Lee Silverman voice treatment versus NHS speech and language therapy versus control for dysarthria in people with Parkinson's disease (PD COMM): pragmatic, UK based, multicentre, three arm, parallel group, unblinded, randomised controlled trial

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ABSTRACT

OBJECTIVES

To assess the clinical effectiveness of two speech and language therapy approaches versus no speech and language therapy for dysarthria in people with Parkinson's disease.

DESIGN

Pragmatic, UK based, multicentre, three arm, parallel group, unblinded, randomised controlled trial.

SETTING

The speech and language therapy interventions were delivered in outpatient or home settings between 26 September 2016 and 16 March 2020.

PARTICIPANTS

388 people with Parkinson's disease and dysarthria.

INTERVENTIONS

Participants were randomly assigned to one of three groups (1:1:1): 130 to Lee Silverman voice treatment (LSVT LOUD), 129 to NHS speech and language therapy, and 129 to no speech and language therapy. LSVT LOUD consisted of four, face-to-face or remote, 50 min sessions each week delivered over four weeks. Home based practice activities were set for up to 5-10 mins daily on treatment days and 15 mins twice daily on non-treatment days. Dosage for the NHS speech and language therapy was determined by the local therapist in response to the participants' needs (estimated from prior research that NHS speech and language therapy participants would receive an average of one session per week over six to eight weeks). Local practices for NHS speech and language therapy were accepted, except for those within the LSVT LOUD protocol. Analyses were based on the intention to treat principle.

MAIN OUTCOME MEASURES

The primary outcome was total score at three months of self-reported voice handicap index.

RESULTS

People who received LSVT LOUD reported lower voice handicap index scores at three months after randomisation than those who did not receive speech and language therapy (−8.0 points (99% confidence interval −13.3 to −2.6); P<0.001). No evidence suggests a difference in voice handicap index scores between NHS speech and language therapy and no speech and language therapy (1.7 points (−3.8 to 7.1); P=0.43). Patients in the LSVT LOUD group also reported lower voice handicap index scores than did those randomised to NHS speech and language therapy (−9.6 points (−14.9 to −4.4); P<0.001). 93 adverse events (predominately vocal strain) were reported in the LSVT LOUD group, 46 in the NHS speech and language therapy group, and none in the no speech and language therapy group. No serious adverse events were recorded.

CONCLUSIONS

LSVT LOUD was more effective at reducing the participant reported impact of voice problems than was no speech and language therapy and NHS speech and language therapy. NHS speech and language therapy showed no evidence of benefit compared with no speech and language therapy.

FUNDING

National Institute for Health Research, Health Technology Assessment programme.

TRIAL REGISTRATION

ISRCTN registry ISRCTN12421382.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Speech and voice problems (known as dysarthria) are very common features of motor impairments in Parkinson's disease

Speech and language therapy in the UK aims to improve communication for people with PD-related dysarthria and their families

NHS speech and language therapy or Lee Silverman voice treatment (LSVT) LOUD are two approaches typically available in the UK, but evidence of their effectiveness is inconclusive

WHAT THIS STUDY ADDS

This trial provided evidence that LSVT LOUD was more effective at reducing the participant reported impact of dysarthria than no intervention or NHS speech and language therapy (treatment as usual)

NHS speech and language therapy showed no evidence of benefit compared to no therapy

This randomised trial provides evidence to guide clinical decision making, emphasising the need to optimise the use of speech and language therapy resources for people with Parkinson's disease

Introduction

Parkinson's disease is a progressive, neurodegenerative disorder leading to declining motor function and non-motor conditions such as dementia, depression, and anxiety. A common motor feature is dysarthria (often referred to as

hypokinetic dysarthria), which may lead to reduced speech volume, word stress patterns, and fluency; speech that is monotone in pitch with imprecise articulation; changed voice quality and breath support; and an irregular speech rhythm.[1] Dysarthria related to Parkinson's disease negatively affects communication, social activities, and participation, potentially leading to stigmatisation, social isolation, and reduced quality of life.[2-5] Dysarthric symptoms vary in their response to increased dopaminergic medication and can become worse with subthalamic stimulation surgery.[6 7]

Speech and language therapy (SLT) for people with dysarthria related to Parkinson's disease aims to maximise communication. Therapy is through exercise interventions targeting motor skills, approaches to support communication between the person with Parkinson's disease and their family, and the use of alternative or augmentative aids to facilitate communication. Several SLT approaches are available to people with Parkinson's disease throughout the UK National Health Service (NHS), although variations in methods and dosage are evident.[8] Lee Silverman Voice Training (LSVT LOUD), for example, is an approach that was developed in the USA, and is partially available in the UK[9-11]; it is an intensive intervention that targets increased vocal loudness through vocal exercises and functional speech tasks. This treatment is unusual in that the method is highly protocolised.

Before conducting this trial, a Cochrane systematic review that included data from two randomised controlled trials (n=41) showed that participants randomly assigned to SLT had increased vocal loudness with two speech samples (5.4 dB and 11.0 dB) compared with people who had no SLT.[12] The small number of trials, limited sample sizes, and high risk of bias due to inadequate or poorly reported randomisation and allocation concealment, meant that evidence was insufficient to determine the effectiveness of SLT for Parkinson's related dysarthria compared with no treatment. Another review,[13] which compared different SLT approaches, did not have sufficient evidence to recommend one SLT approach over another. Overall, 25, mostly small, randomised controlled trials of SLT interventions were published. These trials showed some improvement in outcome measures of vocal loudness when speaking and reading. However, few trials measured communication participation, and only two small randomised controlled trials reported outcomes at 12 months and one at 24 months (appendix 1 supplementary background information).

Following our PD COMM pilot trial of SLT in Parkinson's disease,[14] we developed the UK-wide trial to assess the effectiveness of two current SLT approaches in a pragmatic context in response to a National Institute for Health and Care Research-Health Technology Assessment commissioned funding call. Pragmatic trials are designed to reflect the realities of clinical practice.[15] We aimed to assess the clinical effectiveness of two SLT approaches versus no SLT for dysarthria in a pragmatic randomised controlled trial with a large number of people with Parkinson's disease, using patient-reported outcome measures to reflect the impact of dysarthria on participants' lives. The three options of LSVT, NHS SLT, or no SLT reflects a common treatment scenario within the NHS. We used the PRECIS-2 tool to assess the affect that trial design decisions would have on applicability.[16] The trial was registered in the ISRCTN registry, number ISRCTN12421382.

