# FULL/LONG TITLE OF THE STUDY

A Proof-of-Concept Study of The Complete Vocal Technique (CVT), a pedagogic technique used for Performers, in Improving the Voice and Vocal Function in Patients with Muscle Tension Dysphonia using Telehealth

# SHORT STUDY TITLE / ACRONYM

CVT Therapy for MTD/ CVT4MTD

**RESEARCH REFERENCE NUMBERS**

| | |
|---|---|
| **IRAS Number:** | **306954** |
| **SPONSORS Number:** | **19ET004** |
| **FUNDERS Number:** | The Industrial Researcher Programme (Case number: 8054-00039B) |

**OTHER RESEARCH REFERENCE NUMBERS:**

**SPONSOR: Nottingham University Hospitals NHS Trust**

**PROTOCOL VERSION NUMBER AND DATE: Version 2.1 28 Mar 2022**

**SIGNATURE PAGE**

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

**For and on behalf of the Study Sponsor:**

Signature: Date:

..... ...../...../.....

Name (please print):

.....

Position:

.....

**Chief Investigator:**

Signature: Date:

..... ...../...../.....

Name: (please print):

JULIAN A McGLASHAN

## KEY STUDY CONTACTS

Insert full details of the key study contacts including the following

| | |
|---|---|
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| Key Protocol Contributors | JA McGlashan<br>M Aaen<br>C Sadolin |

## STUDY SUMMARY

| | |
|---|---|
| Study Title | A Proof-of-Concept Study of The Complete Vocal Technique (CVT), a pedagogic technique used for Performers, in Improving the Voice and Vocal Function in Patients with Muscle Tension Dysphonia using Telehealth |
| Internal ref. no. (or short title) | CVT4MTD |
| Study Design | Proof-of-concept study |
| Study Participants | Patients with Type I-III Muscle Tension Dysphonia voice disorder |
| Planned Size of Sample (if applicable) | Ten |
| Follow up duration (if applicable) | Eight weeks |
| Planned Study Period | 28/02/2022 to 26/08/2022 |
| Research Question/Aim(s) | 1) The principal research question is: "Can the approach used in the pedagogic Complete Vocal Technique (CVT) to optimise voice production in singers and performers be applied to patients with Muscle Tension Dysphonia to improve vocal symptoms, vocal function, and meet patient treatment goals using a Telepractice medium?"<br>2) Is the CVT voice therapy (CVT-VT) approach using Telepractice perceived as beneficial by patients, the study SLT-V and study CVT-P?<br>3) Does the CVT-VT approach differ or provide additional benefits to traditional SLT-VT methods in the treatment for patients with MTD |

FUNDING AND SUPPORT IN KIND

| **FUNDER(S)**<br><br>(Names and contact details of ALL organisations providing funding and/or support in kind for this study) | **DETAILS OF FINANCIAL AND NON FINANCIAL SUPPORT GIVEN** |
|---|---|
| **Innovation Fund Denmark** | (Total Grant: £222,685 NUH grant allocation £55,903) |
| **Complete Vocal Institute** | **None** |
| | |

**ROLE OF STUDY SPONSOR AND FUNDER**

The sponsor, Nottingham University Hospitals has overall responsibility for the initiation and management of the study. The study sponsor will monitor the study conduct against applicable regulatory standards. The study sponsor and study funder will have no role in the design, data analysis, interpretation, manuscript writing and dissemination of the results. The sponsor and funders will be consulted for the final decision/s regarding any aspects of this study.

## ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS

There will be no formal Study Steering Group as this is a pilot/feasibility study. PPI has been sought and the study progress will be reviewed monthly by the study team Julian McGlashan, Cathrine Sadolin and Anna White.

### Protocol contributors

| CONTRIBUTOR(S)<br>(Names and contact details of ALL individuals providing contribution to the protocol) | DETAILS OF CONTRIBUTION GIVEN |
|---|---|
| **Julian McGlashan,** | **Design, first author and Coordinator of project** |
| **Mathias Aaen** | **Design, co-developer of project, CVT GRBAS and CVT therapy techniques** |
| **Cathrine Sadolin** | **Design, founder of CVT therapy techniques, co-developer of project, and co-developer of CVT GRBAS** |
| **Anna White** | **Design, co-developer of project, advice and guidance on SLT therapy techniques and assessment** |
| **PPI group** | **Review and feedback on proposed study** |
| **Peer review group** | **Review and feedback on proposed study** |

