Effectiveness of Intensive Voice Therapy Versus Weekly Therapy for Muscle Tension Dysphonia: A Noninferiority Randomised Controlled Trial With Nested Focus Group

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SUMMARY: Objectives. To investigate the noninferiority of intensive voice therapy and compare its effects with weekly voice therapy on multidimensional outcomes of voice and well-being, satisfaction, and attendance in people with muscle tension dysphonia (MTD). The study further aimed to explore clinician's perceptions of barriers and enablers to implementation of intensive therapy.

Study Design. Noninferiority randomised controlled trial with nested focus group.

Methods. Twenty adults with MTD were randomised to receive either weekly voice therapy (1 hour per week for 8 weeks) or intensive voice therapy (1 hour, 4 days per week for 2 weeks). Participants were assessed by a blinded assessor twice before treatment, once post treatment and once at 4 weeks follow up on the primary outcome measure VHI and a range of secondary auditory-perceptual, acoustic, and patient (i.e., VoiSS, satisfaction) and clinician reported outcome measures (i.e., AusTOMs, attendance rates). Five Speech Language Pathologists also participated in a focus group to explore barriers and enablers to implementing intensive therapy, with questions and analyses guided by the Theoretical Domains Framework.

Results. While noninferiority for the primary outcome measure VHI was not confirmed, secondary outcome measures revealed comparable within group clinically important improvements for VoiSS and the AusTOMs, as well as selected acoustic and auditory-perceptual measures for both groups. A trend of more improvements being maintained in the intensive group was identified. Comparably high satisfaction and attendance was also found between groups. Clinicians reported more enablers than barriers to providing intensive therapy which included beliefs that it led to greater progression and consolidation of patient learning, was supported by the local context and was associated with positive emotions. Barriers related to difficulties with booking and scheduling and the belief that intensive therapy was not for all patients.

Conclusions. While the current study was likely underpowered to establish non-inferiority of intensive therapy, secondary outcomes suggested that intensive therapy may produce comparable benefits to voice, wellbeing, satisfaction and attendance compared to weekly therapy and may be a viable therapy option for individuals with MTD. When implementing intensive therapy, clinicians should consider patient's preferences and availability, as well as systems which allow for flexible booking and therapy provision for patients. Clear recommendations for future research including the use of a larger sample and telehealth are also provided.

KEY WORDS: Intensive−Muscle tension dysphonia−Voice treatment−Massed practice−Acoustic −Auditory-perceptual.

INTRODUCTION

Muscle Tension Dysphonia (MTD) is a frequently diagnosed voice disorder, accounting for up to 40% of visits to voice specialists[1]. This type of dysphoniais defined by Baker et al., to occur due to an "inefficient phonatory pattern in response to changes in health, social, employment and social demands".[2] p.104 Due to "habituated vocal misuse patterns," MTD can lead to secondary organic changes such as vocal nodules and Reinke's oedema.[2] p.104 The resulting dysphonia leads to multidimensional changes in voice function affecting auditory-perceptual, acoustic and aerodynamic measures and individuals experiencing potential difficulties in meeting the vocal demands of their familial, social, and occupational roles. The latter may cause financial burdens to employers and individuals through loss of income,[3] as well as reduced wellbeing, and higher incidences of anxiety, depression and adjustment disorders.[4,5] Due to it's prevalence and potentially detrimental impact, the need for effective and efficient treatments for MTD is paramount.

Currently, the gold standard for treatment for MTD is voice therapy delivered by a speech-language pathologist

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(SLP), with three systematic reviews to date revealing moderate evidence for its effectiveness.[6-8] The optimal intensity of voice therapy however is unknown.[9,10] The issue of treatment intensity is complex and encompasses a range of parameters including session frequency, session duration, total intervention duration, and dose (i.e., number of therapeutic inputs or client acts per session)[11]. Typically, session frequency for voice therapy is weekly, with session duration of 30-60 minutes, and total intervention duration ranging widely from several weeks, months or even years.[12,13] While we know the reduced intensity of treatment provided is unlikely to cause harm, the impact these intensity parameters have on the effectiveness of voice therapy has been the basis for further investigation in recent years.[9]

The intensity parameters of session frequency and total intervention duration have been of particular interest, with the impetus for research into more frequent therapy sessions over a shorter duration being twofold. Firstly, more frequent practice within a shorter timeframe, known in motor learning as massed practice, may enhance learning and consolidation of vocal behaviours[14,15] compared to more "distributed" practice used in traditional therapy.[14] Secondly, attendance rates for standard weekly models are notoriously low, with drop outs from recommended voice therapy reported as high as 64.5%,[16] leading to potential clinician frustration, poorer therapy outcomes and health care service costs.[17-19] Researchers have hypothesised that offering massed as opposed to distributed therapy schedules may increase attendance rates.[12,17,19] particularly for occupational voice users who need symptoms to improve quickly to resume work.[20]

While a large body of evidence has demonstrated the effectiveness of massed practice in voice disorders arising from Parkinson's Disease using the Lee Silverman Voice Treatment,[21-24] the evidence in MTD is still in its early stages, however results appear promising. These include several preliminary single-group studies,[15,17,20,25-27] as well more recent controlled studies which compared intensive therapy with traditional distributed therapy schedules,[12,19,28,29] finding comparable results between intensive versus less-intensive therapy . For example, Fu et al.[28,29] compared intensive therapy (four sessions per week for 2 weeks) with traditional therapy (once a week for 8 weeks) in 53 Taiwanese women with bilateral vocal nodules using the Lessac-Madsen resonant voice therapy (LMRVT)[30] and vocal function exercises.[31] Comparable improvements to auditory-perceptual and acoustic outcomes were seen in both groups, which were mostly maintained 6 months post treatment.[28,29] While results suggested intensive therapy may be equally beneficial to traditional weekly models in people with vocal nodules, authors cautioned the study's internal validity which may have been influenced by assigning participants to a therapy group based on their availability rather than random allocation.[32]

More recently, Meerschman et al.,[12] investigated the impact of intensive therapy (80 minutes a day, 5 days a week, for 2 weeks) provided either individually or in a group, versus traditional individual therapy (two 30 minute sessions per week for 6 months) using a prescribed voice training programme[12] in 45 individuals with either organic or functional voice disorders (encompassing MTD).Authors reported similar acoustic and patient reported improvements in those receiving intensive therapy compared to traditional therapy, however higher session attendance for the intensive group. Certain limitations of the study including the heterogenous participant sample and pseudo-randomisation may have however biased results.

Lastly, Wenke et al.,[19] evaluated the impact of intensive versus standard voice therapy in 17 individuals with MTD[19] who were randomly allocated to receive either an intensive (1 hour per day, 4 days a week for 2 weeks) or standard (1 hour a week for 8 weeks) therapy using a combination of Resonant voice[30] and Voicecraft® techniques.[33] Improvements were reported for individuals in both the intensive and standard treatment groups, with comparable outcomes between groups with the exception of attendance being higher in the intensive group.[19] Limitations however including a variable randomisation method, inconsistent treatment across participants and the inclusion of several participants over 60 years, as well as some with professional singing backgrounds, may have influenced the internal validity of findings.

To better understand the effects of intensive versus traditional distributed models of therapy in MTD, further research is needed which attempts to control for the described biases to date, including the use of true randomisation rather than allocation to treatment based on patient preference. A noninferiority trial design may also be useful to determine whether a more intensive service delivery model which may offer more advantages over more distributed or standard weekly models including increased attendance, offers acceptably equivocal voice outcomes. As MTD is a multi-dimensional voice disorder, use of multidimensional voice outcome measures including auditory-perceptual, acoustic, aerodynamic and patient reported measures is critical[10,34] and would also contribute to the evidence regarding which outcome measures are most useful in detecting change following different voice therapy models.[9,35] In addition, while the outcomes and perspective of the patients and service have been evaluated previously, no studies to date have formally investigated the clinician's perspective of delivering intensive therapy including their perceptions of barriers and enablers to implementing voice therapy., Further understanding in this area will help guide future implementation and is an important component of effectiveness studies in determining the feasibility of treatments.

In light of the described gaps in the current evidence, the primary aim of the present study was to determine the noninferiority of intensive voice therapy in adults with MTD compared to weekly voice therapy. Secondly, the study aimed to compare the clinical effects and feasibility of standard weekly voice therapy with intensive voice therapy in relation to auditory-perceptual, acoustic, and patient-

reported measures of voice function, wellbeing client satisfaction and attendance. Thirdly, the study aimed to understand clinician's perceptions of barriers and enablers to implementation of intensive voice therapy. Based on earlier research,[12,19,28,29,36] it was hypothesised that the primary outcome measure for voice therapy delivered intensively would not be inferior to weekly therapy, falling within a clinically acceptable margin. It was also hypothesised that individuals receiving the intensive therapywould demonstrate clinically important improvements to voice outcome measures and wellbeing, and that these would be similar to individuals receiving weekly therapy. Moreover, it was expected that the intensive voice treatment would be a clinically feasible service delivery model resulting in higher patient satisfaction, and higher attendance when compared to weekly therapy, based on previous research.[12,19]

METHODS

Study design

The study used a randomised controlled noninferiority trial research design (parallel group, allocation ratio of 1:1) with a nested focus group, with methods reported where appropriate, as per the CONSORT statement for non-inferiority trials.[37]

Participants with MTD were assessed on two occasions before treatment, immediately post treatment and four weeks after treatment (follow up). The study obtained ethical clearance prior to commencement (HREC/12/QPCH/106) with all participants providing informed written consent prior to participation.

