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)

https://neurodegenerationresearch.eu/survey/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-parkinsons/

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Country

United Kingdom

Title of project or programme

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)

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NIHR

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01/12/2015

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4.4

The project/programme is most relevant to:

Parkinson's disease & PD-related disorders

Keywords

Research Abstract

PHASE III PRAGMATIC MULTICENTRE 3 GROUP RCT with economic evaluation. The randomisation programme will use a minimisation procedure (with a random element) with the following variables: age, disease severity (as estimated by Hoehn and Yahr staging), and severity of speech impairment measured by the Voice Handicap Index. Analysis will be by intention-to-treat. SETTING: Patients will be recruited from ~40 neurology and elderly care outpatient clinics nationwide, building on the 11 pilot sites (Including; City Hospital, Birmingham; Fairfield Hospital, Bury, Royal Devon and Exeter Hospital, Devon, Southern General Hospital, Glasgow). SLT interventions will be delivered within both outpatient and community-based settings as per local practice. Over forty centres from our PD trial network have expressed an interest in taking part. TARGET POPULATION: Patients with a confirmed diagnosis of idiopathic PD (using the UK Parkinson's UK (PUK) Brain Bank Criteria), and self or carer-reported problems with speech when asked the simple question "Do you have any problems with your speech or voice?" Participants should not have had SLT within the last year or have a history of laryngeal pathology or surgery. HEALTH TECHNOLOGIES BEING ASSESSED: LSVT: Therapists are formally trained in this technique and a list of practitioners is held. The treatment focuses on improving intelligibility through vocal loudness. Four 50 minute sessions are delivered each week over 4 weeks and daily home practice is completed. Standard UK NHS SLT: This includes the provision of exercises, techniques and therapeutic devices targeting prosody, respiratory capacity and control, and the articulatory muscles. Dose will be determined by the individuals' needs, but is most likely to reflect the dose reported in the pilot and a survey of current UK SLT practice for PD by Miller et al (2010) of 6-8 sessions over 6-8 weeks. Control: This group will continue with their standard PD care (avoiding benign neglect) and will not be referred for SLT within the 12 months of the study. A process evaluation will be carried out. MEASUREMENT OF COSTS AND OUTCOMES: Baseline characteristics: Age/ date of birth, gender, date of PD diagnosis, Hoehn and Yahr stage and current medication will be recorded by the referring physician. Our pilot study has informed the final choice of outcomes measures for the main trial. Measures will be collected at baseline, 3 (to allow for the varying intervention lengths), 6 and 12 months from randomisation. The primary outcome measure will be the self-completed Voice Handicap Index (VHI) at 3 months. Secondary measures will include; PDQ-39 & Voice-Related QoL scale for the patient, PDQ-39 for the carer. Resource use, EQ5D and ICECAP O for health economic evaluation will be collected at 3, 6 and 12 months.

Lay Summary

Further information available at:

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Investments > €500k

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United Kingdom

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Parkinson's disease & PD-related disorders

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