**KEY PHRASES:** Voice therapy; muscle tension dysphonia; proof-of-concept study

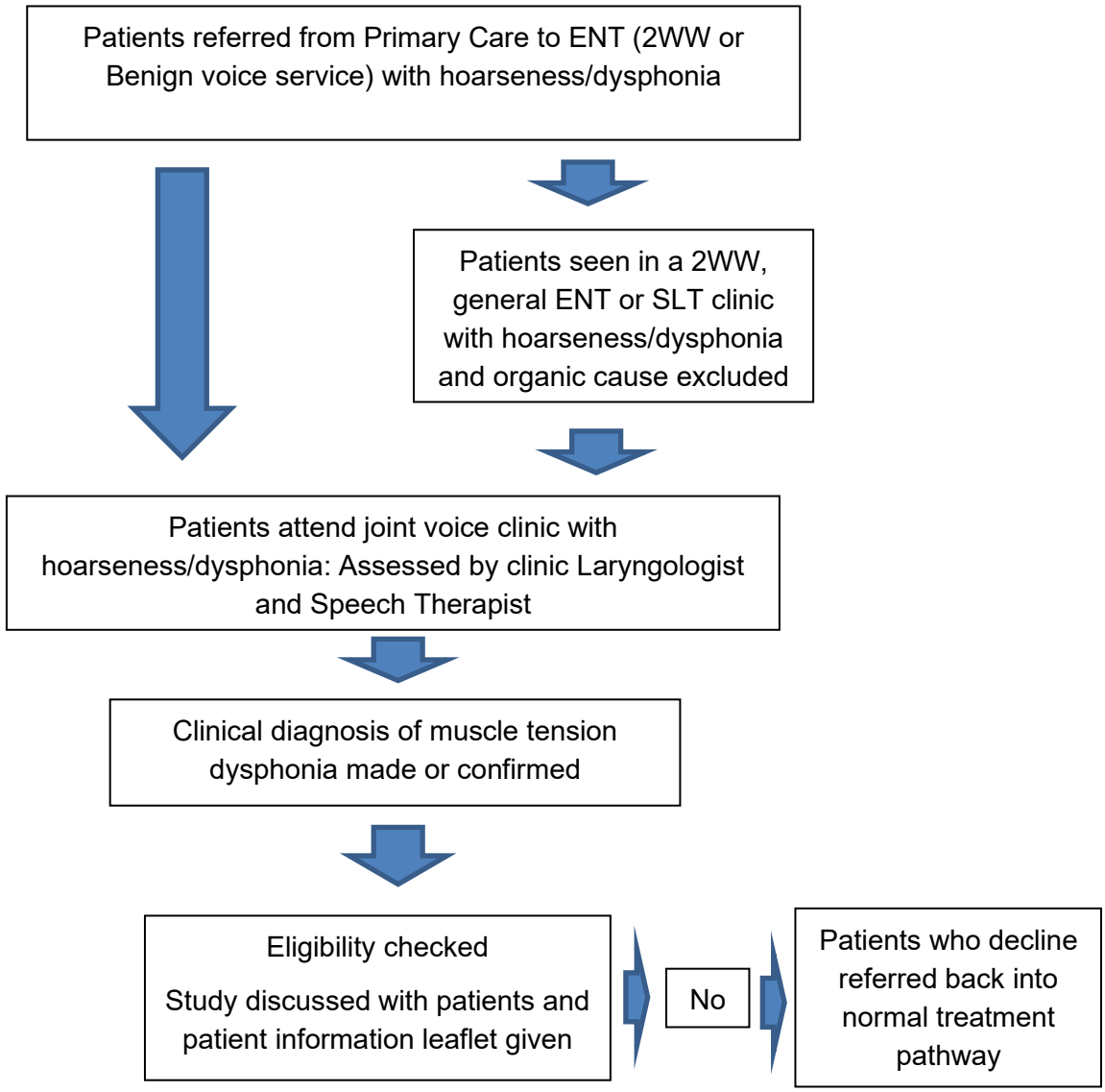
### LIST of CONTENTS

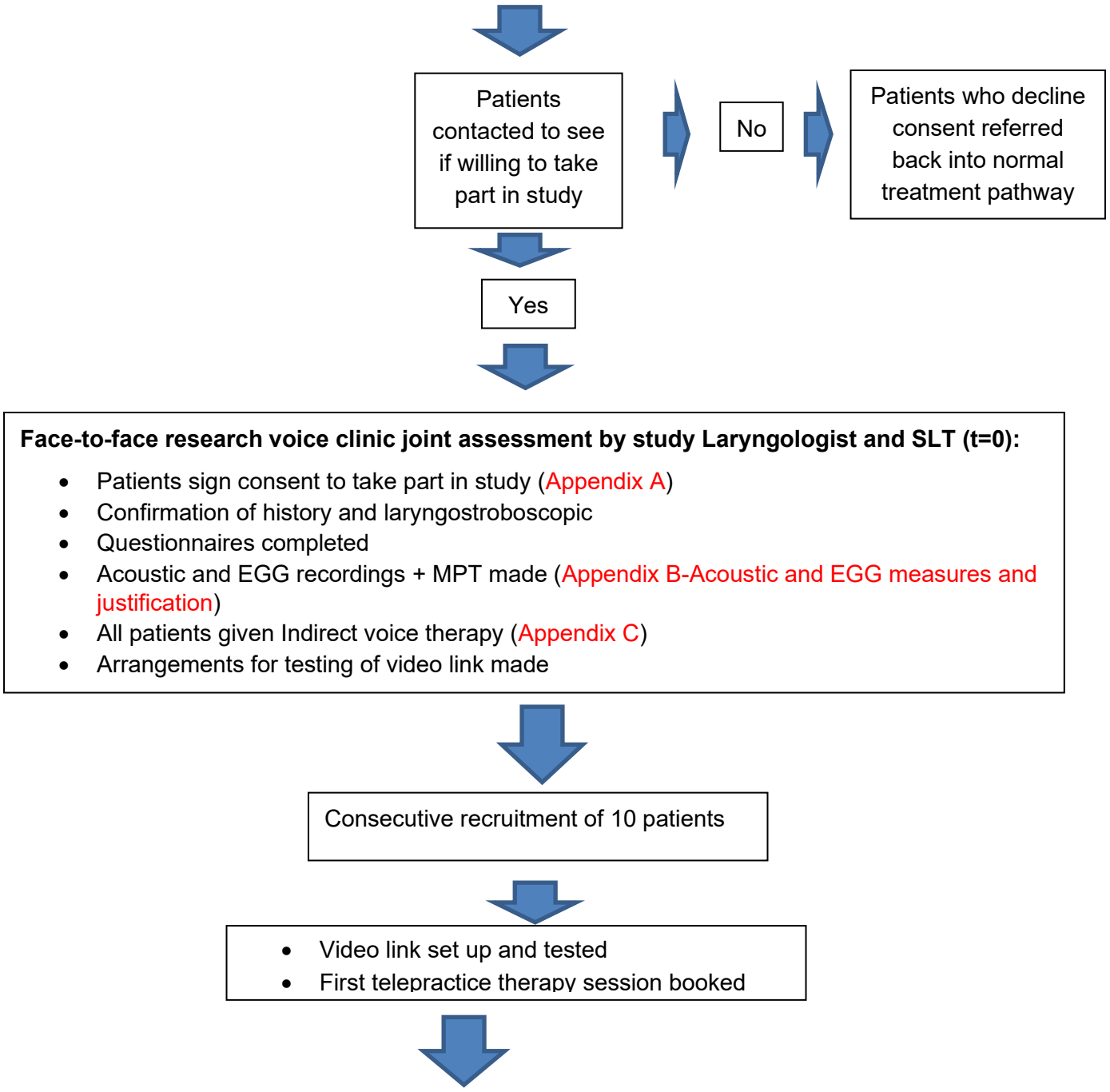
**STUDY FLOW CHART**

Gantt chart:

| Task | Description | Year 2022 | | | |
|---|---|---|---|---|---|
| | | Q1 | Q2 | Q3 | Q4 |
| 1 | IRAS submission | X | | | |
| 2 | Recruit patients | | X | X | |
| 3 | Treat patients | | X | X | |
| 4 | Evaluate metrics | | | X | X |

**Flow diagram:**




Patients contacted to see if willing to take part in study
No
Patients who decline consent referred back into normal treatment pathway
Yes
Face-to-face research voice clinic joint assessment by study Laryngologist and SLT (t=0):
Patients sign consent to take part in study (Appendix A)
Confirmation of history and laryngostroboscopic
Questionnaires completed
Acoustic and EGG recordings + MPT made (Appendix B-Acoustic and EGG measures and justification)
All patients given Indirect voice therapy (Appendix C)
Arrangements for testing of video link made
Consecutive recruitment of 10 patients
Video link set up and tested
First telepractice therapy session booked

**Treating CVT Practitioner (t=0 to t=6)**

Up to 6 sessions (45-60 mins) given online over a total of 6/52

- Medical/SLT assessment documentation available to Practitioner
- Assessment by treating Practitioner and treatment plan including goals agreed with patient
- Structured proforma documenting session goals, and % time of therapy used in each session completed at end of each session to form part of treatment record
- Observation by study SLT-VT, and/or recording of sessions
- Review of progress (log of treatment and study SLT -V observations where performed) by study SLT-V, study CVT-P and Laryngologist after 2 and 4 therapy sessions

If concerns about suitability of treatment for patient, they may exit the study after agreement between study team and patient

**Final face to face session (t=8): Joint assessment by study Laryngologist and SLT**

- Rating of achievement in obtaining goals by patient, study SLT-VT, study CVT-P and treating CVT-P
- Repeat questionnaires
- Repeat acoustic/EGG voice recordings + MPT
- (optional repeat stroboendoscopic laryngeal examination to assess confirmatory improvement in laryngeal appearance and recording of 'no damage' from treatment)

## 1. BACKGROUND

### Muscle Tension Dysphonia

Voice problems (dysphonia) affect one in 13 adults annually, causes a major impact on quality of life and livelihood and is a substantial healthcare burden (Lyberg-Åhlander, Rydell et al. 2019). It is more common in women and in those with vocally demanding professions and the elderly. The causes of voice problems can be broadly divided in to 'organic' and non-organic'. Examples of organic causes are nodules, polyps, cancers, nerve weakness and laryngitis (McGlashan, Costello et al. 2007). Non-organic causes, also known as primary Muscle Tension Dysphonia (MTD) are due to an imbalance of breathing mechanism and/or tightness of the muscles of the voice box or throat, which leads to a decompensation of the voice and the patient becoming symptomatic and dysphonic (Altman, Atkinson et al. 2005); (Mathieson, Hirani et al. 2009);(Van Houtte, Van Lierde et al. 2011). MTD can also be secondary to organic pathology which needs to be excluded before a diagnosis of primary

MTD is made. There are different presenting patterns of primary MTD but generally there are six recognisable patterns both in their presenting symptoms, voice quality and on laryngeal appearance on endoscopy. Three types (MTD patterns I-III) are more related to ineffective voice use, also known as 'voice abuse' or 'voice misuse', while the other three types (MTD patterns IV-VI) have a psychological basis (Belisle and Morrison (1983); (Koufman and Blalock 1991);(Harris 2018);(Rammage, Morrison et al. 2001);(Hsiung and Hsiao 2004);(Koufman 2014); (Rammage, Morrison et al. 2001). MTD forms the largest group of dysphonic patients seeking treatment in the UK accounting for 10-40% of referrals (Carding 2003, Dromey, Nissen et al. 2008).