Participants

Voice participants

Adult outpatients referred to the Gold Coast Hospital and Health Service SLP voice clinic from approximately June 2014 to December 2019 with an MTD as diagnosed by an ENT were invited to participate. Participants were excluded if they had poor English proficiency; known cognitive impairment or neurological pathology; significant hearing loss; a history of malignant vocal fold pathology or laryngeal surgery; benign vocal fold pathology for which voice therapy is not indicated (e.g. vocal polyps, granuloma, cyst); a diagnosed conversion voice disorder or significant mental health history which would impact on their ability to participate in therapy; pregnancy; a professional singing background, or as per previous research,[12,28] were over 60 years of age.

Clinician participants

Speech-language pathologists currently or previously employed by Gold Coast Health were invited to participate in a focus group at the end of the trial. To be included, SLPs must have either provided therapy or assessed at least one participant in the research allocated to intensive therapy.

Randomisation

Following consent, voice participants were randomly allocated to either weekly therapy or intensive therapy. Groups were stratified according to two levels of severity: (1) participants with a mild and mild-moderate rating on the AusTOMs impairment scale,[38] and (2) participants with a moderate or moderate-severe rating on the same scale. A blocked randomised allocation sequence (block size =4) was generated using a web based programme[39] by a researcher, RW, not directly involved in the consenting, assessment or treatment of patients, with participants being enrolled by their treating or assessing SLP. The randomised allocation sequence was concealed to all other researchers and clinicians, including those directly involved in the consenting, assessment and treatment of participants.

Procedure

A nasendoscopy with laryngeal stroboscopy was performed by an Ear Nose Throat (ENT) Specialist to evaluate vocal fold function prior to commencing of treatment and was used to classify the functional voice disorder according to the standard classification by Morrison and Rammage.[40] In some cases, the nasendoscopy and stroboscopy was undertaken by an advanced SLP using the same procedure which was verified by an ENT. A standardised initial case history regarding the participant's perception of their voice, history of the problem, voice usage, and other relevant behaviours (e.g., throat clearing, loud talking) and medical history was undertaken by an SLP. Following the ENT assessment and case history, all participants underwent a battery of multidimensional assessments by an SLP blinded to the allocation of the participant's treatment group (mean years of clinical experience = 21.42 years, SD=13.28, range 10−36 years). Assessments took place in an outpatient clinic room at a public hospital at all four data collection time points.

Outcome measures and data collection

The primary outcome measure used for the present study was mean change in Voice Handicap Index total score[41]. This widely used questionnaire measures the patient's perceived physical, emotional and functional impact that they experience as a consequence of their voice disorder, being an important measure of treatment impact. Secondary outcome measures included acoustic, auditory-perceptual, patient and clinician reported and service based measures.

Recordings for the auditory-perceptualand acoustic measurements were undertaken while the participant was seated in the same position in a hard back chair in the same sound attenuated room (ambient noise 40-44 dB) using the LingWAVES software program (version 2.6) in accordance with the LingWAVES Voice Clinic Suite Handbook.[42] The LingWAVES sound level meter (IEC60651 type 2 ANSI S1.4) and microphone (1/2-inch electric condenser) were mounted on a tripod and consistently positioned 30cm from the participant's mouth. Participants performed the

following tasks with each task being demonstrated by the assessor using scripted instructions prior to recording:

Acoustic measures. *Temporal acoustic measures.*

a ***SIZ ratio:*** The participant was asked to prolong the consonant /s/ and /z/ for as long as possible. This task was completed twice with the assessor labelling the longest of the two trials for analyses.

b ***Maximum Phonation Time (MPT)***: Participants were asked to sustain at a comfortable pitch and loudness the vowel sound /a/ for as long as possible on a single breath, three times. The longest of three trials was used for analyses.

Available normative data for both acoustic variables are found in Table 3.

Acoustic analyses based on sustained phonation tasks. Participants were asked to sustain the vowel /a/ for five seconds at a comfortable pitch and loudness and the following acoustic measures were derived using LingWAVES software: Jitter%, Shimmer%, Irregularity%, Glottal to Noise excitation ratio (Noise) and Fundamental frequency (F0). Participants were also asked to produce a glide from their lowest to their highest pitch three times, with the glide with the highest pitch recorded being used to determine Frequency range, and then produce their lowest audible volume, with the lowest volume (dB) of three attempts used for analyses. From these recordings, maximum F0 and lowest volume (dB) were used together with the MPT and Jitter % to calculate Dysphonia Severity Index (DSI). In addition, Praat (version 5.3.51) was used to measure signal type, F0SD, Noise to Harmonic Ratio (HNR) and Cepstral Peak Prominence- Smoothed (CPPS) using the sustained phonation recording. Ten percent of recordings analysed using Praat were re-analysed to calculate intra and inter-rater reliability.

Acoustic analyses based on connected speech. The following acoustic analyses were derived from reading the of the standardised Rainbow passage[43] using LingWAVES: mean F0, F0SD, mean volume (dB) and volume SD (dB). The second and third sentences of the Rainbow passage and recording of the sentence 'We were away a year ago' were also used to calculate mean F0, F0SD and CPPS using Praat (version 6.0.39). CPPS has been found to differentiate dysphonic from non-dysphonic voices.[44] Ten percent of recordings analysed using Praat were re-analysed to calculate intra and inter-rater reliability.

Auditory- perceptual analyses. Two experienced raters with normal hearing and a mean of 20 years of clinical experience in voice (SD=1.4), who were blinded to assessment time point and group allocation, performed a modified consensus rating using the Consensus Auditory-Perceptual Evaluation of Voice (CAPE-V).[45] Auditory-perceptual voice domains included ratings of Overall Severity, Roughness, Breathiness, Strain, Pitch and Loudness. Stimuli included the sustained phonation recording, the sentence "We were away a year ago" and the Rainbow Passage. Two participants (P1 and P3) did not have The Rainbow Passage recordings at two time points in which case only the sustained phonation and sentence 'We were away a year ago' were rated. Average length of these samples was 6 seconds. Raters were able to listen to as many repetitions of the recording as they required to make a judgement. These same recordings were used in the acoustic analyses to allow for correlations between acoustic and auditory-perceptual ratings as well as reduce listener fatigue. Approximately 10% of the voice samples were rated on a second occasion to calculate intrarater reliability from one of the raters.

Patient and clinician reported outcomes. Voice participants completed the Voice Handicap Index (VHI)[41] and the Voice Symptom Scale (VoiSS)[46] at each assessment time point, with lower scores indicating less impairment. During the post treatment assessment, voice participants were asked to complete a tailored satisfaction questionnaire as published in Wenke et al.,[19]. This questionnaire included 11 questions which used a 5-point Likert scale to indicate level of agreement with statements (5= strongly agree, 4= agree, 3= neutral, 2= disagree and 1=strongly disagree) and three open-ended questions. Prior to treatment, immediately post treatment and at follow up, the blinded assessor also completed the Australian Therapy Outcomes Measure (AusTOMs)[38] for voice which evaluated the impact of the voice disorder on the participant across four domains (impairment, activity, participation and wellbeing) on a 5 point scale.

Service outcomes. The number and duration of sessions, type of therapy technique provided, patient attendance and reason for non-attendance, and amount of homework completed (mins) as reported by the participant, was collected by the treating SLP throughout the duration of the therapy.

Clinician focus group. All eligible clinician participants were invited to attend a focus group to further explore their perspectives of intensive voice therapy. The focus group was facilitated by an independent researcher with over 25 years' experience in clinical SLP who had a prior professional relationship with the majority of participants. The interview questions (see Appendix 1) were provided to clinicians prior to the interview and were guided by the 14 domains of the Theoretical Domains Framework (TDF).[47] The TDF is a commonly used framework which integrates multiple theoretical constructs which help identify key barriers and facilitators to implementation of healthcare interventions.[48] The focus group was approximately 60 minutes in duration, was conducted face to face with some participants joining via videoconference and was audio recorded and professionally transcribed. Two participants were consulted following transcription to confirm the intention of four statements due to reduced audibility.