Methods

Design

We conducted a multicentre, three arm, parallel group, unblinded, randomised controlled trial with concurrent process and economic evaluations conducted in the UK. The process and economic evaluations will be reported in detail elsewhere. Participants were recruited consecutively, with no selection, and randomised at the level of the individual in a 1:1:1 ratio to LSVT LOUD, NHS SLT, or no SLT (control). Participants who were randomly assigned to no SLT could be referred for SLT at the end of trial or during the trial, if deemed medically necessary. If SLT was required for any participant in the no SLT group, then the type and dosage was determined by the therapist responsible for their care. We did not withdraw participants if they did not adhere with their randomly allocated treatment. Participants were followed-up at three, six, and 12 months after randomisation because this was reflective of the assessment time periods used by the NHS staff after treatment. The trial sites and their staff were NHS locations in England, Scotland, and Wales, which were already providing an SLT service. We made changes to the protocol, detailed in appendix 1, table A.

People were eligible to be included in the trial if they had a diagnosis of idiopathic Parkinson's disease as defined by the 1988 UK Parkinson's disease Brain Bank Criteria[17] and if they (or their carer) reported problems with their speech or voice.

We excluded people with Parkinson's disease who: had dementia, as clinically defined by their specialist clinician; had a history of vocal strain or previous laryngeal surgery or evidence of laryngeal pathology including vocal nodules[9]; or received SLT for Parkinson's related dysarthria in the previous two years.

These criteria reflect the population who would be provided with SLT due to voice or speech problems on the NHS, except for previous SLT in the past two years, which would normally not exclude a patient from receiving SLT and also might not have excluded people with dementia assessed as able to comply with treatment. The additional exclusions were to ensure that previous SLT did not bias this study, based on previous work by Ramig and colleauges,[18] additionally, out of concern that patients who had dementia would not be able to comply with the intervention and complete assessments, following feedback from the PD COMM pilot trial.

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Randomisation and masking

A central web based randomisation system was developed and held at the Birmingham clinical trials unit. Randomisation used a minimisation process with age (≤59, 60-70, >70 years), disease severity using the Hoehn and Yahr staging[19] (1.0-2.5, 3.0-5.0), and severity of speech using the voice handicap index[20] total score (≤33, mild 34-44, moderate 45-61, severe >61) as the minimisation variables. A random factor was included within the minimisation algorithm to avoid the treatment allocation becoming predictable.

After providing written informed consent, and completion and collection of all baseline data, the person with Parkinson's disease could be randomised into the trial. To ensure concealment of the next treatment allocation, the local collaborator accessed the secure, central, web-based randomisation system hosted at the Birmingham clinical trials unit to obtain the intervention group that the participant was randomised to. To avoid overloading local services or delays between randomisation and a participant starting treatment, local availability of SLT was confirmed before randomisation. Due to the nature of the interventions, the trial was not blinded.

Procedures

Key members of the site research team were required to attend either a meeting or a teleconference covering aspects of the trial design, protocol procedures, adverse event reporting, collection, and reporting of data, and record keeping. Therapists in the trial were registered with UK regulatory body the Health and Care Professions Council, which sets standards for education, training, and practice.

SLT departments of community based outpatient secondary care provided the interventions and collected trial data. Where specific needs were required, or where the SLT service routinely offered it, care was provided at home.

LSVT LOUD

Delivered over four weeks, LSVT LOUD consisted of four, face-to-face or remote, 50 min sessions each week. Sessions consisted of repetitions of maximum sustained "ah" phonation for as long as possible and then using high and low pitch glides held for 5 s, each in a good quality, loud voice, followed by 10 self-generated functional sentence repetitions.[11] Functional movement exercises using a speech production hierarchy that progressed from reading single words to phrases, sentences, paragraphs, and conversations, were tailored to individual participant's goals. A fundamental part of LSVT LOUD is retraining of auditory sensory feedback.

Participants were set home based practice activities for up to 5-10 mins daily on treatment days and 15 mins twice daily on non-treatment days.[11] Twenty one centres had access to the LSVT companion software, which provided an option of remote delivery.[21] Only speech and language therapists or therapist assistants trained in LSVT LOUD could deliver the intervention.[22]

NHS SLT

Generic NHS SLT is poorly defined within the published literature with no widely accepted standards for content and dosage of intervention. Therefore, local practices for NHS SLT were accepted, except for those within the LSVT LOUD protocol. Some isolated techniques, such as vocal loudness exercises, can be common to both SLT approaches but the distinction between trial interventions could be preserved with the individualised treatment approach, the broader range of NHS SLT strategies and techniques, the intensity of delivery regimen, and the overall dose. NHS SLT dosage was determined by the local therapist in response to individual participants' needs. Prior research suggested that NHS SLT participants would receive an average of one session per week over six to eight weeks.[8]

Outcomes

The primary outcome was the voice handicap index total score at three months post randomisation.[20] Both vocal assessments and participant reported outcomes were trialled in the PD COMM pilot trial.[14] The voice handicap index score that assessed participants was chosen because of the prohibitive additional time involved in vocal assessments, the potential for vocal assessments to skew the results in favour of LSVT LOUD due to the focus on vocal loudness, and the trial's focus on participants' self-perception of functional communication using voice or speech. This assessment is also commonly used in clinical practice with people with Parkinson's disease.

The voice handicap index is a patient reported measure of the impact of communication difficulties and has a score between 0 and 120 (a low score being positive).[20] Secondary outcomes included the voice handicap index subscales; Parkinson's disease questionnaire-39[23]; questionnaire on acquired speech disorders (also known as living with dysarthria)[24]; EuroQol5D[25] (five level version); icepop capabilities measure for older adults[26]; resource use; adverse events); Hoehn and Yahr stage[19], and carer quality of life (Parkinson's disease questionnaire–carers).[27]

Adverse events

Adverse events in people with Parkinson's disease are well known, therefore, we reported only adverse events specific to SLT or serious adverse events related to vocal strain or abuse. Vocal strain could be identified by patients reporting symptoms and therapists noticing clinical signs such as hoarseness. Deaths, if not deemed a serious adverse event according to the trial definition, were reported to the sponsors (Birmingham clinical trials unit) to ensure further trial data collection forms were not sent out. Data for adverse events were sought for all three trial arms.[28]

Statistical analysis

The primary comparisons in PD COMM were LSVT LOUD versus no SLT and NHS SLT versus no SLT. We also compared LSVT LOUD with NHS SLT. We used the

intention-to-treat principle for all primary analyses for both primary and secondary outcomes. All estimates of differences between groups are presented with two sided, 99% confidence intervals, which was a deviation from the protocol in which 95% confidence intervals were stated, to allow for adjustment for multiple comparisons. Statistical analysis was undertaken using the statistical software packages: SAS software, version 9.4, and Stata version 17.

