

PD COMM Pilot Study

PD COMM Pilot study is a randomised controlled trial currently in follow up after recruitment is closed.

Its aim is to evaluate the feasibility of a full scale trial on the effectiveness and cost-effectiveness of speech and language therapy for people with Parkinson's.

Design

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PD COMM pilot is a pilot study to evaluate the feasibility of a full scale trial on the effectiveness and cost-effectiveness of two types of speech and language therapy (SLT) for people with Parkinson's disease (PD) who have self reported problems with voice or speech. Participants will be randomised to Lee Silverman Voice Treatment (LSVT), standard NHS SLT or control (where SLT will be deferred for at least 6 months).

The trial will assess the feasibility and acceptability of the different types of SLT and inform the trial design of a full scale phase III trial including: patient eligibility, recruitment and retention, patient acceptability, sample size calculation, suitability of outcome measures and pilot health economic evaluation.

The trial will necessarily be open label due to the nature of the intervention although assessors of recorded speech will be blinded to treatment.

Aim of Study

The trial will evaluate the feasibility of a clinical trial of two types of SLT versus control for people with PD and will inform the future trial design of a large phase III trial.

Setting

Community-based therapy in 10 elderly care and neurology units in the UK.

Target population

Patients with PD of any age who report problems with voice or speech.

Intervention

SLT will be administered as per local practice (either in the community or in an out-patient setting). LSVT will be administered in 4 sessions per week for 4 weeks of pre-determined content with homework. NHS SLT will have more variability but typically will be 1 session per week for 6 – 8 weeks of varying content as determined by participant need.

Training will be provided for trial therapists to comply with trial uniformity of practice.

Therapists providing the intervention will complete intervention record forms, as used in previous complex intervention trials, to allow monitoring of intervention delivery.

Measurement of outcomes and costs

Outcome measures will be the self-reported Voice Handicap Index (VHI) as intelligibility is the target of the intervention; Assessment of Intelligibility of Dysarthric Speech (AIDS); vocal loudness; comprehension assessments; Parkinson's Disease Questionnaire-39 (PDQ-39); Voice Related Quality of Life Scale (V-RQoL); Living with Dysarthria questionnaire (LwD); EuroQoL (EQ-5D); ICECAP-0; Resource Usage; adverse events and carer quality of life (Parkinson's Disease Carers' Quality of Life Questionnaire).

Assessments will be completed before randomisation and by post at 3, 6 and 12 months after randomisation.