[Optional UoB logo]/[Hospital logo]

PD COMM

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

Carer Information Sheet

Local PI:	[TBC]
Local Nurse:	[TBC]
Local PALS or equivalent service:	[TBC]
BCTU:	[insert Team Leader name and contact details]
	[insert Trial Manager name and contact details]

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CARER INFORMATION SHEET

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

What is the purpose of the study?

We want to know whether speech and language therapy (SLT) helps people with speech or voice difficulties as a result of their Parkinson's disease. Speech and language therapy aims to maximise their ability to communicate within any limitations imposed by their Parkinson's disease (PD).

Currently there is little evidence as to whether SLT benefits people with Parkinson's disease. Two different types of SLT are currently offered by the NHS for people with Parkinson's: standard NHS SLT or Lee Silverman Voice Treatment (LSVT).

The study will determine the whether SLT is effective in treating communication difficulties in people with PD. It will also compare the two different types of SLT to see which approach is most effective. We also want to know if any benefits of SLT seen persist after people have finished their therapy? Once we have completed this study we will be able to use the results to say what is the best way SLT can help PD patients.

Why have I been asked?

The trial will include at least 546 participants with PD and their carers at 40 hospitals throughout the United Kingdom.

We are asking you to take part in the study because you are the main carer for someone with PD who has been asked to take part in the PD COMM trial. We would also like to find out if an effective treatment for SLT would affect your quality of life.

Do I have to take part?

No - It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care the person you care for will receive.

What will happen to me if I take part?

We want to find out whether giving the person with PD you care for SLT affects your own quality of life. We will do this by asking you to fill in quality of life questionnaires before the trial begins, then we will post the same questionnaire to you to fill in at home 3, 6 and 12 months after you enter the study. You will be asked to complete these, then post them back to us in the freepost envelope we will send the participant.

What are the possible disadvantages and risks of taking part?

We do not anticipate any disadvantages or risks in taking part.

What are the possible benefits of taking part?

Although you may not benefit directly from taking part, the information we get from this study may help us to look after future people with PD and their carers better.

Will my taking part in this study be kept confidential?

If you decide to take part in PD COMM, all information collected about you during the course of the trial will be kept strictly confidential in the same way as all of your other medical records. Information from the questionnaires you complete will be sent by yourself to the PD COMM Study Office at the University of Birmingham Clinical Trials Unit (BCTU), on paper, where it will be securely stored under the provisions of the

General Data Protection Regulation and Data Protection Act 2018. This will include a signed copy of your Consent Form. Your name and address will also be given to dedicated staff at the BCTU within the University of Birmingham when you first enter the study, as we will need to send Quality of Life questionnaires to your home address. As we may contact you by post or telephone to ask you to complete questionnaires, we will ask you to give us your permission to do so.

We would store this data on a secure, password-controlled database with access given to only a small number of delegated study staff. This information will be strictly confidential and your personal identifiers (ie name, address, date of birth, telephone number) will only be available to core staff involved in this trial and employed by University of Birmingham. In order to help with analysis of your trial data, some of your data may be passed on to other academic third parties (Kings College London, University College London, Bangor University and Glasgow Caledonian University). Data that is passed on to these parties will have your personal identifiers removed and instead you will only be identifiable by a trial number allocated to you. It is also possible that in the future, other third parties may request access to the trial data (a typical part of research) – we will share you data with them. Regardless of who your data is shared with, we will not provide your name, address, date of birth or telephone number and all parties will have a duty of confidentiality to you as a research participant and will adhere to the same rules and regulations as the BCTU.

Your trial data may be inspected by authorised individuals from the BCTU or from a regulatory authority. The purpose of this is to check that the study is being carried out correctly. All those associated with the study will have a duty of confidentiality to you as a research participant. In line with Good Clinical Practice, at the end of the study, the data will need to be securely archived (stored) for at least 5 years (but ideally not less than 25 years). Arrangements for confidential destruction will then be made.

All information collected in the study will remain strictly confidential in the same way as your other medical records. The information will be put into a computer and analysed, but you will not be identified when the results are reported. Information that you provide about your quality of life will be sent to the Neurosciences Trials Study Office at the University of Birmingham Clinical Trials Unit, on paper and

electronically, where it will be securely stored under the provisions of the General Data Protection Regulation and Data Protection Act 2018.

What will happen to the results of the research study?

The results of the study will be published in a medical journal after the study has been completed, but you will not be identified in any report or publication.

Who is organising and funding the research?

The study is being funded by the National Institute of Health Research Health Technology Assessment programme.

The study has been approved by National Research Ethics Committees and your partner's hospital's Research and Development Department.

The study is being organised and managed at the University of Birmingham by the Birmingham Clinical Trials Unit (BCTU).

Contact for Further Information

Should you want further information about the study please contact: [TBC]

If you decide to take part in this study, you will be given a copy of this information sheet and a signed consent form to keep.

Thank you for taking the time to read this information sheet

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