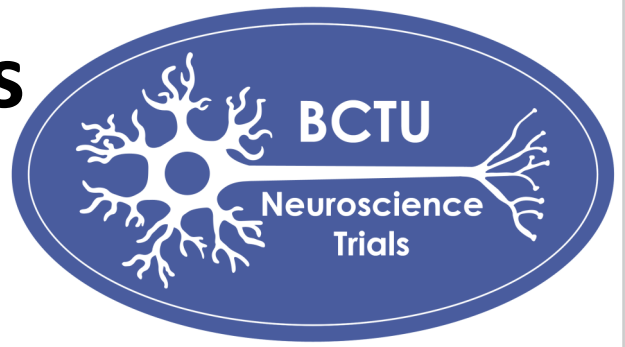


Neuroscience Trials Newsletter

From the Birmingham Clinical Trials Unit
February 2017



February edition

Hello everyone and welcome to another newsletter from the Neurosciences Trials team at BCTU. A quick update about the trials team here; Max Hughes has joined us as our new Trial Co-ordinator. Ravi Dhaliwal has also joined us formally, you might recognise her name as she has been working for us as a student but we are pleased to say we convinced her to stay on with us as a Data Manger after she graduated. Francis who had been with us for many years has left and is now running trials down at the Cambridge Clinical Trials Unit, we are sorry to see him go but wish him all the best.

Please turn over the page to hear about PD COMM trial progress and how being involved in trials really does change clinical practice.

PD COMM Collaborators' meeting and PD Trials Update

Registration to the PD COMM Collaborators' Meeting and PD Trials Update will open soon. The meeting will be held in the Council House (Banqueting Suite) in central Birmingham on Thursday 18th May 2017. You are all cordially invited to attend what should be an exciting and educational meeting. The morning session will consist of a summary of the PD COMM pilot results, leading on to an overview of the nationwide PD COMM trial and its current status.

In the afternoon, therapists, nurses and clinical trial assistants will have a parallel session on the content of the intervention run by the team from Bangor University which is leading this work.

Principle investigators and Parkinson's Disease Clinical Nurse Specialists will have a parallel session commencing with Dr Michelle Hu presenting the first outputs from the combined DISCOVERY and PROBAND Parkinson's disease cohorts. Dr Alan Whone will then give what we know to be a very exciting talk on the latest trial of intracerebral GDNF infusion for Parkinson's disease. There are rumours of TV programmes about this, so be the first to hear it in Birmingham. Professor Clarke will then close with talks on the PD MED LATER trial results and the new NICE Parkinson's disease guidelines.

Please register soon for this excellent CME opportunity!





PD COMM Trial Update

Everyone has been very busy with PD COMM since the last newsletter. So much has changed and we have lots to update you on. Firstly and most importantly, the trial has now opened to recruitment! We now have 14 centres open and 16 participants recruited to the trial. The study aims to recruit 546 participants from centres nationally over 31 months. The participants are being randomised between local standard NHS SLT, LSVT & no therapy (where therapy will be deferred for at least 12 months).

We will also be conducting interviews with participants, carers and therapists. These will be taking place over the telephone or in face-to-face meetings, in which the participants, carers and therapists 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. The first questionnaires have been sent out to therapists and we hope to start interviews shortly.

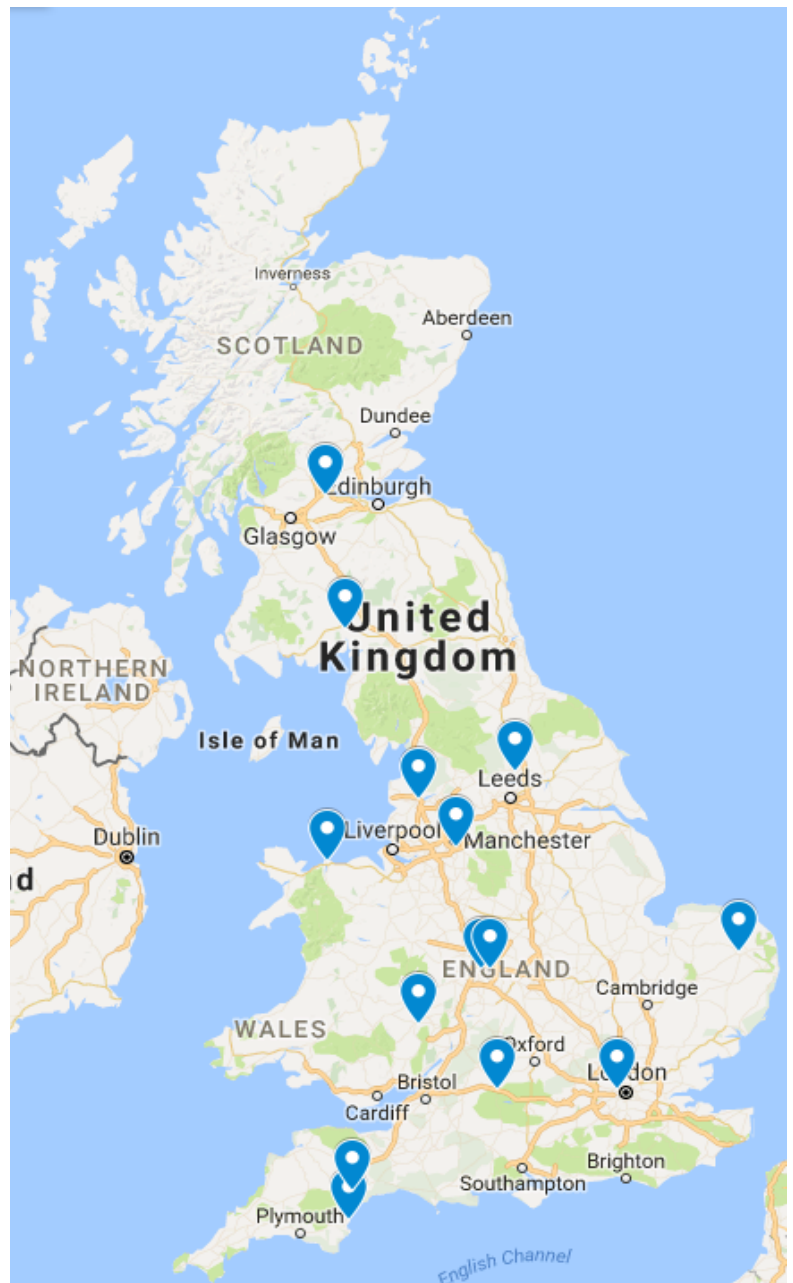
Marian Brady has now recruited a Research Fellow who will provide additional support for Scottish sites, so please watch this space! We are also planning on setting up a therapists forum to be able to share best practice and build a research network. We are currently investigating social media options.

