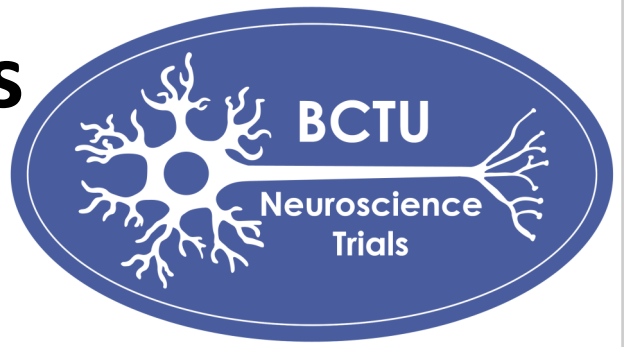


# Neuroscience Trials Newsletter

From the Birmingham Clinical Trials Unit  
August 2017



## August edition

Hello everyone and welcome to another newsletter from the Neurosciences Trials team at BCTU. You are about to hear about what a busy few months we have had. PD COMM is now in full swing with more and more sites opening to the largest trial in LSVT (Lee Silverman Voice Training). We will hear from Prof Clarke about the importance of completing the booklets and follow ups for PD MED. I will also give you a recap on the collaborators meeting which we had in May.

## PD COMM Collaborators' meeting and PD Trials Update



The sun was shining during the PD COMM Collaborators' meeting and PD Trials Update giving us a day we all thoroughly enjoyed and we hope you did too. In the morning we had a couple of great sessions giving us results from the PD COMM Pilot trial and then Dr Christina Smith showed how these results will be used within Speech and Language therapy clinical care.



We also heard from Gillian Beaton, one of our Speech and Language therapists from the pilot trial who gave us a really interesting session on her experiences of working on the pilot trial and all of her tips and tricks to help with running the trial.





### **PD COMM Collaborators' meeting and PD Trials Update continued:**

Then came lunchtime 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 and emails!

In the afternoon there were 2 parallel sessions, the first, led by Prof Chris Burton, was for the SLTs, nurses and trial practitioners. 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. Chris also gave an overview on the process evaluation study that will involve our therapists and participants being interviewed about their experiences of speech and language therapy within the trial. Within this session it was great to see the SLTs and nurses communicating about how to work together to make the trial a success.

The other afternoon session focused on the results from a number of exciting trials that have been carried out over the UK. First up our very own Professor Clarke presented some results for PD MED LATER trial and talked about changes to NICE guidelines. It is very exciting to see the results from the PD MED trial being incorporated into the NICE guidelines showing just how important all research is.

Dr Michele Hu then gave a talk about her research which focuses on Parkinson's disease progression and trying to understand the early stages of the disease. And finally Dr Alan Whone talked about his trial which involved testing intracerebral GDNF in people who have early Parkinson's and seeing whether this can slow down the progression of Parkinson's. There may also be a TV programme about the trial featuring Dr Whone and the team so keep an eye out for that in the coming months.

Finally, we would like to say a big thank you to everyone who attended the meeting and made it a successful day!



## PD COMM Update

PD COMM is still open to recruitment and has been having some great months, with our current best month of April with 8 recruited. Our current recruitment is still slightly below target but we believe that with your continuing hard work, all of the new sites that have joined us since the last newsletter and those in the process of opening, we will get back on track. We



would like to welcome Basildon, Macclesfield District, Guy's and Gloucester, Southern General and Withybush to the study and we are looking forward to working in collaboration with every single one of you.

As you will either have heard at our Collaborator's meeting or earlier on in the newsletter. The PD COMM team in Bangor might be contacting you soon to start the process evaluation section of the study.

**Lastly, please keep recruiting!!**

## Do you have PD MED form fatigue... Think again! Prof Carl Clarke



### **Importance of long-term follow-up in PD MED**

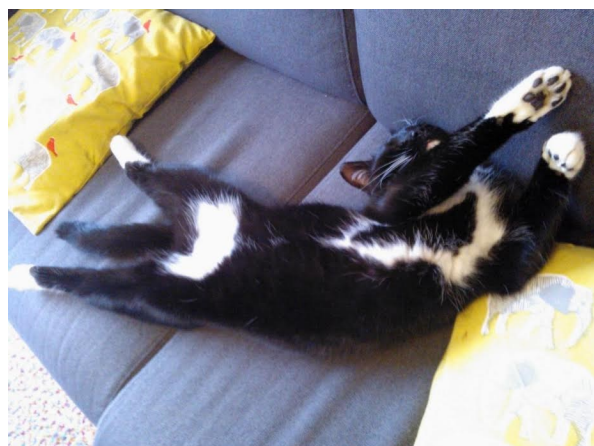
The PD MED trial early randomisation results were published in the Lancet in 2014 and they changed the 2017 version of the UK NICE guidelines for Parkinson's disease. The results of the PD MED later disease randomisation will

be submitted soon for publication and we hope they will also be well received.

We have a costed extension to the PD MED grant from the Health Technology Assessment Programme until 2020 when the trial will close. As you may be aware, the team in BCTU have been cleaning the data, so the statisticians will shortly be re-analysing the PD MED EARLY results. The health economics team in Glasgow will shortly be looking at the Hospital Episodes Statistics (HES) for the PD MED cohorts in more detail.

There are some tantalising trends in the mortality data which we are following. These may give us some of the most important results of the trial. The HES data analysis is one of the first times that so-called 'big data' is being used in the context of a randomised trial.

So, as you can see, there is a lot more work to do! It is clear that the long-term data is of crucial importance. Please keep filling in your forms, whether you be a patient, carer, or a clinician.



*Complete the form before your cat nap!*



## The Statisticians Role in the Neurosciences Team

Smitaa and Becky (pictured) are statisticians working in the Neuroscience team. Smitaa has been in the Neurosciences team for nearly 12 years on various trials: PD MED, PD SURG, PD REHAB and PD COMM. Becky has been here for nearly 5 years, working on PD MED, PD REHAB and PD COMM. They have both worked on these trials from early start up to completion apart from PD MED and PD SURG which were trials that were up and running when they started work at BCTU.

A statistician will firstly be involved in the design of the trial when applying for funding as a badly designed trial cannot be fixed by even the best statistician. When the trial has been approved for funding the statistician will then help with the development of the protocol and case report forms to ensure that we are collecting all the necessary data in a way in which we can answer the trial question. The next stage is building the database to store the data on. At this point the statistician will be involved in user testing and making sure everything is correct on the database according to the case report forms.

Once the trial starts the statistician will attend regular trial management group meetings to provide statistical advice if any issues have occurred and input on decision making from a statistical perspective. They will also perform interim analyses for data monitoring committee meetings which usually take place annually but can happen every 6 months. When the trial is complete they will lock the database and do the final analyses ready for reporting the results to the team, collaborators and for publication.

Statisticians can never tell what problems and issues they are going to have with a trial and for this reason the neurosciences portfolio of trials keep them very busy. That said statisticians are a very sociable bunch, often seen involved in various fun activities and always keeping an eye out for cake!

## Job opportunity available



Professor Cath Sackley, Clinical Investigator for PD COMM, is advertising for a research associate to work with her at King's College London. The primary focus of the post holder's research will be the PD COMM Trial. The post holder will also support applications for funding to evaluate interventions for long term conditions. For more information visit [www.jobs.ac.uk/job/BDA860](http://www.jobs.ac.uk/job/BDA860)

## 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 person with Parkinson's or as a carer to if you are a research nurse or therapist doing your own research into Parkinson's .

## Contact Details

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