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Speech and language therapy interventions for speech problems in Parkinson's disease (Protocol)

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[Intervention Protocol]

Speech and language therapy interventions for speech problems in Parkinson's disease

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ABSTRACT

Objectives

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

To evaluate the effectiveness of speech and language therapy (SLT) interventions on speech and voice problems in people with Parkinson's disease.

We will investigate whether:

- SLT is more effective than no SLT;
- SLT is more effective than placebo or attention control interventions;
- one SLT intervention is more effective than another SLT intervention (including standard care).



Description of the condition

For definition of terms see Table 1.

Parkinson's disease is a progressive neurodegenerative condition estimated to affect as many as 160 people per 100,000 (NICE 2017). An estimated eight out of every nine people who are living with Parkinson's disease will experience problems with the muscular movements required to produce speech (dysarthria) (Yuan 2020). The likelihood of experiencing speech and voice problems also increases as the disease progresses (Miller 2012).

Dysarthria is a collective name for a group of neurogenic speech disorders resulting from disturbances in muscular control and execution of the speech mechanism due to damage to the central nervous system (Darley 1969) or peripheral nervous system damage (e.g. cranial nerves). It is characterized by "abnormalities in the strength, speed, range, steadiness, tone, or accuracy of movements required for breathing, phonatory, resonatory, articulatory, or prosodic aspects of speech production" (Duffy 2013, p. 4).

Many of the features of Parkinsonian dysarthria are attributed in part to hypokinesia (paucity of movement) and rigidity, which are considered to be cardinal features of Parkinson's disease (Mawdsley 1971). Common characteristics of speech problems in those with Parkinson's disease include:

- monotony of pitch and volume (dysprosody);
- reduced stress;
- imprecise articulation;
- variations in speed resulting in both inappropriate silences and rushes of speech; and
- a breathy hoarseness to the speech (hypophonia), caused by the competing challenges of synchronising talking and breathing (Miller 2012).

People living with Parkinson's disease can experience cognitive impairment, which in some cases may lead to difficulties in understanding and using language, and reduced skills in managing conversations (Miller 2017). While these issues do not come under the umbrella of dysarthric speech, they can negatively impact on the ability of individuals to communicate and participate in spoken communication.

Speech and voice problems may be the first presenting clinical sign of Parkinson's disease; they may also be undetected and undiagnosed as people living with the condition begin to compensate, for example, by withdrawing from social situations that require speaking. Communication partners may also initially attribute communication problems to hearing loss, or part of the ageing process. A recent survey reports a wide range of participation restrictions in social, recreational, vocational and everyday living activities for people living with speech and voice problems as a result of Parkinson's disease. The same survey also described the heavy emotional burden linked to these changes, including a loss of self-confidence and feelings of frustration, depression and isolation (Swales 2020). The impact of communication challenges also extends to carers and family members and negatively impacts their quality of life (Miller 2012).

Description of the intervention

A wide range of treatments has been used in the management of speech and voice problems in people with Parkinson's disease. These include:

- pharmacological interventions (Brabenec 2017; Pinho 2020);
- surgical interventions (Chiu 2020; Negida 2018); and
- behavioural treatment techniques and communicationsupporting aids (Herd 2012; Herd 2012a).

Pharmacological interventions have been delivered with mixed success on speech and voice outcomes. A recent meta-analysis identified nine studies (with a total of 119 participants) that explored the association between levodopa therapy and the loudness and intelligibility of speech in people with Parkinson's disease (Pinho 2020). Of these, six studies (83 participants) were included in the meta-analysis. During the levodopa therapy "on" state (i.e. when levodopa is working well), significant improvement in the fundamental frequency (F0) and a reduction in jitter were observed. However, no change in vocal intensity was evident (Pinho 2020).

Surgery also appears to play a limited role in the management of speech problems. Deep brain stimulation (DBS) targeting the subthalamic nucleus or the globus pallidus internus are the most common surgeries. However, it is still unclear how effective DBS is in ameliorating speech and voice problems, with some studies suggesting that it generally has no effect on speech (Negida 2018) and other studies reporting a negative effect in some cases (Chiu 2020; Negida 2018). Other surgical procedures have also been described in the literature, including the use of injectable fillers to temporarily improve vocal cord closure (vocal cord augmentation) (Hill 2003), or surgical implants in the vocal cords (thyroplasty) to improve a weak or quiet voice (Roubeau 2016).

Behavioural treatment techniques of speech and language therapy (SLT) may be more effective than pharmacological and surgical treatments in improving speech intelligibility in Parkinson's, as shown in previous systematic reviews (Bloem 2015; Herd 2012; Herd 2012a; Mahler 2015; Miller 2012; Munoz-Vigueras 2020; Yuan 2020). Although communication aids are used in clinical practice for people with Parkinson's (Armstrong 2000; Swales 2019), and are increasingly available (Linares-del Rey 2019; Parkinson's UK 2020), little is known about their effectiveness.

How the intervention might work

For the purpose of this review, we have defined a speech and language therapy intervention as any form of targeted practice task or activity with the aim of improving speech or voice and associated communication participation. To give this review maximal clinical relevance, the structure of this section follows the American Speech-Language-Hearing Association (ASHA) practice portal for dysarthria treatment (ASHA 2021).

