROI locations. Female PWL were slightly over-represented in the focus group study, however this was seen as a strength to counteract the under-representation of female PWL in existing research. To enable PWL to participate with equity, facilitation strategies were planned at the outset and implemented within the focus groups, EMST study and co-design work to support inclusive and accessible participation.

Whilst the studies in this project contained small sample sizes, rigour was added by applying established methodological approaches and theory such as PRISMA (Page et al., 2021), reflexive thematic analysis (Braun and Clarke, 2020) and the behaviour change wheel (Michie, van Stralen and West, 2011). Within the EMST study, a double-baseline and follow up was applied to enhance the robustness of the outcomes. Additionally, studies were described

using reporting frameworks such as GRIPP2 (Staniszewska et al., 2017) and TIDieR (Hoffman et al., 2014).

8.7. LIMITATIONS

Significant efforts were made to ensure that participants were representative of PWL, however, future work could go further to increase representation. This was confounded by the lack of national data on the demographics of the UK laryngectomy population.

It was not feasible within the focus group study to include non-English speakers. Whilst the co-design study redressed this to an extent with the inclusion of PWL from the local Bangladeshi population, future work should attempt to incorporate in depth views of PWL from varied minority communities.

The focus group study offered the option for participants to take part online via videoconferencing. This was a strength in that it enabled people to take part from locations outside of London (the study location), however, this then introduced potential bias towards people who had the means to access the internet and a suitable device; and who had the digital literacy to take part. Additionally, PWL with comparatively worse tracheoesophageal speech quality may have been reluctant to take part in online discussion due to concerns about communication. For the EMST study, which required face-to-face attendance, the requirement to travel to London on at least four occasions for outcome measurements may have been a barrier for some PWL. Whilst participants did attend from other UK regions (in the EMST and focus group studies), it was not possible to reimburse travel costs outside of London, therefore only people with the financial means to travel to London were able to attend. One participant did attend via taxi journey from within London, however, PWL who were less physically able to attend in person may have been reluctant to apply to the studies. It is also relevant to highlight that PWL participants were self-selecting and therefore may have been particularly motivated to engage with voice therapy. It would be pertinent to consider this factor in future feasibility testing.

A limitation of the study was that stakeholders did not have lived experience of receiving or, in many cases, providing tracheoesophageal voice therapy. This led to challenges for stakeholders when considering their views on aspects of voice therapy. An additional challenge is the heterogeneity of physical function after laryngectomy as a sequela of different tumour presentations and varied oncological treatment requirements. This supports the need for an intervention which can be individualised to specific patient needs and priorities.

An underlying challenge of the study was the lack of existing evidence, which meant that there were limitations in understanding how representative study outcomes were. There was, however, good congruence between the separate studies as described in this chapter, which increased confidence in the outcomes. Similarly, the limitations in existing measures of tracheoesophageal voice may have impacted upon sensitivity to change of perceptual voice quality change during the EMST study. The area of perceptual measurement of tracheoesophageal voice is a key area for future research, and as a necessary component of evaluating a future intervention.

8.8. CONCLUSION

This doctoral study has contributed novel insights to clinical knowledge and the evidence base for tracheoesophageal voice rehabilitation, building towards the development of a rehabilitative intervention for PWL who use a voice prosthesis to communicate.

From its inception, the study was designed to be translational with the anticipated findings of VITAL being directly and practically applicable to clinical practice for PWL and SLTs, once further tested for efficacy. The study followed established guidance for intervention development and incorporated a mixed-methods, holistic approach to investigation to ensure that clinician and service user perspectives were embedded in the intervention development and that outcomes were relevant to stakeholders through partnership working.

Systematic review demonstrated that existing evidence for tracheoesophageal voice rehabilitation is insufficient to inform clinical practice; whilst a survey of clinical practice found that SLTs were motivated to provide tracheoesophageal voice therapy, yet the lack of evidence and clinical guidelines, and insufficient resourcing were barriers to doing so. The priorities of PWL were established through qualitative, feasibility and co-design studies, which found that PWL want a personalised, collaborative intervention that embeds impairment-based voice interventions in a holistic framework to support activity and participation.

The preliminary theory and future research directions set out the next stages of intervention development towards refinement, testing of feasibility and acceptability. This will lead to a new tracheoesophageal voice therapy approach for PWL, captured under the acronym VITAL (Voice Therapy Approach for people with Laryngectomy). The outcomes will further enhance clinical practice and add to the evidence base within this clinical area. Findings have the potential to add to guidelines for communication rehabilitation after laryngectomy and to positively impact functional communication for PWL.

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APPENDIX 3.1 | PRISMA Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	Title page
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	Page 2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Introduction section
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Introduction section
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Methods>Eligibility
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Methods>Information sources
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Methods>Search strategy
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	Methods>Selection process
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	Methods>Data collection process
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	Data extraction table 3
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	Data extraction table 3
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	Methods>Risk of bias assessment
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	Methods>Effect measures
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	Methods>Synthesis methods
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	Not applicable
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	Methods>Synthesis methods
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	Methods>Synthesis methods
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	Methods>Effect measures
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	Not applicable
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	Results>Risk of bias across studies
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	Not applicable

RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Figure 1
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	Supplementary Material B
Study characteristics	17	Cite each included study and present its characteristics.	Results>Study characteristics
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Results>Risk of Bias
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	Table 3
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	Results>Data synthesis
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Not applicable
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	Results>Data synthesis
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	Results>Data synthesis
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	Results>Data synthesis
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	Results>Data synthesis
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	Discussion section
	23b	Discuss any limitations of the evidence included in the review.	Discussion>limitations
	23c	Discuss any limitations of the review processes used.	Discussion>limitations
	23d	Discuss implications of the results for practice, policy, and future research.	Conclusion
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	Methods
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	Methods
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	Not applicable
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	Title page
Competing interests	26	Declare any competing interests of review authors.	Title page
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	Supplementary material

Appendix 3.1: PRISMA checklist

APPENDIX 3.2 | Prospero registration

Review Title

A systematic review of tracheoesophageal voice therapy in post laryngectomy rehabilitation

Original Language Title

English

Anticipated start date

01/07/2021

Anticipated completion date

31/07/2022

Stage of review at time of submission

Preliminary searches

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Organisational affiliation of the review

City, University of London

Review team members and their organisational affiliations

[REDACTED]

Funding sources/sponsors

Barts Charity NMAHP Clinical Doctoral Fellowship

Conflicts of interest

None

Collaborators

None

Review question

What therapy approaches are used to improve tracheoesophageal voice production in people with laryngectomy and what is their effectiveness?

Searches

The search will be carried out during June/July 2021. The search will not be restricted by language or publication date.

The following databases will be searched:

CINAHL, Medline, Health Policy Reference Centre, APA PsychInfo, Embase, AMED, Cochrane and Emcare. Additionally, citation and manual searches will be carried out.

Searches will be re-run prior to final analysis to identify any new studies for inclusion.

The following search terms will be used for title and abstract search, and the following subject headings will also be used.

Laryngectom* OR tracheoesophag* OR alaryngeal OR 'surgical voice restoration' OR Laryngectomy OR Tracheoesophageal voice prosthesis OR voice prosthesis OR Larynx prosthesis OR Speech, alaryngeal OR Alaryngeal speech

AND

voice OR communicat* OR speech OR phonat* OR Voice OR Voice quality OR Voice disorders OR Communication OR Speech OR Phonation

AND

Therap* OR intervention OR treat* OR strateg* OR rehabilitat* OR training OR program* OR Therapy OR Rehabilitation OR Rehabilitation, Speech and Language OR Speech and Language Rehabilitation OR Voice Training OR Voice therapy

Condition or domain being studied

Voice rehabilitation following total laryngectomy with tracheoesophageal puncture

Participants/Population

People with tracheoesophageal voice prosthesis after total laryngectomy

Inclusion criteria:

Adults >18 years

Male/Female and non-binary

Total laryngectomy with tracheoesophageal voice prosthesis, due to any diagnosis

Exclusion criteria:

Not total laryngectomy, exclude:

partial laryngectomy

hemilaryngectomy

tracheostomy

Research studies using mixed populations will be included if the findings for people with tracheoesophageal voice following laryngectomy are reported separately; or if population meeting the inclusion criteria forms 25% or more of the sample.

Interventions/Exposures

Inclusion criteria:

Intervention studies of any design

Intervention targets rehabilitation of tracheoesophageal voice after laryngectomy

Exclusion criteria:

Non behavioural interventions will be excluded, e.g., surgery, instrumental interventions

Comparators/controls

Any type of comparator e.g., comparison over time, group or task.

Types of study to be included

Published, peer reviewed research studies with any comparator/control and full text available.

Studies which do not meet the criteria will be included for descriptive context.

Context

Interventions delivered in any setting (e.g. hospital, rehabilitation centre, community) will be included.

Main outcomes

Any outcome that relates to voice, speech and communication and their impact across WHO ICF domains and quality of life or well-being. This is an under-researched area without many validated measures therefore outcomes will be looked at across different areas.

Additional outcomes

As detailed above

Measures of Effect

Heterogeneity is expected in the outcome measures used. Data permitting the following will be completed:

- Cohen's d for individual studies
- Standardized mean differences for eligible group-level studies

Data extraction (selection and coding)

The PRISMA flowchart will be used as a framework to document study selection. Covidence software will be used to record the data extraction process.

Title and abstract screening will be completed by the first author for the primary inclusion criteria (total laryngectomy with tracheoesophageal voice prosthesis, adult). A minimum of 10% will also be checked by another rater within the review team.

Following this the first author and a second researcher will independently screen titles and abstracts of the included papers against all of the inclusion and exclusion criteria.

Papers which are deemed to meet the criteria will be included for full text review. Any disagreement on inclusion will be resolved via consensus between the raters. A third reviewer will have the final decision on any unresolved disagreement.

The reference list and citations for included papers will be screened for any studies that may have been missed.

A data extraction tool will be developed, which will include:

- Study design
- Study setting
- Sample size
- Source of funding
- Year of publication
- Participant demographics
- Intervention details
- Outcome measures used
- Outcomes and efficacy/effectiveness of the intervention

The first author will complete data extraction. The second reviewer will complete data extraction on a minimum 30% sample of included papers to ensure consistency.

Risk of bias (quality) assessment

The quality of the included studies will be rated by two of the review team. Disagreements in rating will be resolved via consensus between the two raters. If consensus cannot be reached, the senior researcher will have the final decision.

Assessment of quality will be undertaken at study level. This will include (as applicable), review of randomisation method, allocation generation and concealment, blinding, reporting of compliance and treatment of incomplete data.