Patients with dysphonia have problems with one or more of the following: hoarseness, abnormal pitch or loudness, variability in quality or control of their voice. In the UK, patients with persistent or unexplained hoarseness who are over the age of 45 are referred under the two-week wait (2WW) cancer referral process (NICE 2015, Douglas, Middleton et al. 2021). In other cases, referral to an Ear, Nose and Throat (ENT) benign voice service is usually considered if the dysphonia persists for more than six weeks, it has not improved with simple measures such as voice rest, reducing irritation to the vocal cords and drinking plenty of fluids (known as vocal hygiene advice) or it is impacting significantly on the patient's work or their social life. In practice patients with MTD may come through both the 2WW and benign voice pathways.

**Diagnosis and traditional treatment of MTD (see Appendix A for more details)**

Patients are diagnosed with MTD by an ENT surgeon from the history of their vocal complaint and by excluding an organic cause on examination of their voice box (larynx) with a small flexible video camera passed through their nose. Treatment is with voice therapy given by a Speech & Language Therapist who has specialised in voice disorders (SLT-V) (MacKenzie, Millar et al. 2001);(Wilson, Deary et al. 2002, Roy 2008). Voice therapy consists of two main types: Indirect Voice Therapy and Direct Voice Therapy (Van Stan, Roy et al. 2015) and is guided by advice from professional organisations such as Royal College of Speech and Language Therapists Clinical Guidelines (Taylor-Goh 2017) and the American Speech-Language-Hearing Association (ASHA) Clinical Practice Guideline: hoarseness (dysphonia) (Schwartz, Cohen et al. 2009). **Indirect therapy** consists of education, information, vocal hygiene and stress management (Roy, et al., 2001; Thomas & Stemple, 2007). **Direct therapy** consists of establishing healthy voice production (Colton & Casper, 2011; Stemple, 2000) by rebalancing the three subsystems of voice production namely breathing (respiration), voice production (phonation) and more efficient use of resonance (Guenther, Ghosh et al. 2006, Stemple, Roy et al. 2020).

The aim of voice therapy is generally to (a) return the patient's voice to normal or as best as possible within their anatomic and physiologic capabilities and (b) to satisfy the patient's occupational, social and emotional vocal needs (Aronson and Bless 2009) and (c) promote habit changes that will ensure voice improvement will be maintained (Mathieson 2001). Therapeutic goals should be specific and

determined by the patient prior to therapy to empower the patient in shared decision making with the aim of improving motivation and compliance (Shewell 2009, Titze and Verdolini Abbott 2013, Titze, Riede et al. 2018). In addition, the aim should be maximum improvement in the minimum time ((Mathieson 2001) page 372).

Many SLT-Vs use traditional, hierarchical, therapy techniques focusing in the early stages on postural and relaxation techniques, followed by breathing exercises, voicing and resonance work with final consolidation and review (Harris 2018). Often the numerous methods of treatment are used, often targeted on abnormal findings on clinical examination (Jones 2016) (see Table 1).

**Table 1 (modified from Jones, 2016). Note CVT would be expected to address each aim**

| AIM | Silent inspiration | Silent giggles/ laugh | Yawn, sigh | Accent method | Breath before tone | Plosive consonant closure | Glottal onset | Simultaneous onset | Humming | Glottal fry/ creak | Sob/ whine | Chewing | Vocal function exercises | Laryngeal manipulation | Twang | Siren | SOVT | Resonance work |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Reduce pharyngeal constriction/ lower larynx | | | x | x | | | | | | | x | x | | x | | | x | |
| Reduce glottic/ false vocal fold constriction | x | x | | x | x | | | x | x | | x | | | | | | | |
| Reduce antero-posterior or posterior-anterior constriction | | | x | x | | | | | | | x | | | x | | | | |
| Improve vocal fold closure/ establish modal voice | | | | x | | x | x | x | x | x | x | | x | | x | | | |

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Improve crico-thyroid tilt** | | | | | | | | | | | | | | | | x | | |
| **Improve vocal projection** | | | | | | | | | x | | | | | | x | | | x |

However, patients find transferring these techniques into conversational voice challenging and it is recognised that patients do not always complete their therapy sessions in up to 18-65% of cases. Numerous reasons have been put forward for this including clinician and clinic-related factors, gender, ethnicity, age, employment and perceived vocal severity, complex laryngeal diagnoses, additional medical problems, time commitment for treatment sessions or lack of rapid progress, adequate, if not complete, improvement in symptoms or failure to achieve goals (Smith, Kempster et al. 2010, Portone-Maira, Wise et al. 2011, Wenke, Coman et al. 2021). There is greater treatment satisfaction and likelihood of success if Direct Voice Therapy techniques are functionally orientated and have a more meaningful effect on quality of life (Grillo 2021) with an emphasis on carryover activities into conversation so they are more relevant to the patient's daily vocal demands (van Leer and Connor 2010, Ziegler, Dastolfo et al. 2014, Grillo 2021). There is also increasing recognition that a patient may require more than one 'voice' to addresses the changing vocal needs (e.g., quiet talking, talking over noise, and yelling) in different environments (Grillo 2021, Grillo 2021).

Although Direct voice therapy is the mainstay of treatment for MTD, there are a vast number of methods of treatment and a general lack of good quality studies their effectiveness (Bos-Clark and Carding 2017). This is made more difficult by MTD being a mixed group of conditions with different patterns of presentation and numerous patient specific factors. Voice therapy along with other rehabilitation treatments has been portrayed as a "black box" and many recognised treatment regimens overlap in their therapeutic goals (Van Stan, Roy et al. 2015). This makes it difficult to determine why patients improve, which therapy tasks are most beneficial and for how long they should be given (Dejong, Horn et al. 2004, Hart, Tsaousides et al. 2014, Van Stan, Roy et al. 2015, Turkstra, Norman et al. 2016).

Traditionally voice therapy has been given in a clinic environment face-to-face. However, with the onset of the COVID pandemic, Voice Therapy has almost entirely been given using telepractice via a video link. Telehealth (aka telepractice) has been defined as *"delivery of health care services, where*

*patients and providers are separated by distance… (it) can contribute to achieving universal health coverage by improving access for patients to quality, cost-effective, health services wherever they may be"* (https://www.who.int/gho/goe/telehealth/en). Prior to the COVID pandemic, telepractice had been used by Speech and Language therapists mostly for geographical reasons and difficulties in patients' attending outpatient clinics. There are relatively few studies in its use for voice disorders (Reynolds, Vick et al. 2009) and most studies on effectiveness have involved small cohorts of patients with a range of voice pathologies such as Parkinson's disease (Mashima, Birkmire-Peters et al. 1999, Mashima, Birkmire-Peters et al. 2003, Tindall, Huebner et al. 2008, Constantinescu, Theodoros et al. 2011, Fu, Theodoros et al. 2015). There are few Randomised Controlled Studies comparing face-to-face versus Telepractice and only one study of MTD patients using the same voice therapy technique (Flow phonation). This showed no significant difference in outcome between the two methods of delivery (Rangarathnam, McCullough et al. 2015). Disadvantages of telepractice for voice therapy include generic problems with technology, patient environmental and cultural considerations, some instructional and practical issues with inability to deliver more 'hands-on' techniques such as laryngeal manipulation (Keck and Doarn 2014, Molini-Avejonas, Rondon-Melo et al. 2015, Edwards-Gaither 2018, Lin, Chien et al. 2020).