Therapy programme

The therapy provided is reported in accordance with the TIDieR guidelines.[49] Prior to commencing therapy, all voice participants attended a single one-hour vocal hygiene education session facilitated by an SLP using a standardised PowerPoint presentation format in either a group or individual format, and were provided with a series of standardised vocal care handouts to take home. Participants in both groups were then provided with individual voice therapy in a clinic room by a certified SLP who had undergone professional training in voice therapy which included 2-3-day face to face workshops and work shadowing with other more experienced voice therapists. Treating SLPs (mean years of clinical experience = 2.75 years, SD= 1.63, 5 female, 1 male) were asked to provide Resonant Voice Therapy, based on the Lessac-Masden Resonant Voice Therapy[30] to all participants. This therapy focused on the participant producing a resonant voice, described as a voice pattern that involves feedback through sensing oral vibration sensations in the alveolar ridge and facial plates,[50] through a hierarchy of prescribed voice and speech tasks progressing from producing sounds /m/ and /n/, followed by syllables (e.g., mee, mar, mor, moo), words, phrases and sentences. Therapy sessions also included 13 basic training stretches as described by Verdolini to help relax the facial, neck and shoulder muscles[30] as well as selected Voicecraft® techniques[33] including: sob, twang, silent giggle, onset of tone, and gentle onset, dependant on the participant's profile of voice impairment. All participants were offered a total of 8 hours of treatment, with participants randomly allocated to receive weekly treatment offered one 1-hour treatment session per week for eight weeks, and participants allocated to intensive treatment offered four 1-hour treatment sessions per week for two weeks. All participants were asked to practice tasks learnt in the therapy sessions independently, with the treating SLP documenting how long the participant reported undertaking home-based practice at each session.

Data analyses

A sample size of 12 participants (6 per group) allowing for a 50% drop out rate, was needed to detect a noninferiority margin of 13.5 (i.e., 75% of MCID of 18 based on Jacobson et al's originalmeasures with anSD of 5.6) for the primary outcome measure VHI total[41]) with an alpha of 0.05 and 80% power. Statistical analyses were performed using the SPSS computer software program (version 26, IBM, USA) and STATA (version 15.1) employing an intention to treat protocol. To determine whether there were any clinically or statistically significant differences between the first and second pre assessments, Wilcoxon matched pairs tests were undertaken. Except for the AusTOMs which was only completed once during the preassessment, the average of the first and second pre assessments were used for analyses. To address the primary aim of determining the noninferiority of the intensive group treatment, the between group difference for the primary outcome measure (VHI total score) post treatment and at follow up were calculated using a linear regression analysis with the pre-treatment score as the covariate. As per previous research,[51] the 95% confidence interval of the difference in scores between groups was then calculated to determine whether the confidence interval's upper bound was entirely between the noninferiority margin of 75% of the MCID (i.e., 13.5 VHI total) and zero.

To address the secondary aim, within-group treatment effects for the clinical quantitative variables (i.e., acoustic, auditory-perceptual, Likert-scale ratings) following treatment (i.e., between pre-treatment and post treatment and pre-treatment and follow up) were determined using paired *t*-tests or Wilcoxon matched pairs tests depending on whether the data followed a normal distribution. To identify differences in clinical and service outcomes existing between groups, independent t-tests or Mann Whitney *U* tests (depending on the normality of data) were performed for the satisfaction questionnaire items and service outcomes. For all other continuous outcome measures (i.e., acoustic, perceptual and self-report ratings), pre-post change scores of each group and pre-follow up change scores of each group were compared between groups using independent t-tests or Mann Whitney *U* tests (depending on the normality of data).

For secondary outcome measures, p-values of each test were reported however in accordance with the American Statistical Association and other expert recommendations,[52-55] an arbitrary statistical threshold to govern the significance of findings was not applied. Rather, *P*-values were interpreted in the context of what is considered to be a minimalclinically important difference (MCID), or "the smallest change in an outcome that is meaningful to patients"[56] as based on existing literature or a consensus of local experts. This general approach to move away from reporting results as being 'statistically significant' based on the arbitrary "$P<0.05$" and interpreting p-values more fluidly in the context of clinically important changes has been adopted in several recent randomised controlled trials.[57-59] Reported p-values were therefore not adjusted for multiple comparisons based on these recommendations, as *P*-values were not used to govern the interpretation of whether a finding was significant.[52,53] To determine whether any association between the acoustic and auditory-perceptual variables occurred, post hoc tests using Spearman's rank correlation were conducted on the CAPE-V variables and acoustic variables that demonstrated a meaningful improvement following treatment. Intra-rater reliability for perceptual analyses and inter- and intra- reliability for the acoustic analyses were performed using an intraclass correlation coefficient (ICC) based on a single rater (single measure), two-way random effects model with absolute agreement. Intra-rater agreement was excellent (ICC= >0.950) for all acoustic variables. Inter-reliability revealed on average excellent agreement (ICC=0.92), ranging from excellent for HNR (ICC= 0.999), CPPS vowel (ICC=0.986), CPPS sent (ICC=0.966), F0 sent (ICC= 1.000) and F0 rainbow (ICC=1.000), good agreement for CPSS rainbow (ICC=0.894), F0 vowel (ICC=0.789), and moderate for F0 SD (ICC=0.726). Intra-rater reliability identified moderate to good agreement across CAPE-V

ratings including overall severity (ICC=0.836), roughness (ICC=0.639), breathiness (ICC=0.767), strain (ICC=0.880). Intra-rater agreement for perceptual ratings of pitch (ICC=-0.166) and loudness (ICC=0.177) were poor and therefore results were not included for analyses.

Qualitative data analyses

The focus group interview and free-form questionnaire responses were analysed by researcher RW as separate project files with NVivo 12 software.[60] Qualitative content analyses were used to identify meaning units from participants' comments and formed into categories and subcategories.[61] For the focus group data, meaning units relating to barriers and enablers were grouped into categories and subcategories using the Theoretical Domains framework, as a deductive coding framework,[47] with further inductive content analyses being undertaken for meaning units not pertaining specifically to a barrier or enabler to implementation. A second researcher EC reviewed the categories formed and where a discrepancy occurred (for four to five meaning units) discussion with RW was made until a consensus was reached.

RESULTS

As shown in Figure 1, a total of 413 patients were assessed for eligibility, with 95 participants meeting criteria and invited to participate. Following consent, 20 participants were randomly allocated to receive either intensive or weekly voice therapy. Demographics of allocated participants are found in Table 1. Mann-Whitney *u* tests revealed

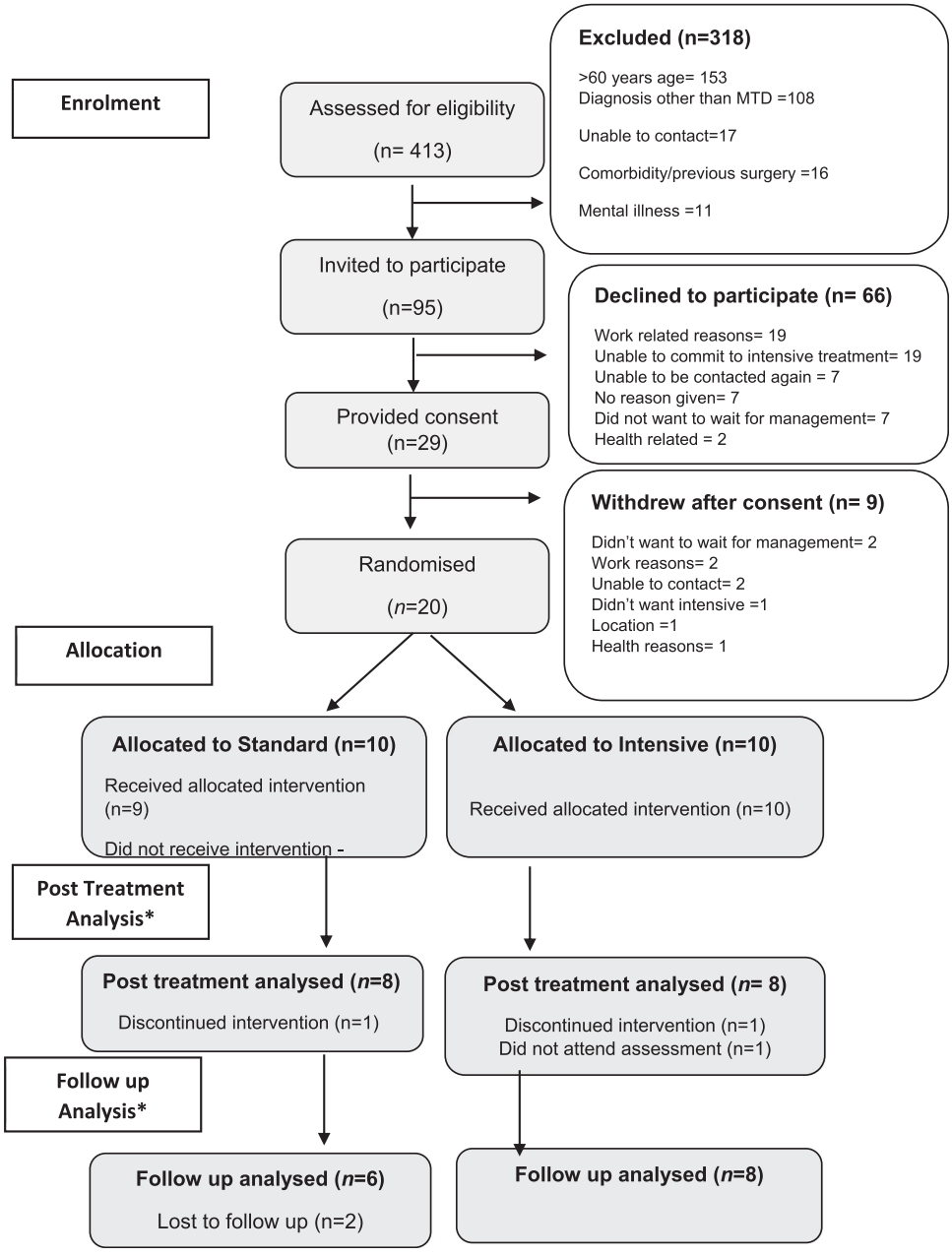

FIGURE 1. Schematic flowchart of participants through study.

