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PD COMM Study

Submission date
18/04/2016

Recruitment status
No longer recruiting

Registration date
18/04/2016

Overall study status
Completed

Last Edited
07/10/2024

Condition category
Nervous System Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Parkinson's disease (PD) is a common movement disorder, affecting approximately 120,000 people in the UK. It is a lifelong condition, which involves the gradual loss of nerve cells (neurons) in a part of the brain called the substantia nigra. These neurons are normally responsible for producing dopamine, a chemical messenger (neurotransmitter) which carries signals around the brain that help to coordinate movement. In people suffering from PD, these neurons gradually die over time, causing the level of dopamine in the brain to gradually fall. As the levels of dopamine become lower, the brain is unable to coordinate movement as effectively, causing abnormal movements such as stiffness, tremor (uncontrollable shaking) and slowness of movement (bradykinesia). Over two thirds of people with PD report having speech-related problems which has a great impact on their lives, leading to increased physical and mental demands during conversation, reduced independence and social withdrawal. Speech and language therapy (SLT) is recommended for people with PD but few patients are able to access it, with a recent Parkinson's UK survey reporting that just 37% of the patients included had received SLT. This may be due to, in part, to the limited scientific evidence of a benefit of SLT for people with PD. Currently two different types of SLT are available in the UK: standard NHS SLT, which normally consists of one hour per week for six to eight weeks; and Lee Silverman Voice Training (LSVT), a more intensive therapy comprising of four sessions per week for four weeks. It is currently unclear if one or both of these treatments are effective or acceptable to people with PD, and if so, whether the benefits continue once the treatments have stopped. The aim of this study is to compare LSVT, traditional NHS SLT and a no therapy in people with PD.

Who can participate?
Adults with PD of unknown cause (idiopathic) who report problems with their speech/voice

What does the study involve?
Participants are randomly allocated to one of three groups. Participants in the first group receive four sessions of LSVT for four weeks. Participants in the second group receive traditional NHS SLT. The frequency of sessions varies but there is typically be one session per week for six to eight weeks. Participants in the third group do not receive any SLT for the duration of the study. Participants in all groups complete a number of questionnaires at the start of the study, and then again by post after 3, 6 and 12 months.

What are the possible benefits and risks of participating?
Participants who receive therapy may find it helpful in improving their speech/voice related problems. There may be a small increased risk of vocal strain or abuse, however this is minimal.

Where is the study run from?
The study is run from the University of Birmingham and takes place in 40 elderly care and neurology units in the UK.
A list of over 40 sites can be found at: https://www.birmingham.ac.uk/research/activity/mds/trials/bctu/trials/pd/PD-COMM/participants/index.aspx

When is the study starting and how long is it expected to run for?
October 2015 to April 2022

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Miss Pui Au
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Contact information

Type(s)
Public

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Scientific

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Additional identifiers

Central Portfolio Management System (CPMS)
11652

Study information

Scientific Title
A multi-centre randomised controlled trial to compare the clinical and cost effectiveness of Lee Silverman Voice Treatment versus standard NHS speech and language therapy versus control in Parkinson’s disease (PD COMM)

Acronym
PD COMM

Study objectives
The aim of the study is to evaluate the effectiveness and cost-effectiveness of two types of speech and language therapy (SLT) compared to no treatment (control) for people with Parkinson’s disease (PD) who have self-reported problems with their speech or voice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands - Coventry & Warwickshire Research Ethics Committee, 17/12/2015, ref: 15/WM /0443

Study design
Phase III multicentre three-arm unblinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Parkinson's disease

Interventions
Patient will be randomised to one of three study arms.

Group 1: Participants take part in four one-hour sessions of LSVT with a therapist per week and daily home based practice of varying length for four weeks. The focus of LSVT is to “think loud”; improving phonation and vocal loudness through better vocal fold adduction. The intervention will replicate the dose and content recommended by the originators and delivered in clinical practice and previous “standard” LSVT trials. The LSVT intervention consists of four 50 minute sessions per week delivered over four weeks. Each session follows a similar structure: 25 minutes of repeated and intensive maximum effort drills, and 25 minutes of high effort speech production task. Participants will also be set 5 to 10 minutes of home-based practice tasks on

treatment days, and up to 30 minutes of home-based practice tasks on non-treatment days. The content of the intervention will consist of repeated repetitions of sustained “ah” phonation, maximum fundamental frequency range high and low pitch glides, and functional sentence repetition for the first half of each session, and exercises using speech hierarchy that progresses throughout the duration of the treatment programme (single word, phrases, sentences, paragraph reading, conversation) during the second half of the sessions. Throughout all of the sessions, the focus of the intervention will be to “think loud”, maintaining the vocal loudness produced during vowel phonation throughout all other task during the treatment.

