Neuroscience Trials Newsletter

From the Birmingham Clinical Trials Unit

January 2012

Welcome to 2012

I hope you've had a great break and some time to relax. With the New Year, here in the unit I've taken a moment to look towards the new opportunities that will arise this year and I've looked at what goals we want to try and achieve. Firstly, a fully peer reviewed release of the PD MED results, which we feel will definitely have an influence on current practice. We also aim to have PD REHAB fully recruited by the end of June and if we're lucky over-recruit! But hopefully that's just the start.

After the last newsletter I was asked why the team name has changed from PD Trials to the Neurology Trials Team. The change is because we as a trials team are giving ourselves the opportunity to expand into areas of Neurology other than PD (although this still is and will continue to be an important field to us). Currently there are some very early plans potentially looking at Transverse Myelitis (neurological disorder caused by anti-inflammatory process of the spinal cord) as well as Huntington's disease (neurodegenerative genetic disorder that affects muscle coordination and leads to cognitive decline and dementia).

In this month's Newsletter we have a fantastic article from Howard Bridge, a member of the Patient & Public Involvement group working with us on the PD REHAB study. Howard has given us a personal insight into the time when he was first diagnosed with Parkinson's disease.

We also have articles from Nikki Clague (Lead Therapist) from Leicester General Hospital and James Chal who works at the Birmingham & Black Country Comprehensive Local Research Network, as well as all the usual study updates.

Finally, I'd like to send our thanks to our Neurosciences Team Leader Dr Cally Rick and our Senior Statistician Natalie Ives on successfully completing the Parkinson's UK 10K Spooky Sprint. Not only did they both beat their times from last year, they also raised over £500 in the process, all of which will go to Parkinson's UK.

PD COMM Pilot Update

Just a quick update for the PD COMM Pilot this month as we move towards getting the study set up so the sites can recruit their first patients. We now have a fully ethically approved protocol (approved November) and are progressing with getting the local Research & Development approval for each hospital. This pilot study will only be open to 4 preselected centres (Royal Devon & Exeter Hospital, Fairfield Hospital, City Hospital (B'ham) and Southern General Hospital), but if successful, and depending on how fast it can recruit the sixty patients expected, it will then be moved forward to a full nationwide trial.

Also, for all involved we will be having the PD COMM Pilot launch meeting 19th January at the Holiday Inn, Birmingham. All of the invites have been sent out and replies are coming in thick and fast. This one day meeting will give some background information on why this research is needed, explain some of the study design decisions, as well as give all the staff involved an idea on how the study should be run within a hospital clinic.

“I can confirm you have Parkinson’s” - Howard Bridge

Not the worst words you can hear but hardly welcome. Not likely to be a shock either because you have probably been under investigation and observation for some months. But what now? What do you want to hear now that the diagnosis is confirmed? The answer to that question will vary widely so I can only give a personal response.

First I wanted the best advice I could get on what **to do.** The situation I dreaded most was someone saying to me in 10 years time “If only you had….when first diagnosed…”. I wanted to be sure that I had done everything possible to minimise the impact of the condition. No one had anything to say on this matter.

Second I wanted advice on how to handle my new circumstances. I concluded early on that I would not fight a battle I could not win but would learn to live with Parkinson’s and whatever it brought. I was not offered any help in making this psychological adjustment.

Third I wanted the best assessment possible of the way the condition would develop including likely timescales and any landmarks – such as the point at which particular treatments were likely to be appropriate. Two milestones were pointed out to me – starting to take l-dopa and deep brain stimulation.

Fourth I wanted good, focused information. I went to the web and was offered 11 million pages! I needed something more filtered than that. I eventually found it at the Parkinson’s Disease Society.

I realise now that there are no categorical answers to these questions and I ended up talking to and listening to a knowledgeable lady on the help-line at Parkinson’s UK (then the Parkinson’s Disease Society) who explained that the condition is personal and varied as is the reaction to different medications and the rate of progress. Despite there being no definitive answers these were the questions I wanted to ask - for myself and those closest to me. This last point is very important. Parkinson’s and the associated medication mean change – in appearance, speed of action, personality – and family members in particular have to live with the consequences. So, they should be involved in the answers to the above questions, and given the opportunity to ask their own. They should be given this opportunity before treatment begins, in fact as soon as they hear the fateful words “I can confirm….”