**The Complete Vocal Technique**

(Aaen, McGlashan et al. 2019, Aaen, McGlashan et al. 2021)The Complete Vocal Technique (CVT) is primarily a method of teaching singers and singing teachers to produce any singing or speaking voice sound that is required. It has been used for over 35 years particularly in Europe and CVT practitioners (CVT-P) undergo an accredited 3-year training programme. It uses a hierarchical approach with terminology that is clearly defined and supported with scientific characterisation (McGlashan, Thuesen et al. 2017, Thuesen, McGlashan et al. 2017, Aaen, McGlashan et al. 2019, Aaen, McGlashan et al. 2021, Leppävuori, Lammentausta et al. 2021). It is based on four key building blocks enabling the singer to produce vocal sounds regardless of genre of music (Complete Vocal Institute, 2015; Sadolin, 2017). The first building block in CVT training is to ensure a healthy voice is produced by adopting the three overall principles: adequate support for the voice, use of a degree of twang ('necessary twang') and avoidance of jaw protrusion and tightening of the lips. Secondly one of four main vocal modes (Neutral, Curbing, Overdrive and Edge) is chosen which provides a set up for the larynx and the choice is determined by vocal demand (loudness, pitch range, vowel and genre 'norm' (vocal style) that is required, Neutral relates to normal conversational voice while the Curbing is a medium loud voice. Overdrive can used for voice projection up to a shout loudness, while Edge can be used for a yelling quality. It would be expected that training in Neutral and Overdrive would allow good vocal function for most social situations. The third is then to adjust the degree of sound colour (from dark to light) mostly by lowering and raising the larynx. The fourth element is to add specific vocal effects such as vibrato, ornamentation, distortion etc., which can be added once the first three

have been achieved. In this way the precise sound required by the singer can be fashioned in any style or genre of music. The principles can and have been applied to training the speaking voice and provide a recipe for producing any desired voice quality for any environmental situation. A similar approach, that has not been widely adopted, has also been described by Grillo (Grillo 2012) whereby the aim is not to support the production of 'one voice', as is frequently the case with traditional SLT-VT, but to provide the patient with a range of 'new' voices to meet their vocal needs.

Training programmes using CVT methodology have been developed to enable singers and singing teachers to improve their singing voice, achieve vocal goals and overcome technical issues many of which are due to unintentional hyper-constrictive muscle activity within the larynx and vocal tract. Voice therapy based on CVT principles (CVT voice therapy (CVT-VT)) has also been applied to professional speaking voice users and singers presenting with acute vocal problems leading to hoarseness or loss of voice when time is of the essence in getting a vocalist back to performing. This CVT-VT can help with deconstriction and improved voice production and projection. Although widely used by CVT-Ps CVT-VT has not been formally evaluated in performers or applied to non-performers although the principles of treatment of good voice production and deconstriction are applicable to both groups.

The application of telepractice during the COVID pandemic has also become a necessity in teaching singing teachers including at the Complete Vocal Institute (CVI) in Denmark where almost all tuition is now delivered on-line. Informal feedback from singers has been positive (Mathias Aaen, personal communication) with many advantages (reduction in cost and travel time) outweighing the disadvantages (peer support of singers in small groups, some technical issues). It is likely a complete return to previous methods of delivery of SLT and CVT practice will not happen after the COVID-19 pandemic with the adoption of the new methods of service delivery for both. However, ultimately a hybrid method of face-to-face and telepractice service may become the preferred method of practice.

## 2. RATIONALE

Although traditional voice therapy techniques are generally successful in improving dysphonia there is a general lack of good quality studies on its efficacy (Bos-Clark and Carding 2017). SLT-VTs have used mainly voice quality or physiological approaches (see Table 1) to guide therapy. Treatment studies have frequently focused on changes in outcome measures without adequate description and classification of the therapeutic processes that caused the measurement changes (Van Stan, Roy et al. 2015). This makes it difficult to determine why patients improve, which therapy tasks, and the associated treatment dosages, were effective for specific patients and patient populations (Dejong, Horn et al. 2004, Hart, Tsaousides et al. 2014, Van Stan, Roy et al. 2015, Turkstra, Norman et al. 2016). This can lead to, in some circumstances, prolonged courses of treatment, restoration of a voice that cannot be carried over into conversational use or a voice that does not meet the occupational or social requirements of the patients.

The rationale for this study is that the techniques employed in the CVT, have a clear, precise framework, that has well defined terms (Complete Vocal Institute, 2015; Sadolin, 2017) and has been evaluated using endoscopic, perceptual, acoustic and electroglottographic methods (McGlashan, Thuesen et al. 2017);(Thuesen, McGlashan et al. 2017);(Aaen, McGlashan et al. 2019, Aaen, McGlashan et al. 2020);(Aaen, McGlashan et al. 2021) for the singing voice. The CVT system has been used and continually developed over 35 years and now accounts for the largest agreeing group of singing teachers in the world. It is being used consistently in universities, conservatories, and in singing schools across Europe. It provides a structure and language that allows singers to create the voice quality they require in a healthy and sustainable way. It also allows singers to optimise vocal function and overcome unhealthy constrictive patterns, so the techniques lend themselves to patients with MTD. 'Training programmes using CVT methodology have been developed to enable singers and singing teachers to improve their singing voice, achieve vocal goals and overcome technical issues many of which are due to unintentional hyper-constrictive muscle activity within the larynx and vocal tract. Voice therapy based on CVT principles (CVT voice therapy (CVT-VT)) has also been applied to professional speaking voice users and singers presenting with acute vocal problems leading to hoarseness or loss of voice when time is of the essence in getting a vocalist back to performing. This CVT-VT can help with deconstriction and improved voice production and projection. Although widely used by CVT-Ps CVT-VT has not been formally evaluated in performers or applied to non-performers although the principles of treatment of good voice production and deconstriction are applicable to both groups. If successful CVT-VT may provide SLT-VTs with additional tools to help manage patients with MDT.

## 3. THEORETICAL FRAMEWORK

The modes, sound colour and effects underpinning CVT have been studied using endoscopic, perceptual, acoustic and electroglottographic (EGG) analysis and each of these elements have been characterised (McGlashan, Thuesen et al. 2017, Thuesen, McGlashan et al. 2017, Aaen, McGlashan et al. 2021). There are similarities, but also significant differences, in vocal tract configuration between hyper-functional muscle tension dysphonia patterns and a healthy loud ('shouting') quality singing (Overdrive) and hypofunctional muscle tension dysphonia patterns and healthy production of a quiet breathy voice 'Neutral with air' (Saldias, 2019; Leppävuori et al, 2020). Similarities include a high vertical larynx position, small hypopharyngeal width, and epilaryngeal outlet. Differences include higher pitch, a wider lip and jaw opening, and larger volumes of the oral cavity (Saldias, 2019). Observation and anecdotal application by CVT teachers of non-singing dysphonic patients attending a Joint Voice Clinic has demonstrated that CVT methodology can be used successfully in a complimentary way to traditional SLT methods. CVT would be expected to achieve all the physiological aims as outlined in Table 1.

There is little literature of using singing therapy for patients with MTD or other types of dysphonia. However with more rehabilitation singing teachers and vocal coaches attending Voice Clinics and working closely with Speech Therapists, there is a general 'borrowing' and 'exchange' of techniques (Harris and Chalfin 2018). Vocal demands of singers and actors have similar requirements in voice and breath control, voice projection, overcoming stresses and avoidance of inappropriate hyper-constrictive muscle tension patterns as other professional voice users such as teachers, call centre workers. Therefore, potentially they can benefit from input from the specialised knowledge and experience of voice coaches and singing teachers. In addition, not infrequently singers' voice problems often stem from speaking voice problems.