The following scales will be used to assess quality:

- For before and after studies with no control group, the NIH study quality assessment tool (1)
- For randomised and non-randomised controlled trials, the Physiotherapy Evidence Database (PEDro) scale (2)
- For single case studies, the Risk of Bias in N-of-1 Trials scale (ROBiN-T)(3)
- For other studies, the CASP critical appraisal checklists (4) or Joanna Briggs Institute critical appraisal tools (5) will be selected, depending on the study design

The TIDieR framework will be used to assess the quality of the intervention reporting (6).

(1) National Heart, Lung and Blood Institute. 2021. Last accessed 01/06/2021. <https://www.nhlbi.nih.gov/health-topics/study-quality-assessment-tools>

(2) Maher, C.G. Sherrington, C. Herbert, R.D. Mosely, A.M. Elkins, M. 2003. Reliability of the PEDro scale for rating quality of randomised control trials. *Physical Therapy*, 83(8), pp713-721.

(3) Tate, R.L. Perdices, M. Rosenkoette, U. Wakim, D. Godbee, K. Togher, L. McDonald, S. 2013. Revision of a method quality rating scale for single case experimental designs and n-of-1 trials: The 15-item Risk of Bias in N-of-1 Trials (ROBiNT) Scale. *Neuropsychological Rehabilitation*. 23(5), pp 619-638

(4) CASP checklists. Available at: <https://casp-uk.net/casp-tools-checklists/>

(5) Joanna Briggs Institute Critical Appraisal Tools. Available at: <https://jbi.global/critical-appraisal-tools>

(6) Hoffmann, T.C. Glasziou, P.P. Milne, R. Moher, D. Barbour, V. Johnston, M. Lamb, S.E. Dixon-Woods, M. Wyatt, J.C. 2014. Better Reporting of Interventions: Template for intervention description and replication (TIDieR) checklist and guide. *British Medical Journal*, 348: g1687

Strategy for data synthesis

Data synthesis will take place if a minimum of ten studies meet the inclusion criteria and are of adequate quality.

A narrative synthesis approach will be used to describe and combine the qualitative data obtained from included studies. The process will be carried out in accordance with the four elements of the ESRC framework for narrative synthesis, (for example, development of a preliminary synthesis of findings of included studies).

Data for narrative synthesis will include:

- Study design, for example the study type, design and setting
- Sample size and participant characteristics
- Type and characteristics of the intervention
- Outcome measures used
- Targeted outcomes of the intervention
- Effectiveness of the intervention

Synthesis of quantitative data will include the above elements in addition to statistical detail of effectiveness. Descriptive statistics will be used to summarise participant characteristics and other variables; and metrics of efficacy/effectiveness, such as standardised mean differences and effect sizes, will be provided.

Data permitting, we will perform meta-analysis. A heterogeneity assessment using the I^2 measure to ascertain if a meta-analysis can be performed. Synthesis will take place if two or more studies meet criteria. Individual patient data will be presented separately for single case studies.

Popay, J. Roberts, H. Sowden, A. Petticrew, M. Arai, L. Rodgers, M. Britten, N. Roen, K. Duffy, S. 2006. Guidance on the Conduct of Narrative Synthesis in Systematic Reviews. ESRC Methods Programme.

Analysis of subgroups or subsets

It is anticipated that included studies will be of small to medium sample sizes and heterogenous, therefore subgroup analyses are not planned.

Type and method of review

Intervention

Systematic review

Cancer, ENT, Rehabilitation

Language

English

Country

United Kingdom, England

Other registration details

None

Reference and URL for published protocol

n/a

Dissemination plans

On completion the systematic review will be submitted to peer-reviewed journal. It will also form a chapter of a doctoral thesis.

Keywords

Laryngectomy, alaryngeal, tracheoesophageal, voice, rehabilitation, systematic review

Details of any existing review of the same topic by the same authors

n/a

Current review status

Preliminary searches

Any additional information

The systematic review is being carried out within a doctoral fellowship and forms part of the VITAL project: a novel Voice Therapy Approach for people with Laryngectomy.

The VITAL project is focused on advancing practice in voice rehabilitation through the development and feasibility testing of a novel voice therapy approach for tracheoesophageal speakers.

APPENDIX 4.1 | Clinician survey

Demographics
Age
20-30 years
31-40 years
41-50 years
51-60 years
61-66 years
67+
Gender
Female
Male
Other – Specify (optional)
Years of experience working with people who have a laryngectomy
Less than 2
2-5 years
6-10 years
11-15 years
16-20 years
More than 20 years
Approximate percentage of your typical caseload which is people with laryngectomy
5% or less
6-10%
11-30%
31-50%

51-75%
More than 75%
Main region in which you work
Republic of Ireland
Northern Ireland
Scotland
Wales
England – North East
England – North West
England – Yorkshire and the Humber
England – East Midlands
England – West Midlands
England – East of England
England – London
England – South East
England – South West
Sector in which you work (select all that apply)
Public sector
Private sector
Independent practice
Other – specify compulsory
Setting in which you work (select all that apply)
Inpatient
Outpatient
Community centre/clinic
Domiciliary based care
University
Other, please describe (free text)

Section	COM-B	TDF
Theoretical knowledge		
Are you aware of any therapy approaches for improving tracheoesophageal voice production?	Capability	Knowledge
Yes / No		
If yes, please list (free text)		
Do you know of any guidelines relating to tracheoesophageal voice therapy?	Capability	Knowledge
Yes / No		
If yes, please list (free text)		
In your opinion what knowledge and skills are required to provide tracheoesophageal voice therapy compared to standard voice therapy?	Capability	Knowledge
Please describe (free text)		
Clinical training		
Have you had any training in providing tracheoesophageal voice therapy?	Capability	Skills
Yes/No		
If yes, please describe your training (free text)		
Have you had any training in psychological approaches to support your practice with laryngectomees?		
Motivational interviewing		
Solution focused brief therapy		
Acceptance and commitment therapy		

Advanced Communication Skills for the cancer workforce		
Counselling skills for SLTs		
Other (please describe)		
Clinical practice		
Do SLTs in your department routinely offer voice therapy to tracheoesophageal speakers?	Opportunity	Social influences
Yes/no		
Do you personally offer voice therapy to tracheoesophageal speakers?	Capability	Memory, attn and decision processes
Never / occasionally / often / routinely		
How likely are you to provide tracheoesophageal voice therapy to the next voice prosthesis user you work with?	Motivation	Intentions
Very likely / somewhat likely / neither likely or unlikely / not very likely		
What assessments do you use to assess voice quality in tracheoesophageal speakers?	Capability	Skills
Sunderland Tracheoesophageal Voice Perceptual Scale (STOPS)		
Voice Handicap Index (VHI)		
Vocal Profile Analysis (VPA)		
GRBAS		
Consensus Auditory Perceptual Evaluation of Voice (CAPE-V)		
Buffalo Voice Profile		
Descriptive perceptual assessment		
In house assessment tool (Describe)		
Other, please describe (free text)		

(for above) How often do you do this? Never / occasionally / often / routinely	Capability	Memory, attn and decision processes
Aside from voice quality, what additional factors do you consider when assessing tracheoesophageal voice?	Capability	Skills
Breath support		
Aerodynamic assessment		
Tracheal manometry		
Posture		
Muscle tension		
Anatomical considerations e.g. flap bulk, fibrosis		
Choice of voice prosthesis		
Choice of HME/baseplate system		
Shape of stoma/peri-stomal area		
Secretion load		
Humidification		
Sensory abilities e.g. vision and hearing		
Hand dexterity		
Suitability for hands-free device		
Communication opportunities and environments		
Other, please describe (free text)		
(for above) How often do you do this? Never / occasionally / often / routinely	Capability	Memory, attn and decision processes
Do you routinely record voice samples during tracheoesophageal voice assessment?	Capability	Memory, attn and decision processes
Yes/No		
If yes, what samples do you record?		

Sustained vowel phonation		
Reading passage e.g. the rainbow passage		
Spontaneous speech		
Reciting e.g. days of week, counting		
Pitch glides		
Other – Please describe		
What voice therapy approaches or strategies do you use in your clinical practice with tracheoesophageal speakers?	Capability	Skills
Breathing exercises		
Deconstriction / reducing muscle tension		
Resonance work		
Articulation exercises		
Projection or volume control exercises		
Pitch control exercises		
Other, please describe (free text)		
Do the approaches or strategies that you use result in improved communication for tracheoesophageal speakers?	Motivation	Belief about consequences
Yes/No/Sometimes		
Do you offer a standard number of sessions for tracheoesophageal voice therapy?	Opportunity	Environmental context and resources
Yes/no		
If yes, how many?		
Do you set specific goals relating to tracheoesophageal voice quality?	Motivation	Motivation and goals
Never/occasionally /often/routinely		

Barriers/Facilitators/Motivators		
What challenges have you encountered in delivering tracheoesophageal voice therapy?	Motivation	Belief about capability
Please describe (free text)		
What would help you?	Capability	Behavioural regulation
Please describe (free text)		
Are there any local protocols, guidelines or resources that encourage you to offer tracheoesophageal voice therapy?	Opportunity	Environmental context and resources
Yes/no - if yes please describe		
Do you have sufficient clinical resources to provide tracheoesophageal voice therapy?	Opportunity	Environmental context and resources
Yes/no		
How do you feel about providing tracheoesophageal voice therapy? (e.g. anxious, motivated, interested, positive, nervous)	Motivation	Emotion
Please describe (free text)		
Are there any groups that influence your clinical practice with tracheoesophageal speakers e.g, CENs, patient groups, social media, charities, local networks, MDT peers?	Opportunity	Social influences
Yes/no		
If yes, please describe		

Tracheoesophageal voice therapy is important in overall SLT management of laryngectomy rehabilitation	Motivation	Belief about consequences
Strongly disagree/disagree/agree/strongly agree		
Once a functional voice has been established, how much of a priority is it to improve the quality of tracheoesophageal voice?	Motivation	Motivation and goals
Very important/important/not very important/not at all important		
What factors help you decide how to prioritise improving quality of tracheoesophageal voice? (free text)	Motivation	Motivation and goals
Are you involved in evaluating suitability for tracheoesophageal puncture?	Motivation	Social/prof. role and identity
Yes/no/sometimes		
Are you involved in troubleshooting problems encountered by tracheoesophageal speakers?	Motivation	Social/prof. role and identity
Yes/no		
Thinking specifically about the work you do with laryngectomees, do you feel valued by your multidisciplinary team?	Motivation	Social/prof. role and identity
Never/occasionally/often/always		

Are there any comments about tracheoesophageal voice rehabilitation that you would like to add?		

APPENDIX 4.2 | Ethical approval for clinician survey



Dear Freya



Project title: Advancing practice in voice rehabilitation with VITAL: a novel Voice Therapy Approach for people with Laryngectomy. (Part one: Survey)

Start date: 8 Jul 2021

End date: 30 Sep 2022

I am writing to you to confirm that the research proposal detailed above has been granted formal approval from the School of Health Sciences Research Ethics Committee. The Committee's response is based on the protocol described in the application form and supporting documentation. Approval has been given for the submitted application only and the research must be conducted accordingly. You are now free to start recruitment.

Please ensure that you are familiar with [City's Framework for Good Practice in Research](#) and any appropriate Departmental/School guidelines, as well as applicable external relevant policies.

Please note the following:

Project amendments/extension

You will need to submit an amendment or request an extension if you wish to make any of the following changes to your research project:

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- Change or add researchers involved in the project, including PI and supervisor;
- Change to the sponsorship/collaboration;
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- Change the procedures undertaken by participants, including any change relating to the safety or physical or mental integrity of research participants, or to the risk/benefit assessment for the project or collecting additional types of data from research participants;
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- Change to the insurance or indemnity arrangements for the project;
- Change the end date of the project.

Adverse events or untoward incidents



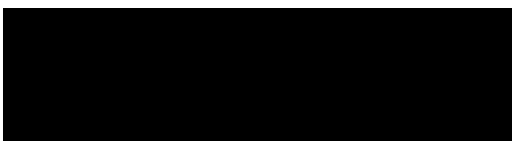
You will need to submit an Adverse Events or Untoward Incidents report in the event of any of the following:

- a) Adverse events
- b) Breaches of confidentiality
- c) Safeguarding issues relating to children or vulnerable adults
- d) Incidents that affect the personal safety of a participant or researcher

Issues a) and b) should be reported as soon as possible and no later than five days after the event. Issues c) and d) should be reported immediately. Where appropriate, the researcher should also report adverse events to other relevant institutions, such as the police or social services.

Should you have any further queries relating to this matter, please do not hesitate to contact me. On behalf of the School of Health Sciences Research Ethics Committee, I do hope that the project meets with success.

Kind regards



APPENDIX 4.3 | Ethical approval for ROI participation in clinician survey



Dear Freya



Project title: Advancing practice in voice rehabilitation with VITAL: a novel Voice Therapy Approach for people with Laryngectomy

Start date: 13 Oct 2021

End date: 30 Sep 2022

I am writing to you to confirm that the research proposal detailed above has been granted formal approval from the Language & Communication Science Proportionate Review Committee. The Committee's response is based on the protocol described in the application form and supporting documentation. Approval has been given for the submitted application only and the research must be conducted accordingly. You are now free to start recruitment.

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Adverse events or untoward incidents

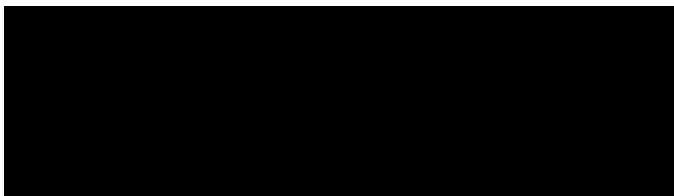


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Should you have any further queries relating to this matter, please do not hesitate to contact me. On behalf of the Language & Communication Science Proportionate Review Committee, I do hope that the project meets with success.



APPENDIX 5.1 | Ethical approval for focus group study



Dear Freya



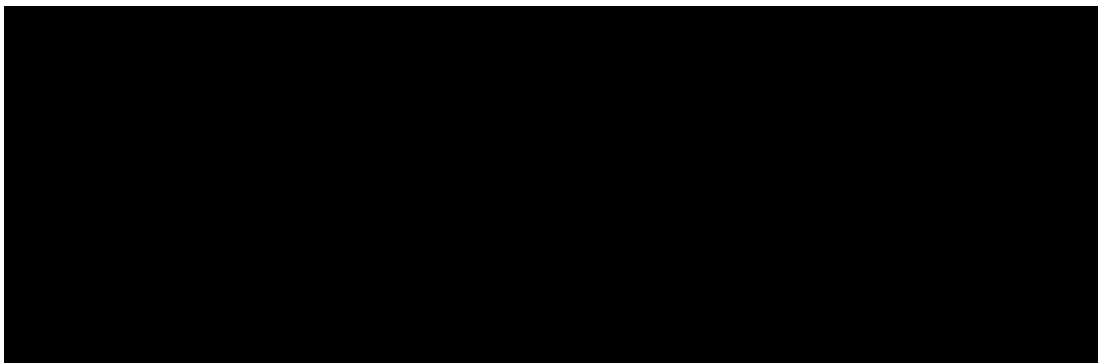
Project title: Advancing practice in voice rehabilitation with VITAL: a novel Voice Therapy Approach for people with Laryngectomy. (Focus group sub-project)

Start date: 1 Jul 2022

End date: 31 Dec 2022

I am writing to you to confirm that the research proposal detailed above has been granted formal approval from the Language & Communication Science Proportionate Review Committee. The Committee's response is based on the protocol described in the application form and supporting documentation. Approval has been given for the submitted application only and the research must be conducted accordingly. You are now free to start recruitment.

The approval was given with the following conditions:



2. Please make it clear on your information sheet that the meeting place for individual interviews should be a 'community space' and not in the person's home (as this would require further ethical review), thank you.

Please ensure that you are familiar with [City's Framework for Good Practice in Research](#) and any appropriate Departmental/School guidelines, as well as applicable external relevant policies.

Please note the following:

Project amendments/extension

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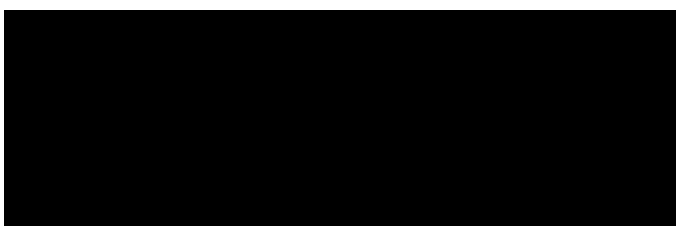
Adverse events or untoward incidents

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APPENDIX 5.2 | Standards for Reporting Qualitative Research (SRQR) guidance

Topic		Item
Title and abstract		
S1	Title	Concise description provided on first page of chapter
S2	Abstract	N/A for thesis chapter
Introduction		
S3	Problem formation	Introduction section
S4	Purpose or research question	Stated under Objectives section
Methods		
S5	Qualitative approach and research paradigm	Described under Data Analysis section
S6	Researcher characteristics and reflexivity	Reported in Reflexivity Statement
S7	Context	Reported in Introduction section
S8	Sampling strategy	Described under Recruitment section
S9	Ethical issues pertaining to human subjects	Described in Ethical Approval section
S10	Data collection methods	Reported in Data Collection section
S11	Data collection instruments and technologies	Described in Topic Guide and Data Collection sections
S12	Units of study	Described under Participant Characteristics and Results sections
S13	Data processing	Reported in Data Analysis section
S14	Data analysis	Reported in Data Analysis section
S15	Techniques to enhance trustworthiness	Member checking with participants
Results		
S16	Synthesis and interpretation	Main findings set out in Results section and interpreted in Discussion section
S17	Links to empirical data	Participant quotations used throughout

Discussion		
S18	Integration with prior work, implications	Findings discussed and linked to literature in Discussion section
S19	Limitations	Described under Limitations section
Other		
S20	Conflicts of interest	None to declare. Potential bias as SLT highlighted in Reflexive Statement
S21	Funding	Doctoral fellowship funded by Barts Charity

APPENDIX 5.3 | Topic guide for focus groups

Introduction

- Welcome to group
- Researchers to introduce themselves and role
- Introduction to purpose of the focus group
- Participants to introduce themselves
- Setting of ground rules:
 - Safe space for all to contribute
 - Opinions - no right/wrong answers
 - Explain confidentiality and data use
 - Purpose of recording
 - Try not to speak at same time to support recording
 - Break out room if need time out or feeling distressed
 - Ok if need time out – switch camera off for a bit
 - Use chat function to support voice

Experience of voice rehabilitation after laryngectomy

- What were your experiences of starting to use a voice prosthesis?
 - When did this happen?
 - Setting: during inpatient stay or later?
- What support was given to help with voice production?
 - Prompt on what SLT they had, how much, how often
- How did you find that?
 - Prompt on likes and dislikes and why
- Was it useful to you?
 - What worked, what was missing from SLT?
- What information did you receive about voice rehabilitation? Was it the right amount?

What voice rehabilitation should look like

- What would you like voice therapy to achieve / to do?
- What support would you like to have received?

Prompt on what support/therapy should entail; how much, how often, f/up

- How did that compare with experience?
- What areas are important for SLTs to support?

Prompt on areas to consider: breathing, articulation, volume, pitch, confidence, transferring out of the therapy room, mental attitude, motivation for therapy

- What has worked for them before?
- Should voice therapy involve others?

Prioritisation within wider post laryngectomy rehabilitation

- How did the timing of your voice therapy feel?
- What was a priority for you after your surgery?
- When should voice therapy be offered?

Summary / reflection / additional comments

Thank you, what happens next, address for voucher, any concerns or safeguarding needs?

APPENDIX 6.1 | GRIPP2 short form for co-design study

Section and topic	Item	Reported on section
Aim	Report the aim of PPI in the study	Introduction > Study aims
Method	Provide a clear description of the methods used for PPI in the study	Methodology
Study results	Outcomes – Report the results of PPI in the study, including positive and negative outcomes	Results
Discussion and conclusions	Outcomes – Comment on the extent to which PPI influenced the study overall. Describe positive and negative effects	Results and Conclusion sections
Critical perspective	Comment critically on the study, reflecting on the things that went well and those that did not, so others can learn from this experience	Critical reflection

APPENDIX 6.2 | Ethics approval for co-design study



Dear Freya



Project title: Advancing practice in voice rehabilitation with VITAL: a novel Voice Therapy Approach for people with Laryngectomy

Start date: 11 May 2023

End date: 31 Dec 2023

I am writing to you to confirm that the research proposal detailed above has been granted formal approval from the Language & Communication Science Proportionate Review Committee. The Committee's response is based on the protocol described in the application form and supporting documentation. Approval has been given for the submitted application only and the research must be conducted accordingly. You are now free to start recruitment.

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Adverse events or untoward incidents

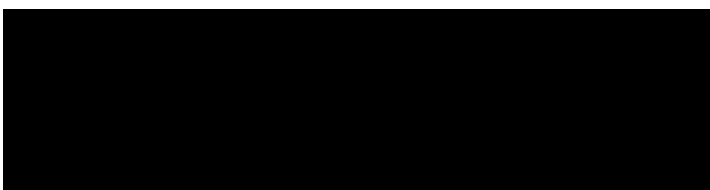


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Should you have any further queries relating to this matter, please do not hesitate to contact me. On behalf of the Language & Communication Science Proportionate Review Committee, I do hope that the project meets with success.