TABLE 1.
Participant Demographics

Participant	Group	Gender	Age	Severity	Diagnosis	ENT diagnosis	ENT rating	Months since onset (months)	Occupation
10	Standard	Female	58	Moderate	MTD	MTD	Type 5	20	Volunteer reception work
12	Standard	Female	58	Mild	MTD	MTD	Type 3	8	Retired teacher
13	Standard	Male	30	Mild	MTD	MTD, Chronic cough	Type 3	24	Nurse
4	Standard	Male	53	Mild	MTD	MTD- over adduction of false VF	Type 2b	120	Business owner
7*	Standard	Female	23	Mild	MTD + organic changes	mild nodule formation at the anterior 1/3 of vocal folds	Type 1, 3	18	Chef
9#	Standard	Male	53	Moderate	MTD	MTD, phonatory gap	Type 3	NA	Fly in fly out worker
17	standard	Female	40	Moderate	MTD	MTD	Type 3	36	Drama teacher, lecturer, now mother
18	Standard	Female	38	Mild	MTD	Functional dysphonia	Type 3	3	Mother
19	Standard	Female	52	mod-severe	MTD	MTD	Type 2b, 3	84	Nurse
20	standard	Female	49	mild	MTD	MTD	Type 3	7	Voice over artist
		Mean age (SD)=45.4 (12.1)						**Mean months =35.5 post onset (40)**	
1	Intensive	Male	50	Moderate	MTD	MTD	Type 2b	12	National Presenter
2	intensive	Male	19	Mild	MTD	MTD	Type 2b, 3	60	University student
3	Intensive	Male	24	Mild	MTD	MTD	Type 2b, 3	3	Tennis coach
5*	Intensive	Male	31	Moderate	MTD + organic changes	Vocal nodules R> L, MTD	Type 3	72	Medical intern
6^	Intensive	Female	20	Mild	MTD + organic changes	R pre-nodule formation and phonatory gap	Nil constriction	9	Massage therapist
8	Intensive	Female	30	Moderate	MTD	MTD	Type 3	36	Sales/Marketing/ reception
11	Intensive	Male	50	Moderate	MTD + organic changes	Fluctuating MTD, R> L and Phonatory gap.	Type 3	12	Unemployed
14	Intensive	Female	26	Mild		VF nodules	Type 3	24	

(*Continued*)

TABLE 1. (*Continued*)

Participant	Group	Gender	Age	Severity	Diagnosis	ENT diagnosis	ENT rating	Months since onset (months)	Occupation
					MTD + organic changes				Childcare teacher
15	Intensive	Female	48	Mild	MTD + organic changes	VF nodules	Type 1	84	Teacher
16	Intensive	Male	36	Mild-moderate	MTD	MTD	Type 3	120	Personal Trainer
		Mean age=33.4 (12.1)					**Mean months = 43.2 post onset (39.2)**		

N.B. *=participants completed 2 therapy sessions. ^= no post treatment or follow up data available. #= participant did not complete any assessment or treatment, MTD= muscle tension dysphonia. Ratings based on scale by Morris and Rammage (1995); 1= laryngeal isometric, 2a= glottic hyperadduction, 2b=supra-glottic hyper-adduction, 3=supra-glottic anteriorposterior contraction. AP= anteriorposterior, NA= information not available

participants in the intensive group were younger in age however no differences were found for time post onset between the two groups. There were also more males in the intensive group (60%) than the standard group (20%). There were no important differences between the first and second pre assessments for any of the variables apart from mean vowel F0 (second assessment was on average 13Hz higher) and the maximum frequency range (second assessment on average 110Hz lower).

Eight participants in each group completed post treatment assessments (see Figure 1), and eight participants in the intensive group and six in the weekly group completed follow up assessments. In the intensive group, one participant withdrew due to work reasons during treatment, and another completed treatment but was unable to be contacted to complete the post and follow up assessments. In the weekly group, one participant withdrew prior to the initial assessment due to work reasons, and another participant discontinued treatment after two therapy sessions after being unable to be contacted. Service outcomes related to treatment attendance however were available for all participants who completed at least one treatment session (n=19). Due to recording or equipment failure, auditory-perceptual, aerodynamic and acoustic measures were unable to be analysed for two participants in the intensive group post treatment and one participant at follow up, and for one participant in the standard group post treatment and three participants in this group at follow up. Therapy techniques participants received are found in Table 2.

Primary outcome measure

The noninferiority analysis revealed a mean difference post treatment between weekly and intensive therapy of 10.83 for the VHI total score with a 95% confidence interval of -4.17 to 25.85. As the upper limit of the 95% confidence interval was outside the noninferiority margin of 13.5 and zero, non-inferioirity was not established. At the follow up timepoint, the mean difference between intensive and weekly therapy was much smaller being 3.38, with the 95% confidence interval (-21.39 to 14.62), which was outside the 13.5 non-inferiority margin.

Secondary outcome measures

Acoustic measures

As shown in Table 3, *P*-values suggested several within group improvements were found following both treatments. In theweekly group, this included improvements approaching normative values for Shimmer % and Jitter immediately post treatment and at follow up compared to pretreatment, and for irregularity and CPSS for sentences immediately post treatment.[62,63] In the intensive group, improvements approaching more normative values were found for Shimmer % and irregularity immediately post treatment, with improvements being maintained at follow up. There were no meaningful differences between groups for any of the acoustic measures.

TABLE 2.
Therapy Techniques Used

Group	Partic.	Stretch	Resonant Voice	Sob	Twang	Silent giggle	Onset of Tone	Gentle onset
Standard	10	✓				✓	✓	
	12	✓	✓					
	13	✓	✓					
	4	✓	✓			✓	✓	
	7^	✓				✓	✓*	
	17	✓	✓					
	18	✓	✓		✓*			
	19	✓	✓			✓	✓	
	20	✓	✓	✓		✓	✓	
Intensive	1	✓	✓	✓*		✓*		
	2	✓	✓		✓*	✓	✓	
	3	✓	✓		✓	✓	✓	
	5^	✓	✓					
	6	✓			✓*	✓	✓	
	8	✓	✓		✓	✓		
	11	✓	✓			✓	✓	
	14	✓	✓			✓		✓
	15	✓	✓					
	16	✓	✓		✓*	✓*		

^ =participant completed <3 sessions*= Participant used this technique for 1 session only

Auditory-perceptual ratings

Mean auditory-perceptual ratings are shown in Table 4. There were clinically important improvements (>10 mm)[64] to ratings of overall severity from pre to post treatment in both treatment groups, with p-values suggesting that these differences were real, however this was not maintained at follow up for either group. Ratings of roughness improved for the intensive group post treatment remaining below baseline at follow up. Strain improved immediately post treatment for both groups, continuing to decrease in the intensive group at follow up, however increased at follow up in the weekly group.

Post hoc correlations were conducted between perceptual and acoustic measures that were found to show meaningful change post treatment (i.e., overall severity, roughness, strain, shimmer, jitter, irregularity and CPPS sentences). The only strong correlations found were between strain and irregularity (r= -0.663), strain and jitter (r = 0.669) post treatment and at follow up, and overall severity (r = 0.739) and strain (r = 0.833) with CPSS for sentences post treatment and at follow up respectively.

Patient reported measures

VHI and VoiSS. Improvements to the VHI total score immediately post treatment were found for both groups (see Table 5), with clinically important improvements at follow up for both groups (i.e., being >18 points)[41], which were also reflected by low *P*-values. Total scores of the VoiSS demonstrated similar meaningful improvements (>18 points) in the weekly group post treatment compared to pretreatment, and remained below baseline at follow up. For the intensive group, a clinically significant improvement was found for the VoiSS total score at follow up but not immediately post treatment compared to pretreatment. No clinically important between group differences were found for the VHI or VoiSS total scores.