## 4. RESEARCH QUESTION / AIM(S)

The aim of this proof-of-concept study is to evaluate whether the approach used in the Complete Vocal Technique to improve voice production in singers and performers can be applied to patients with Type I-III Muscle Tension Dysphonia pattern using a Teleheath medium.

### 4.1. Objectives

The primary objective of this proof-of-concept study is to determine whether a CVT-VT approach improves vocal symptoms and function in patients with Type I-III Muscle Tension Dysphonia using a validated patient self-assessment questionnaire of the physical, functional and emotional aspects impact of the dysphonia.

Secondary objectives include:

1) to assess whether a CVT approach improves the voice, voice function and meets the goals of the therapy treatment from the patient perspective,
2) to assess whether a CVT approach meets the goals of the therapy treatment from and SLT-V and CVT-P perspective
3) to document and qualitatively evaluate the elements and/or techniques used in the treatment sessions and assess if or how they differ from mainstream SLT-VT techniques and give 'added value',
4) to assess a variety of secondary outcome measures for the treatment of MDT based on perceptual, acoustic and electroglottographic (EGG) assessments and self-reported measures to establish the best measures that reflect symptomatic, physiologically relevant, and patient-centred measures reflecting improvement in symptoms and daily function for patients
5) to evaluate the results with an aim of assessing the feasibility of performing a larger RCT.

### 4.2. Outcome

The main outcome measure is an improvement in the validated Voice Handicap Index self-assessment score following up to six sessions of therapy by an authorised CVT-P in patients with MTD (Appendix 1)

Secondary outcome measures include:

1) A questionnaire to evaluate the acceptability of the approach to patients (Appendix 2)
2) A questionnaire to evaluate the perceived effectiveness of the therapy from the Therapist's perspective. (Appendix 3)
3) Qualitative comparison of the specific techniques used by the CVT-P based on a log of techniques used during the therapy session (Appendix 4) and qualitative assessment of anonymised, redacted transcripts of therapy sessions in those who have given additional consent
4) Comparison of pre- and post-treatment results of:
    a. a range of simultaneously acquired acoustic and EGG measures made on voice recordings of continuous speech, phrases based on phonetically selected texts and sustained vowels (Appendix B)

b. psychoacoustic evaluation of the recorded voice samples using the CAPE-V (Appendix 5) and CVT derived assessment tools (Appendix 6)
c. vocal tract discomfort scale – a self-reported rating scale (Appendix 7)
d. change in the aerodynamic measure, the Maximum Phonation Time (MPT) (Appendix 8)

5) Review of qualitative and quantitative results with recommendations on the feasibility and design of performing a larger RCT. The results will be published in a peer reviewed publication

## 5. STUDY DESIGN AND METHODS OF DATA COLLECTION AND STATISTICAL ANALYSIS PLAN

The aim of this proof-of-concept study is to evaluate whether the approach used in the Complete Vocal Technique to improve voice production in singers and performers can be applied to patients with Type I-III Muscle Tension Dysphonia pattern using a Teleheath medium. Ten cconsecutive patients seen in an NHS Joint SLT/ENT Voice clinic who meet the inclusion/exclusion criteria and who give consent will be invited to take part in the study. In addition, MTD patients awaiting SLT-VT will be invited to take part in the study. Data including validated patient self-assessment questionnaires, audio-perceptual evaluation of the voice, acoustic and EGG recordings of the voice and an aerodynamic measure (MPT), will be collected after recruitment in a research clinic at the beginning of the study (t=0) and again at the end of the study (t=8). Data will be collected by the study Laryngologist or study SLT. Additional questionnaires will also be given to patients and Therapists at the end of the study to obtain feedback on satisfaction with achievement of goals, the therapy, and the use of Teletherapy to deliver the treatment. Quantitative standard descriptive and inferential statistics methods will be applied to compare pre-and post-therapy measures using the VHI as the primary outcome measure as well as the selected secondary outcome measures.

**VHI**

Paired-samples t tests will be applied to the pre-treatment and post-treatment primary outcome measure scores (total VHI score).

**Acoustic, EGG and MPT measures**

Paired-samples t tests will also be applied to the secondary acoustic outcome measures (EGG, acoustic and MPT measures), together with 95% confidence intervals.

To control for Type 1 error of the primary outcome and secondary outcome analyses while maintaining an acceptable level of statistical power, the alpha level for all t-test comparisons will also be assessed at .025. Treatment effects will be assessed by comparing the pre-treatment to post-treatment change (Δ) scores, plotted as a forest plot in order to display the average Δ change for each outcome measure and corresponding 95% confidence interval. Any significant treatment effects will be followed up with calculations of effect size using Cohen's d.

Measurement reliability for acoustic analyses will be calculated by reanalysis of 10% of the recordings. The recordings chosen for reliability analysis will be randomly selected from the total number of recordings. Pearson product–moment correlations will be used to assess inter-measurer and intra-measurer reliability of the acoustic and EGG measurements.

**CAPE-V**

For the secondary outcome measure CAPE-V, three experienced judges will be asked to rate all voice samples using the first four dimensions (overall severity, roughness, breathiness, and strain; on 100-mm visual analog scales (VAS) (Kempster et al, 2009). The judges will be blinded to pre- and post-treatment status of the voice samples. The voice samples will be presented in random order. The rating forms will be scored, and then scores for each subject will be averaged across the three judges. Average scores will be used for group analyses. Interrater agreement will be assessed using procedures described by Kreiman and Gerratt (1998). Agreement equivalent to within 1 point on a 7-point Equal Appearing Interval (EAI) scale will be calculated for each possible pair of raters for each voice sample. On a 100-mm visual analog scale, scores that fall within 7.2 mm will be considered to be in exact agreement on a 7-point EAI, and scores that are within 21.5 mm (7.2 + 14.3 mm) will be considered to be within 1 scale value. Two scores will be considered to agree if they fall within ±21.5 mm on the VAS (probability of chance agreement p = 0.39). The probability of agreement will be calculated by totaling all pairs of scores that agree and dividing by the total number of score pairs. Twenty percent of the voice samples will be randomly selected to be repeated for each judge. Repeat ratings will be used to assess intra-rater agreement, using the same calculation. To test for differences in the four CAPE-V dimensions, a multivariate analysis of variance will be applied to the pre-treatment to post-treatment change (Δ). Paired-samples t tests will also be applied to pre-treatment to post-treatment changes for each of the four dimensions within each group. A multiple comparison adjustment will be made for the four comparisons using the Bonferroni multiple-comparison procedure. The confidence intervals will be similarly adjusted for four comparisons, so the reported 95% confidence interval (CI) will actually be a 98.75% CI, which is a Bonferroni-adjusted CI.

**Other Questionnaires**

Comparison of the total score of the frequency and the total score of the severity of symptoms evaluated in the Vocal Tract Discomfort (VTD) scale pre- and post-treatment will be compared using paired sample t-tests. The comparison of the frequency and the severity of particular symptoms of the VTD scale pre- and post-treatment will be made by means of the non-parametric Mann – Whitney U test. Comparison of the frequency and the intensity of particular VTD items in the respective subgroups of patients pre- and post-treatment using ANOVA. Finally, the relationships between the results of the VTD scale and VHI and MPT will be estimated by means of the Pearson *r* coefficient. Other non-validated questionnaires will be reported using descriptive statistics.