Group 2: Participants will be prescribed NHS SLT as per usual local practice, this is likely to entail a one hour session per week over a 6 to 8 week period. Treatment will be individualised to suit each participant’s needs and local practice. The standard SLT may include interventions aimed at rehabilitating the underlying impairments of dysarthria, behavioural compensatory strategies and augmentative and alternative communication (ACC) strategies aimed at improving communicative function and participation. The participant’s family/ carer(s) will be involved as appropriate.
Treatments targeted at impairment level may include exercises focused on improving capacity, control and co-ordination of respiration, techniques for improving phonation intensity and co-ordination with respiration (but not LSVT), and exercises to improve the range, strength and speed of the articulatory muscles.
Behavioural therapy may include interventions aimed at reducing prosodic abnormality such as exercises targeting pitch, intonation, stress patterns, and volume variation, and techniques to address the overall rate of speech including the use of therapeutic devices such as pacing boards. AAC strategies such as topic and alphabet supplementation through communication books and boards may be employed, along with AAC devices such as voice amplifiers, delayed auditory feedback systems, and masking devices. The practice of pitch limiting voice treatment may also be utilised within the standard SLT intervention. The above methods may include techniques used in LSVT e.g. vocal intensity exercises, but will be distinct by the individualised treatment, other SLT strategies, intensity of delivery and dose.
Dose will be determined by the participant’s individual needs, but the duration is unlikely to exceed twelve weeks of treatment. It is most likely to reflect the median dose as reported in a survey of current UK SLT practice for PD of 6 sessions delivered over 42 days. The PD COMM Pilot study found the median dose to be 6 sessions (range 1 – 12) over an average of 9.6 weeks (standard deviation 6.1 weeks).

Group 3: Participants allocated to no therapy, your general practitioner or hospital specialist to defer arranging any SLT until 12 months after you join the trial. Participant questionnaires will be completed at Baseline, 3, 6 and 12 month time points.

All participants will be expected to stay in the study for its 12 month duration. Participant questionnaires will be completed at Baseline, 3, 6 and 12 month time points. Participants randomised to therapy will expect to have received all therapy sessions by three months.

Carers of the main recruit can also join the study, if they have agreed to join, we would expect a short quality of life questionnaire to be completed at baseline, 3, 6 and 12 month time points.

Intervention Type
Other

Primary outcome(s)

Current primary outcome measure as of 01/11/2019:
The functional, physical and emotional impacts of a voice disorder on a patient's quality of life is measured using the Voice Handicap Index (VHI) at 3 months

Previous primary outcome measure:
The functional, physical and emotional impacts of a voice disorder on a patient's quality of life is measured using the Voice Handicap Index (VHI) at baseline 3, 6 and 12 months

Key secondary outcome(s))
Current secondary outcome measures as of 08/04/2019:
1. Subscales of the VHI: emotional, functional, and physical at baseline and 3, 6 & 12 months;
2. Parkinson's Disease Questionnaire 39 (PDQ-39) summary index and the eight individual dimensions of the PDQ-39: mobility, activities of daily living, emotional well-being, stigma, social support, cognition, communication and bodily discomfort at baseline and 3, 6 & 12 months;
3. Questionnaire on Acquired Speech Disorders (QASD) at baseline and 3, 6 & 12 months;
4. EuroQol-5D-5L and visual analogue scale at baseline and 3, 6 & 12 month;
5. ICEpop CAPability measure for Older people (ICECAP-O) at baseline and 3, 6 & 12 months;
6. Hoehn and Yahr stage at baseline and 12 months;
7. Adverse and Serious Adverse Events;
8. Parkinson's Disease Questionnaire - Carers (PDQ-Carer) at baseline and 3, 6 & 12 months;