Speech and language therapy interventions may include, but are not limited to, those which aim to be restorative or compensatory. Restorative approaches aim to restore or improve impairment or maintain function in speech intelligibility (clarity); prosody (i.e. patterns of stress and intonation) and naturalness; and efficiency. Approaches may incorporate principles of motor learning and include exercises to target speech production subsystems such as



respiration (breathing), phonation (voice), articulation (speech), or a combination of these. Restorative approaches are also likely to encourage the individual's awareness of their speech or voice and their ability to make changes (Swales 2019; Yorkston 2017).

Compensatory approaches focus on improving or maintaining comprehensibility (i.e. how well someone's meaning is understood) by increasing the speaker's use of communication strategies, improving listener/conversational partner skills and capacity (Better conversations 2021) and altering the communication environment. They also aim to increase effective use of alternative and augmentative communication (AAC) and augmentative devices (e.g. to amplify the voice or to support reduced rate of speech).

Why it is important to do this review

Speech and voice problems are common in people with Parkinson's disease and international guideline evidence supports timely referral for assessment, education and advice (Working group CPG 2014; Grimes 2019; Keus 2014, NICE 2017). However, survey data from people living with Parkinson's disease in Australia (Swales 2020) and the UK (Miller 2011; Miller 2011a) indicate that referral rates are low and service provision limited.

It is essential that people living with Parkinson's disease, their carers and healthcare professionals can obtain optimal evidence relating to the most effective treatments to address speech and voice problems. Systematic reviews provide an important source of evidence for making informed clinical decisions, and in line with Cochrane guidance (Cumpston 2021), it is important that these are kept up to date. Since the publication of the two previous Cochrane Reviews on this topic (Herd 2012; Herd 2012a), there have been a number of new clinical trials that have evaluated the effects of speech and language therapy interventions in Parkinson's disease which may have a meaningful impact on the review findings. Therefore, a comprehensive and up-to-date systematic review of randomized controlled trials (RCTs) is needed to summarize the available data on the effectiveness of speech and language therapy interventions for the treatment of speech and voice problems in Parkinson's disease. This review brings together and updates the two previously published Cochrane Reviews (Herd 2012; Herd 2012a).

OBJECTIVES

To evaluate the effectiveness of speech and language therapy (SLT) interventions on speech and voice problems in people with Parkinson's disease.

We will investigate whether:

- SLT is more effective than no SLT;
- SLT is more effective than placebo or attention control interventions;
- one SLT intervention is more effective than another SLT intervention (including standard care).

METHODS

Criteria for considering studies for this review

Types of studies

We will include all randomized controlled trials (RCTs) (i.e. studies in which participants are randomly allocated to different intervention groups using established methods such as random number generators). We will include other complex trial designs (e.g. multi-arm RCTs, cross-over RCTs, cluster-RCTs and stepped-wedge cluster RCTs). We will exclude all other study designs including quasi-randomised controlled trials. We will include all peer-reviewed publications (including abstracts) and other published and unpublished data that meet our inclusion criteria.

Types of participants

We will include RCTs involving people with a diagnosis of idiopathic Parkinson's disease (as defined by the authors of the studies). We will apply no age limit for participants experiencing speech or voice problems as a consequence of their Parkinson's. We will include participants with any duration of Parkinson's disease, on any pharmacological therapy and any duration of treatment. This includes participants who have had, or are undergoing, deep brain stimulation or surgery.

We will include studies that report mixed populations providing we are able to extract separate data for people living with Parkinson's disease. We will exclude studies involving participants with atypical Parkinsonism (e.g. drug-induced Parkinsonism).

Types of interventions

We will include any speech and language therapy (SLT) intervention (restorative, compensatory or a combination of approaches) which is aimed at addressing speech and voice problems in Parkinson's disease. We have defined a speech and language intervention as any form of targeted practice task or activity with the aim of improving speech or voice and associated communication participation. Interventions will be included regardless of their frequency or duration. RCTs that are focused on swallowing dysfunction or drooling (or both) that do not measure speech and voice outcomes will not be included. We do not plan to include any RCTs that are solely focused on writing or micrographia.

Eligible comparators may include:

- no treatment;
- a placebo or attention control intervention; or
- another speech or communication intervention (including standard care).

Types of outcome measures

Primary outcomes

The critical outcome is level of communication participation (immediately post-intervention).

We will employ the definition of communication participation as reported in Eadie 2006: "taking part in life situations where knowledge, information, ideas, or feelings are exchanged. It may take the form of speaking, listening, reading, writing, or nonverbal means of communication. Communicative participation may occur in multiple life situations or domains and includes, but

is not limited to, personal care, household management, leisure, learning, employment, and community life".

Communication participation is measured using outcome tools, for example the Voice Handicap Index (Jacobson 1997), Communicative Participation Item Bank (Baylor 2013), and Communication Effectiveness Index- modified (Yorkston 1999). Where trials provide data on more than one communication participation outcome measurement instrument, we will extract and analyse the measure occurring earliest in the above list.

Secondary outcomes

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Additional important outcomes are as follows.