**Recording and Analysis of therapy sessions**

Those patients who agree for their therapy sessions to be recorded will have these recordings made using NUH Trust approved software on an NUH Trust laptop/computer together with the other

patient data in a secured research database storage area. The anonymised sessional recordings will then be transcribed by a member of the research team and redacted to exclude any personal or identifiable information. In addition, a qualitative assessment of the anonymised therapists' sessional treatment records will be made using a preliminary organising framework and initial codes based on the target of the therapy methods applied during the treatment sessions. These codes will be based on physiological principles, laryngeal setting, treatment methods based on the terms used in the voice therapy and CVT literature and will be coded using the qualitative research management software NVivo based on the principles of Template Analysis (King, 2012), a commonly used thematic analytical framework allowing for a priori and crystalising themes in qualitative analyses. The main aim is to identify the differences and similarities of SLT-VT and CVT-VT approaches to therapy.

## 6. STUDY SETTING

- Single centre study
- Patients will be recruited from the ENT/SLT joint voice clinic at the ENT Department, Queen's Medical Centre Campus, Nottingham University Hospitals.
- In addition, patients with a diagnosis of MTD who are on the waiting list for SLT-VT will be invited to take part in the study.
- Site specific requirements to run the study: The initial and final assessments need to be performed in the research clinic in the ENT Department to allow specialist acoustic, EGG, MPT and videostroboscopic examinations (optional) to take place.
- Therapy treatment sessions will be done using Teleheath through a CVT-P patient video link. Documentation of therapy sessions will be done using standardised proformas (on-line or paper) (based on Appendix 4)

## 7. SAMPLE AND RECRUITMENT

### 7.1. Eligibility Criteria

All patients who meet the inclusion/exclusion criteria and who give consent will be invited to take part. Ten consecutive patients will be recruited. All participants will have a multidisciplinary and multidimensional assessment (see Table 2) and considered for the study if they have a clinical diagnosis of Type I-III MTD based on consensus agreement of the patient by an SLT-V and

Laryngologist and meet the study criteria. No participants will be excluded based on race, ethnicity, or gender.

**Table 2 – Diagnosis of MTD (See Appendix A for more details)**

| |
|---|
| 1) The history of the presentation of the condition and its compatible with a Primary MTD diagnosis;<br>2) Presenting vocal symptoms such as hoarseness, change in voice quality, limitations in pitch, loudness, flexibility, and/or stamina of the voice;<br>3) Absence of organic pathology such as structural abnormalities, neurological and inflammatory conditions on endoscopy;<br>4) Auditory-perceptual voice change judgment which include one or more of the following characteristics: variable or abnormal in quality (strained, pressed, creaky, rough, breathy and asthenic voice), have an abnormal habitual pitch with or without a restricted fundamental speaking frequency range or have abnormal loudness and loudness variability during speech;<br>5) The presence of muscle soreness, tenderness or other evidence of hyperfunction in the thyrohyoid or cricothyroid space and/or suprahyoid muscles on physical examination,<br>6) Laryngoscopic findings of laryngeal hyperfunction pattern (MDP Type 1-III). |

#### 7.1.1. Inclusion criteria

**Table 3: Inclusion criteria**

| |
|---|
| Males & females |
| 18 or above |
| Clinical diagnosis of primary MTD based on history and laryngoscopic assessment (Type (I-III) MDT pattern) through joint assessment by a SLT-V and laryngologist |
| Current voice problems, persistent for greater than 2 months |
| Severity of disorder a) VHI ≥ 30 and b) patient wants therapy |
| Patient willingness to undergo treatment |
| Consent to participate in study protocol |

#### 7.1.2. Exclusion criteria

**Table 4: Exclusion criteria**

| |
|---|
| Organic vocal pathology 1) Structural/neoplastic disorders (e.g. carcinoma, cyst, polyp, papilloma, Reinke's oedema); 2) neurological disorders (e.g. vocal cord palsy, paresis, spasmodic dysphonia); 3) inflammation (e.g. infection, reflux (RFS >7) or significant relevant systemic disease (e.g. severe COPD) or need for surgery |

| |
|---|
| Significant psychological issues identified during initial assessment (with option to withdraw if discovered during the treatment periods and agreed by both patient and Therapist) |
| MDT pattern (IV-VI) compatible with significant primary psychological aetiology on laryngoscopy |
| Transgender voice issues |
| Previously incompletely treated dysphonia, neurological disease, or upper aerodigestive tract malignancy |
| Had previous VT or CVT training or pharmacological treatment for their voice problem (other than proton pump inhibitors or an alginate recommended for disorders of laryngopharyngeal reflux–related symptoms) |
| A hearing impairment that would prohibit or impact on telepractice treatment |
| Significant concomitant health problems affecting voice |
| Not have or be able to use a computer with video link at home or in hospital even with support |
| Not able to commit to the study protocol |

### 7.2. Sampling

The paper questionnaires and forms will be completed by patients during the attendance at the research clinic at (t=0) and (t=8) and administered by the study Laryngologist and SLT-VT and form part of the Case Report Form (CRF). The acoustic and EGG voice recordings will also be made at these research clinic appointments by a member of the study team. CRFs and study documentation will be stored in a locked cabinet in a locked ENT department room. Questionnaire and other form data will be transcribed onto a digital platform and kept in patient folders in a secure Network storage area and a copy of relevant clinical data will also form part of the patient's digital health record (DHR). Acoustic and EGG data will be similarly stored with print outs of summary statistics forming part of the patient's DHR and CRF.

#### 7.2.1. Size of sample

As this is a proof-of-concept study the sample size of ten patients was selected arbitrarily to generate the necessary results for a power analysis for future studies.

#### 7.2.2. Sampling technique

### 7.3. Recruitment

All patients presenting to Joint Voice Clinic in the ENT Department at the Queen's Medical Centre, Nottingham University Hospitals with a diagnosis of MTD will be considered. In addition, patients with a diagnosis of MTD who are on the waiting list for SLT-VT will be invited to take part in the study. Those who meet the inclusion and exclusion criteria will be invited to take part in the study (Appendix D_CVT4MTD_Invitation to Patient on WL for treatment of MTD- v0.01 2021_12_29). The aim is to maximise the number of patients in a relatively short time frame.

#### 7.3.1. Sample identification

The study will be publicized to all ENT and SLT staff within the department. Patients will then be highlighted to the study Laryngologist and SLT who will then arrange for them to be initially reviewed in the Joint Voice clinic. Travel and parking fees for the two additional trips to the hospital that will be involved in this study or if the patient has to attend because it is not possible to establish a video link with them at home.

#### 7.3.2. Consent

Informed consent will be obtained prior to the participant undergoing any activities that are specifically for the purposes of the study. Identification of patients with capacity, who meet the inclusion and exclusion criteria will be given a patient information leaflet (See 19ET004 Appendix E CVT4MDT Participant information sheet V2.0 21 Mar 2022) outlining the protocol will be provided in the voice clinic. Those patients will then be contacted by phone and those who are willing to take part will be invited to the research clinic. They will have an opportunity to ask further questions and those that agree will be formally consented (see 19ET004 Appendix F CVT4MTD_Informed-Consent-Form V2.0 21 Mar 2022)

## 8. ETHICAL AND REGULATORY CONSIDERATIONS

### 8.1. Assessment and management of risk

The main risk is of failure to improve with treatment although this is thought to be minimal as this pilot study involves administration of existing types of therapy applied to singers. The study treatment session documentation will be reviewed by the study Laryngologist, Speech and CVT therapists after the second and fourth treatment sessions. Ad hoc observation of the CVT-P treatment sessions will be made by the Study SLT-VT if the patient has given consent. The patient, recordings and questionnaires will be reviewed at the research clinic appointment at the end of the study (t=8) and

patients offered further assessment and treatment as necessary. If the researcher or therapist were to come into information which had safeguarding implications or discloses information where the patient has the potential to be exposed to risk or harm or to cause harm to others, this would be raised in the first instance with the Chief Investigator who would escalate the issue according to NUH's safeguarding policy or clinical teams. All members of the study team, including the CVT-Ps, will have contracts or honorary contracts with NUH, have undergone pre-employment checks including safeguarding and GCP training.