To estimate differences in the voice handicap index total score at three months between the two groups of interest, a linear regression model was used with the voice handicap index baseline score and the minimisation variables: age and severity of Parkinson's disease (Hoehn and Yahr) included in the model as covariates. Various supporting (eg, per protocol) and sensitivity analyses (eg, to assess impact of missing data) were undertaken for the primary outcome. Subgroup analyses were also performed for the primary outcome to assess whether the treatment effect differed according to age, baseline voice severity, and Parkinson's disease severity.

Continuous secondary outcome measures (eg, Parkinson's disease questionnaire-39) were analysed using linear regression models adjusting for relevant baseline score and the minimisation variables (baseline voice handicap index, age and severity of Parkinson's disease). The primary analysis of the secondary outcomes was at three months as per the primary outcome. Secondary analyses assessed the outcomes at both six and 12 months using linear regression analysis as per the primary analysis, and also using repeated measures models that included all data across the three, six, and 12 month assessment points. Adverse events and Hoehn and Yahr stage at 12 months were summarised descriptively. Medication doses were recorded, and we calculated levodopa dose equivalents for all medication using the accepted formula.[29] Where the participant had a non-professional carer, the carer was also invited to join the trial and complete the Parkinson's disease questionnaire-Carer questionnaire at three, six, and 12 months.

Sample size

As the minimal clinically important change score for the voice handicap index, our primary outcome, has not yet been established, a 10 point difference in voice handicap index between both types of SLT and no SLT (control) as observed in the Parkinson's disease COMM pilot trial was used to inform the sample size calculations.[30] Using a two sided t-test and the upper standard deviation of 26.27 obtained from the pilot trial (effect size 0.38) with 80% power and α=0.01; 163 participants per group were required. A sample size of 546 participants in total (182 participants per arm) was planned, anticipating 10% attrition.

Process evaluation

For the intervention process evaluation, individual participant data were extracted from treatment record forms and therapy notes for a subset of trial participants. A piloted data extraction form, designed with reference to TIDieR and dysarthria management guidelines descriptions,[31] supported the categorisation of therapy descriptions across both SLT interventions. One researcher completed the data extraction forms and a second independently checked a sample. Interviews with patients were also completed to explore their experiences of the implementation of their intervention.

Trial oversight

Independent trial steering and data monitoring committees provided oversight and included members with Parkinson's disease. Interim data analyses of the primary outcome and adverse events were supplied in confidence to the data monitoring and ethics committee. This committee could recommend discontinuation of the trial to the trial steering committee if the recruitment rate or data quality were unacceptable, or if any issues were identified that may compromise participant safety.

Patient and public involvement

This project was originally designed in 2010 in response to a commissioned call by the National Institute for Health and Care Research for this specific trial design. The National Institute for Health Research, Health Technology Assessment commissioning stream works with stakeholders including patients and the public to prioritise questions to commission, as such, patients and the public were involved in this trial design. The project was not funded at the time of commissioning, so we developed a standalone pilot trial to test for feasibility and acceptability of the proposed trial. During the pilot trial, we surveyed patients with Parkinson's disease from our patient and public involvement group. We asked these patients what was more important to them: vocal loudness or ability to communicate, which helped to determine the primary outcome measure for the substantive PD COMM trial. From the results of the pilot trial, we refined our design, based on the acceptability of the outcomes to the participants, and clinicians and selected our primary outcome measure based on the views of the patient and public involvement group and the co-applicants. The commissioned call was then funded by the National Institute for Health and Care Research.

The Birmingham Clinical Trials Unit hosts a patient and carer group with experience of neurological disease. The PD COMM group also worked with the local Parkinson's UK branch and several individuals who contributed to the development, design, interpretation, oversight, reporting, and dissemination of the study.

We fully accept that the patient and public involvement was significantly less than we would do today, however, this was not considered unusual at the time particularly given the nature of the commissioned call and the substantial input of the participants and patient and public involvement group in the pilot trial.

Results

Over the 42 month recruitment period from 26 September 2016 to 16 March 2020, 388 people with dysarthria related to Parkinson's disease were randomly assigned from 41 of 42 recruitment centres: 130 participants to LSVT LOUD, 129 participants to NHS SLT, and 129 participants to no SLT (fig 1). The covid-19 pandemic impacted on the provision of SLT services for people with Parkinson's disease and, following discussions with the trial steering committee and the funder, the trial was closed to recruitment in 30 November 2020 after a period of recruitment suspension (16 March until 30 November) and before achieving the recruitment target (388 of 546 recruited; 71% of target). In total, 109 (84%) of 130 participants started LSVT LOUD, 119 (92%) of 129 participants