Satisfaction. As shown in Figure 2, satisfaction ratings were comparable between groups, with ratings generally being "agree" or "strongly agree" for the majority of items across both groups, and p-values reflecting minimal differences. Categories from the open-ended questions included (1) Positive factors about the therapy (2) Negative factors about the therapy and (3) Suggestions for improvement (see Appendix 2 for quotes). Participants across both groups reported positive aspects of treatment including positive perceptions of the therapists and therapy exercises and outcomes of therapy. In regard to outcomes of therapy, participants in the intensive treatment group reported that the therapy helped facilitate consolidation of their learning and their awareness of their voice, while participants in the weekly group reported they learnt about their voice function and demonstrated improved confidence. Only one participant in the intensive group and two participants in the weekly group provided comment in relation to negative aspects of treatment including intensive therapy being too frequent and reduced flexibility and feeling self-conscious, respectively. Suggestions for improvement from two participants within each group were provided including suggestions from an intensive therapy participant to continue

TABLE 3.
Group Results for Acoustic Parameters

Task	Normative value	Group	Pre mean* (SD)	Post mean (SD)	FU mean (SD)	Mean/Median change scores (95% CI/ IQR)*		Within group difference(p=)		Between group difference in change scores (p=)	
						Pre-Post	*Pre-FU*	*Pre-post*	Pre-FU	*Pre-post*	Pre-FU
s/z ratio	< 1.4	STANDARD	1.00 (0.33)	0.92 (0.38)	0.95 (0.52)	0.03 (-0.27, 0.33)	-0.09 (-0.40, 0.23)	0.830	0.600	0.523	0.168
		INTENSIVE	1.07 (0.28)	0.86 (0.26)	0.89 (0.21)	-0.14 (-4.16, 0.136)	-0.11 (-0.266, 0.056)	0.269	0.167		
MPT (seconds)	F=15-25 M= 25-35	STANDARD	16.66 (8.77)	18.24 (7.22)	15.87 (7.45)	0.64 (-4.33, 5.61)	3.9 (-2.26, 10.06)	0.765	0.165	0.789	0.418
		INTENSIVE	16.63 (7.56)	15.96 (7.96)	15.63 (6.61)	-1.34 (-5.25, 5 2.57)	-1.67 (-5.11, 1.77)	0.444	0.288		
Jitter %	<0.5%	STANDARD	0.94 (1.45)	0.31 (0.31)	0.28 (0.27)	-2.86 (-0.4. 0.09)	-0.11 (-0.18, 0.04)	0.176^	0.046^	0.694^	0.573^
		INTENSIVE	0.29 (0.28)	0.18 (0.14)	0.14 (0.08)	-0.03 (-0.04, 0.03)	-0.03 (-0.10, 0.03)	0.726^	0.293^		
Shimmer %	<5%	STANDARD	10.86 (5.77)	6.28 (1.58)	8.76 (4.54)	5.98 (1.19, 10.78)	-2.61 (-8.43, -0.80)	0.022	0.028^	0.434	1.00^
		INTENSIVE	11.20 (5.46)	7.17 (2.72)	7.19 (4.07)	4.08 (0.797, 7.36)		0.022	0.036		
Irregularity	<1.0	STANDARD	1.21 (0.45)	0.85 (0.24)	1.02 (0.50)	0.45 (0.03, 0.86)	0.33 (-0.15, 0.81)	0.039	0.136	0.121^	0.836^
		INTENSIVE	1.12 (0.29)	0.93 (0.19)	0.91 (0.25)	-0.13 (-0.22, 0.03)	-0.17 (-0.27, -0.07)	0.036	0.018		
Noise	<1.0	STANDARD	0.86 (0.77)	0.84 (0.58)	0.92 (0.53)	0.13 (-0.65, 0.90)	0.18 (-0.31, 0.66)	0.701	0.397	1.00^	0.851
		INTENSIVE	0.78 (0.30)	0.78 (0.43)	0.55 (0.16)	0.07 (-0.26, 0.39)	-0.14 (-0.38, 0 .10)	0.647	0.214		
Mean F0 vowel		STANDARD	171.90 (28.34)	190.94 (48.66)	184.1 (33.64)	-16.68 (-49.95, 16.59)	-2.34 (-20.78, 16.11)	0.067	0.273	0.432^	0.418
		INTENSIVE	156.60 (59.29)	164.00 (68.78)	157.91 (58.23)	10.00 (-8.65, 28.65)	6.60 (1.1, 47.7)	0.245	0.128		
F0SD vowel	N/A	STANDARD	13.46 (12.56)	6.05 (7.89)	12.88 (14.92)	-10.36 (-20.28, -0.43)	-8.06 (-25.44, 9.31)	0.043	0.267	0.149^	0.755^
		INTENSIVE	4.41 (5.00)	1.14 (0.36)	1.87 (1.69)	-2.3 (-6.00, 1.40)	0.81 (-2.29, 3.92)	0.042	0.176		
HNR+	>20dB	STANDARD	16.55 (4.53)	19.44 (3.25)	14.76 (5.77)	3.67 (-0.13, 7.47)	0.92 (-3.40, 5.24)	0.056	0.586	0.341	0.450
		INTENSIVE	15.48 (4.16)	15.74 (5.01)	18.74 (4.75)	1.28 (-3.75, 6.31)	2.62 (-0.95, 6.19)	0.519	0.122		
CPPS vowel		STANDARD	17.29 (4.17)	18.08 (1.45)	16.28 (2.75)	1.33 (-1.94, 4.59)	1.08 (-2.11, 4.27)	0.358	0.401	0.432^	0.530^
		INTENSIVE	17.78 (2.52)	16.96 (2.06)	19.10 (2.12)	-1.24 (-3.42, 0.94)	0.19 (-1.44, 1.81)	0.190	0.789		
F0 Range (Hz)	M: 78- 698 F: 139- 1108	STANDARD	502.75 (259.43)	436.00 (232.69)	372.71 (115.48)	14.97 (-82.49, 112.44)	64.24 (-32.03, 160.51)	0.720	0.147	0.824	0.820
		INTENSIVE	536.02 (320.26)	491.90 (368.23)	516.85 (332.03)	-2.60 (-93.08, 87.85)	-78.65 (-194.69,37.37)	0.946	0.148		
DSI	>4.4	STANDARD	4.68 (2.28)	5.71 (1.21)	4.50 (2.04)	-1.64 (-3.82, 0.55)	-0.59 (-3.58, 2.40)	0.116	0..634	0.445	0.783
		INTENSIVE	4.59 (3.25)	5.58 (3.19)	5.43 (2.31)	0.86 (-0.30, 2.02)	0.21 (-1.61, 2.04	0.122	0.787		
Mean F0 reading (Lingwaves)	M: 84-178 F: 127-275	STANDARD	182.50 (28.38)	179.47 (33.70)	158.15 (35.18)	4.07 (-16.67, 24.75)	23.45 (-13.83, 60.73)	0.647	0.168	0.208	0.147
		INTENSIVE	146.49 (45.68)	158.09 (53.34)	136.40 (32.38)	9.23 (-4.53, 23.01)	2.04 (-10.39, 14.47)	0.157	0.702		
Mean F0 Reading (PRAAT)		STANDARD	192.23 (26.11)	177.79 (42.12)	177.74 (36.18)	-4.07 (-24.75, 16.62)	-23.45 (-60.73, 13.83)	0.2282	0.609	0.284	0.168
		INTENSIVE	174.53 (39.76)	179.56 (20.53)	178.61 (20.50)	6.43 (-43.57, 56.42)	7.98 (-12.74, 28.69)	0.4710	0.345		
Mean F0 Sentences		STANDARD	200.37 (29.80)	194.17 (33.10)	178.00 (47.96)	-11.73 (-34.47, 11.01)	-23.66 (-83.91, 36.59)	0.254	0.337	0.628^	0.073^
		INTENSIVE	174.22 (52.66)	160.06 (43.59)	182.01 (41.29)	-5.03 (-70.23, 60.16)	17.57 (-1.58, 36.72)	0.851	0.066		
F0SD. reading	N/A	STANDARD	109.62 (38.99)	109.20 (53.01)	85.65 (31.52)	8.98 (-20.54, 38.51)	20.47 (-8.30, 49.24)	0.484	0.127	0.152^	0.234^
		INTENSIVE	73.46 (15.26)	90.65 (25.45)	74.18 (27.73)	17.19 (-10.55, 44.93)	3.05 (-21.81, 27.91)	0.186	0.774		
Mean dB reading+	74 dB	STANDARD	65.10 (2.28)	66.69 (7.22)	63.20 (5.25)	-1.95 (-8.82, 4.94)	1.30 (-3.23, 5.82)	0.515	0.495	0.389	0.587
		INTENSIVE	64.51 (3.67)	64.63 (2.30)	64.68 (2.82)	-0.59 (-3.07, 1.88)	-0.24 (-2.43, 1.94)	0.588	0.795		
dB SD. reading	N/A	STANDARD	14.14 (3.06)	14.57 (3.20)	13.40 (2.91)	-0.09 (-1.73, 1.54)	0.79 (-0.95, 2.54)	0.892	0.295	0.896	0.445^
		INTENSIVE	13.42 (2.28)	14.18 (6.30)	13.54 (1.69)	0.43 (-5.00, 5.87)	0.16 (-2.17, 2.49)	0.856	0.869		
CPPS Rainbow passage	>19.10	STANDARD	9.38 (1.49)	9.49 (1.09)	8.94 (1.33)	-17.16 (-48.44, 14.13)	-8.48 (-50.91, 33.95)	0.128	0.141	0.164^	0.548^
		INTENSIVE	9.44 (1.10)	8.44 (1.22)	8.77 (1.58)	-0.18 (-0.73, 0.38	0.04 (-0.82, 0.90)	0.285	0.893		
CPPS sentences		STANDARD	12.31 (2.53)	13.30 (1.91)	11.75 (3.18)	1.60 (0.28, 2.91)	0.67 (-1.56, 2.89)	0.025	0.476	0.122	0.941
		INTENSIVE	11.76 (1.88)	10.86 (1.39)	11.68 (2.18)	0.05 (-1.96, 2.05	0.57 (-1.63, 2.77)	0.951	0.550		

