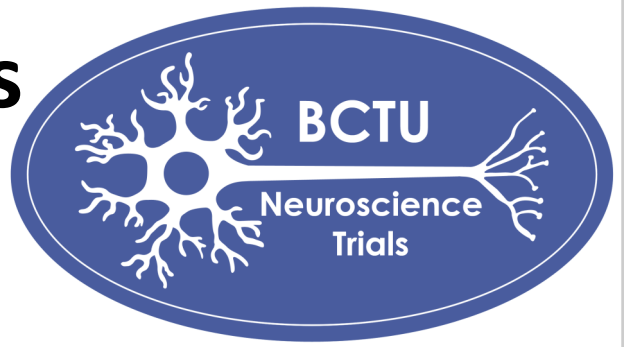


Neuroscience Trials Newsletter

From the Birmingham Clinical Trials Unit
December 2014



December 2014 edition — Lauren Genders

Hello and welcome to our last newsletter of the year. 2014 has been a busy year for the trial team and BCTU, we have moved departments (from the school of cancer sciences to Health and Population Sciences), published the first results from the PD MED trial in the Lancet, closed then PD REHAB and PD SURG trials, finished recruiting to the PD COMM Pilot trial. We have submitted new grant applications to continue our valuable collaborations and answer outstanding research questions in Parkinson's.

The New Year will continue to be busy, we are submitting the PD COMM full application to the NIHR HTA in January, and have other applications in the pipeline. We also have a number of publications in draft form that we plan to publish next year.

The Neurosciences Team Leader, Cally Rick, got her running



Parkinson's UK Spooky Sprint

shoes on and she and her family ran Parkinson's UK 5k Spooky Sprint with 800 other people in Nottingham on Saturday 1st November.



BCTU Christmas Tree

BCTU will be closed from 4pm on the 23rd December 2014 until 9am on the 5th January 2015, so we will answer any correspondence from this time as soon as we return. We would like to wish you have Merry Christmas period and a happy new year. See you all in 2015!!

Bud's Run -

Birmingham Runners Lead the Race to Find a Cure for Parkinson's

A charity fun run and gala dinner held recently in Birmingham raised over £23 000 for Parkinson's UK, with the aid of some famous sports people past and present.

"Bud's Run" and "Bud's Bash" were staged at the University of Birmingham in honour of top running coach Bud Baldaro, who has inspired hundreds of distance and middle distance runners of all standards in his forty year career. Bud was diagnosed with Parkinson's in 2009, and is determined to raise as much money as possible to try and find a cure for his condition. He has coached students at the University for over 20 years, and continues to perform a mentoring role there despite his illness.

Bud's Run con't...

World marathon record holder Paula Radcliffe is a great admirer of Bud, and has known him for many years. She flew in especially from her Monaco home to start "Bud's Run", a 5K that looped around the University's leafy Edgbaston campus.

Paula said: "It was great to be part of such a vibrant and powerful event. Bud has always been a huge support for me. I particularly remember Bud after the Beijing Olympics, when I was struggling to get back into shape and struggling with injury. He was a real help."

Bud said: "I'm overwhelmed at the positive response we had to both events, and delighted at the money everyone raised. It was amazing to see so many people pull together for such a good cause. Having Paula there was a big bonus, as she is a true hero in our sport. I'd also like to thank all our sponsors and partners for making the events possible."

Hannah England, who Bud coached to a World Championships silver medal in the 1500m, was there to lend her support. Hannah's husband, international steeplechaser Luke Gunn, gave a light-hearted commentary on events.

527 runners entered the packed 5K, with lots of familiar faces from Bud's career turning out. There was also a 2K "INEOS GO Run for Fun" for kids, and a 1K loop for elderly runners and those with small children. Some of Bud's athletes baked cakes to raise extra money, and many wore special running vests made for the day.

Later that evening, the University's majestic Great Hall held host to "Bud's Bash", a charity gala dinner. The 500-strong audience heard from four unforgettable speakers, who all paid tribute to Bud's kindness, wisdom and generosity.

Olympian Hannah England, former world 5000m record holder Dave Moorcroft, West Bromwich Albion hero Daryl Burgess, and champion fundraiser Bryn Williams shared their stories, jokes and memories of their adventures with Bud. A raffle and online charity auction also helped bring in extra funds for Parkinson's UK.



BCTU Stand at Bud's Run





PD MED goes from strength to strength

We hope you have all been able to access the first publication from the PD MED EARLY trial which appeared in The Lancet in June 2014 and more recently in the print version. The PDF version will become open access from December 2014.