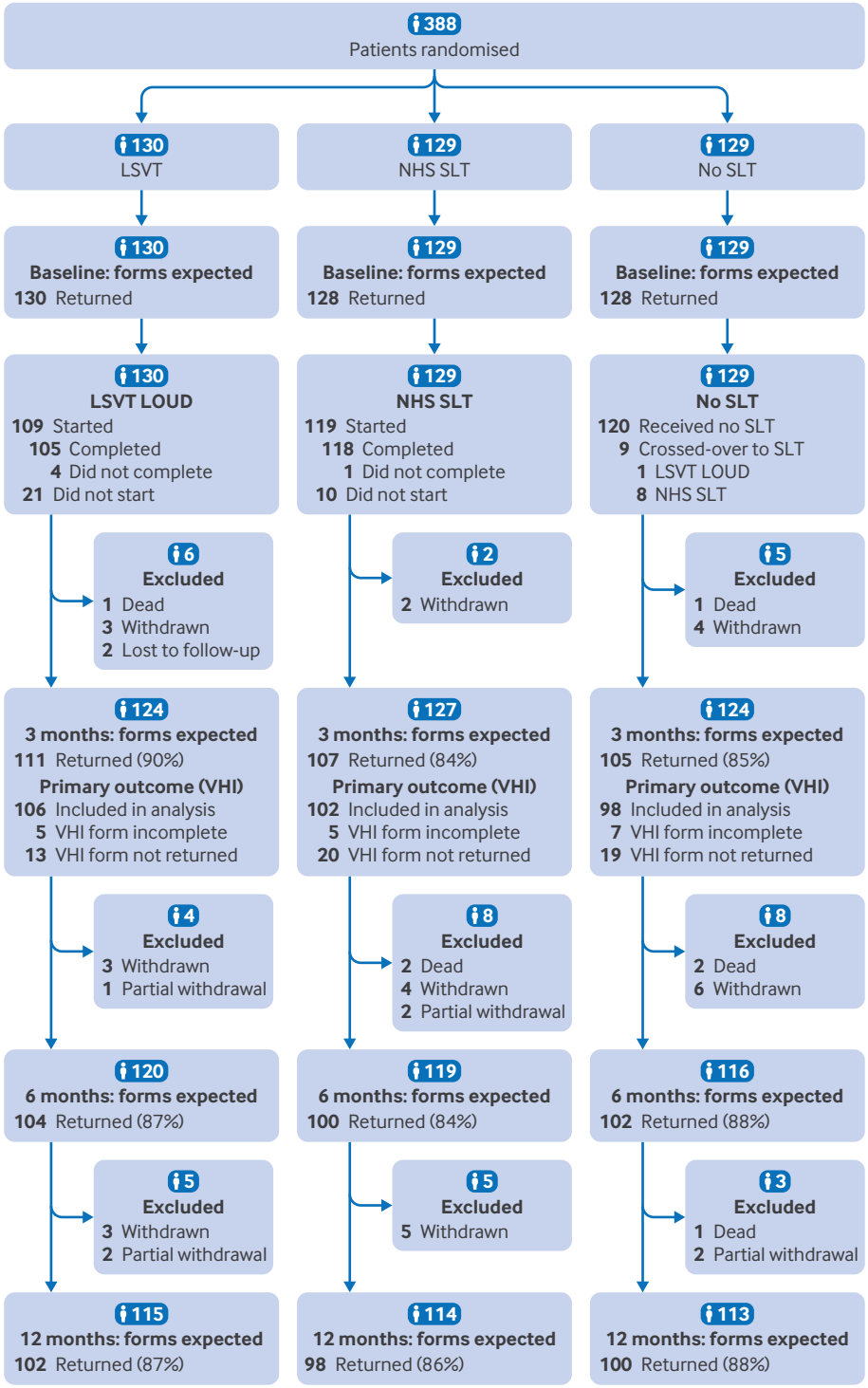

Fig 1 | Trial flowchart. CONSORT is based on participant completed data. Participants who were partially withdrawn remained in the trial, but only had clinical follow-up. LSVT LOUD=Lee Silverman voice treatment; SLT=speech and language therapy; VHI=voice handicap index

started NHS SLT, and 120 (93%) of 129 participants did not receive SLT for the no SLT group. Reasons for withdrawal from the trial varied and included: SLT was too burdensome, Parkinson's disease deteriorated, other commitments, and participant wanted SLT.

Participants were predominantly male (286/388; 74%), about half were 70 years or older and just under two thirds had mild (Hoehn and Yahr stage ≤2.0) Parkinson's disease (table 1). Data collection form return rates were high throughout the trial; for the primary outcome, 99% of baseline forms were returned and 86% or more were returned at each time point. The total time recorded spending on the interventions was three times greater for the LSVT LOUD group and delivered over more sessions (mean 1216 mins (standard deviation 454); median 16 sessions) than in the NHS SLT group (404 mins (234); five sessions) over a shorter period (LSVT LOUD seven weeks (7); NHS SLT 11 weeks (11)) (appendix 1, table B). The companion software was used for seven LSVT LOUD participants from five sites with a range of three to eight sessions per participant. Some of the activities related to the therapy were similar in time allocation across the interventions (i.e.[goal setting, information provision and advice, and liaison/ onward referral). By contrast, active therapy time per participant differed with a mean of 752 mins (standard deviation 287) for LSVT LOUD plus 15 min (45) for other therapy given to the LSVT LOUD group compared with 149 mins (113) of therapy in the NHS SLT group, reflecting LSVT LOUD's greater therapy intensity (hours per week) and frequency (days per week) (appendix 1, table B).

From evaluation into a subset of records of participants who completed therapy, most SLT interventions were delivered by qualified speech and language therapists on a one-to-one basis in outpatient settings. Some participants received therapy in a group (NHS SLT) or remotely via computer software (LSVT LOUD) and some received therapy from an assistant (across SLT interventions) (appendix 1, table B). As expected, LSVT LOUD activity was only reported in the therapy records of LSVT participants, including the use of LSVT worksheets.[32] NHS SLT mainly described impairment based and compensatory therapy, but also application of augmentative and alternative communication strategies, functional therapy, and generalisation. Both interventions used sheets, lists, pictures, and reading passages and magazines to practise speech production techniques learned in therapy. The treatment content reports showed variability and the likely tailoring of interventions to individual participants' needs. Many LSVT LOUD records reported tailoring by level of difficulty and functional relevance, but such tailoring was less frequently reported in NHS SLT (appendix 1, table B).

Participants were considered adherent if they attended at least 14 of 16 LSVT LOUD sessions within 3 months of randomisation, if they completed their NHS SLT sessions within three months of randomisation, or if they received no therapy in the no SLT group. Adherence to LSVT LOUD was similar (59%; 77/130) to NHS SLT (54%; 70/129), although not as high as for the no SLT group (93%; 120/129). Participants in the no SLT (control) group were considered not adherent if they reported receiving SLT over the course of the 12 month follow-up, with an exception for SLT only for dysphagia. Patient interview data showed considerable determination to engage with the trial interventions successfully; although, some patients indicated that they found the intensity of LSVT LOUD to be challenging. The support of family members and adjustment of personal and family routines were key to facilitating participation.

Negative difference favours SLT treatment for comparison of SLT *v* No SLT; and favours LSVT for comparison of LSVT *v* NHS SLT; except for the ICECAP-O and EuroQol5D where a positive difference favours SLT treatment for comparison of SLT *v* No SLT; and favours LSVT for comparison of LSVT *v* NHS SLT.

For the voice handicap index total score at three months (primary outcome), LSVT LOUD was 8 points lower (ie, better) than for no SLT (−8.0 points (99%

Table 1 | Participant demographics and disease characteristics

Characteristics	LSVT LOUD (n=130)	NHS speech and language therapy (n=129)	No NHS speech and language therapy (n=129)
Demographics			
Age (years), mean (SD)	69.9 (8.4)	69.7 (9.4)	70.2 (8.1)
Gender			
Male, no (%)	91 (70)	100 (78)	95 (74)
Female, no (%)	39 (30)	29 (22)	34 (26)
Body mass index, mean (SD)	25.6 (4.4)	26.2 (4.5)	26.6 (4.7)
Stage of Parkinson's disease			
Duration of Parkinson's disease (years), mean (SD)	5.8 (5.8)	5.1 (4.6)	6.1 (6.1)
Hoehn and Yahr stage, no (%):			
≤2.0	78 (60)	83 (64)	73 (57)
2.5	17 (13)	10 (8)	22 (17)
3.0	29 (22)	31 (24)	33 (25)
≥4.0	6 (5)	5 (4)	1 (1)
Levodopa equivalency (mg/day), mean (SD)	551.4 (342.8)	557.2 (365.1)	597.6 (416.9)*

LSVT=Lee Silverman voice treatment LOUD; SD=standard deviation.
*Parkinson's disease medication was collected on the entry form; entry forms were not received for two participants in the no speech and language therapy group.

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confidence interval (CI) −13.3 to 2.6), P<0.001). No evidence suggested a difference between the NHS SLT and no SLT groups (1.7 points (−3.8 to 7.1), P=0.43). The total score for voice handicap index in the LSVT LOUD group was nearly 10 points lower than that in the NHS SLT group (−9.6 points (−14.9 to −4.4), P<0.001) (table 2). Preplanned supporting and sensitivity analyses of the primary outcome were conducted and aligned the results of the primary outcome analysis (appendix 1, table C). The secondary analyses of the primary outcome, voice handicap index total score at six and 12 months and over the whole 12 months using a repeated measures analysis, gave similar results to those observed in the primary analysis at three months (table 3).

The subgroup analyses of the primary outcome with an exploratory hypothesis reported evidence of an interaction between the severity of the impact of voice problems (voice handicap index) and treatment (test for interaction P=0.007), but not for Parkinson's disease severity (P=0.7) or age (P=0.7). Generally, the intervention effect increased as the baseline voice handicap index score increased; for example, for LSVT LOUD, greater benefits were observed among those reporting more severe voice handicap index scores at baseline (appendix 1, table D).

For all subscales (emotional, functional, and physical) of the voice handicap index (secondary outcomes), the scores were lower (ie, better) for LSVT LOUD compared with no SLT and NHS SLT at three months and for the overall trial period, with significant benefits observed for the emotional and functional subscales. No evidence suggested a difference between NHS SLT and no SLT at any time point across all three voice handicap index subscales (table 2 and table 3).

At three months, QASD scores (secondary outcome) were lower (ie, better) with LSVT LOUD compared with no SLT and NHS SLT. No evidence suggested a difference between the NHS SLT and no SLT groups (table 2). Similar results were seen at six and 12 months, and over the whole trial follow-up period (table 3).

The Parkinson's disease questionnaire-39 (secondary outcome) assesses eight domains (mobility, activities of daily living, emotional wellbeing, stigma, social support, cognition, communication, and bodily discomfort) and overall quality of life. At three months, the largest differences were observed in the communication domain for LSVT LOUD versus no SLT: −6.2 points (99% CI −11.9 to −0.6, P=0.004), which exceeded the minimum clinically important difference for this domain (table 2 and table 3, and appendix, table E). For the icepop capabilities measure for older adults and EuroQol5D utility and visual analogue scores (secondary outcomes), no evidence of a difference was found for any of the comparisons at any time point (table 2 and table 3).

Table 2 | Primary and key secondary outcomes at three months

	Baseline, mean (SD; n)			Three months, mean (SD; n)			Adjusted mean difference between groups at three months (99% CI) *		
Outcomes	LSVT	NHS SLT	No SLT	LSVT	NHS SLT	No SLT	LSVT *v* No SLT	NHS SLT *v* No SLT	LSVT *v* NHS SLT
Primary outcome									
VHI total score	44.6 (21.9; 130)	46.2 (24.8; 129)	44.3 (22.3; 129)	35.0 (20.1; 106)	44.4 (24.8; 102)	40.5 (21.5; 98)	−8.0 (−13.3 to −2.6) P<0.001	1.7 (−3.8 to 7.1) P=0.43	−9.6 (−14.9 to −4.4) P<0.001
Participant completed secondary outcomes									
VHI emotional subscale	13.3 (8.8; 130)	14.2 (10.1; 127)	13.6 (9.0; 126)	9.7 (8.0; 110)	13.0 (9.6; 106)	12.2 (8.4; 104)	−3.0 (−5.1 to −0.9) P<0.001	0.2 (−1.9 to 2.4) P=0.78	−3.2 (−5.3 to −1.1) P<0.001
VHI functional subscale	15.3 (7.4; 130)	15.7 (8.6; 127)	15.1 (8.0; 128)	12.5 (6.8; 108)	15.3 (8.7; 104)	14.6 (7.7; 100)	−2.9 (−4.8 to −1.1) P<0.001	−0.0 (−1.9 to 1.9) P=0.97	−2.9 (−4.7 to −1.1) P<0.001
VHI physical subscale	16.0 (7.9; 130)	16.7 (7.6; 126)	15.8 (6.8; 128)	13.7 (7.5; 110)	16.0 (7.9; 106)	14.4 (6.8; 103)	−1.5 (−3.4 to 0.4) P=0.04	0.7 (−1.3 to 2.6) P=0.38	−2.2 (−4.1 to −0.3) P=0.003
QASD	29.9 (19.9; 123)	31.5 (19.9; 122)	30.2 (19.0; 123)	23.5 (19.4; 103)	27.6 (21.0; 100)	26.6 (19.1; 103)	−5.4 (−9.8 to −1.0) P=0.002	−1.1 (−5.6 to 3.3) P=0.52	−4.3 (−8.7 to 0.1) P=0.01
PDQ-39 summary index	27.9 (16.6; 130)	29.5 (16.5; 128)	28.4 (15.2; 128)	27.6 (17.6; 111)	28.8 (16.1; 107)	29.2 (15.9; 107)	−2.2 (−5.6 to 1.1) P=0.08	−1.2 (−4.6 to 2.2) P=0.36	−1.0 (−4.4 to 2.3) P=0.41
PDQ-39 communication	34.7 (22.0; 130)	35.4 (23.3; 128)	34.4 (24.2; 128)	29.5 (24.6; 111)	32.6 (22.4; 107)	33.4 (23.9; 107)	−6.2 (−11.9 to −0.6) P=0.004	−2.7 (−8.4 to 3.0) P=0.22	−3.5 (−9.1 to 2.1) P=0.10
ICECAP-O	0.81 (0.13; 129)	0.81 (0.11 128)	0.81 (0.13; 128)	0.80 (0.15 109)	0.80 (0.11; 107)	0.82 (0.12; 106)	0.001 (−0.03 to 0.03) P=0.9	−0.003 (−0.03 to 0.03) P=0.8	0.004 (−0.03 to 0.04) P=0.7
EuroQol5D utility	0.64 (0.20; 129)	0.61 (0.23; 128)	0.61 (0.22; 128)	0.61 (0.22; 111)	0.61 (0.23; 106)	0.63 (0.22; 106)	−0.02 (−0.08 to 0.03) P=0.3	−0.02 (−0.07 to 0.04) P=0.5	−0.01 (−0.07 to 0.05) P=0.7
EuroQol5D VAS	68.2 (18.1; 130)	67.4 (16.6; 128)	67.5 (18.7; 128)	66.1 (20.8; 110)	67.5 (18.9; 107)	68.1 (17.6; 105)	−0.9 (−5.9 to 4.2) P=0.7	1.3 (−3.8 to 6.4) P=0.5	−2.1 (−7.1 to 2.8) P=0.3
Carer completed secondary outcomes									
PDQ-carer summary index	28.4 (19.9; 61)	24.8 (19.2; 65)	24.9 (17.1; 58)	27.5 (22.6; 54)	29.9 (22.5; 56)	22.8 (19.3; 50)	0.6 (−5.6 to 6.9) P=0.8	6.2 (0.1 to 12.3) P=0.009	−5.6 (−11.6 to 0.4) P=0.02

CI=confidence interval; ICECAP-O=icepop capabilities measure for older adults; LSVT=Lee Silverman voice treatment LOUD; PDQ-Carer=Parkinson's disease questionnaire-carer's; PDQ-39=Parkinson's disease-39 questionnaire; QASD=questionnaire on acquired speech disorders; SD=standard deviation; SLT=speech and language therapy; VAS=visual analogue scale; VHI=voice handicap index.
VHI total ranges from 0 to 120, where low scores are good; VHI emotional, functional, and physical subscales: ranges from 0 to 40, where low scores are good; QASD ranges from 0 to 90, where low scores are good; PDQ-39 ranges from 0 to 100, where 0=no problem at all and 100=maximum level of problem; ICECAP-O score ranges from 0 to 1, where low scores are bad; EuroQol5D ranges from −0.594 to 1.0, where low scores are bad; EuroQol5D VAS ranges from 0 to 100, where low scores are bad; PDQ-Carer ranges from 0 to 100, where low scores are good.
*Analysis adjusted for baseline value (eg, baseline VHI subscale) and the minimisation variables (baseline VHI total score, age, and Hoehn and Yahr stage).

Table 3 | Secondary analyses of primary and key secondary outcomes

	Mean (SD; n)			Mean difference (99% CI)*		
Outcomes	**LSVT**	**NHS SLT**	**No SLT**	**LSVT *v* No SLT**	**NHS SLT *v* No SLT**	**LSVT *v* NHS SLT**
VHI total score:						
Six months	36.7 (24.1; 100)	43.6 (25.0; 96)	40.6 (22.4; 98)	−7.2 (−13.3 to −1.1)	−0.01 (−6.2 to 6.2)	−7.2 (−13.3 to −1.0)
12 months	38.2 (24.0; 97)	42.0 (24.1; 92)	42.5 (22.4; 96)	−6.7 (−12.6 to −0.8)	−1.1 (−7.1 to 4.9)	−5.6 (−11.5 to 0.4)
Overall†	—	—	—	−6.7 (−11.4 to −2.0) P<0.001	0.6 (−4.2 to 5.3) P=0.76	−7.3 (−12.0 to −2.6) P<0.001
VHI emotional subscale:						
Six months	9.8 (9.0; 102)	12.8 (9.6; 99)	11.7 (8.8; 100)	−3.0 (−5.5 to −0.6)	−0.3 (−2.7 to 2.2)	−2.8 (−5.2 to −0.4)
12 months	10.8 (9.0; 102)	12.6 (9.6; 97)	12.7 (8.2; 99)	−2.6 (−5.0 to −0.3)	−0.4 (−2.8 to 2.0)	−2.2 (−4.6 to 0.1)
Overall†	—	—	—	−2.7 (−4.5 to −0.9) P<0.001	0.001 (−1.9 to 1.9) P=1.00	−2.7 (−4.5 to −0.9) P<0.001
VHI functional subscale:						
Six months	12.7 (7.8; 101)	15.4 (8.8; 98)	14.0 (7.7; 99)	−2.5 (−4.5 to −0.6)	−0.1 (−2.0 to 1.9)	−2.5 (−4.4 to −0.5)
12 months	13.9 (8.0; 99)	14.4 (8.3; 94)	14.4 (7.9; 98)	−1.5 (−3.5 to 0.5)	−0.4 (−2.4 to 1.6)	−1.1 (−3.0 to 0.9)
Overall†	—	—	—	−2.2 (−3.8 to −0.6) P<0.001	−0.1 (−1.7 to 1.5) P=0.89	−2.1 (−3.7 to −0.5) P<0.001
VHI physical subscale:						
Six months	14.2 (8.4; 102)	15.5 (7.0; 99)	14.5 (7.2; 102)	−1.5 (−3.6 to 0.5)	−0.3 (−2.4 to 1.7)	−1.2 (−3.2 to 0.8)
12 months	14.3 (8.5; 100)	15.8 (8.2; 97)	15.4 (7.6; 99)	−2.0 (−4.1 to 0.1)	−0.4 (−2.5 to 1.7)	−1.6 (−3.7 to 0.5)
Overall†	—	—	—	−1.5 (−3.2 to 0.1) P=0.02	0.1 (−1.6 to 1.8) P=0.84	−1.7 (−3.3 to −0.02) P=0.009
QASD:						
Six months	24.6 (21.3; 98)	28.0 (20.6; 92)	26.4 (20.0; 99)	−4.0 (−8.6 to 0.7)	−1.0 (−5.8 to 3.7)	−2.9 (−7.7 to 1.8)
12 months	25.6 (21.2; 94)	30.4 (21.6; 95)	28.1 (19.4; 97)	−4.6 (−9.8 to 0.6)	0.3 (−4.9 to 5.5)	−4.8 (−10.1 to 0.4)
Overall†	—	—	—	−4.9 (−8.7 to −1.1) P<0.001	−0.8 (−4.7 to 3.0) P=0.58	−4.1 (−7.9 to −0.3) P=0.006
PDQ-39 summary index:						
Six months	27.4 (18.4; 104)	29.2 (17.7; 100)	27.6 (15.7; 102)	−1.6 (−5.4 to 2.2)	−0.03 (−3.9 to 3.8)	−1.6 (−5.4 to 2.2)
12 months	28.5 (17.6; 102)	31.6 (17.1; 98)	29.8 (16.8; 100)	−2.1 (−6.1 to 2.0)	1.1 (−3.0 to 5.2)	−3.1 (−7.2 to 0.9)
Overall†	—	—	—	−1.8 (−4.9 to 1.4) P=0.14	−0.4 (−3.5 to 2.8) P=0.76	−1.4 (−4.5 to 1.7) P=0.25
PDQ-39 communication:						