Note: N/A= not available. FU= follow up, MPT= Mean Phonation Time. F0= Fundamental frequency. SD=Standard Deviation. M= Male, F= Female. DSI= Dysphonia Severity Index. CPPS= cepstral peak prominence (smooth), ^= Non parametric statistics undertaken and median, IQR reported.

TABLE 4.
Mean Auditory-Perceptual CAPE-V Ratings

Auditory-Perceptual Domain	Group	Within group differences			Mean/Median change scores (95% CI/ IQR)		*P*=		Between group differences in change scores *P*=	
		Pre mean (SD)	Post mean (SD)	FU mean (SD)	***Pre-post***	**Pre-FU**	***Pre-post***	**Pre-FU**	**Pre-post**	**Pre-FU**
Overall Severity	STANDARD	33.20 (18.95)	21.14 (6.28)	28.00 (18.93)	-8 (-19.5, -1)^	-4 (-11, 11)^	0.043^	0.786^	0.630	0.964
	INTENSIVE	24.95 (11.99)	11.00 (3.93)	14.20 (11.03)	-8.8 (-14.44, -3.15)	-6.1 (-22.01, 9.81)	0.012	0.347		
Roughness	STANDARD	24.95 (16.50)	18.71 (11.62)	20.40 (11.26)	-7.57 (-17.10, 1.96)	-3.3 (-20.45, 13.85)	0.099	0.622	0.639^	0.703
	INTENSIVE	22.15 (10.05)	9.20 (2.38)	13.00 (16.90)	-10.5 (-15.95, -5.05)	-11 (-18, 2.5)^	0.006	0.345^		
Breathiness	STANDARD	22.45 (17.61)	15.14 (8.51)	20.00 (22.39)	-4 (-16.79, 4.81)	-5.6 (-16.01, 4.81)	0.473	0.210	0.268^	0.146
	INTENSIVE	16.55 (14.13)	12.40 (11.19)	15.40 (12.34)	2.5 (-8.02, 13.02)	4 (-8.87, 16.87)	0.545	0.436		
Strain	STANDARD	24.10 (16.05)	14.57 (7.27)	30.40 (20.13)	-9.5 (-19.5, 1.0)	12.5 (3.5, 14.5)^	0.091^	0.500^	0.543	0.208
	INTENSIVE	18.55 (15.16)	8.80 (13.63)	4.80 (4.44)	-5.4 (-16.23, 5.44)	-8 (-18, 0)^	0.238	0.144^		

N.B. ^Non-parametric statistics applied and medians and IQRs being presented.

therapy and participants from the weekly group recommending using videos for home practice and having increased flexibility with appointment times.

Clinician reported measures

AusTOMs. Clinically important within group improvements (>0.5 point change) were found across impairment, activity, participation and wellbeing for both groups post treatment, with all ratings remaining higher than pre-treatment at follow up (see Table 5). For the intensive therapy group only, clinically significant improvements were additionally found between post treatment and follow up for impairment level ratings, indicating continued improvement over time. There were no clinically significant between group differences for any of the four AusTOMs domains.

Service outcomes. As shown in Table 6, there were no meaningful differences between groups for the majority of service outcomes except for total time of homework completed, with the weekly group completing on average 2.5 hours more of homework. When this time was analysed on homework completed per week, results differed by approximately 18 minutes per week.

Clinician focus group. A total of five clinicians consented to participate in the clinician focus group, with mean years of clinical experience = 12.6 years (SD=7.45). There were five main categories identified as shown in Table 7, including: (1) enablers to intensive voice therapy (2) barriers to intensive voice therapy (3) future directions, (4) generic comments regarding intensive voice therapy and (5) research related challenges. Exemplary quotes for these categories and subcategories can be found in Appendix 3.

Enablers to intensive therapy. Three quarters of all clinician comments described enablers to implementing intensive therapy. A third of these comments related to the clinician's beliefs about the consequences of delivering intensive therapy. This included that intensive therapy led to greater progression and consolidation of the patient's learning. One clinician commented, *"I felt much more success sometimes working with patients and allowing them to consolidate their skills so much more. Transfer[sic] was much easier with intensive rather than the standard group*." (C1). Another clinician elaborated, *"sometimes by session six, seven, eight, we had conquered a lot more content that we might normally" [C5]*

Clinicians also believed that intensive therapy had benefits to the service in regards to attendance, *"...because the patient can see the finish line, they're potentially more likely to attend those eight sessions" (C4),* and was useful for patients who were motivated to attend a shorter block, "*...particularly for those who are occupational voice users who do have limited time to engage in previously traditional modes of voice therapy* "(C1).

Enablers relating to environmental context and resources included having a local context and "*facilities around you to*

TABLE 5.
Group Means for VHI, VoiSS and AusTOMs Ratings

Measure	Group	Within group differences							Between group differences in changes scores	
		Pre mean (SD)	Post mean (SD)	FU mean(SD)	Mean/Median change scores (95% CI/ IQR)*		(*P*=)		(*P*=)	
					Pre-post	*Pre-post*	*Pre-post*	Pre-FU	Pre-Post	Pre-FU
VHI Total	STANDARD	48.83 (25.65)	24.38 (15.70)	29.14 (22.52)	25.06 (4.39, 45.73)	11.83 (-6.41, 30.07)	0.024	0.076	0.955^	0.260
	INTENSIVE	50.50 (17.10)	35.38 (16.27)	28.00 (19.59)	14.62 (3.34, 25.91)	20.75 (10, 32.5)^	0.020	0.012^		
VoiSS Total	STANDARD	46.17 (19.90)	24.13 (17.23)	28.86 (22.50)	−18.5 (-39.88, 2.88)	-11.5 (−29.11, 6.11)	0.034	0.068	0.804	0.362
	INTENSIVE	48.15 (16.48)	32.63 (16.34)	27.12 (17.50)	-15.62 (-33.15, 1.90)	-21.13 (-37.98, -4.27)	0.073	0.021		
AusTOMs Impairment	STANDARD	3.67 (0.50)	4.42 (0.53)	4.33 (0.82)	0.86 (0.22, 1.50)	0.67 (0.12, 1.49)	0.017	0.025	0.523	0.451
	INTENSIVE	3.43 (0.72)	4.00 (1.07)	4.50 (0.83)	0.59 (-0.11, 1.30)	0.92 (0.30, 1.53)	0.087	0.012		
AusTOMs Activity	STANDARD	3.56 (0.73)	4.43 (0.53)	4.50 (0.84)	0.86 (-0.13, 1.84	0.83 (0.12, 1.21)	0.078	0.14	0.532	0.605
	INTENSIVE	3.25 (0.42)	4.50 (0.76)	4.50 (0.84)	1.5 (0.25, 2)^	1.5 (0, 2) ^	0.024^	0.059^		
AusTOMs Participation	STANDARD	3.78 (0.83)	4.71 (0.48)	4.67 (0.82)	1.00 (0.75, 1.92)	1.00 (0, 1)^	0.038	0.046^	1.00^	0.485^
	INTENSIVE	3.80 (0.42)	4.75 (0.46)	4.83 (0.41)	0.88 (0.34, 1.41)	1 (1, 1)^	0.006	0.034^		
AusTOMs Wellbeing	STANDARD	3.88 (1.05)	4.50 (0.65)	4.58 (0.66)	0.36 (-0.92, 1.63)	0.25 (-0.98, 1.48)	0.518	0.623	0.517	0.241
	INTENSIVE	3.80 (0.92)	4.75 (0.46)	4.83 (0.41)	0.75 (0.01, 1.49)	1.00 (0.06. 1.94)	0.0480	0.0410		

Note: SD= standard deviation FU= follow up ^Non-parametric statistics applied and medians and IQRs being presented.

be able to provide that intensive treatment." (C1), as well as clinicians who had flexibility over *"when patients could be booked in"* (C5). Clinicians reported experiencing positive emotions such as excitement as an enabler to providing therapy and enjoyed the rapport they built with patients; "*You're seeing them so often your rapport developed really nicely"* (C4). Clinicians also reported reinforcement of "*seeing that we're making a difference and hearing that feedback from our patients is a really encouraging thing"* (C1), as an enabler to providing the intensive therapy.

