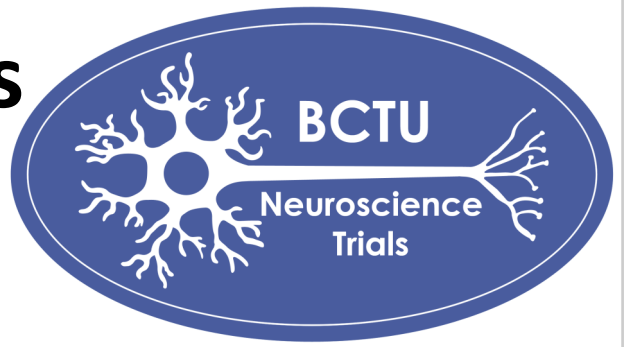


Neuroscience Trials Newsletter

From the Birmingham Clinical Trials Unit
January 2019



2019

Happy New Year!

Hello everyone and welcome to another newsletter from PD MED and PD COMM at BCTU. We have a very exciting year ahead for PD MED, we are now in our 19th and final year of follow up! We will be bringing you all the latest news from PD MED and PD COMM.

Coming up in this edition we have an overview of the PD Trials Collaborators day along with an update on recruitment for the PD COMM trial.

We would like to give a big thank you to all of our participants and clinicians who are returning data we couldn't do your research without you.

Last year of PD MED follow up



As we start 2019 this year is going to be slightly different for PD MED. After 19 years we are now in our final year of follow up - you will be receiving the last set of questionnaires or follow up forms to complete over the next 12 months.

We are very excited by this and are looking forward to being able to analyse the data. With this in mind we would like to take this opportunity to thank both our participants and carers for completing the participant booklets and the clinical staff at the hospitals for sending us the annual follow up forms. PD MED is a longitudinal study looking into the treatment of Parkinson's disease. The trial currently has over 18^h years of follow up (reaching 19 years by the end of 2019!), with everyone having been in the trial for at least 9 years. As Parkinson's disease is a chronic condition it is valuable to know the long term impact of treatment drugs, so we really appreciate your continued involvement and in sending back this final information request. We have already published results that have helped to change NICE guideline for the treatment of Parkinson's disease. With your help and continuing support in completing these booklets we hope to gain more information to help shape the future of Parkinson's disease treatment.





PD COMM Update: securing a recruit- ment extension - Max Hughes

You're hopefully aware that we as the Sponsor began negotiations with the funder (HTA) back in December 2017, following lower than anticipated recruitment rates. Numerous recovery strategies were presented to the HTA, and of these, they favoured a simple extension to recruitment (over two



further years). However in order for them to consider this, PD COMM needed to meet an agreed, revised recruitment target between the months of Jan – Jun 2018 (see graph below).

We were very pleased to announce that following a huge amount of hard work and commitment from the Trusts involved in PD COMM, we were able to exceed this revised recruitment target, and have continued to do so thereafter. This stands us in great stead for the HTA agreeing an extension. However it's important to point out that the HTA are yet to make a decision, and so nothing is agreed. The next step has been the HTA inviting us to put in a formal for-cost extension. Whilst all of this is underway, in order to avoid a recruitment pause, the HTA agreed that the recruitment end date could be extended from 30th November 2018 to 31st May 2019.

We continue to keep the HTA updated on current recruitment, so it's important we continue to meet or exceed our revised recruitment target. It is with great pleasure we let you know that at present we are continuing to do this, and this is down to the hard work and commitment shown by the Trusts involved. This excellent news demonstrates further that PD COMM is a deliverable trial worthy of an extension. Of course we want to make the HTA's decision to extend recruitment as easy as possible, so it's important we continue to push hard with recruitment and try to ensure that every eligible patient presenting is approached!

If you are involved in PD COMM, please don't stop pushing – it is your hard work that will decide the future of trial! We at the Trials Office are extremely proud of your continued efforts and are very grateful you have chosen to be part of PD COMM family!

Finally a huge thank-you goes out to all of our trial participants - without your agreement to take part, we could not do this research. We hope your experience of the trial, and of being part of the PD COMM family has been as rewarding for you as it has been for us!

PD COMM SLT day 2018

The PD COMM SLT day this year was held in Glasgow on 21st Nov 2018. Attendance was fantastic with nearly 50 SLTs representing sites from all across Great Britain able to make it. Talks included linguistic changes in PD, the use of technology in adult acquired dysarthria and non-motor issues in PD. Many of the talks were filmed, and we hope to make these available in due course. There were also group activities on how healthcare professionals understand their practice, and the contrasting experiences of PD COMM SLTs. We're very pleased to report that feedback from the day was fantastic, and we would like to thank everyone who attended, helping to make it such a wonderful day. Another SLT Day is already planned for around the same time this year – so if you're an SLT working on the trial, and interested in attending, we would love it if you could make it, as we really hope it will be excellent opportunity to share, learn and network. So keep any eye out - invites will be sent out some time in the second part of this year!