- Speech and voice production parameters (i.e. measure of impairment). This may include measures of:
 - total impairments measured using, for example, dysarthria rating scales, intelligibility rating scales;
 - objective and subjective acoustic measures of speech samples measured using, for example, pitch, loudness, sentence length; and
- measures of laryngeal activity, using, for example, fibre optic laryngoscopy, stroboscopy.
- Activities of daily living measured using, for example, Sickness Impact Profile (SIP) communication subsection.
- Handicap and quality-of-life measures, both disease-specific (e.g. Parkinson's Disease Questionnaire - 39 (PDQ39)) and generic (e.g. Short Form - 36 (SF36)).
- Depression and anxiety measured using, for example, the Hospital Anxiety and Depression Scale (HADS), Beck Depression Inventory, Parkinson's Anxiety Scale.
- Adverse events (examples may include dysphonia, vocal nodules or fatigue).
- Carer outcomes measured using, for example, the Carer Strain Index.

We will not select studies based on reported outcomes. All relevant outcome measures will be included in the review wherever possible. Where two or more outcome measurement instruments are used to capture the same outcome then we will review the data availability (numbers of participant data, completeness of the datasets) to inform the inclusion of an outcome measurement instrument. Where two or more outcome measurement instruments were used in a single trial to capture the same outcome, and where data availability is equal across both outcome measurement instrument datasets, then we will consider overlap with outcome measurement instruments used in other trials. We will then consider statistical heterogeneity. Finally, where all outcome measurement instruments remain equal in relation to the above factors, then we will arbitrarily choose one outcome measurement instrument and conduct a sensitivity analysis based on the alternative outcome measurement instruments.

We will extract outcomes which are recorded at the end of the intervention ('immediate' point) and outcomes measured at a 'follow-up' time point. Where multiple follow-up time points are available, we will extract data which reflect the following time points: short-term (less than three months, up to six months), medium-term (more than six months, up to 12 months) and longer-term (more than 12 months).

Search methods for identification of studies

Electronic searches

We will develop a comprehensive search strategy in MEDLINE combining uncontrolled vocabulary terms and Medical Subject Heading (MeSH) terms for (a) Parkinson's disease AND (b) speech and language AND (c) randomized controlled trial filter (e.g. Glanville 2019; Lefebvre 2021). Searches will be peer-reviewed in accordance with Peer Review of Electronic Search Strategies (PRESS) guidelines (McGowan 2016).

The search will be adapted and run on each of the following major electronic databases, from inception to present (unless stated otherwise). We will apply no language restrictions.

- MEDLINE Ovid (see Appendix 1) (1946 to current).
- Cochrane Database of Systematic Reviews (CDSR) and Cochrane Register of Controlled Trials (CENTRAL) (Wiley Cochrane Library) (Appendix 2).
- Embase Ovid (1974 to current).
- CINAHL EBSCO (Cumulative Index to Nursing and Allied Health Literature) (Appendix 3).
- Linguistics and Language Behavior Abstracts (LLBA) ProQuest (from inception to current) (www.proquest.com/llba).
- Speech Pathology Database for Best Interventions and Treatment Efficacy (speechBITE), University of Sydney (speechbite.com) (from inception to current).

Searching other resources

We will also conduct systematic supplementary searches to identify other potentially relevant studies. This will include searches of the following major trial registers for ongoing trials.

- CenterWatch Clinical Trials listing service (www.centerwatch.com).
- US National Institutes of Health Ongoing Trials Register, ClinicalTrials.gov (www.clinicaltrials.gov).
- World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictrp/en).

We will also search the following grey literature databases and web search engines from inception to present.

- e-theses online service (EThOS) (ethos.bl.uk/Home.do).
- Google Scholar (scholar.google.com/) (top 250 most relevant entries).
- Networked Digital Library of Theses and Dissertations (NDLTD) (ndltd.org/).
- DART-Europe E-theses Portal (www.dart-europe.eu/basicsearch.php).
- Open Access Theses and Dissertations (oatd.org).
- PQDT Open (www.proquest.com/?defaultdiss=true).

We will also conduct forward citation tracking, using Google Scholar, for the main publications for each of the included studies. We will also search the reference lists of all included studies for any potentially relevant studies. We also plan to contact the authors of relevant randomized trials to identify additional studies of relevance to this review.

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Data collection and analysis

Selection of studies

One review author (PC) will run the searches and will exclude any obviously irrelevant titles. Pairs of review authors (PC, SR, AN, MB) will independently apply the selection criteria to abstracts; this stage will be managed in Covidence. Pairs of review authors (PC, SR, AN, MB) will independently apply the selection criteria to the full papers. Disagreements between review authors will be resolved through discussion, involving a third content expert review author (AN, MB) where necessary. We will record the selection process in sufficient detail to complete a PRISMA flow diagram (Moher 2009), and studies that are judged as ineligible for inclusion will be listed in the characteristics of excluded studies table, together with reasons for their exclusion.

Data extraction and management

One review author will systematically extract data from all papers using a pre-developed data extraction file (Microsoft Excel). We will pilot the extraction form on at least five studies prior to use. All data extraction will be cross-checked by a second review author, and any disagreements resolved through discussion, involving a third review author if necessary.

Multiple reports of the same study will be brought together, and data extraction will consider all publications related to that study. Where there is a protocol and also a report of a completed study, we will report the completed study as the "main" publication, referring to both for data extraction, but using the main publication if there is conflicting information relating to a study.

We will extract the following data from each eligible trial.

