

PD COMM TRIAL SCHEMA



Eligibility

Inclusion criteria

- People who have idiopathic PD defined by the UK PDS Brain Bank Criteria (Appendix 1 of the protocol).
- Person with PD or carer report problems with their speech or voice when asked.

Exclusion criteria

- Dementia as usually defined clinically by the person with PD's physician.
- 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.
- Received SLT for PD speech or voice related problems in the past 2 years.

Randomisation

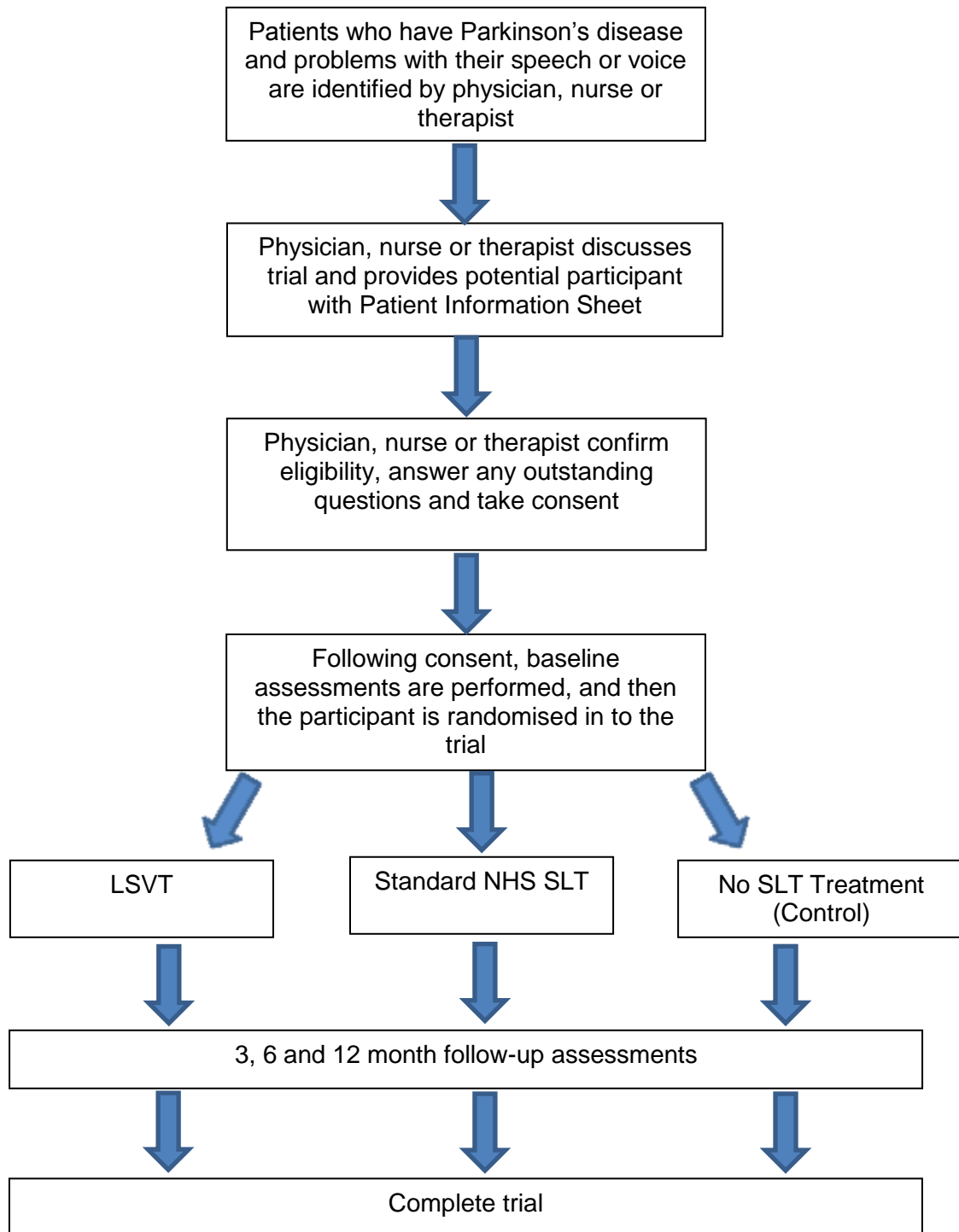
- Obtain participant's written informed consent.
- Administer baseline assessments and participant questionnaires.
- Go to the web-based randomisation service www.trials.bham.ac.uk/PDCOMMTrial and complete all the questions (as in the randomisation notepad) to randomise the participant. (If website is not available, call 0800 953 0274 during working hours).
- Receive treatment allocation and a participant trial number
- Send completed documents to the BCTU

Treatment

- The randomiser informs participant of their allocation, informs the SLT of allocation if allocated to one of the active treatment arm (LSVT or standard NHS therapy) and arranges for letter to be sent to participant's GP
- The therapist records in detail the treatment administered on the study therapy initial interview log and treatment form. Participant record any speech exercises completed at home on the home-based therapy diaries.

Follow up

- The majority of assessments will be participant/carers based, with postal questionnaires sent from BCTU at 3, 6 and 12 months.
- Clinicians complete a 12 month Clinical Assessment form or the Exit Form if participant deceased or withdrawn.
- Only targeted Adverse Events and Serious Adverse Events are being collected such as vocal strain requiring a hospitalisation or referral to outpatient clinic. Refer to section 9.2 of the protocol.



For queries, contact the PD COMM Trial office on 0121 415 9126/7/8/9