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INVESTIGATE STUDIES NEWSLETTER

September 2011

WELCOME

Welcome to the first of our INVESTIGATE study newsletters. Our intention is to send out updates to trial staff in the various collaborating sites every few months during the course of the study. These will be distributed by email, and will be stored on our *BaseCamp* area, and from the trial website at <http://www.investigate-trial.com>. We aim to keep colleagues up to date with progress on the various components of the study, including any protocol amendments, publications, meetings and perhaps most importantly, recruitment numbers. If there are any items that you feel would benefit from dissemination between sites, please let Cath or Paul know.

CHRIS CHAPPLE

Many of you will be aware that Chris was taken seriously ill in the summer. The latest news we have from his wife Mary is that he is making steady improvements, and our best wishes go to them both. Meanwhile, thanks to Susannah and Altaf for getting things moving on recruitment in Sheffield.

CLINICIAN SURVEY

The clinician survey link was circulated to all members of BSUG and BAUS-SFNUU in August. There has been an encouraging response to date, but with reminders going out shortly we hope to boost this further. In particular there seem to be a large number agreeing to contact for the qualitative interview study.

TSC AND DMEC MEETINGS

The 1st meetings of TSC & DMEC were in Newcastle on 5th August 2011, along with a meeting of investigators; it was good to have all sites represented, and to be able to put faces to names. Feedback from external members of committees was very positive.

PROTOCOL PUBLICATION

The study protocol was published in the open access online journal 'Trials' in July. This can be accessed at: <http://www.trialsjournal.com/content/12/1/169>.

PROTOCOL AMENDMENT

The original protocol has been amended to include the additional health economics questionnaire and economic analysis plan; this was approved by REC on 9th August. The amended protocol v1.1 has been circulated and can be accessed on Basecamp <https://newcastleuni.basecampHQ.com>.

TRIAL WEBSITE

I'm sure you will all have seen the trial website <http://www.investigate-trial.com>. We are keen to keep this updated, so any thoughts or contributions would be welcome. Submissions for the 'Who are we' section in particular are badly needed.

RECRUITMENT

All sites now have R&D approval, and Clinical Trials Agreements have been signed off. These stages have taken much longer than we had anticipated, but all sites should be in a position to start recruitment now. We all now need to progress recruitment as quickly as possible if we are to keep to our planned timescales. Current recruitment figures are shown below and will be updated and circulated regularly by Cath, who is responsible for notifying accruals to the CRN Portfolio. Apart from their significance as a measure of how well we are progressing with the trial, the recruitment figures are important in dictating the provision of NHS support costs to individual sites through the Clinical Research Network. Hopefully we will have something greater than zero in all the rows by the time for the September accrual notification!

Site	Jun	Jul	Aug	Sep	Site total
Newcastle	0	1	10		11
Gateshead	1	5	1		7
Wansbeck	0	0	1		1
Leicester	0	0	0		0
Sheffield	0	0	0		0
Swansea	0	0	0		0
Monthly total	1	6	11		19