PD COMM Recruitment

Site	Recruits
Central Middlesex	3
Birmingham City	2
Norfolk & Norwich Uni	2
Torbay District General	2
Royal Devon & Exeter	2
Harrogate District	1
Birmingham Heartland	1
Hereford County	1
Buccleough Lodge Day	1
Great Western	1
Llandudno	0
Dumfries & Galloway	0
Forth Valley Royal	0
Royal Preston	0

We are also in the final stages of opening the following sites:

- Taunton and Somerset NHS Foundation Trust
- East Cheshire NHS Trust
- North Lincolnshire NHS Trust
- Cardiff and Vale University Health Board





PD MED – Hospital Episode Statistics and Office of National Statistics

In the June 2016 Neurosciences newsletter, Francis wrote an article on Hospital Episode Statistics (HES) and Office of National Statistics (ONS) data. In our continuing efforts to ensure that we are processing your data fairly and lawfully, and also to ensure that you kept informed about how we are using your data. We have had the following statements supplied to us from the Health and Social Information Centre, HSCIC (the HSCIC has recently been renamed NHS digital) in conjunction with the office of national statistics that we would like to share with you. Therefore we would like to clarify our statement about the sharing and processing of your confidential information for PD MED and the role of HSCIC in our recent Newsletter.

We have sent identifiable data (NHS number, full name (including middle initial), date of birth, address and sex) with a study specific identifier (trial number) to the HSCIC. HSCIC have a record of all hospital admissions and outcomes data from the Hospital Episode Statistics (HES) dataset and will link this information to individual participants in the study. This linkage is carried out under Section 251 of the NHS Act 2006.

In addition the HSCIC are able to provide us with information about people who may have passed away in order that we do not make contact and cause any distress to relatives. This information includes date and cause of death information supplied by HSCIC on behalf of the Office for National Statistics and is sourced from civil registration data.

The HSCIC then provides the study with anonymised data (this means that your identifiable data has been removed) together with your study identifier and cause and date of death.

If you can any questions please feel free to contact us.



Draft NICE guidelines

The National Institute for Health and Care Excellence (NICE) have updated the guidelines in regards to the advice they give clinicians and therapists who treat people with Parkinson's. We are pleased to say that the work we have done, along with the help of all of our collaborators and our participants, has meant that NICE are changing their guidelines. We would like to thank everyone who has been involved in all of our trials, and it goes to show that your hard work can indeed change clinical practice!

Having had a look through we can show you some examples of how these trials have made a difference to the guidelines.

- PD MED led to the firm adoption of levodopa as first line treatment for early PD.

- PD REHAB led to the recommendation that patients with early PD should only be referred to a physiotherapist or occupational therapist with specialist knowledge of PD.

- PD SURG supported the use of DBS

We expect to improve the quality of life for people with Parkinson's due to the new guidelines and our research.

The expected publication date for these guidelines is April 2017.





Study Updates

The PD COMM Pilot data analysis is complete and the final report has been sent to The Dunhill Medical Trust. The results paper is being prepared for submission and plan to do this shortly. We also plan to publish the vocal assessments and the participant reported outcomes (quality of life). We will be presenting more of these results at our upcoming Collaborators meeting in May. We would like to thank you all for your hard work in making the data collection as successful as possible. In the meantime you are able to keep up to date with the progress of the trial on the PD COMM Pilot website. (www.birmingham.ac.uk/pdcomm).



The PD MED LATER data, including long term follow up data, has now been analysed and the paper is in the final stages of being written. We plan to submit this for publication very soon. As soon as we have finalised the paper we will let you know. We also have a health economics paper, comparing the ICECAP to EQ-5D, which currently being reviewed prior to submission. Please be aware that we are in the process of data cleaning for the early participants, so if Ravi gives you a call please do your best to help her. We have very much valued your dedication to the trial. We are now well into the 16th 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 had our extension request for PD MED approved by the NIHR HTA so we have now 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).

You might also be interested in this message from Lori Ramig...

The Durham LSVT LOUD Certification and Training Workshop is coming soon!

March 9-10. There are still spaces available!

Also the London Course is June 23-24.

Details for both courses are on www.lsvtglobal.com.

Please note this is not part of the PD COMM training and we are afraid we will not be able to cover costs or expenses.

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.



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