### 8.2. Research Ethics Committee (REC) review & reports

Before the start of the study, approval will be sought from the REC at NUH to approve the study protocol, informed consent forms and other relevant documents. Any substantial amendments that require review by REC will not be implemented until the REC grants a favourable opinion for the study.

**For NHS REC reviewed research**

- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the HRA.

### 8.3. Peer review

Initial approval was obtained by the Innovation Fund Denmark when successfully obtaining funding for the the whole project and was discussed with The NUH SLT team. The CVT treatment protocols and assessment methods were discussed with other experienced CVT teachers at the Complete Vocal Institute in Copenhagen. The CVT-VT treatment protocols and assessment methods were also discussed within the wider Speech Therapy team in the ENT Department at NUH. External Peer review has been obtained from Professor Paul Carding, Director of Oxford Institute of Nursing, Midwifery and Allied Health Research, Oxford Brookes and Oxford Universities and Fiona Robinson, Advanced Practitioner SLT at Nottingham University Hospital, Director of H F Robinson Ltd and SVS Training Ltd and previous Head of Service for Speech & Language Therapy Nottinghamshire Healthcare.

**Patient & Public Involvement**

The project was discussed at a PPIE drop-in session on 2nd December 2021. The group consisted of experienced research reviewers. Feedback was that the project was interesting, and the aims were clear. There was a question about governance, safeguarding and supervision of the CVT-P. The panel were reassured that all non-clinical members of the study team and the CVT-P would have honorary Trust

contracts and be subject to Trust employment terms and conditions, undergo GCP training, the therapy would be overseen by the study SLT-V who would observe some of the sessions and a review progress after second session. All patients could withdraw from the study at any time and the patients would all be reviewed at eight weeks to determine if their goals of therapy had been met and whether further assessment of treatment was required.

In addition, the protocol with a questionnaire (see 19ET004 Appendix G CVT4MDT Patient & Public Involvement & Engagement survey sheet v0.3 V1.0 12 Jan 2022) was given to five patients attending the Joint Voice clinic on 14th December 2021. Two patients had MTD and the rest had other voice problems. The results were overall very positive.

1) Did you understand the information given in the sheet?

Yes = 5 No = 0

Is there anything which isn't clear? No comments

2) Having read through the info sheet, would you theoretically consider taking part in this study?

Yes = 5 No = 0

Please say why or why not? No comments

3) Do you think the aim of this pilot study, to test whether CVT-VT used in performers can help patients with MTD, is a good idea?

Yes = 5 No = 0

If No, please say why not?

It seems useful & practical

The project sounds very helpful.

If CVT-VT therapy works this can support recovery more quickly

4) Do you have any concerns about patients having therapy with a specialist vocal coach (CVT-VT) rather than a Speech & Language therapist (SLT-VT) in this study?

Yes = 1 No = 4

If Yes, please say why? No comments

Are CVT as good as SLT? Are they medical people?

Giving patients every chance to heal their voice early rather than waiting at length for an ENT appointment

5) Do you have any concerns or comments about receiving your therapy using a video link?

Yes = 0 No = 5

If Yes, please say why? No comments

6) If you were a participant, would you be happy, have no strong opinion or be unhappy if the therapy sessions were recorded for more detailed analysis (please circle)?

Happy = 4 No strong opinion = 1 Unhappy = 0

7) If you were a participant, would you be happy, have no strong opinion or be unhappy if a specialist Speech and Language Voice Therapist observed the CVT Therapy sessions (please circle)?

Happy = 5 No strong opinion = 0 Unhappy = 0

8) Do you have any other comments or suggestions about the project?

9) Finally, would you be happy to be contacted in the future to give feedback on this or other voice related studies?

Yes No

If Yes, please let us know your name and how we can contact you?

Three patients responded positively

### 8.4. Regulatory Compliance

Before recruitment of any patients into the study, the Chief Investigator or designee will apply for HRA approval for the study and will make contact with the R&D department and the local Clinical Research Network. Prior to commencing recruitment, we shall confirm that NUH has the capacity and capability to conduct the study, as per the HRA approval letter. Any amendment to the protocol should be considered that it may potentially affect a site's capacity to continue in the study, the Chief Investigator will inform the Sponsor of the proposed amendment. The amendment will be submitted as per Section 8.7.

### 8.5. Protocol compliance

Protocol deviations, non-compliances, or breaches are departures from the approved protocol. Accidental protocol deviations can happen at any time. However, they will be documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately. Frequently recurrent deviations from the protocol are not acceptable and will require immediate action and could potentially be classified as a serious breach.

### 8.6. Amendments

We shall follow the following process for dealing with amendments in this study involving the NHS:

It is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC. If the sponsor wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor must submit a valid notice of amendment to the REC for consideration. The REC will provide a response regarding the amendment within 35 days of receipt of the notice, informing the HRA of the amendment. Site R&D departments will also need to be provided with the information on the amendment in order to assess their continued capacity and capability. Their level of review will be dictated by the category as assessed by the REC or HRA (A, B or C). Guidance on the categorisation of amendments for studies involving the NHS can be found on the HRA website.

http://www.hra.nhs.uk/resources/after-you-apply/amendments/

If applicable, other specialist review bodies (e.g. CAG) need to be notified about substantial amendments in case the amendment affects their opinion of the study.

Non-substantial amendments also need to be notified to the HRA as well as the relevant R&D departments of participating sites to assess whether the amendment affects the continued capacity for that site. Note that some amendments that may be considered to be non-substantial for the purposes of REC and/or MHRA may still need to be notified to NHS R&D (e.g. a change to the funding arrangements).

Any amendments (*substantial or non-substantial*) considered necessary by the study team will only be made after discussion with the R&D department of the sponsor at NUH. Approved amendments will be reflected in an update in the protocol version.

### 8.7. Adverse Events

**Reporting Procedures:**

All adverse events will be recorded. Depending on the nature of the event the reporting procedures below will be followed. Any questions concerning adverse event reporting will be directed to the Chief Investigator in the first instance.

**Definitions**

**Adverse Event (AE):** any untoward medical occurrence in a patient or clinical study subject.

**Serious Adverse Event (SAE):** any untoward and unexpected medical occurrence or effect that:

- Results in death
- Is life-threatening – refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe
- Requires hospitalisation, or prolongation of existing inpatients' hospitalisation
- Results in persistent or significant disability or incapacity
- Is a congenital anomaly or birth defect

Medical judgement should be exercised in deciding whether an AE is serious. Important AEs that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious.

**Non serious AEs**

All such events, whether expected or not, should be recorded.

**Serious AEs**

An SAE form should be completed and sent to the Chief Investigator within 24 hours.

All SAEs should be reported by the Chief Investigator directly to the Research Ethics Committee where in the opinion of the Chief Investigator, the event was:

'related', i.e. resulted from the administration of any of the research procedures; and

'unexpected', i.e. an event that is not listed in the protocol as an expected occurrence

In this instance, RDSAE@nuh.nhs.uk should be copied into all correspondence with the REC. Reports of related and unexpected SAEs should be submitted within 15 days of the Chief Investigator becoming aware of the event, using the TAFR01910 SAE form for non-IMP studies. The most recent copy of the form can be found via NUH intranet pages.

Local investigators should report any SAEs as required by their Local Research Ethics Committee and/or Research & Development Office.

