

*[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**

### **Information Sheet for Participants taking part in Interviews**



Local PI: [TBC]

Local Nurse or Coordinator: [TBC]

Local PALS or equivalent service: [TBC]

BCTU: Cally Rick (0121) 415 9129

Max Hughes (0121) 415 9127

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## **PARTICIPANT INFORMATION SHEET**

You are being invited to take part in an interview about your experience of the PD COMM study. Before you decide it is important for you to understand why the interview 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 this part of the PD COMM trial?**

This part of the PD COMM trial wants to explore your views and your experiences regarding your involvement in the trial. We want to know your opinions so that we can understand better the results from the main trial. We also want to know if there is something that you think we should have done differently.

### **Why have I been invited to take part in this interview?**

You have been invited to take part in this part of the study because you have agreed to be a participant in the PD COMM trial.

### **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 a 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 not take part in this interview will not affect your involvement in the PD COMM trial. You can participate in the trial even if you do not wish to be interviewed.

## **What will I have to do?**

As part of the study, we will ask you to share your experiences and your views about your involvement in the PD COMM study. This will involve a phone or face to face interview lasting no more than 30 minutes at a time, date and place of your convenience. You will be free to omit any questions that you do not wish to answer and you can stop the interview at any point. The interviews will be confidential and you will not be personally identified.

## **What are the possible disadvantages and risks of taking part?**

You should not experience any ill effects from taking part in this interview. However, during the course of the interview, you may discuss sensitive issues as you reflect on your personal experiences. If you feel upset and wish the interview to stop, please tell the researcher. You can stop the interview at any time.

## **What are the possible benefits of taking part?**

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 disease better in the future.

## **What if something goes wrong?**

We do not anticipate that anything will go wrong. 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 interview, you should ask to speak to the researcher (Patricia Masterson Algar – contact details below) who will do their best to answer your questions.

## **Will my taking part in this study be kept confidential?**

All information collected in the interview will remain strictly confidential. The data will be held by Bangor University and will be securely stored under the provisions of the 1998 Data Protection Act. All the consent forms and any other documents bearing patient identifiable information will be stored in locked cabinets on the university

premises to which only the researcher will have the key. The interview recordings will be downloaded and saved on the Bangor University secure server before being erased from the recorder. Transcriptions will not contain any identifiable information. All computer files (e.g. Excel spreadsheet) with identifiable information (participant contact details) will be encrypted and password protected and will be saved in the university server with access limited to appropriate persons. Only the researcher and the designated transcriber will have access to the recordings as well as transcriptions.

### **What will happen to the results of the research study?**

The results obtained from this interview data may be published in scientific papers, but your name will not appear in any public document, nor will the results be published in a form that would make it possible for you to be identified.

### **Who is organising and funding the research?**

The PD COMM trial is being funded by the National Institute of 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.

This part of the study involving an interview is being carried out by researchers at Bangor University 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:

Patricia Masterson Algar  
School of Healthcare Sciences  
Bangor University  
LL57 2EF  
Tel: 01248 383129  
Email: [p.m.algar@bangor.ac.uk](mailto:p.m.algar@bangor.ac.uk)

If you decide to take part in this interview, 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

## **Funding acknowledgement**

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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.