PD REHAB - Therapist Experiences in Leicestershire - Nicola Clague-Baker

In Leicestershire, we became involved in the PD REHAB trial in May 2010. The main consultant involved (and Principal Investigator) is Dr Nelson Lo and the therapy lead is myself Nicola Clague-Baker. The Physiotherapy team involved include Sue Seaman, Rebecca MacDonald and Sue Forrest and the Occupational Therapy team include James Taylor, Claire Brownson and Diana Bovington.

We have enrolled eight patients on to the trial over this time, some of these being treated in their own home and some as outpatients. Sue Seaman has been the main consenter and commented that “it has been good to be involved in the practical process of research and gaining more understanding of the patients’ perspective of research, however, it has been very time-consuming and it has been difficult balancing your normal workload with this extra workload”. She also felt that “an hour is not enough to consent the patients on to the trial. The patients need help with the writing and reading and understanding of the trial”.

In the community Rebecca MacDonald commented that “I have been surprised by the patients that have made reference to their lack of knowledge as to what therapy can provide in terms of support and advice as well as treatment.” She added that ”each of the patients I have seen declare during initial assessment that 'there is nothing that therapy can do' and seem to have accepted that the disease is not curable and therefore decline is inevitable… Patients do not seem to be aware that their Parkinson’s symptoms can be rehabilitated to a degree and that there are certain preventative measures that can be taken to prevent functional decline i.e. with regards to posture etc.”

Overall the response to the trial from both therapists and patients has been positive and a true learning experience for us all. Rebecca finishes by adding “I personally feel the impact on our service has been quite positive - being involved in a national trial and being able to help patients at an earlier stage of their disease where we can provide preventative advice”.

Comprehensive Local Research Network – Supporting Research in the NHS - James Chal

"To provide every NHS patient the opportunity to participate in a Clinical Trial" is the goal the Government expects to achieve through its investment into research in the NHS, as announced in the Plan for Growth Report (March 2011).

The National Institute for Health Research (NIHR) was set up in 2006 to create a world-class health research system to deliver this vision within the NHS. The infrastructure for delivering research is largely provided through the NIHR Clinical Research Network (CRN). The CRN comprises:

Six Topic Specific Research Networks (Cancer, Dementia and Neurodegenerative Diseases, Diabetes, Medicines for Children, Mental Health and Stroke).
A Primary Care Research Network.
A Comprehensive Clinical Research Network, which is made up of 25 Comprehensive Local Research Networks (CLRNs) throughout England, covering all other disease areas.

The Birmingham and the Black Country (BBC) CLRN here in Birmingham, has a small core team which works with an Executive Group, CLRN Board and the local Topic Specific and Primary Care Research Networks to support the delivery of research across all of its 19 member NHS Trusts.
A CLRN's key functions are to:

Establish and fund a clinical research infrastructure to support a high quality portfolio of clinical research and facilitate patient participation into studies.

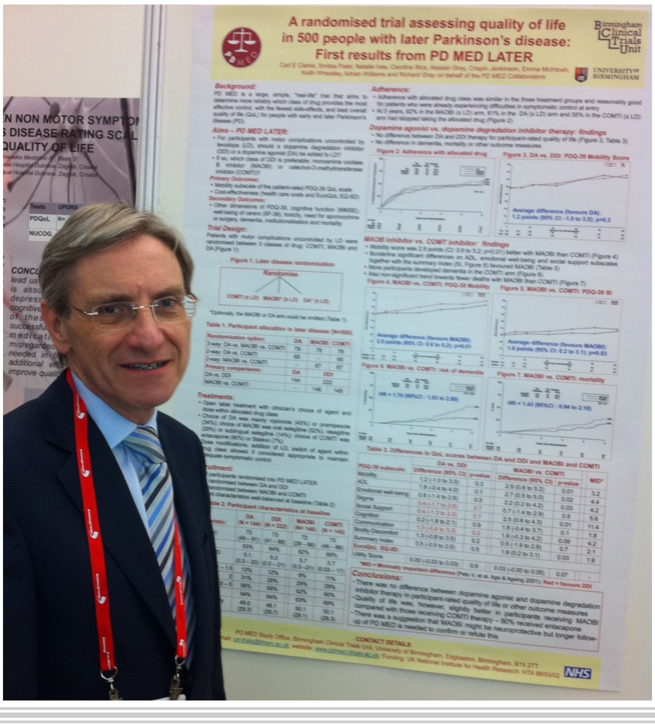
Provide NHS Service Support Infrastructure for Portfolio projects in all NIHR Clinical Research Networks.

Provide and deploy resources for research management and governance to ensure that the research portfolio is delivered to the highest standards.