Six months	26.5 (22.7; 104)	32.0 (23.1; 100)	29.4 (20.7; 102)	−5.8 (−11.6 to −0.05)	−0.7 (−6.5 to 5.1)	−5.1 (−10.9 to 0.7)
12 months	29.8 (24.0; 102)	33.6 (22.7; 98)	31.1 (21.6; 100)	−3.8 (−9.8 to 2.1)	1.0 (−5.0 to 7.1)	−4.9 (−10.9 to 1.1)
Overall‡	—	—	—	—	—	—
ICECAP-O:						
Six months	0.80 (0.15; 103)	0.79 (0.13; 99)	0.80 (0.12; 100)	0.02 (−0.01 to 0.05)	0.005 (−0.03 to 0.04)	0.01 (−0.02 to 0.05)
12 months	0.80 (0.15; 102)	0.76 (0.16; 98)	0.79 (0.14; 100)	0.02 (−0.01 to 0.06)	−0.02 (−0.06 to 0.02)	0.04 (0.003 to 0.08)
Overall‡	—	—	—	0.01 (−0.02 to 0.04) P=0.36	−0.003 (−0.03 to 0.02) P=0.76	0.01 (−0.01 to 0.04) P=0.22
EuroQol5D utility score:						
Six months	0.61 (0.23; 104)	0.59 (0.23; 100)	0.60 (0.22; 101)	0.01 (−0.05 to 0.07)	−0.0009 (−0.06 to 0.06)	0.01 (−0.05 to 0.07)
12 months	0.59 (0.24; 102)	0.56 (0.24; 98)	0.56 (0.23; 100)	0.02 (−0.04 to 0.09)	−0.01 (−0.07 to 0.05)	0.03 (−0.03 to 0.10)
Overall†	—	—	—	0.002 (−0.5 to 0.05) P=0.93	−0.01 (−0.05 to 0.04) P=0.75	0.01 (−0.04 to 0.06) P=0.68
EuroQol5D health score:						
Six months	65.4 (20.4; 103)	66.4 (18.1; 99)	66.0 (19.2; 101)	0.9 (−4.9 to 6.7)	2.5 (−3.4 to 8.4)	−1.6 (−7.4 to 4.3)
12 months	68.0 (18.9; 102)	64.7 (19.7; 99)	65.1 (19.2; 100)	3.2 (−2.7 to 9.1)	1.7 (−4.3 to 7.6)	1.6 (−4.4 to 7.5)
Overall†	—	—	—	0.7 (−3.7 to 5.1) P=0.68	1.6 (−2.9 to 6.1) P=0.35	−0.9 (−5.3 to 3.5) P=0.60
PDQ-carer summary index:						
Six months	26.4 (22.7; 55)	31.2 (23.1; 54)	25.1 (20.5; 45)	−3.3 (−10.3 to 3.6)	3.7 (−3.2 to 10.6)	−7.0 (−13.6 to −0.4)
12 months	30.9 (21.4; 51)	34.1 (25.0; 48)	28.6 (21.0; 40)	−1.3 (−9.5 to 7.0)	6.2 (−2.1 to 14.5)	−7.5 (−15.3 to 0.3)
Overall†	—	—	—	−0.9 (−6.6 to 4.9) P=0.7	5.4 (−0.4 to 11.1) P=0.02	−6.3 (−11.8 to −0.7) P=0.004

CI=confidence interval; ICECAP-O=icepop capabilities measure for older adults; LSVT LOUD=Lee Silverman voice treatment LOUD; PDQ-Carer=Parkinson's disease questionnaire-carer's; PDQ-39=Parkinson's disease-39 questionnaire; QASD=questionnaire on acquired speech disorders; SD=standard deviation; SLT=speech and language therapy; VAS=visual analogue scale; VHI=voice handicap index.
VHI Total: ranges from 0 to 120 to where low scores are good; VHI emotional, functional, and physical Subscales: ranges from 0 to 40, where low scores are good; ASD: ranges from 0 to 90, where low scores are good; PDQ-39: ranges from 0 to 100, where 0=no problem at all and 100=maximum level of problem
ICECAP-O score: ranges from 0 to 1, where low scores are bad; EuroQol5D: ranges from −0.594 to 1.0, where low scores are bad; EuroQol5D VAS: ranges from 0 to 100, where low scores are bad; PDQ-Carer: ranges from 0 to 100, where low scores are good.
*Analysis adjusted for baseline value (eg, baseline VHI subscale) and the minimisation variables (baseline VHI total score, age, and Hoehn and Yahr stage). Negative difference favours SLT treatment for comparison of SLT *v* No SLT; and favours LSVT for comparison of LSVT *v* NHS SLT; except for the ICECAP-O and EuroQol5D where a positive difference favours SLT treatment for comparison of SLT *v* No SLT; and favours LSVT for comparison of LSVT *v* NHS SLT.
†Estimate obtained from a repeated measures analysis.
‡Model failed to converge.

The carer quality of life summary index score (secondary outcome) was lower (ie, better) for both LSVT LOUD and no SLT groups when compared with NHS SLT at three months (table 2). Differences in favour of LSVT LOUD and no SLT when compared with NHS SLT were also observed in the anxiety and depression subscale for the carers at three months (appendix 1, table F).