Onwards and upwards: Collaborators' day 2018— Avril Nicoll

BCTU's portfolio of studies to benefit people with Parkinson's disease include the PD MED trial of drug treatments and the PD COMM trial of routine speech and language therapy interventions. Every year the unit hosts a day for its NHS collaborators from all over the UK, including doctors, Parkinson's specialist nurses, research nurses and allied health professionals.

Our 2018 Collaborators' day in June focused on PD COMM. As trials of behavioural interventions for communication difficulties are rare, it's not surprising that over half of those attending were speech and language therapists. Attendees came from Wales, Scotland and Clinical Research Network regions of England. Most frequently speech and language therapists were the only professionals from their site. However, trial recruitment depends on a coordinated effort, so we were pleased to see teams of research nurses, doctors and research nurses, and doctors and speech and language therapists.

The PD COMM update gave attendees a chance to put faces to names. Neurosciences Team Leader Cally Rick offered comprehensive background, and Trial Manager Max Hughes covered progress with recruitment and the case for a for-cost extension from funder NIHR HTA. From the process evaluation, Avril Nicoll outlined distribution of responsibilities for data analysis, while Patricia Masterson-Algar shared responses to date to the speech and language therapists' questionnaire.

Given his unabated enthusiasm for Parkinson's research, it's hard to believe consultant neurologist Carl Clarke has recently semi-retired! A co-investigator on PD COMM, he gave an overview of PD MED and PD GEN.

Trialists in Parkinson's disease have a common goal of embedding high quality research for patient benefit in the NHS, and we have much to learn from each other about trial design and implementation. Improved falls prevention is a research priority, as people with Parkinson's have double the falls expected in a healthy matched population. From Jess Pooley (University of Bristol) we heard how the CHIEF PD trial will look at drug intervention to prevent falls, while Ann Ashburn and Kim Seymour (University of Southampton) gave us insight into interpreting forthcoming findings from the PD SAFE physiotherapy falls prevention trial. Helen Dawes (Oxford Brookes University) introduced us to the proven benefits of exercise for alleviating motor symptoms in Parkinson's disease, and the possible metabolic reasons behind the problem of fatigue.

Returning to PD COMM, specialist speech and language therapist Gillian Beaton (Glasgow) and Avril Nicoll reflected critically on the idea that people with Parkinson's routinely need an invasive

laryngeal examination before starting one of the trial interventions, Lee Silverman Voice Treatment (LSVT). Exploring the issue from different perspectives, including burden of treatment for patients and the NHS, and consequences of variation in practice, they invited us to consider if this may be an example of a low value practice which initiatives such as Choosing Wisely and Realistic Medicine are seeking to address.



Collaborators' day 2018 (cont)

Returning to PD COMM, specialist speech and language therapist Gillian Beaton (Glasgow) and Avril Nicoll reflected critically on the idea that people with Parkinson's routinely need an invasive laryngeal examination before starting one of the trial interventions, Lee Silverman Voice Treatment (LSVT). Exploring the issue from different perspectives, including burden of treatment for patients and the NHS, and consequences of variation in practice, they invited us to consider if this may be an example of a low value practice which initiatives such as Choosing Wisely and Realistic Medicine are seeking to address.



Unlike standard NHS speech and language therapy, which is usually offered weekly, LSVT is four times a week over four weeks, supplemented by home practice. To explore the challenges this presents for service delivery, Christina Smith chaired a lively panel session with four experienced speech and language therapists talking through sharing clients, seeing them in their own home or via the internet, involving trained assistants, and using Companion Software. They also discussed their experiences of offering group intervention, with and without carers, as part of standard NHS intervention or to supplement LSVT.

The need for evidence to inform practice applies not only to the NHS but to research, and Kris McGill focuses his efforts on the problem of trial recruitment. Drawing on findings from his systematic review and qualitative analysis of interviews with leading trialists in stroke rehabilitation, he emphasised the pivotal role of clinicians and their relationship with trial teams. The Collaborators' day is one way of developing this relationship, and we look forward to welcoming you to another stimulating and thought-provoking day in 2019.



PD GEN update

Aliquots of the PD GEN samples have been sent to Professor Huw Morris at UCL for genotyping. Professor Morris and his team will be correlating genotype with clinical progress in the PD MED and PD SURG participants over the next year.

The remaining PD GEN samples will continue to be stored in Birmingham. We are in the process of moving them to the University of Birmingham Biobank storage facility where they will still be available for use by anyone with a suitable project after applying to the PD GEN Management Group.

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

Please supply your articles, stories or experiences to: Newsletter contact
Lauren Sturdy, Neuroscience Trials Office, BCTU, Public Health Building,
University of Birmingham, B15 2TT
Email: neuroscience@trials.bham.ac.uk
Phone: 0121 415 9128

 Tweet @PDCOMM_trial