- Author, year.
- Study design and methods: aim, trial design, geographical setting (country), recruitment details (including period, if applicable), number of trial centres and their location, trial registration number, setting, date, number of participants randomized, number lost to follow-up or withdrawn, number analysed.
- Participant characteristics: inclusion and exclusion criteria, mean or median age or range, sex composition, diagnoses, diagnostic criteria for Parkinson's disease. We also plan to extract data relating to participant factors which may result in inequitable access to interventions using the PROGRESS-plus framework (Cochrane Methods Equity 2021). This will include extracting data related to: place of residence, race/ethnicity/culture, language, occupation, gender, religion, socioeconomic status, social capital; and data related to personal characteristics potentially associated with discrimination (e.g. age or disability).
- Intervention characteristics: details of the intervention will be extracted in accordance with TIDieR guidelines (Hoffman 2014), including type of SLT intervention, materials, procedures, provider and relevant qualification and training, mode of delivery, regimen, tailoring, modification, adherence, details of other concomitant treatments. We will also report details of the target of intervention and any theoretical approach underpinning the intervention (RELEASE Collaboration 2020).
- Details of any adverse events/unintended consequences.

- Comparator characteristics: details on the comparator, using the TIDieR headlines (Hoffman 2014) described above.
- Assessed outcomes: raw data for each eligible outcome (see notes for Types of outcome measures), details of other outcomes specified and reported, and data collection time points.
- Baseline and follow-up results data (mean and standard deviation, or other summary statistics as appropriate) for relevant outcomes. We will extract data for an 'immediate' time point recorded at the end of the intervention period; and for a 'follow- up' time point. Where multiple follow-up time points are available, we will extract data which reflect the time points stipulated in Secondary outcomes.
- Sources of trial funding and any potential conflict of interests (as reported by study authors) (Boutron 2021).

Assessment of risk of bias in included studies

Two review authors will independently document the methodological quality of the included studies using the first version of the Cochrane risk of bias tool for randomized trials (Higgins 2011). Each study will be judged as being at high, low or unclear risk of bias for the following domains.

- Random sequence generation (selection bias).
- Allocation concealment (selection bias).
- Blinding of participants and personnel (performance bias).
- Blinding of outcome assessment (detection bias).
- Incomplete outcome data (attrition bias).
- Selective reporting (reporting bias).
- Other potential confounders (e.g. baseline comparability of groups; whether an a priori power calculation had been conducted).

Where inadequate details are provided in the original report, data will be sought from study authors. Any disagreements will be resolved through discussion, involving a third review author if necessary.

Measures of treatment effect

We will carry out meta-analyses of pairwise comparisons for outcomes where direct evidence is available, using Review Manager software (RevMan 2020). For continuous variables, we will calculate the mean difference (for measurements using the same scale) or standardised mean difference (for measurements using different scales) with 95% confidence intervals (CIs). For dichotomous variables, we will calculate Peto odds ratio with 95% CIs.

We plan to use measures based on differences in final value scores (i.e. measured post-intervention) within the meta-analyses wherever possible. We will only combine change-from-baseline scores with post-intervention measurement outcomes in a meta-analysis of MDs, using separate subgroups which we will pool as described in the *Cochrane Handbook* (Higgins 2021).

Unit of analysis issues

While we anticipate that most studies will employ a parallel randomized design, we plan to meta-analyse any complex trial designs (multi-arm, cluster-randomized and cross-over) using established guidance reported in the *Cochrane Handbook* (Higgins 2021). Specifically for the following study designs we have planned the following.



- Multi-arm studies: for studies reporting more than one active intervention arm which may be eligible for inclusion within the same comparison (against a control, placebo, or no-treatment group), we will divide the control group data between the pairwise comparisons in order to avoid double counting participants within an analysis. The unit of allocation will be at the individual level.
- Cross-over randomized studies: we plan to analyse the data from the first phase of the trial unless there is a relevant comparison (e.g. early versus late intervention). The unit of allocation will be at the individual level.
- Cluster-randomized design: we plan to treat this using the group (or cluster) as the unit of allocation, and we will follow methods for analysis of cluster-randomized trials as described in the *Cochrane Handbook* (Higgins 2021). We will use adjusted data for clustering if they are reported by the authors. However, if no adjustment has been used, then we plan to adjust the raw data using the intra-cluster correlation coefficient (ICC), using methods described in the *Cochrane Handbook* (Higgins 2021). If the ICC is not reported for a study and we are unable to obtain the ICC value from the authors then we plan to use the ICC for the study's own sample size calculation instead.

Dealing with missing data

We plan to contact study authors by email (where possible) on at least two occasions to obtain missing data relevant to our critical and important outcomes. We will contact authors when these data are missing from identified reports or where study reports do not provide means or standard deviations (or data from which these can be calculated by the review authors).

In cases where only partial summary data are reported, we will calculate these values from available information using methods described in the *Cochrane Handbook* (Higgins 2021). In cases where data need to be transformed (e.g. from median and interquartile range (IQR) scores to mean and standard deviation), we will use methods described in Weir 2018.

Assessment of heterogeneity

We will assess statistical heterogeneity between trials using the I^2 statistic available in Review Manager 5.4 (RevMan 2020). If statistical heterogeneity exists (in the absence of co-existing clinical or methodological heterogeneity), we will use a random-effects model to pool the trials. We will use a fixed-effect model if there is no evidence of clinical, methodological or statistical heterogeneity.

We will interpret the I² statistic using the following guidance, according to the *Cochrane Handbook* (Deeks 2021):

- 0 to 40%: potentially unimportant;
- 30% to 60% may represent moderate heterogeneity;
- 50% to 90% may represent substantial heterogeneity; and
- 75% to 100%: considerable heterogeneity.