Previous secondary outcome measures:
1. Self-completion PRO designed to address aspects of functioning and well-being for those affected by Parkinson's disease is measured using the Parkinsons Disease Questionnaire 39 (PDQ-39) at baseline 3, 6 and 12 months
2. The impact that the voice disorder is having on the patient's voice-related quality of life is measured using the Voice related Quality of Life Scale (V-RQoL) is measured at baseline 3, 6 and 12 months
3. Evaluate the speech difficulties as perceived by individuals with dysarthria is measured using the Living with Dysarthria questionnaire (LwD) is measured at baseline 3, 6 and 12 months
4. Quality of Life measure is measured using the EQ-5D - Euroqol is measured at baseline 3, 6 and 12 months
5. Measure of capability in older people for use in economic evaluation is measured using the ICECAP-O (ICEpop CAPability measure for Older people) at baseline 3, 6 and 12 months
6. Resource Usage is measured using the resource usage questionnaire at baseline 3, 6 and 12 months
7. Carers Quality of Life is measured using the Parkinson's Disease Carers' Questionnaire at baseline 3, 6 and 12 months

Completion date
29/04/2022

Eligibility

Key inclusion criteria
Current inclusion criteria as of 08/04/2019:
1. People who have idiopathic PD defined by the UK PDS Brain Bank Criteria. These criteria are in standard use throughout the NHS in the UK and supported by the NICE guidelines
2. Person with PD or carer report problems with their speech or voice when asked

Previous inclusion criteria:
1. People who have idiopathic PD defined by the UK PDS Brain Bank Criteria. These criteria are in standard use throughout the NHS in the UK and supported by the NICE guidelines
2. Person with PD or carer report problems with their speech or voice when asked
3. Aged 18 years and over

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
388

Key exclusion criteria
Current participant exclusion criteria as of 08/04/2019:
1. Dementia as usually defined clinically by the person with PD's physician
2. Evidence of laryngeal pathology including vocal nodules or a history of vocal strain or previous laryngeal surgery within their medical records or from discussions with client, as LSVT is not appropriate for this group
3. Received SLT for PD speech or voice related problems in the past 2 years
NB: Individual involvement in the trial is 12 months, but participants randomised to the control group can be referred for SLT at the end of trial (e.g. after 12 months) or, if it becomes medically necessary during the trial (e.g. within 12 months of randomisation).

Previous participant exclusion criteria:
1. Dementia as usually defined clinically by the person with PD's physician
2. Evidence of laryngeal pathology including vocal nodules or a history of vocal strain or previous laryngeal surgery within their medical records or from discussions with client, as LSVT is not appropriate for this group
3. Received SLT for PD speech or voice related problems in the past 2 years
4. The investigator is certain that the person with PD will not require SLT during the 12 months of the trial. Individual involvement in the trial is 12 months, but participants randomised to the deferred treatment group can be referred for therapy after 12 months

Date of first enrolment
01/05/2016

Date of final enrolment
30/11/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Birmingham
Neuroscience Trials Office
Birmingham Clinical Trials Unit
Public Health Building
School of Health & Population Sciences
Birmingham
United Kingdom
B15 2TT

Study participating centre
Recruiting from ~40 centres nationally, please go to www.birmingham.ac.uk/PDCOMM for the trial centres
United Kingdom
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Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Requests for data generated during this study will be considered by Birmingham Clinical Trials Unit (BCTU) (via bctudatashare@contacts.bham.ac.uk). Data will typically be available within 6 months after the primary publication unless it is not possible to share the data (for example: the trial results are to be used as part of a regulatory submission, the release of the data is subject to the approval of a third party who withholds their consent, or BCTU is not the controller of the data).

Only scientifically sound proposals from appropriately qualified Research Groups will be considered for data sharing. The request will be reviewed by the BCTU Data Sharing Committee in discussion with the Chief Investigator and, where appropriate (or in absence of the Chief Investigator) any of the following: the Trial Sponsor, the relevant Trial Management Group (TMG), and independent Trial Steering Committee (TSC).

A formal Data Sharing Agreement (DSA) may be required between respective organisations once the release of the data is approved and before data can be released. Data will be fully de-identified (anonymised) unless the DSA covers the transfer of patient identifiable information. Any data transfer will use a secure and encrypted method.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		10/07/2024	11/07/2024	Yes	No
Results article		01/10/2024	07/10/2024	Yes	No
Protocol article	protocol	29/08/2017		Yes	No
Protocol article	protocol	27/05/2020	29/05/2020	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes