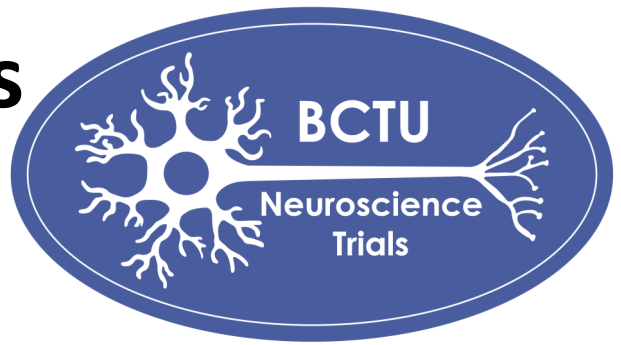


Neuroscience Trials Newsletter

From the Birmingham Clinical Trials Unit
June 2016



June 2016 edition—Lauren Genders

Hello everyone and welcome to another newsletter from the Neurosciences Trials team at BCTU. You are about to hear just what a busy 6 months we have had since we last sent out our newsletter!

If you look below we can now finally give you information regarding the upcoming PD COMM trial.

In March we had our joint collaborators and PD COMM Launch meeting at the Council Houses in Birmingham. We certainly enjoyed the



A chilly but sunny Collaborators' meeting

day, and we hope all of you who were able to come did too. Please turn to page 2 for a brief overview of the day. Then on page 3 Francis gives some information about the HES and ONS data we use in the PD MED. Finally as normal a brief update on the other trials.



PD COMM Trial

In the last couple of newsletters we have been teasing you with information about the PD COMM study. This is the full scale trial after having completed the pilot. Since our last newsletter so much has happened. The NIHR HTA (National Institute for Health Research, Health Technology Assessment) has agreed the final trial design and we have ethical approval.

The trial will be looking into the effectiveness and cost-effectiveness of speech and language therapy (SLT) for people with Parkinson's. Professor Cath Sackley is our Chief Investigator and Professor Carl Clarke is the clinical lead; rounding out the team leads are Professor Marian Brady and Dr Christina Smith as our lead speech and language therapists. The trial will be run by the Neuroscience trial team here at the BCTU.

Currently in the UK, there is no national standard provision of SLT to people with PD who report speech or vocal difficulties. An alternative to the local standard NHS SLT is Lee Silverman Voice Training (LSVT) – an intensive 4 week programme of impairment based therapy. However, there is very little evidence to show the effectiveness of SLT and access to speech and language services varies across the country.

PD COMM Pilot tested the feasibility of a full scale clinical trial and aided in improving the trial design. The design was simplified removing vocal assessments and a questionnaire from the participant booklet to reduce the burden on participants and therapists. So we would like to once again extend a thank you for to all of our PD COMM participants and the therapists, nurses and clinicians that took part in the study.



PD COMM Trial cont...

The study aims to recruit 546 participants from centres nationally over 31 months. The participants will be randomised between local standard NHS SLT, LSVT & no therapy (where therapy will be deferred for at least 12 months). We also want to know if the benefits of Speech and Language Therapy are seen and maintained in our participants for 12 months. Once we have completed the study, we will be able to say what is the best way SLT can help Parkinson's patients.

In addition to the trial we will also be conducting interviews with participants who are taking part. These will be taking place over the telephone or in face-to-face meetings, in which the participants will be able to share their views and experiences of taking part in the trial. This section of the trial will be looked after by Professor Chris Burton and the team at Bangor University.



PD COMM Trial Launch and PD Trials Collaborators' Meeting

We had a great day at the PD COMM launch and PD Trials Collaborators' meeting and we hope you did too. In the morning we had a couple of great sessions from Professors Cath Sackley and Carl Clarke who spoke on the clinical trial evidence for Speech and Language Therapy (SLT) in PD, PD COMM pilot trial design and the new and improved trial design for PD COMM! We also heard some of the results that were found in PD COMM pilot (watch this space for more details in future newsletters!)

Then lunchtime came and we had a great opportunity for the doctors, nurses and therapists who work across our trials to get together and discuss the new results and differing practices from

around the country. We enjoyed meeting you all and putting a face to a name and vice versa, you found out who it is that sends you all those letters!



Professors Cath Sackley and Carl Clarke

In the afternoon there were 2 parallel sessions, the first, lead by Prof Chris Burton, was for the SLTs and interested nurses. In which we discussed LSVT in practice all around the country and considered the potential barriers in the way when providing this service and then how this will be rolled out into the trial.

The second session was an update on the trials in the Neurosciences portfolio, which included the ongoing analyses of the PD MED trial (PD MED later, Health Economics and Quality of Life) as well as an update from Professor Karen Morrison about PD GEN.



PD MED – Hospital Episode Statistics— Francis Dowling

In the September 2015 Neurosciences newsletter, Sharon Muzerengi wrote about conducting a project designed to look at various aspects of hospitalisation in people with Parkinson's. This is an important area of research as hospitalisation is one of the major costs to the NHS for the disease. The results will be presented at the Movement Disorder Society conference in Berlin this month and a scientific paper is being prepared. These results will be expressed in terms of groups of patients and individuals will not be identifiable.

The hospitalisation data for this project was obtained from the Health & Social Care Information Centre (HSCIC). As discussed in a previous newsletter, when people are admitted to hospital, details of their admission including reasons for admission, investigations, procedures performed, and administered treatment are recorded and transferred to a central NHS database. This is held by the HSCIC, soon to be rebranded NHS digital. HSCIC data are used by healthcare organisations and NHS Commissioners for healthcare planning decisions, as well as researchers whose work will benefit the health and social care system in the UK.

As part of the PD MED project, we collect information for participants and carers about their quality of life and resource use. Clinicians send information about your medication and care. We also make ongoing use of Office of National Statistics data which supplies details of people passing away and access to cancer registry information.

Although you have all signed consent forms and have let us have access to your medical records, the HSCIC decided that the consent that you have signed did not cover the use of HES data. Due to the nature of the study and for how long it has been going, it was not possible to go back and re-consent all the participants in the PD MED trial. We applied for an S251 waiver to give us a legal basis for the collection of HES data. It took nearly 3 years to make all the applications and pass through the systems for us to be given HES data. We have received one extract of the HSCIC's Hospitalisation Episode Statistics (HES) data in late 2015.

Without the HES data we would not have been able to look at hospitalisations to the level we have. These data have been extremely valuable to look at the hospitalisation rates/patterns and associated costs to the NHS.

Your long term commitment to completing forms has made the PD MED study an incredible resource that was bolstered by the ability to access HES data. I hope this little peek behind the curtain has been interesting and given you a small idea about our long term commitment to PD MED. PD MED has already provided benefit to the current NHS with the first results paper, but we are committed to continue using this resource to make an ongoing difference to the treatment of people with Parkinson's.



MDS Berlin

If any of our collaborators are going to the Movement Disorders Society Congress this month then please look out for us. We are very excited as the PD MED Later results poster has been selected to be on the guided tour, so if you are coming please join us for Professor Carl Clarke giving a short presentation on the poster in Berlin.

The other Neurosciences trials will have posters at the conference, they include the PD MED Later disease results, PD COMM Pilot results, PD MED ICECAP-O comparison with EQ5D and PDQ39 and Hospitalisations in PD MED. If you would like to know who to be on the lookout for Professors Carl Clarke and Cath Sackley and Dr Sharon Muzerengi. (It could be our version of where's Wally!)

Study Updates



The PD COMM Pilot data has now all been analysed by our stats team and the final report has been sent to the Dunhill Medical Trust. We presented the results to our collaborative group in our meeting this March and they will be presented to the wider scientific community at the MDS Berlin conference and we will also be presenting this data at the Parkinson's UK conference this November in Leeds. The paper is currently being written by Prof Cath Sackley and once we have this finalised we will be sending out the results to you. We would like to thank you all for your hard work in making the data collection as successful as possible. In the mean time you are able to keep up to date with the trial on the PD COMM Pilot website. (www.birmingham.ac.uk/pdcomm).



The PD MED LATER data has now been analysed and paper are currently being written. As soon as we have finalised the paper we will let you know. The results were presented to our collaborative group in our meeting this March and they will be presented to the wider scientific community at the MDS Berlin conference this June. We have very much valued your dedication to the trial. We are now well into the 15th year of PD MED so we would like to take the opportunity to thank you all for completing the Patient and Carer booklets and for continuing to send us the information back in the follow up forms. We are still collecting the follow up information from clinicians, patients and carers, so please do be on the look out for those envelopes! The long term follow up is crucial for the accuracy of future results and establishing the best medical practice for patients with Parkinson's. We have submitted an extension request for PD MED to the NIHR HTA which would hopefully see us extended until 2020. If you would like to find out some more information of the PD MED Trial and keep up to date with the trial, please visit our website. (www.birmingham.ac.uk/pdmed)



We would like to thank you all for your hard work in giving and collecting samples. Thanks to your dedication, PD GEN is one of the largest PD DNA banks in the world. The samples are stored in the Molecular Neurology Laboratory at the University of Birmingham and are available for applications for research. If you want any more information then please check our website (www.birmingham.ac.uk/pdgen).



Finally for PD REHAB, if you remember in the last newsletter we gave you the exciting news that we had published the results in the JAMA Neurology. The paper was open access for only the first week of it being published, however if you weren't quick enough it will become full access again from 17th July 2016. Just type 'PD REHAB JAMA Neurology' into your search engine and it should appear. If you want any more information then please check our website (www.birmingham.ac.uk/pdrehab).

The newsletter needs your help!

I hope that you have enjoyed reading your copy of the BCTU Neurosciences Trial newsletter. If you would like to write an article for the next edition I would be very happy (and grateful). Articles can be on any aspect that you find interesting, and can be as brief or extensive as you want. Subjects from your experiences as a patient with Parkinson's or as a carer to if you are a research nurse doing your own research into Parkinson's .



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