One of the principal ways in which the CLRN supports Chief Investigators and their research teams is through the Lead Network Service. This service facilitates the set-up and conduct of non-commercial, multi-centre research studies, including assisting in obtaining NHS Permission and ensuring that appropriate personnel and services are in place at each site involved in the study: this includes things like research nurse support, training and support and advice to researchers of all levels.

For further information, in the West Midlands please contact Theresa Morton, CLRN Senior Manager, BBCCLRN@uhb.nhs.uk or telephone 0121 627 2843.

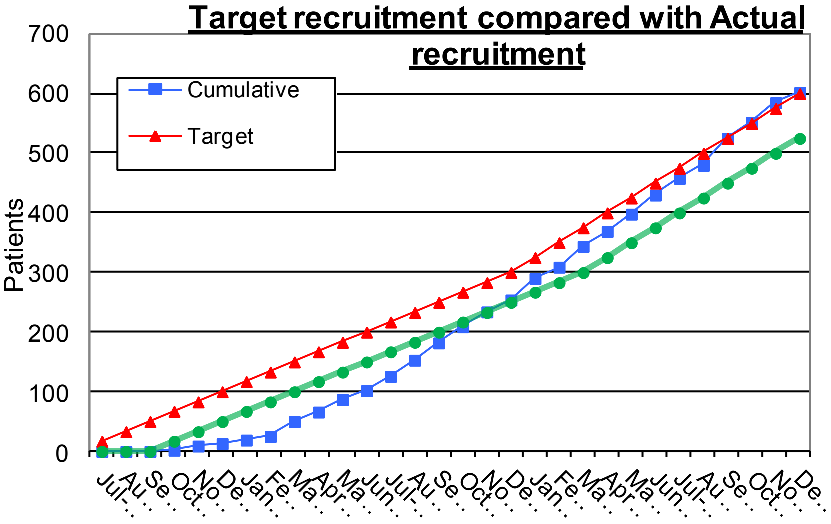
If you are not supported by Dendron and would like to get assistance, please visit the CLRN's website at http://www.crncc.nihr.ac.uk/about_us/ccrn and contact your local CLRN.



First Public Presentation of the first PD MED Results - Prof Carl Clarke

After over 11 years of work by everybody involved I'm proud to announce we have publically presented the first PD MED results for both early and later disease. These results were presented at the World Parkinson's Congress meeting held in Shanghai in December 2011 by Prof. Richard Gray and myself. The results were well received and we are convinced that the results will change practice in the treatment of Parkinson's disease sufferers worldwide
I'd like to thank everyone involved, it's been a long hard slog but well worthwhile. I'd also like to thank all of the Dendron teams involved in the trial. We are all indebted to our patients for their commitment to the trial.
I look forward to sharing the full study results in peer reviewed papers which we will be submitting shortly.

Recruitment and Study Updates



In our last quarterly newsletter, I described the recruitment as having turned around and improved dramatically for PD REHAB, so much so we had hit our original target line. Well not much has changed in three months, although we had a disappointing December this was not to be unexpected and with the previous two months of excellent recruitment under our belts we ended 2011 once again bang on target. Not only should a big thanks go out to everyone involved in PD REHAB, from the healthcare professionals to the patients who are prepared to join in with research. But I would like to reiterate the message “Stay on target” for 2012: we can’t get complacent this late into recruitment as we still need to hit our target of 750 by June 2012 or, even better, beat it!

PD GEN is currently our only other study in recruitment. At the moment it stands at 1860 samples taken, with 1213 being Parkinson’s disease patient samples and 617 carer samples. Currently over a third of all patients who join PD REHAB are happy to consent, have a blood sample taken and complete a short questionnaire for PD GEN.

PD MED is no longer recruiting and is now entering its eleventh year of collecting follow up information with all patients having at least got through the second year time point. At this point, the most important information to reiterate is to please ensure that you continue to complete forms for the PD MED study. Our form return rates are good and are still in the 90% region up until 4 Yrs for most forms, with only a slight drop off at 4 years for the carer completed form and clinician completed follow up forms.
For our biggest PD MED news of this quarter, turn to page 3.

PD SURG is also in its eleventh year and closed to recruitment – indeed, all patients have now had five years of follow up and the main results are published. This doesn’t mean that work has stopped however – far from it. Work on the health economic analysis of surgery for PD is ongoing, and the paper should be published soon. Work is also being done on other of the trial. For example, work on life spans for the internal generators used and whether stimulation parameters can influence battery life is ongoing, and the PD SURG dataset is being used to test the ability of the STIMULUS algorithm to predict which patients would be most suitable for and would benefit most from surgery to treat Parkinson’s.

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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