Where we find substantial or considerable levels of heterogeneity, we will explore reasons for this heterogeneity using pre-planned subgroup and sensitivity analyses (see Subgroup analysis and investigation of heterogeneity).

Assessment of reporting biases

In order to minimize the impact of reporting biases, we will conduct comprehensive searches of multiple databases and other sources, including clinical trial registries, to identify any unpublished studies (see Search methods for identification of studies). We will also look for outcome reporting bias in studies by recording all trial outcomes, planned and reported, and noting the absence of anticipated outcomes or less detailed reporting of non-significant outcomes. We will contact study authors to try to obtain any missing data.

To assess whether trials included in any meta-analysis are affected by reporting bias, we will construct funnel plots (Egger 1997) when a meta-analysis includes results of at least ten trials, following established guidance (Higgins 2021).

Data synthesis

We will conduct pairwise meta-analysis (using Review Manager 5.4) for all critical and additional outcomes listed in Types of outcome measures, for the following comparisons:

- SLT intervention versus no SLT intervention;
- SLT intervention versus placebo or attention control; and
- one SLT intervention versus another SLT intervention (including standard care).

Our analysis will pool all types of SLT interventions within the relevant comparison. We will stratify our analysis according to the type of SLT intervention, where appropriate to do so. This will be based on the similarity of the included interventions and clinical relevance. We will judge our confidence in each pooled outcome using the GRADE approach and create summary of findings tables for each comparison, as outlined in the Summary of findings and assessment of the certainty of the evidence section.

If we are unable to conduct a meta-analysis, we will use a narrative synthesis and evidence tables (i.e. effect estimates and 95% confidence intervals of each trial in tables for each comparison). Narrative findings will be reported in accordance with Synthesis Without Meta-analysis (SWiM) guidelines (Campbell 2020).

Subgroup analysis and investigation of heterogeneity

Where there are sufficient data, we plan to undertake the following subgroup analyses, to explore differences in effect estimates based on:

- the duration of the speech problem prior to intervention, i.e. brief duration (less than six weeks); short duration (six weeks to six months); medium duration (six to 12 months); longer duration (longer than 12 months);
- whether the intervention is the first therapy that has been delivered for that specific speech problem or whether it is a subsequent intervention;
- type of intervention (i.e. restorative, compensatory or a combination of approaches);
- who provided or facilitated the SLT interventions (i.e. speech and language therapist/other healthcare professional/carer or volunteer);
- severity of overall Parkinson's symptoms/stage of disease, according to the Hoehn and Yahr Scale (Hoehn 1967);



- severity of speech problems at baseline; and
- source of funding and potential conflict of interest of authors of included studies (Boutron 2021).

We will use the test for subgroup interaction in Review Manager 5.4 (RevMan 2020) to perform these analyses.

Sensitivity analysis

We plan to explore statistical heterogeneity by carrying out sensitivity analyses to explore the impact of the following.

- Publication type. We will do this by removing unpublished data (i.e. abstracts or dissertations) from the analysis.
- Trials judged as being at high risk of bias for the following categories: selection bias (e.g. trials with a non-random component in the generation sequence) and detection bias (e.g. studies with no blinding or incomplete blinding of outcome assessors).
- Studies that appear to be visual outliers. We will do this by removing each study from the analysis.

Summary of findings and assessment of the certainty of the evidence

We will construct summary of findings tables for the comparisons of:

- SLT intervention versus no intervention;
- SLT intervention versus placebo or attention control; and
- one SLT intervention versus another SLT intervention (including standard care).

In the summary of findings tables we will present key findings from the review, including a summary of the quantity of data, the magnitude of effect size, and the overall quality of the evidence. We will summarize the short-term findings (measured immediately at the end of intervention) for our critical outcome (communication participation) and the following additional outcomes:

- quality of life (disease-specific measures);
- activities of daily living (disease-specific measures);
- speech and voice production parameters: objective acoustic measures of sound pressure level (SPL) in reading and spontaneous speech (monologue);
- adverse events; and
- carer outcomes.

The summary of findings tables will provide information about the quality of the evidence for each outcome, which will be assessed using the GRADE approach (Guyatt 2008; Guyatt 2011). The quality assessment will be performed independently by two review authors, with agreement reached through discussion. The evidence will be assessed across the following domains:

- study limitations (e.g. risk of bias due to poor study design or conduct) (Guyatt 2011a);
- publication bias (Guyatt 2011b);
- imprecision of results (e.g. wide confidence intervals for treatment effect) (Guyatt 2011c);
- inconsistency of results (e.g. large I² value) (Guyatt 2011d); and
- indirectness of evidence (e.g. variations in participants, interventions, comparisons and outcomes) (Guyatt 2011e).

We will then use these assessments to arrive at an overall judgement regarding quality of the evidence for each outcome, according to the following categories:

- high quality (further research is very unlikely to change our confidence in the estimate of effect);
- moderate quality (further research is likely to have an important impact on our confidence in the estimate of effect, and may change the estimate);
- low quality (further research is very likely to have an important impact on our confidence in the estimate of effect, and may change the estimate);
- very low quality (we are very uncertain about the estimate).

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- Editorial Assistant (conducted editorial policy checks and supported editorial team): Leticia Rodrigues, Central Editorial Service.
- Copy Editor (copy-editing and production): Jessica Sharp.

