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A pilot assessor-blinded randomised controlled trial of Lee Silverman Voice Treatment versus standard NHS Speech and Language Therapy in Parkinson's Disease

Submission date
22/03/2012

Recruitment status
No longer recruiting

Registration date
22/03/2012

Overall study status
Completed

Last Edited
30/01/2018

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11652

Study information

Scientific Title
A pilot assessor-blinded randomised controlled trial of Lee Silverman Voice Treatment versus standard NHS Speech and Language Therapy in Parkinson's Disease

Acronym
PD COMM Pilot

Study objectives
Parkinsons disease (PD) is a common movement disorder, affecting approximately 120,000 people in the UK. 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 advocated for people with PD but current provision is low, with a recent Parkinsons UK survey reporting that just 37% of the patients included had received SLT. This may be attributed, in part, to the limited scientific evidence of a benefit of SLT for people with PD. Currently 2 different types of SLT are available in the UK: standard NHS SLT, typically consisting of 1 hour per week for 6 - 8 weeks and Lee Silverman Voice Training (LSVT), a more intensive therapy comprising of 4 sessions per week for 4 weeks. From the literature it is unclear if one or both of these treatments is effective or acceptable to people with PD, and if there is a benefit whether it continues once the treatments have stopped.

We propose a pilot study in which LSVT, traditional NHS SLT and a no intervention control will be compared in people with PD. People with PD will be randomly assigned to one of the 3 groups and their communication effectiveness and quality of life will be compared before and after treatment, and 6 and 12 (Participant forms only) months later to see if any benefit remains. This pilot trial will be used to assess the feasibility of running a larger trial with enough participants to determine if either or both treatments are effective. The pilot will test recruitment, compliance, outcome measures and effect size. In light of the findings, the design of the study may be refined for the large scale trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC 22/11/2011, ref: 11/WM/0343

Study design
Randomised interventional treatment

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
Patient will be randomised between Standard NHS SLT versus Lee Silverman Voice Training versus no treatment.

Patients who recieve therapy should do so within one month of randomisation and have their course finished by three months. Followed up at 12 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
VHI - Voice Handicap Index measured at baseline, 3 months, 6 months & 12 months.

Secondary outcome measures
1. AIDS - Assessment of Intelligibility of Dysarthic Speech measured at baseline, 3 months, 6 months
2. Comprehension Assessment measured at baseline, 3 months, 6 months
3. EQ-5D - Euroqol measured at baseline, 3 months, 6 months & 12 months
4. ICECAP-O measured at baseline, 3 months, 6 months & 12 months
5. LwD - Living with Dysarthia questionnaire measured at baseline, 3 months, 6 months & 12 months
7. Parkinson's Disease Carers' Questionnaire Quality of Life Assessment measured at baseline, 3 months, 6 months & 12 months
8. PDQ-39 - Parkinsons Disease Questionnaire 39 measured at baseline, 3 months, 6 months & 12 months
9. Resource Usage measured at 3 months, 6 months & 12 months
10. Vocal Loudness measured at baseline, 3 months, 6 months
11. V-RQoL - Voice related Quality of Life Scale measured at baseline, 3 months, 6 months & 12 months.

Overall study start date
01/04/2012

Completion date
31/10/2013

Eligibility

Key inclusion criteria
1. Idiopathic Parkinsons disease defined by the UK PDS Brain Bank Criteria.
These criteria are in standard use throughout the NHS in the UK and were supported by the NICE guidelines.
2. PD patients who have self or carer-reported problems when asked:
"Do you have any problems with your speech or voice?" by their physician or PD nurse specialist
3. Male and female participants

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria
1. Dementia as usually defined clinically by the patients physician. From our experience in PD MED, some patients with moderate to severe dementia have difficulty in completing self-assessment forms
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 in the last 2 year
4. The investigator is certain the person will need SLT within 6 months

Date of first enrolment
01/04/2012

Date of final enrolment
31/10/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Birmingham
Birmingham
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B15 2TT

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
Early Drug Development Centre for Clinical Haematology
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Sponsor type
University/education

Website
http://www.birmingham.ac.uk/

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Charity

Funder Name
Dunhill Medical Trust

Alternative Name(s)
The Dunhill Medical Trust, DMT

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	07/06/2014		Yes	No
Results article	results	10/01/2018		Yes	No