Sponsor Contact Details for SAEs:

I. Email (RDSAE@nuh.nhs.uk)

II. Hand delivered not mailed (R&I, NHSP, C Floor, South Block, QMC)

Any queries please contact a member of staff in the Research & Innovations department:

Email: researchsponsor@nuh.nhs.uk

### 8.8. Data protection and patient confidentiality

All investigators and study site staff will comply with the requirements of the General Data Protection Regulation 2018 and Data Protection Act 2018 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Regulation's/Act's core principles.

All personal information will be collected and kept secure, either in digital format (Acoustic, EGG and video recordings) as part of the patient's hospital record on a password protected NUH Trust Network storage area or as part of the Case Study form. These will be stored in a locked cabinet within a locked room within a restricted access area of the ENT department. A digital copy of the relevant treatment record will be uploaded to the patient's Digital Health Record which is only accessible to Trust clinical

staff through an approved username and Password protected log in. A separate record containing participants identifiable data will be created and stored on the NUH Trust Network Storage in a password encrypted file separate from the research data.

Study specific data will be stored for 5 years. Clinical assessment and therapeutic details and outcome data will be stored in accordance with NUH's policy for. Some statistical analysis of data may be performed outside the Trust by members of the study group in Denmark or The Netherlands. Only encrypted, anonymised, coded data will only be transferred following the creation of coded, depersonalised data where the participant's identifying information is replaced by an unrelated sequence of characters to named individuals listed as part of the Investigator team. The key for the coding of participants in the form of an encrypted, password-protected spreadsheet, will be kept on the secured Network storage area at NUH.

### 8.9. Indemnity

Julian McGlashan, Anna White and Suzanne Slade have NUH NHS Trust indemnity. Mathias Aaen and Cathrine Sadolin will be given Honorary contracts with NUH and thus be covered by Trust indemnity within the confines of the study. All equipment used for quantitative assessment of patients has passed MESU inspection.

*As Nottingham University Hospitals NHS Trust is acting as sponsor for this study, NHS indemnity applies. NHS bodies are legally liable for the negligent acts and omissions of their employees.* Non-*negligent harm is not covered by the NHS indemnity scheme. The Nottingham University Hospitals NHS Trust, therefore, cannot agree in advance to pay compensation in these circumstances. In exceptional circumstances an ex-gratia payment may be offered*

### 8.10. Access to the final study dataset

The final dataset will be made available to the study investigators (Julian McGlashan, Mathias Aaen, Cathrine Sadolin, Anna White) and in an anonymised form to the Statistical team. It is not anticipated that the data will be used for secondary analysis. However, if this should be required, it can only be undertaken with the consent of the participants. All patient documentation should reflect the future use of these data in research.

## 9. DISSEMINATION POLICY

### 9.1.Dissemination policy

The data arising from the study will be owned by the study investigators and Nottingham University Hospitals. On completion of the study, the data will be analysed and tabulated and a Final Study

Report prepared. The full study report can be accessed by application to the study authors or the Research & Innovation Department at Nottingham University Hospitals. The participating investigators will only have rights to publish any of the study data subject to prior agreement with the study investigators. The aim would be to submit the results for review within a peer reviewed publication within 12 months of completion of the study. Funding from the supporting body will be acknowledged within the publications and a copy of the Final Study report will be included in the report to the Funding body. The study protocol will be made available to all participants on request and will be published in an Open Access journal. If a participant specifically requests the statistical code for generating the results or the results of the study, it will be provided after the Final Study Report had been compiled and the results have been published. The anonymised participant level dataset, and will be made publicly available, if necessary, as part of the supplementary material for any publication or on request if access restricted by the Journal.

### 9.2. Authorship eligibility guidelines and any intended use of professional writers

The study investigators will write any ensuing papers. No professional writers will be used.

# 10. APPENDICES

## 10.1. Appendices 1- Required documentation

19ET004 **Appendix 1** VHI -Voice Handicap Index V1.0 12 Jan 2022

19ET004 **Appendix 2** Achievement of goals Patient feedback questionnaire V1.0 12 Jan 2022

19ET004 **Appendix 3** Achievement of goals Therapist feedback questionnaire V1.1 21 Mar 2022

19ET004 **Appendix 4** Log of Therapist Treatment in session V1.0 12 Jan 2022

19ET004 **Appendix 5** CAPE-V rating form V1.0 12 Jan 2022

19ET004 **Appendix 6** CVT Speech Assessment V1.0 12 Jan 2022

19ET004 **Appendix 7** Vocal tract Discomfort scale V1.0 12 Jan 2022

19ET004 **Appendix 8** Maximum Phonation Time V1.0 12 Jan 2022

19ET004 **Appendix A** MTD V1.0 12 Jan 2022

19ET004 **Appendix B** Acoustic and EGG measures and justification V1.0 12 Jan 2022

19ET004 **Appendix C** Indirect Voice therapy Advice sheet V1.0 12 Jan 2022

19ET004 **Appendix D** CVT4MTD_Invitation to Patient on WL for treatment of MTD V1.0 12 Jan 2022

19ET004 **Appendix E** CVT4MDT Participant information sheet V2.0 21Mar 2022

19ET004 **Appendix F** CVT4MTD_Informed-Consent-Form V2.0 21 Mar 2022

19ET004 **Appendix G** CVT4MDT Patient & Public Involvement & Engagement survey sheet v0.3 V1.0 12 Jan 2022

**Appendix H**: Schedule of Procedures (see below)

**Appendix I**: Amendment History (see below)

### 10.2. Appendix H – Schedule of Procedures

| Procedures | Visits (insert visit numbers as appropriate) | | | | |
|---|---|---|---|---|---|
| | Screening Joint Voice Clinic | Research voice clinic (t=0) | Therapy sessions (x6) | Research voice clinic (t=8) | |
| Identification of eligible patients | x | | | | |
| Informed consent | | x | | | |
| Demographics | | x | | | |
| Medical history | | x | | | |
| Outcome measures | | x | | x | |
| Therapist documentation | | | x | | |
| Additional questionnaires | | | | x | |

### 10.3. Appendix I – Amendment History

| Amendment No. | Protocol version no. | Date issued | Author(s) of changes | Details of changes made |
|---|---|---|---|---|
| | | | | |

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Participant Consent Form

Version: 2.0 Date: 21 Mar 2022

# A Proof-of-Concept Study of The Complete Vocal Technique (CVT), a pedagogic technique used for Performers, in Improving the Voice and Vocal Function in Patients with Muscle Tension Dysphonia using Telehealth

**Principal Investigator: Julian McGlashan**

Patient Study ID: …..…….. Initials: ……

**Patient initial each box**

1. I confirm that I have read and understand the information sheet dated _____ (version _____) for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected. ☐

3. I understand that my medical records may be looked at by authorised individuals from the Sponsor for the study and the UK Regulatory Authority in order to check that the study is being carried out correctly. ☐

4. I understand that even if I withdraw from the above study, the data collected from me will be used in analysing the results of the trial. ☐

5. I consent to the storage including electronic, of personal information for the purposes of this study. I understand that any information that could identify me will be kept strictly confidential and that no personal information will be included in the study report or other publication. ☐

6. I understand that the information collected about me will be used to support other ethically approved research in the future, and may be shared anonymously with other researchers. ☐

7. I agree that my GP, or any other doctor treating me, will be notified of my participation in this study. ☐

8. I agree to take part in the study. ☐

**9. Optional additional consent:** I agree to my therapy treatment sessions being recorded with transcripts made but with all personal identifiable material removed. ☐

**10. Optional additional consent:** I agree to a Speech and Language therapist observing the therapy treatment given by the CVT Practitioner. ☐

| | | |
|---|---|---|
| Name of the patient *(Print)* | date | Patient's signature |
| Name of person receiving consent *(Print)* | date | Signature |