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ADDITIONAL TABLES

Table 1. Glossary

Term	Heading
Amplitude	The maximum absolute value of a periodically varying quantity. For a sound wave, the maximum variation in pressure relative to static conditions (e.g. atmospheric pressure). Small variations pro- duce weak (or quiet) sounds whilst large variations produce strong (or loud) sounds. (See 'loud- ness', below).
Articulation	The production of vowels and consonants using both the moving parts of the mouth (e.g. tongue and lips) and the fixed structure of the mouth (e.g. hard and soft palate). It does not involve the voice box.
Concealment of allocation	The process used to conceal foreknowledge of group assignment, which should be seen as distinct from blinding. The allocation process should be impervious to any influence by the person making the allocation. Adequate methods of allocation concealment include: centralised randomization schemes (telephone randomization) or sequentially numbered opaque sealed envelopes.
Decibel (dB)	A unit used to express relative difference in power or intensity, usually between two acoustic or electric signals, equal to ten times the common logarithm (i.e. base 10) of the ratio of the two levels, i.e. 10 log10 (W2/W1) where W1 is the reference power level and W2 is the quantity being specified in dB relative to W1. It is commonplace to want to express in decibels, quantities that are related not to power, but power squared. Examples include sound pressure and voltage. In such cases the expression for the decibel level becomes 20 log10 (p2/p1). So that individual quantities can be specified, default reference values are defined for sound pressure (20x10E-6 pascals), sound power (10E-6 watts) and sound intensity (10E-12 watts per square metre). For other quantities (e.g. voltage) a value of unity is often used implicitly. The reference level for sound pressure (corresponding to 0 dB) was originally set as an approximation to the threshold of human hearing. A whisper has an intensity of ~30 dB, normal speech ~60 dB, a shout ~90 dB and a jet aircraft ~120 dB.
Dysarthria	Dysarthria is a collective name for a group of speech disorders resulting from disturbances in mus- cular control of the speech mechanism due to damage of the central nervous system. It designates problems in oral communication due to paralysis, weakness or inco-ordination of the speech mus- culature.
Dysprosody	Abnormal prosody (see 'prosody'). Loss of the 'melody' of speech.
Frequency	The number of complete cycles of a periodic process occurring per unit time. For sound waves this is the number of times the pressure variation cycle occurs in one second. The unit used to measure frequency is the hertz (Hz) (see below).
Fundamental frequency (F0)	The fundamental frequency is the inverse of the period (T0); i.e. F0 = 1/T0. For complex sounds such as speech, F0 will normally correspond to the frequency of the lowest harmonic. It is measured in hertz (see below). The aim of SLT is to increase the fundamental frequency of Parkinsonian speech as this leads to improved intelligibility. See also 'pitch', below.
Fundamental frequency vari- ability	The variation in fundamental frequency (see above) of speech. Measured as the standard deviation of F0 in hertz or semitones (STSD). The aim of SLT is to increase F0 variation and thus decrease the monotonicity of the patient's speech. See also 'pitch'.
Hertz (Hz)	Hertz is the unit of frequency expressed in cycles (sound waves) per second.
Hypophonia	A breathy hoarseness to the speech.



Table 1. Glossary (Continued)	
Intelligibility	Degree of clarity with which utterances are understood by average listeners. It is influenced by ar- ticulation, rate, fluency, vocal quality and intensity (see below).
Intensity (of sound)	The sound power propagating through a unit area of the sound field in a given direction. For example, the sound intensity of a point source radiating spherical waves and of a given sound power, will diminish as the distance from the source is increased, in proportion to the inverse of the square of this distance (1/distance squared). It is a vector quantity since it specifies both a magnitude and direction, therefore direct measurement is not straightforward. Sound intensity has units of watts per square metre, but can also be expressed in decibels (see above). Sound intensity is related to the square of the sound pressure, but the exact relationship depends on the characteristics of the sound field.
Intention-to-treat data analy- sis	Data are analysed according to the randomization allocation, irrespective of protocol violations and withdrawals. Withdrawals, and therefore missing data points, are usually compensated for by using the last observation carried forward. Intention-to-treat analyses are favoured in assessments of effectiveness as they mirror the non-compliance and treatment changes that are likely to occur when the intervention is used in practice and because of the risk of attrition bias when participants are excluded from the analysis.
Loudness	Loudness is usually the subjective impression of the level of a sound. However, in the text of this review we have also mentioned 'objective' loudness. We define this as being loudness measured mechanically (see 'intensity', 'sound pressure level' and 'decibels'). The subjective loudness of a sound is defined as being relative to the perceived loudness of a 1000 Hz tone generating a sound pressure level of 70 dB. Loudness is influenced by frequency, level and waveform shape and is governed by the physiology of the ear. It is measured in units of phons. Typically, an increase in sound pressure level of 10 dB results in a doubling of loudness. However, at low levels of loudness, the increase is more like 6 dB for a corresponding perceived change. Loudness is sometimes also referred to as volume.
Monotonicity	A lack in variation of both loudness (see above) and pitch (see below).
Period (T0)	The length of each sound wave (cycle) in time is called the period of a waveform. It is equal to 1/fre- quency.
Per protocol data analysis	Data are analysed according to what therapy the patients received, rather than according to their randomized allocation. Withdrawals are removed from the analysis. This form of data analysis risks attrition bias.
Phonation	The mechanism of producing sounds with the vocal chords.
Pitch	The perceptual correlate of frequency (see above). Normally, the pitch of a complex sound is a function of its fundamental frequency (see above). Equal steps in pitch are roughly equal to logarithmic steps in amplitude.
Prosody	Prosody is defined as that aspect of spoken language which consists in correct placing of pitch and stress on syllables and words. It is responsible for conveying subtle changes of meaning independently of words or grammatical order. In addition to this semantic role, it makes a major contribution to the emotional content of speech.
Rainbow passage	A reading passage that is phonetically balanced and has all the vowel and consonant sounds present in the English language.
Reference values for sound pressure, sound power and sound intensity (P0)	So that individual quantities can be specified in terms of decibels, default reference values are defined for sound pressure (20x10E-6 pascals), sound power (10E-6 watts) and sound intensity (10E-12 watts per square metre). For other quantities (e.g. voltage) a value of unity is often used implicitly. The reference level for sound pressure (corresponding to 0 dB) was originally set as an approximation to the threshold of human hearing. However this equivalence has since been questioned.



