[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

Patient Information Sheet

Local PI:	[TBC]
Local Nurse or Coordinator:	[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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PARTICIPANT 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. Speech and language therapy aims to maximise your ability to communicate within any limitations imposed by your Parkinson's.

Currently there is little evidence as to whether SLT benefits people with Parkinson's. 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).

This study will determine whether SLT is effective in treating communication difficulties in people with Parkinson's. 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 continue 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 people with Parkinson's .

Why have I been asked?

The trial will recruit 546 people with Parkinson's at hospitals throughout the United Kingdom.

We are asking you to take part in the study because you have Parkinson's, you have reported some speech or voice problems and you may potentially benefit from SLT. You may also have indicated to the charity Parkinson's UK that you are willing to take part in research.

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 you will be asked to sign an informed consent form. If you do decide to take part, you are still free to withdraw at any time and without giving a reason, though it would be very helpful if you would give us a reason for withdrawing from the study. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

Before you decide to take part, please read carefully the rest of this leaflet. If you think your partner/ carer might be interested in giving their views too, please show it to them as well. If you have any unanswered questions, please ask the research team member (usually your Parkinson's nurse specialist).

What will happen to me if I take part?

This is what is called a randomised study. Sometimes, because we do not know which way of treating patients is best, we need to make comparisons of different treatment options. You will be put into 1 of 3 groups. The group you are selected to participate in will be decided by a computer at random. Participants in each group then have a different treatment and these are compared. You will either receive:

(i) Standard National Health Service (NHS) SLT treatment, **or**

(ii) a specific SLT called LSVT, **or**

(iii) you will have no SLT (for your speech) until twelve months after you join the study.

This means that you have a 2 in 3 chance of receiving therapy, and a 1 in 3 chance of not receiving therapy during the first 12 months of the trial. It is important that you understand and accept this risk. There will also be some demands on your time which are described below.

If you are prepared to go ahead and take part in the study, you will be asked to sign an informed consent form.

You will then be asked to complete the study questionnaires. There are up to seven brief questionnaires and up to two brief questionnaires for your carer if they choose to join the trial. The questionnaires are easy to do and have been used in Parkinson's studies and other conditions for many years. It will take around 20 minutes for you to

complete all of these questionnaires. The same questionnaires will be repeated at 3, 6 and 12 months after joining the trial. These will be sent to you to fill in at home by the PD COMM trial office at the University of Birmingham Clinical Trials Unit (BCTU). You will be asked to complete these, and then post them back to BCTU in the freepost envelope they will send you. Your clinician will also provide information to the PD COMM trial team on your health when you enter the trial and from your routine clinic appointment 12 months later.

If you are allocated to one of the two SLT treatment groups, then the research staff (usually your Parkinson's Nurse) will arrange for you to see a speech and language therapist. This will be by your usual provider – but, depending on local practice, may be at a hospital different from where you were randomised. If you are allocated standard NHS SLT, your treatment will be tailored to your personal requirements according to local practice, typically involving six to eight sessions over eight weeks. If you are allocated to LSVT, you will receive sixteen one-hour treatment sessions over 4 weeks, focusing on increasing vocal loudness. The BCTU will be collecting copies of your therapy notes that relate to this study only. These therapy notes will have your name, address, date of birth, telephone number, NHS number and hospital number removed and replaced with a trial number. You will not be affected by this as they will be collected directly from your participating service. You will be asked to complete a brief diary on how much time you spend on home-based practice accompanying your SLT.

If you are allocated to no therapy, we will ask your general practitioner or hospital specialist to defer arranging any SLT until 12 months after you join the trial, unless it becomes medically necessary.

Should you consent to take part in the PD COMM study, you will be asked to indicate if you are happy to be contacted to take part in an interview about your involvement in PD COMM. If you are, the University of Bangor team may contact you to see if you wish to be involved in a face to face interview lasting no longer than 30 minutes, at a time, date and place of your convenience. The interviews are optional – you can participate in the trial even if you do not wish to be interviewed. The Interviews will be confidential and you will not be personally identified. Should you indicate interest in taking part in the interview, a separate Patient Information Sheet with further information will be provided.

What are the possible disadvantages and risks of taking part?

We do not anticipate any disadvantages or risks in taking part. For those who receive therapy, there may be a small increased risk of vocal strain during therapy. Your therapists are trained to minimise this risk by carefully treating you and monitoring your progress.

What are the possible benefits of taking part?

We hope that those receiving therapy of either type find it helpful. For all participants although you may not benefit directly from taking part, the information we get from this study may help us to look after patients with Parkinson's better in the future.

What if something goes wrong?

We do not anticipate that anything will go wrong. We will of course take great care that nothing goes wrong, but if you are harmed by taking part in this research you should understand that there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action, but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way that you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you: ask to speak to the complaints manager of the hospital.

If you have a concern about any aspect of this study, you should ask to speak to the researcher (TBC) who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can contact your local Patient Advice and Liaison Services (PALS) group or local equivalent group (TBC).

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 about you, your Parkinson's and progress will be sent by your doctors to the PD COMM Study Office at the University of Birmingham Clinical Trials Unit (BCTU), on paper and electronically, 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 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 asking about your progress, we will ask you to give us your permission to do so. If you agree to it, your GP, and the other doctors involved in your clinical care, will be notified of your participation in the study and kept informed of your progress, unless you request otherwise.

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, NHS number and hospital 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 your 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.

If you indicate on the consent form that you are happy to be contacted to take part in an interview, some of your trial data, including your name, address, telephone number and treating hospital may be shared with Bangor University. This is so Bangor University can decide whether to select you to discuss further about taking part in an interview, and so that they can contact you to do this. Again, Bangor University 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 relevant medical records and 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 about your Parkinson's and progress will be sent by your doctors to the PD COMM Trial Office at the University of Birmingham Clinical Trials Unit (BCTU), on paper and electronically, where it will be securely stored under the provisions of the General Data Protection Regulation and Data Protection Act 2018.

We would also like your permission to tell your GP that you are taking part in the study. You may still take part in the study if you do not wish us to contact your GP.

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. People with Parkinson's and their carers are part of the study team. They will help us write up our findings in ways that are understandable to everyone and share this information with the wider Parkinson's community.

What happens if I get too unwell to continue?

If you become unable to continue you will be withdrawn from the study and we will not send you any further questionnaires. We will keep the information you gave us before you became unable to continue and it will be used in the results of the study.

Who is organising and funding the research?

The PD COMM trial is being funded by the National Institute for Health Research Health Technology Assessment programme (NIHR HTA).

The PD COMM trial has been approved by National Research Ethics Committees and your 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).

Who has looked at the research?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, well-being and dignity. This study has been reviewed and approved by Coventry and Warwick Research Ethics Committee.

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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Department of Health disclaimer: The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.