APPENDIX 6.3 | Intervention pathway mapping

Stage	Activity	Barriers	Solutions	Comments/ideas
Pre op	Pre-treat session with protected time to focus in depth on voice and communication, including: Detailed communication history (think of approach used in stroke or laryngeal voice therapy, Identifying person's communicative roles – life, work, social Activities involving use of hands that may affect communication	Where to fit this in to busy pre-op pathway Time is an issue as this is an extra session Surgery not being done in my centre. Pathway issue around knowing someone Is needing pre-op	Discuss with MDT about a particular time/making this essential If it is specifically a voice case hx does it need to be an SLT that does this, could be an assistant or student following a protocol Start or end an MDT session with protected time Finding the best time	Needs a dedicated session to get best out of patient Concern that we don't always know the true outcome for people Might not be the person's agenda Issue is that people get to post-op and they just stop doing their activities. Idea that communication history is known so SLTs can check

			Using a questionnaire for people to fill out for the background communication history – a communication passport Going out to the home to get a real idea of the person Fine tune the pathway to know who needs pre-op	what they have continued / stop doing. Who is this person? Getting them closer to the real you. Also using B5 and students good to open up workforce and engage people early.
Pre op	Laryngectomy visitor session	Not always easy to find someone who will come in, or who is representative	Thinking big – a national system or register of people who are willing to have this role. Could NALC help us?	

		Amount of expert patients available can vary Can be quite time consuming	Video of a pre-op session that could be shared Does it really need to be a match by gender? Is it more other things to match on Use of upskilled SLTa	
Pre op	Direct to information resources, online videos etc	The burden of information. Fear vs informing	Patient by patient experience. Be guided by their agenda. Go slowly	Patients wanted us to ask at pre-treat stage, how do you want to access this information. How do you want it given?

		Making videos of quality and that are representative Access issues to digital content	Discuss with orgs like Shout at Cancer or NALC, could they host this and build on existing content? Map out where to access pre-existing videos, could this be put in Basecamp? Communication café – getting people set up online. Use SLT and OT students? Digital champion schemes. Link people up. Person watches them at hospital,	Remember to offer voice banking
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			SLT or assistant sets them up	
Post op	Early visit from SLT to establish a form of communication and to discuss next steps	Discharged when medically fit but not socially ready. D/c too soon	Add into pre-op questions.	What are the communication needs when you come home, what is urgent? Is the person on their own or not? What communication needs to be set up as a minimum
Post-op	OP – Initial voice assessment session. Protected time to discuss only communication. Identification of immediate needs and priorities	Where to find the protected time? Capacity issue.	Restructuring clinic time, this is probably same amount of time but not organised as a protected thing?	Needing more B5s

		Training needs so that team has SVR capacity	Pre-plan a double session Can CNS do other things e.g. HME/baseplates to allow SLTs to focus on the therapy. Or SLTa/B5 Training issues	
Post op	OP – repeat session with laryngectomy visitor to answer questions, provide reassurance etc	Asking for more commitment from lary visitor When does it become a job for the experienced larys?!	If as a follow up can make a judgement call as to whether SLT presence is needed. Asking where is there funding for for the lary buddy to	Should expert visitors register as volunteers, could this mean their travel is reimbursed?

		Identifying the best time	come in? Travel and time costs.	Do charities provide any funding for this?
Post op	1:1 sessions with SLT to establish foundations of voicing: Stoma and VP care Secretion management Optimise base plate/HME Establish voice or identify further investigation needs	This is probably part of existing care but could this be more structured, maybe with a protocol or guidance of some kind	Work on a protocol, could this be through RCSLT endorsement	
Post-op	Rolling voice group for prosthesis users using group therapy approach. Facilitating learning from more proficient people	Admin burden of setting this up - not enough resource Parity of input for people who don't use a prosthesis	Could this be done assistant or across a few trust offering a group in the local area?	NELFT using the expert patient programme – could we do something similar to use further down the line e.g. 6month timepoint

		A rolling group might be a challenge for teams with a smaller caseload	The yearly session could be a better way to pick up people's needs Group doesn't have to be weekly, could be	
Long term	Offer at least yearly MOT specifically to discuss: Any issues with voice (and other?) Have communication needs changed? New equipment Signposting to other support services	Admin set up of implementing Engagement might need to be support	Can be good to pick up on changing needs over time.	

APPENDIX 7.1 | Ethical approval for EMST feasibility study



Dear Freya



Project title: Advancing practice in voice rehabilitation with VITAL: a novel Voice Therapy Approach for people with Laryngectomy. (EMST sub-project)

Start date: 28 Jul 2022

End date: 31 Jul 2023

I am writing to you to confirm that the research proposal detailed above has been granted formal approval from the Senate Research Ethics Committee. The Committee's response is based on the protocol described in the application form and supporting documentation. Approval has been given for the submitted application only and the research must be conducted accordingly. You are now free to start recruitment.

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Adverse events or untoward incidents

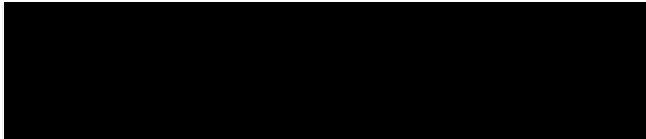


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Should you have any further queries relating to this matter, please do not hesitate to contact me. On behalf of the Senate Research Ethics Committee, I do hope that the project meets with success.



APPENDIX 7.2 | Practice tracking diary

Practice tracker:

Complete five sets of five repetitions each day. Tick off the repetitions as you go along

Remember to take a break in between each set and pause for longer if you feel dizzy, lightheaded, or unwell

WEEK ONE																													
Day 1	1	2	3	4	5	B	1	2	3	4	5	B	1	2	3	4	5	B	1	2	3	4	5	B	1	2	3	4	5
Day 2	1	2	3	4	5	R	1	2	3	4	5	R	1	2	3	4	5	R	1	2	3	4	5	R	1	2	3	4	5
Day 3	1	2	3	4	5	E	1	2	3	4	5	E	1	2	3	4	5	E	1	2	3	4	5	E	1	2	3	4	5
Day 4	1	2	3	4	5	A	1	2	3	4	5	A	1	2	3	4	5	A	1	2	3	4	5	A	1	2	3	4	5
Day 5	1	2	3	4	5	K	1	2	3	4	5	K	1	2	3	4	5	K	1	2	3	4	5	K	1	2	3	4	5

How was your practice this week?

You can write any thoughts here about what went well, what you found difficult or any other comments you would like to make

APPENDIX 7.3 | Acceptability questionnaire

For researcher to complete with participant at each intervention follow-up visit and t3, t4

How did you find the practice this week overall?

What did you like about it?

Did you experience any problems?

Were there any issues with equipment?

Would you change anything about the EMST practice?

How was the intensity? (five sets of five repetitions, five days per week)

Were you able to practice each day and complete all repetitions?

Have you noticed any changes since you started using EMST?

Do you feel you have had enough support from us to complete EMST?

How beneficial do you think EMST is on a scale of 1-10 (10 best)?

What about the frequency of contact with SLT – was it too little or too much?

Is there anything else you would like to add?

Researcher to confirm modality of next follow up appt (face to face / telephone / text / email)

APPENDIX 7.4 | TIDieR checklist for EMST

Item no.	Item	Description
1.	BRIEF NAME: Provide the name that describes the intervention	Expiratory Muscle Strength Training (EMST)
2.	WHY: Describe any rationale, theory or goal of the elements essential to the intervention	Targetting expiratory muscle engagement through training will increase expiratory muscle strength. In turn this will improve cough strength and facilitate mucus clearance. Based on previous research it is hypothesised this may also increase volume and perceptual quality of tracheoesophageal voice.
3.	WHAT: Materials: describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or training of intervention providers	An EMST device is required, which is a hand-held threshold pressure device. Participants will also require strongly adhesive baseplate and materials such as elastic bands to improve device airseal at the neck stoma. Participants will provided with written information on how to use and clean the EMST device, a practice tracking diary and written space to capture reflections on practice.
4.	WHAT: Procedures: describe each of the procedures, activities and/or processes used in the intervention including enabling or support activities	The intervention requires participants to complete 25 exhalations per day into the device, for five days per week. This will be carried out for five weeks. Participants will then complete a six-week maintenance period of 25 breaths per day for two days per week. Each week of the initial five-week intervention, participants will attend a check-in appointment with the research team to discuss the intervention, monitor challenges and progress, and to adjust the device when required.

Item no.	Item	Description
5.	WHO PROVIDED: Describe expertise, background and any specific training given	SLTs with specialism in laryngectomy rehabilitation and voice therapy
6.	HOW: Describe the modes of delivery and whether provided individually or as a group	Two individual face-to-face therapy sessions to set up the device and implement safe practice, followed by weekly individual check-in sessions, which may be in person or via virtual contact according to participant preference.
7.	WHERE: Describe the type of locations where the intervention occurred	Small meeting room at City, University of London
8.	WHEN AND HOW MUCH: Describe the number of times the intervention was delivered, over what time period including number of sessions, schedule, duration, intensity or dose	The intervention was carried out for 25 repetitions per day, on five days per week, for five weeks. Following the initial five-week intervention, participants completed a six-week maintenance period of 25 breaths per day for two days per week. Participants were advised to complete the 25 daily breaths in five sets of five repetitions, spaced throughout the day according to their schedule. The device threshold was set to 75% of maximal expiration pressure and adjusted according to gain in function at weekly check-ins.
9.	TAILORING: If the intervention was personalised, titrated or adapted; describe what, why, when, how	Participants could decide when to schedule the daily repetitions according to their normal daily routines. The weekly check-ins were offered as face-to-face, online meeting, video-call or email/SMS chat. This was decided by participants according to their preference. The threshold pressure setting of the device was set according to individual's maximum expiratory pressure at baseline and adjusted as required.

Item no.	Item	Description
10.	MODIFICATIONS: If the intervention was modified describe the changes	Device adaptations were made to support the use of the EMST device at the neck stoma
11.	HOW WELL: Planned: if intervention adherence or fidelity were assessed, describe how and by whom, and with what strategies	Adherence to the protocol was tested through the research team's review of weekly practice diary, discussion with participants and through attendance data. The research team followed a set protocol in delivering the intervention.
12:	HOW WELL: Actual: If intervention adherence or fidelity were assessed, describe the extent to which the intervention was delivered as planned	The intervention was delivered as planned. There was 100% adherence to dosage in the five-week initial block, however, two participants completed this over 6/7 weeks. Two participants reduced the dosage in the maintenance period.