Table 1. Glossary (Continued)

Respiration	Breathing.
Sound pressure and Sound pressure level (SPL)	Sound pressure is the root mean square (r.m.s) variation in pressure from the static value (e.g. the atmospheric pressure) and is measured in pascals. The r.m.s variation in pressure from the static value (e.g. the atmospheric pressure). Sound pressure is measured in pascals, but can be expressed in decibels (see above), 20 log10(sound pressure/20x10E-6) whereupon it is referred to as sound pressure level. Sound pressure is a scalar quantity and is therefore relatively easy to measure: for example, a microphone responds to sound pressure. The reference level for sound pressure (corresponding to 0 dB) was originally set as an approximation to the threshold of human hearing. However, this equivalence has since been questioned.
Volume	Equivalent to loudness (see above).

From Herd 2012; Herd 2012a

APPENDICES

Appendix 1. MEDLINE Ovid Search strategy

- 1. randomized controlled trial.pt.
- 2. controlled clinical trial.pt.
- 3. randomized.ab.
- 4. placebo.ab.
- 5. drug therapy.fs.
- 6. randomly.ab.
- 7. trial.ab.
- 8. groups.ab.

9. or/1-8

- 10. exp animals/ not humans.sh.
- 11. 9 not 10
- 12. exp Parkinson Disease/
- 13. Parkinson\$.mp.

14. 12 or 13

- 15. exp Speech Disorders/
- 16. exp Articulation Disorders/
- 17. exp Voice Disorders/
- 18. motor speech disorder\$.tw.
- 19. exp Speech, Alaryngeal/
- 20. exp Speech, Esophageal/
- 21. exp Speech Therapy/

22. Speech Production Measurement/ or Voice Training/

23. (speech or speak\$ or spoken).tw.

24. (dysarthr\$ or intelligib\$ or dyspros\$ or hypophoni\$ or monoton\$ or phon\$ or presbyphon\$ or dysphon\$).tw.

25. ((voice or loud\$ or vocal\$ or articulat\$ or communicat\$) adj3 (disorder\$ or impair\$ or problem\$ or dysfunction\$ or difficult\$ or train \$)).tw.

26. ((linguistic or dysarthr\$) adj3 (therap\$ or train\$ or rehab\$ or treat\$ or remediat\$ or intervention\$ or pathol\$ or counsel\$ or exercise \$ or task\$ or drill\$)).tw.

27. (SLT or SLP).tw.

- 28. Communication Aids for Disabled/ or Communication Disorders/ or Communication/
- 29. functional therap\$.mp.
- 30. (expiratory muscle strength training or VFE or vocal function exercise\$).mp.
- 31. or/15-30
- 32. 11 and 14 and 31

Note: We applied the RCT filter (see Lefebvre 2021)

Appendix 2. CENTRAL search strategy

#1 MeSH descriptor: [Parkinson Disease] explode all trees

#2 (Parkinson*):ti,ab,kw

#3 #1 or #2

- #4 MeSH descriptor: [Speech Disorders] explode all trees
- #5 MeSH descriptor: [Articulation Disorders] explode all trees
- #6 MeSH descriptor: [Voice Disorders] explode all trees
- #7 MeSH descriptor: [Speech Sound Disorder] explode all trees
- #8 (motor speech disorder*):ti,ab,kw
- #9 MeSH descriptor: [Speech, Alaryngeal] explode all trees
- #10 MeSH descriptor: [Speech, Esophageal] explode all trees
- #11 MeSH descriptor: [Speech Therapy] explode all trees
- #12 MeSH descriptor: [Speech Production Measurement] explode all trees
- #13 MeSH descriptor: [Voice Training] explode all trees
- #14 (speech or speak* or spoken):ti,ab,kw

#15 (dysarthr* or intelligib* or dyspros* or hypophoni* or monoton* or phon* or presbyphon* or dysphon*):ti,ab,kw

#16 ((voice or loud* or vocal* or articulat* or communicat*) NEAR/3 (disorder* or impair* or problem* or dysfunction* or difficult* or train*)):ti,ab,kw

#17 ((linguistic or dysarthr*) NEAR/3 (therap* or train* or rehab* or treat* or remediat* or intervention* or pathol* or counsel* or exercise* or task* or drill*)):ti,ab,kw