Barriers to intensive therapy. Fewer barriers were reported by clinicians in the focus group. Of those raised, most were related to environmental context and resources or beliefs about consequences to delivering intensive therapy. The former included issues with booking and scheduling patients; "*booking in the patients, co-ordinating the rooms between the voice outpatient room and the room next door for the assessments was a mild logistic challenge"* (C4). Patients' "*travel up to the hospital, potentially, on a daily basis"* (C3) and clinician's working part time were also reported by some clinicians as barriers. Barriers related to clinician's beliefs about the consequences of delivering intensive therapy included that it was not for all patients, but rather for the *"right patient*" (C2), and that there may be less time for consolidation of skills in different contexts, "*within a two-week period less people had opportunity to see the width of how they might use their voice.. that meant that they weren't as confident necessarily going into all scenarios that they were going to end up using their voice*" (C5).

Other categories. Other categories identified from the focus group (see Table 8 and Supplementary file 3) included future directions for continued implementation, general experiences about intensive therapy and challenges related to the research. Examples of suggestions for future directions included having more flexibility with the frequency of therapy offered and the patients whom it was offered to, as one clinician suggested *"it could potentially be opened up to patients who, perhaps, have phono traumatic lesions "*(C3). The use of videos for home practice, individualised where possible, and telehealth were also suggested.

Clinicians additionally provided positive general comments about intensive therapy, describing it as a *"positive experience"* (C1) and reported now using it with "*other patient groups as well"* (C3) outside of the research project. Challenges specific to the research raised included patients having to be willing to commit to either intensive or weekly therapy before consenting, which *"could mean [the patients being] nervous about doing intensive and they decided not to participate because of that (C5)"* and also reduced flexibility with research timeframes for assessment and therapy.

DISCUSSION

The present study was unable to support the hypothesis that intensive therapy was noninferior to standard therapy in regards to the primary outcome measure VHI total. Comparison of the clinical effects of intensive therapy

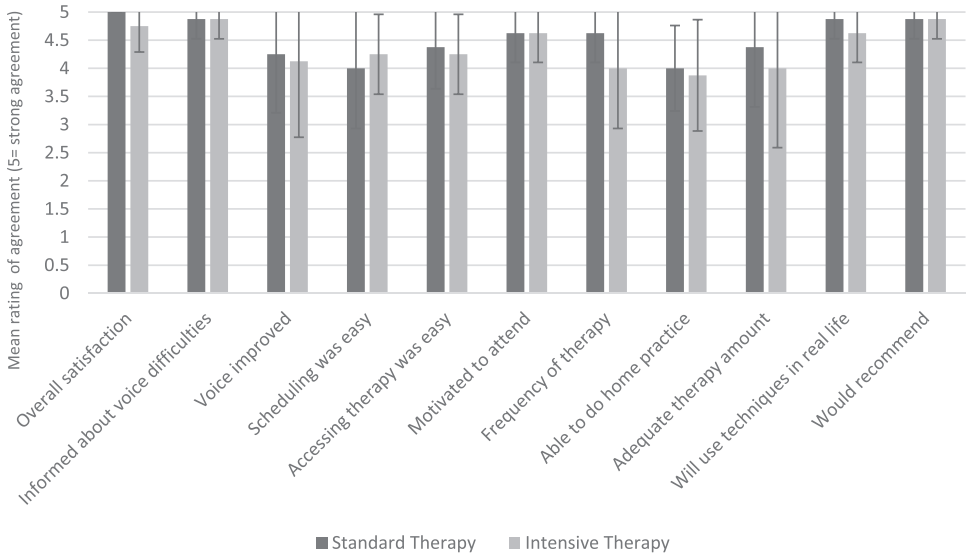

FIGURE 2. Mean satisfaction questionnaire ratings and individual responses.

howeverrevealed similar improvements to weekly therapy in individuals with MTD on a range of multidimensional voice measures. Indeed, similar clinically important improvements to patient and clinician reported measures including VHI, VoiSS, and AusTOMs, auditory-perceptual ratings of overall severity and roughness and selected acoustic measures including shimmer and irregularity were found following both intensive and weekly therapy. Interestingly, additional improvements to several measures were made from post treatment to the follow up period in the intensive group. In addition, the intensive treatment was feasible to implement and was perceived positively by patients and clinicians. However, in contrast to original hypotheses intensive therapy yielded similar satisfaction and attendance to weekly therapy.

The finding that noninferiority was unable to be established for the primary outcome measure may be due to the study being underpowered. Sample size calculations used based on the SD provided in the VHI development paper of 5.4 {Jacobson, 1997 #19} were not representative of the large SD found in the present study for this variable (ranging from 15.7 to 25). As such, the study was likely underpowered to establish noninferiority for this particular measure. Although non-inferiority was also not detected at follow up for the VHI, the mean difference on the VHI total score for the intensive group compared to the weekly group was less than 4 points; a difference which is not considered to be clinically meaningful.

The comparable clinical improvements between intensive and weekly therapy reported for other measures are similar to previous research[12,19,29] and contribute to the evidence base that intensive therapy may be a viable treatment option for certain individuals with MTD. Interestingly, in the intensive group, greater improvements from baseline were made at follow up compared to immediately post treatment for total VHI and VoiSS scores, as well as AusTOMs impairment ratings. The same effect was not shown in the weekly group, whereby participants generally demonstrated a more marked improvement post treatment which then either plateaued or slightly deteriorated at the 4 week follow up assessment, rather than the intensive group participants who demonstrated more gradual improvements post treatment that continued to increase at follow up. A similar effect of improved scores at follow up for VHI and

TABLE 6.
Mean Service Outcomes

Variable	Standard mean (SD) n = 9	Intensive Mean (SD) n = 10	Between group differences(*P*=)
Average session duration (mins)	56.77 (4.25)	56.55 (4.44)	0.842
Total treatment received (hrs)	6.40 (1.90)	6.80 (1.92)	0.497
% original appointment attendance	84.72 (24.03)	87.50 (23.57)	0.661
% rescheduled appointments	2.77 (8.33)	0 (0)	0.720
% appointments cancelled	13.88 (23.75)	12.50 (23.57)	0.720
total duration homework completed (hrs)	4.27(2.61)	1.73 (1.04)	0.043
total homework completed per week (hrs)	0.53 (0.33)	0.86 (0.52)	0.118

N.B (SD)= standard deviation

TABLE 7.
Enablers and Barriers to Intensive Therapy Reported in Clinician Focus Group

TDF domain	Enablers (total comments= 62)	Frequency of mention	Barriers (total comments= 22)	Frequency of mention
Beliefs about consequences	Greater continuity, progression and consolidation of patient learning	7	Not for all patients	4
	Service benefits to waiting lists and attendance	5	Less time for patient to consolidate skills in different contexts	3
	Useful for patients motivated to attend shorter block	5	Tasks may be repetitive	1
	Clinician satisfaction with intensive therapy	2		
Environmental Context and Resources	Local context well-resourced to deliver intensive therapy	5	Booking & scheduling patients using existing systems	8
	Clinician flexibility and availability for therapy appointment booking	5	Patient travel and preference for location	2
	Reduced waiting times for endoscopy review to access therapy earlier	2	Clinician's working part time clinically	2
Emotions	Enjoyment and excitement in providing therapy and building patient rapport	5	Hesitant feeling when providing intensive therapy for older patients	1
	Patients excited to receive intensive therapy	1		
	Emotional investment in success of research	1		
Reinforcement	Seeing successful outcomes for the patient and research	4		
	Seeing results sooner	1		
	Increasing patient attendance	2		
Optimism	Confident of success of therapy	3		
Behaviour regulation	Use of individualised specific cues helps practice	3	Pt's self-monitoring impacts home practice	1
Goals	Clinician desire to continue to use intensive schedule	3		
	Clinician desire to see patients improve	1		
Intentions	Need to continue to use to keep therapy options open	2		
Knowledge	Evidence base for intensive therapy	2	Lack knowledge of outcomes for severe patients	1
Memory, Attention, and Decision processes	More useful for some patients if preference is for shorter block	2		
	Clinical-decision making skills help decide patient appropriateness	1		
Skills	Having variety of clinical skills to use in therapy	1		
	Use existing skills, no new skills needed	1		
	Clinician decision making skills in deciding who is appropriate	1		
Social influences	Positive feedback from patients	1		
	Encouragement from service	1		