At 12 months, the median Hoehn and Yahr stages were similar to baseline, and the amount of treatment (reported using levodopa equivalency) had increased since baseline (appendix 1, table G). No serious adverse events were reported in this trial. Adverse events were reported in 36/130 (28%; 93 adverse events) participants in the LSVT LOUD group, 16/129 (12%; 46 adverse events) participants in the NHS SLT group,

and none in the no SLT group. Most adverse events reported were vocal strain, with a higher number in the LSVT LOUD group (80 events) compared with the NHS SLT group (45 events). Two participants from the LSVT LOUD group crossed over to the NHS SLT group following a vocal strain adverse event. One participant who experienced a dry aching throat following LSVT LOUD completed only nine sessions.

Discussion

Statement of principal findings

LSVT LOUD was more effective at reducing the participant reported impact of voice problems for people with dysarthria related to Parkinson's disease than was NHS SLT and no SLT after three months. These results remain robust when the potential effects of non-adherence to treatment and the impact of missing data were investigated. The continued benefit of LSVT LOUD on dysarthria over the 12 month trial period compared with NHS SLT and no SLT is encouraging, but re-intervention might still be required should the treatment effect wear off or as their Parkinson's disease progresses and their dysarthria deteriorates. A benefit was also observed in quality of life related to communication (using the Parkinson's disease questionnaire-39) for patients randomly assigned to receive LSVT LOUD, which exceeded the minimal clinically important change score of 4.2.[33] The higher rate of vocal strain with LSVT LOUD treatment was mostly a minor, transient issue at an acceptable rate in relation to the level of benefit; although, the occurrence of this adverse effect reinforces the need for management by suitably skilled therapists. We consider the higher costs of delivering the intensive LSVT LOUD face to face by a qualified speech and language therapist and alternative methods of adapting delivery that could support a more sustainable service delivery in the economic analysis that will be published separately. However, given the relative benefits, the PD COMM trial results support the adoption of LSVT LOUD as an effective SLT intervention option for dysarthria related to Parkinson's disease.

NHS SLT reflected mixed theoretical therapeutic intervention tailored to the individual by the therapist. In PD COMM, no clear evidence suggested a benefit for NHS SLT compared with no SLT or LSVT LOUD after three months. The confidence intervals are, however, moderately wide, which may reflect variability in the intervention offered. NHS therapy was delivered at a much lower intensity and did not show benefit over control. Therefore, these results should not be interpreted as evidence of no beneficial effect for all NHS SLT theoretical approaches, across all dosages. Further research is required to understand the effectiveness of specific aspects of the intervention, including dosage.

Strengths and weaknesses of the study

In terms of trial limitations, most participants were in the early stages of Parkinson's disease with mild speech impairment, which may not reflect the whole population of people with Parkinson's disease who need SLT.[34] We did not collect sufficient screening data to assess this aspect. Differences in access to therapy and intervention format could not be concealed from participants, making trial blinding unfeasible. Trial outcomes were questionnaires completed by participants or carers. Thus, participants' and carers' knowledge and expectations about their treatment allocations, particularly to no treatment, may have contributed to an increased risk of performance bias.

The disadvantage of many previous trials of dysarthria related to Parkinson's disease has been the use of sound pressure level (ie, speech volume) without including participant reported outcome measures. The use of a participant reported outcome measure is an advantage because the voice handicap index measures how the participant perceives the impact that their voice problems on their daily activities and their quality of life, which is a more meaningful measure of communication for them.[12 13] Future trials of new interventions may benefit from developments in the field of clinically relevant participant reported outcome measures,[35] which explore participation rather than impairment outcomes.

Variation in experience levels of speech and language therapists, particularly with respect to being newly trained in LSVT LOUD specifically for the trial, presents a risk that this trial may not have captured the full potential of the SLT approaches. While the duration of treatment between the two active treatment populations differs, the treatment could have been stopped at any point within the three month window from randomisation. As a result, both interventions could have finished near to the primary outcome data collection point and both interventions could have happened in a short period. Finally, due to the covid-19 pandemic, the trial closed early (suspended March 2020, closed November 2020) to recruitment, and thus did not recruit to the planned sample size. Additionally, some follow-up data were lost because the data could not be accessed within the time frame. However, we do not believe that these amendments would have changed the trial's overall conclusions and clinical implications. Our meta-analysis of the PD COMM pilot and full trial data supports this assumption (appendix 1, figures 2, 3, and 4).

Possible use for clinicians and policy makers

This large, pragmatic trial compares two commonly used SLT approaches against each other and against no therapy. A robust signal shows that, after three months, LSVT LOUD is effective compared with no SLT for the reduction of dysarthria related to Parkinson's disease, which persists throughout the 12 months from starting treatment. This effect, combined with the lack of evidence of effectiveness of NHS SLT shown in this trial, means that optimal use of speech and language therapy resources for people with Parkinson's disease need to be discussed.

Unanswered questions and future research

Evidence from language rehabilitation in relation to people who had strokes suggests that effective therapeutic interventions were associated with dosage (total hours), frequency (number of days per week), and intensity (hours per week) regimens beyond a specific threshold. Thus, SLT may have a dose effect, and treatment threshold might be relevant and interact with participant characteristics, such as severity.[36] The PD COMM trial was not designed to provide evidence about the relative benefits of NHS SLT versus LSVT LOUD at equal doses or different dose combinations.

Attention should, however, be given to factors beyond the treatment content when determining the make-up of future SLT services: the availability of speech and language therapists, access to outpatients, home and remote visits, software, costs, and frequency of treatment required. This trial also encourages a closer look at the effect of SLT provision on carers, and further research involving outcomes for carers could optimise future SLT care for people with Parkinson's disease.

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Dissemination to participants and related patient and public communities: Once the results are published, we plan to disseminate the results widely, on our university websites, our X channels (formerly Twitter), and with Parkinson's UK. We would expect this research to form a large part of future NICE guidance.

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Ethical approval: The trial was approved by the West Midlands–Coventry and Warwickshire Research Ethics Committee (15/WM/0443).

Data sharing: All requests for access to PD COMM data should be submitted to the corresponding author for consideration by the current investigator. Access to anonymised patient level data with a data dictionary may be granted following review, no earlier than six months after this publication with no end date. Proposals for data access will need to describe how the data will be used. Transfer of data will be by a secure method and only after approval by the Trial investigator team.

Transparency: The lead author (the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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