By January 2015, all patients will have reached the 5 years follow up point, and the median follow up will be around 7.5 years. The statistics team will be re-analysing the data around then, so it is crucial that we all continue to complete the annual follow up forms, both patients and clinicians. It is possible that the small benefit in quality of life of initial levodopa therapy over dopamine agonists and MAOB inhibitors may translate into effects on the long-term outcome measures we are recording of dementia, institutionalisation and death. Now that would cause a stir!

We focussed on getting the PD MED EARLY results published ahead of the PD MED LATER results. Given this delay, the large withdrawal rate from medication across all arms of the trial, and the appreciable mortality rate, we have decided to re-analyse the LATER trial around January 2015 and then to produce a single definitive report. Amongst other things, we need to see if the benefits of MAOB inhibitors over COMT inhibitors in later Parkinson's disease persist.

Armed with the new data, we plan to apply to our funders, the Health Technology Assessment Programme, for a grant extension for possibly another 5 years beyond the end of the existing grant in October 2015. We will consider carefully the future of PD MED LATER and whether further data collection would be useful.

It would be nice to hold another Collaborators' Meeting to present the new data in the autumn of 2015, but I doubt this could be funded from the existing grant. However, by then, we may have funding for a full scale PD COMM trial examining the efficacy of two forms of speech and language therapy versus no treatment in Parkinson's disease. We will hold a launch meeting for PD COMM which would allow us to present the PD MED results.

So, PD MED goes on! Please keep collecting the data and sending it back to the University of Birmingham Clinical Trials Unit.

A really big thank you to all involved.

P.S. PD REHAB was submitted to the BMJ on Friday 17th October 2015. Keep your fingers crossed!

Best wishes

Carl

Professor C E Clarke

BCTU Parkinson's PPI Group

BCTU believes that clinical studies are a partnership between all stakeholders and that patients and the public should be involved in all aspects of research. The Parkinson's Patient and Public Involvement (PPI) Group was set up back in May this year, in the aim to ensure our studies ask the right research questions and that the results are meaningful to patients.

So far, this group of volunteers, consisting of people with Parkinson's and their carers, have kindly spent time each month on a number of projects. They have reviewed sections of the grant application to help us secure funding for new projects; commented on the design and feasibility of new clinical studies; shared with us their past experience in receiving specific treatment in the NHS; and reviewed documents for dissemination of results for our studies. They have helped tremendously in bringing our research closer to patients and the public.

Study Updates



PD COMM is now in the final stages of follow up. We have now received everyone's voice recording (for those who had them) and are now collecting data for the 12 month follow up time-point. We are also data cleaning so will be sending out queries on a rolling basis. As you have heard the PD COMM team will be submitting an application to the NIHR HTA in January to fund a full scale phase III trial. We have already identified 40 sites to roll the trial out across the country, with a planned start date of October 2015. 3 People with Parkinson's who have received SLT have also volunteered to provide their personal perspective on the trial. We will keep you up to date with the progress of the application in our newsletters but in the mean time you are able to keep up to date with the trial on the PD COMM website. (www.birmingham.ac.uk/pdcomm).



For those of you who may have missed it in our last newsletter, the results of PD MED have now been published in The Lancet (see here for the abstract ([http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(14\)60683-8/abstract](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(14)60683-8/abstract)) or type 'PD MED Lancet' into a search engine). We are still collecting the follow up information from patients, carers and their clinicians so please continue to send your booklets back in. As we have heard from Professor Carl Clarke the long term follow up is crucial for the accuracy of future results and establishing the best medical practice for patients with Parkinson's. If you would like to find out some more information of the PD MED study and keep up to date with the trial, please visit our website. (www.birmingham.ac.uk/pdmed)



PD REHAB has recruited all of the participants, who now should have finished all of the follow up visits. The data has now been analysed by our statistics team. We have submitted the paper to the British Medical Journal and are waiting for their decision. We will let you know once we have any news. The final report has been sent to the HTA and we have responded to their reviewer's comments. We will send out the end of study report to all of our sites shortly. In the meantime please see our website for any other information about PD REHAB. (www.birmingham.ac.uk/pdrehab)



We are performing the final data cleaning for the PD SURG trial, all participants have now reached the 7 year follow up time point and we are working on the analysis of the long term data. Please do not be surprised if you do receive a letter requesting some information. As soon as this has been completed we will be able to write up and let you know our finding. In between newsletters you can always check our website for the latest up to date news. (www.birmingham.ac.uk/pdsurg).



We are still collecting samples for PD GEN from participants and carers from all of our trials, However there is a big final push to get samples from our PD REHAB patients before the end of the year. If you want any more information or want to keep updated with all that is happening in PD GEN then please check our website (www.birmingham.ac.uk/pdgen)

I still need articles!!! Please help

Contact Details

If you're interested in sharing with our community of Doctors, Nurses, Therapists and Patients, please supply your articles, stories or experiences to:

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