TABLE 8.
Other Categories form Clinician Focus Group

Category	Subcategory	Frequency of mention
Future Directions if continued implementation	More flexibility with patient inclusion and therapy schedule	4
	Explore home practice including use of videos	3
	Use of telehealth	3
	Consider influence of COVID-19 on voice and attendance	2
	Need to define what is intensity better	2
General experiences of intensive therapy	Positive experience providing intensive therapy	3
	Have used intensive with other patients outside research	3
	Home practice not dependant on treatment intensity provided	1
Challenges with research	Recruitment process	2
	Reduced flexibility with assessment and treatment scheduling	2

AusTOMs impairment ratings following intensive therapy[19] was previously reported and may indicate motor learning continued after the two week treatment potentially reinforcing vocal behaviours and subsequent perception of voice function beyond active rehabilitation.[12,19] Although not observed in our study, progressive improvements in voice activity and participation have been reported by participants up to 12 months following standard voice therapy, and were reported to potentially be the effect of learning to manage their voice within their home contexts and/or becoming more accustomated to their voice disorder.[65]

A similar pattern of ongoing improvements over time were found for select acoustic measures. For example both groups showed improvements post treatment for the two acoustic measures that were below normative values prior to treatment: shimmer and irregularity. Similar improvements to these variables have been found in other studies of MTD following treatment.[6,28,66,67] However, while the intensive group in the present study showed continued improvement at follow up for irregularity, the mean value in the weekly group approached pretreatment values. It should also be noted the few other changes to acoustic measures following treatment in the present study may be the result of most of these measures being within normative ranges before treatment, thereby being less likely to show change following treatment. The present findings thereby add to the current evidence base for which acoustic measures may be more likely to demonstrate change in response to treatment, an area requiring further attention in MTD and voice disorders in general.[9]

Clinically important improvements post treatment in auditory-perceptual ratings of overall severity, roughness and strain were found following both groups.[68] While the CAPE-V has not been used in any previous studies of intensive treatment in MTD, the current findings may suggest it could be a useful outcome measure for monitoring treatment outcomes in MTD, as shown in other studies.[66,67] Greater improvements to perceived overall severity, roughness and strain were found at follow up for the intensive group compared to the weekly group, suggesting more sustained maintenance effects following intensive voice therapy. This trend, also observed in other multidimensional measures may further substantiate some of the focus group clinician's beliefs and client comments that the intensive therapy may have promoted greater consolidation of learning, as proposed elsewhere.[14,15] Indeed, Ziegler et al.,[69] reported the greatest barrier that voice therapy patients with MTD perceive is transferring learned behaviours to normal speech. The massed practice provided with greater session frequency in the intensive group meant that patients received more day to day practice with greater focus on their voice during this two-week period and increased opportunity to consolidate learning and transfer to everyday communication tasks outside the session. While participants in the weekly group completed more home practice, it is possible that they were not practicing the correct techniques, as postulated by focus group clinicians, which may have led to reduced maintenance of effects outside the therapy period.

In contrast to previous research[12,19] and clinician's beliefs from the focus group that intensive therapy reduces patient cancellations, the present study found comparable attendance rates, with mean attendance being relatively high at approximately 85% of sessions for both groups. The contrasting findings from Wenke et al[19] may be partially attributed to the different demographics. All participants in Wenke et al's study[19] were female, and more were either retired or not working (n=3) compared to the number in the present group who were not working (n=1) and male (n=3), both being factors that can influence attendance[65]. Both Wenke et al.,[19] and Meerschman et al.,[12] also allocated participants based on availability and preference to attend rather than true randomisation[12] which may have inflated attendance rates in the intensive group. Furthermore, Meerschman's[12] traditional therapy group was for 6 months thereby increasing the opportunities for non-attendance compared to the present study's standard weekly group only being 8 weeks in duration.

The study was the first to our knowledge to systematically explore the barriers and enablers to providing intensive therapy from a clinician perspective, as well as the first to use the

TDF. Currently, few publications have explored clinician perspectives of providing therapy to MTD and where published, used surveys[70] which do not allow as in-depth understanding of underlying issues. In the present study, noticeably more enablers were identified, mostly related to clinicians' motivations (i.e., beliefs about consequences, emotions, reinforcement) or opportunities (i.e., environmental context and resources) to providing intensive therapy[48]. Of interest, clinicians reported a greater sense of rapport building when delivering intensive therapy. Positive rapport and a strong therapeutic alliance between the client and clinician is an important component of successful voice treatment[71-73] and has been previously reported by SLPs to be enhanced when using intensive treatment schedules in the aphasia population likely due to the increased time building the therapeutic relationship.[74,75]

Another belief clinicians reported about intensive therapy was that it may not be suitable for everyone and their circumstances. This belief was substantiated by an unexpected low consent rate of approximately 30% of individuals in the present study, with the most common reason for declining being unable to commit to the intensive therapy for work related reasons. Many of these patients who declined to participate in the therapy, agreed to receiving standard weekly therapy outside of the research project, indicating that a two-week block of 4 days per week may be too intensive for some individuals. It could be inferred that a "one size fits all" approach is unlikely suitable in voice therapy, and as clinicians in the focus group and other researchers recommend, there may be a need for flexible therapy schedules that respond to the changing needs and circumstances of patients.[12,14]

Limitations and Future Directions

Certain limitations of the research are acknowledged. Firstly, while all clinicians received training regarding the study protocol and providing resonant voice therapy, one participant in the intensive group and two participants in weekly group did not receive resonant voice therapy as prescribed. Having multiple SLPs was the only viable option to delivering therapy across the six-year study and although it likely was more reflective of "real world practice," it may have contributed to the reduced therapy protocol adherence. Future studies should include stricter measures to monitoring treatment fidelity to prevent future protocol deviations. Such would also allow the potential active ingredients of therapy to more readily controlled for when evaluating the effect of intensity parameters on treatment outcomes. Secondly, while the study explored the intensity parameter of massed practice by measuring session duration, frequency and overall intervention duration, the cumulative intensity of therapy provided was unable to be determined because dose was not investigated.[11] Future studies should therefore measure dose (i.e., number of therapeutic inputs or client acts per session) so that this information can be used to provide greater understanding of the optimal intensity of therapy. Thirdly, while the amount of homework completed was recorded as part of the research, clinicians and a participant reported that this may have been enhanced through the use of videos or recordings and may warrant further exploration in future research. The use of telehealth to deliver intensive therapy, which has been investigated with promising outcomes in 10 women with vocal nodules,[27] may be another avenue to explore further in MTD, particularly in light of social distancing measures arising from the COVID-19 pandemic. Group differences in age and gender were also apparent in the present study. To address this limitation, future research that uses a larger sample size would be beneficial, as well as being across different sites and longer follow up period is needed to validate the short- and long-term effects of intensive therapy in MTD. A larger sample size would also ensure that future studies are adequately powered to establish non-inferiority.

Clinical implications

Intensive therapy may be a viable therapy option for some individuals with MTD however there are important implications for SLPs and managers to consider at a patient, clinician and service level prior to implementation. At a patient level, clinicians should take into account the individual's personal circumstances and preferences. Indeed, massed practice schedules may be more suitable for patients who can commit to a shorter block with frequent sessions amidst other responsibilities. Providing voice therapy over telehealth may also be more convenient and reduce travel time for some patients, and the innovative use of multimedia (e.g., videos) to enhance home practice should be considered. At a clinician level, SLPs should be aware of the potential benefits to their own satisfaction and motivation when providing intensive therapy including positive emotions associated with providing therapy and the enhanced opportunity to build rapport with patients. It is also recommended that SLPs receive targeted professional development in the area of voice before providing intensive (or weekly) therapy and regular professional supervision, as this was provided to all SLPs in the present study. At a service level, clinicians and managers should consider systems and administrative support which allow flexible bookings of patients into intensive therapy, particularly for patients currently working. This may include flexible clinician rostering to allow early morning or later afternoon sessions (i.e., scheduled around a patient's working hours), as well as ensuring staff providing voice therapy services are rostered at least 4 days a week if providing the same level of intensity as the present study.

Conclusion

While non-inferiority for the primary outcome measure was not established, likely due to the study being underpowered, intensive voice therapy (delivered 1 hr day/ 4 days a week for 2 weeks) for people with MTD may result in similar benefits to voice function and wellbeing, satisfaction and attendance rates compared to standard weekly therapy. A trend

of more sustained improvements in voice function following intensive therapy compared to weekly treatment was also identified. Clinicians involved in delivering the intensive therapy expressed positive experiences overall and provided important practical considerations for SLPs and managers. The present study also provides clear recommendations for researchers to further advance this growing field of enquiry.

COMPETING INTERESTS

The authors have no competing interests to declare.

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SUPPLEMENTARY DATA

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