#18 (SLT or SLP):ti,ab,kw

#19 MeSH descriptor: [Communication Aids for Disabled] explode all trees

#20 MeSH descriptor: [Communication Disorders] explode all trees

#21 MeSH descriptor: [Communication] explode all trees



#22 (functional therap*):ti,ab,kw

#23 (expiratory muscle strength training or VFE or vocal function exercise*):ti,ab,kw

#24 #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23

#25 #3 and #24

Appendix 3. CINAHL EBSCO (Cumulative Index to Nursing and Allied Health Literature) search strategy

S1 MH randomized controlled trials

- S2 MH double-blind studies
- S3 MH single-blind studies

S4 MH random assignment

S5 MH pretest-posttest design

- S6 MH cluster sample
- S7 TI (randomised OR randomized)
- S8 AB (random*)

S9 TI (trial)

S10 MH (sample size) AND AB (assigned OR allocated OR control)

S11 MH (placebos)

- S12 PT (randomized controlled trial)
- S13 AB (control W5 group)
- S14 MH (crossover design) OR MH (comparative studies)
- S15 AB (cluster W3 RCT)
- S16 MH animals+
- S17 MH (animal studies)
- S18 TI (animal model*)
- S19 S16 OR S17 OR S18
- S20 MH (human)
- S21 S19 NOT S20

S22 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15

- S23 S22 NOT S21
- S24 (MH "Parkinson Disease")
- S25 TI Parkinson* OR AB Parkinson*
- S26 S24 OR S25
- S27 (MH "Speech Disorders+")
- S28 (MH "Articulation Disorders")
- S29 (MH "Voice Disorders+")

S30 TI motor speech disorders OR AB motor speech disorders



S31 (MH "Speech, Alaryngeal+")

S32 (MH "Speech, Esophageal")

S33 (MH "Speech Therapy+")

S34 (MH "Speech Production Measurement+") OR (MH "Voice Therapy+") OR (MH "Speech Rate")

S35 TI (speech or speak* or spoken) OR AB (speech or speak* or spoken)

S36 TI (dysarthr* or intelligib* or dyspros* or hypophoni* or monoton* or phon* or presbyphon* or dysphon*) OR AB (dysarthr* or intelligib* or dyspros* or hypophoni* or monoton* or phon* or dysphon*)

S37 TI ((speech or voice or loud* or speak* or spoken or vocal* or articulat* or communicat*) N3 (disorder* or impair* or problem* or dysfunction* or difficult* or train*)) OR AB ((speech or voice or loud* or speak* or spoken or vocal* or articulat* or communicat*) N3 (disorder* or impair* or problem* or dysfunction or difficult* or train*))

S38 TI ((linguistic or dysarthr*) N3 (therap* or train* or rehab* or treat* or remediat* or intervention* or pathol* or counsel* or exercise* or task* or drill*))) OR AB (((linguistic or dysarthr*) N3 (therap* or train* or rehab* or treat* or remediat* or intervention* or pathol* or counsel* or exercise* or task* or drill*))

S39 TI (SLT or SLP) OR AB (SLT or SLP)

S40 (MH "Communication Aids for Disabled+") OR (MH "Communicative Disorders+")

S41 TI functional therap* OR AB functional therap*

S42 TI (expiratory muscle strength training or VFE or vocal function exercise*) OR AB (expiratory muscle strength training or VFE or vocal function exercise*)

S43 S27 OR S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41 OR S42

S44 S23 AND S26 AND S43

Note: RCT filter from Glanville 2019

CONTRIBUTIONS OF AUTHORS

All authors have contributed to the following International Committee of Medical Journal Editors (ICMJE) criteria:

- 1. substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work;
- 2. drafting the work or revising it critically for important intellectual content;
- 3. final approval of the version to be published; and
- 4. agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

DECLARATIONS OF INTEREST

Pauline Campbell (PC) declared funding from the Heath Technology Assessment Programme, National Institute of Health Research (NIHR).

Scott Rooney (SR): none declared.

Avril Nicoll (AN) declared being employed as a contract researcher on a PDCOMM trial, funded by the NIHR, which may be eligible for inclusion in the review. As part of this role, AN declared that they had received training in one of the trial interventions.

Marian C Brady (MCB) is a speech and language therapist, Fellow of the Royal College of Speech and Language Therapists. MB has declared funding for employment from the Chief Scientist Office. MB has also held research grants from the Heath Technology Assessment Programme, National Institute of Health Research. MB was involved in the Phase 2 randomized controlled trial, Lee Silverman Voice Treatment versus standard NHS Speech and Language Therapy versus control in Parkinson's disease (PD COMM pilot), which may be eligible for inclusion in the review.

Christina Smith (CS): none declared.

Katherine Deane (KD) declared that they were a member of the PD COMM Data Monitoring Committee (ISRCTN: 12421382). KD also declared previous authorship of two relevant Cochrane Reviews (see Herd 2012; Herd 2012a).

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Clare Herd (CH): none declared.

Claire L Tomlinson (CLT): none declared.

Carl E Clarke (CEC): declared that they had previously been on the advisory board for BIAL and Kyowa Kirin Services Ltd.

Catherine M Sackley (CMS): declared employment by King's College London and has held research grants for RCTs. CMS also declared that they were involved in the Phase 2 randomized controlled trial, Lee Silverman Voice Treatment versus standard NHS Speech and Language Therapy versus control in Parkinson's disease (PD COMM pilot), which may be eligible for inclusion in the review.

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