

## Thank you and best wishes for the festive season!

Dear TOPS Trialists,

Thank you for all the hard work on TOPS this year, alongside the increasing pressures of regular clinical work in a period when budgets are reducing.

We are now in the 5th year of the trial and have 22 centres up and running. Our total number of participants is now **381**. And a special toast to Inge Trindade and colleagues in Brazil who have exceeded 100!

The present grant expires in June 2015 so it is great to have established a strong and steady graph of monthly recruitment that will bring us in on final target within 18 months.

After discussions with NIH we have agreed to submit the application for the final grant (July 2015-June 2020) on March 5<sup>th</sup>. This gives a safe margin so there will be no interruption. They pointed out of course that success is dependent not just on recruitment, but also on evidence of the safe and timely arrival of case report forms and other records including speech recordings in Liverpool and Manchester.

**So this means that January and February will be crucial for keeping up to date, or getting up to date, on record completion and transfer.**

But let's enjoy Christmas first! Gunvor and I will have a better chance of a white Christmas than most of you as we'll be joining the Scandinavians, while the Brazilians will be starting their summer holidays, and the British will start dreaming of theirs.

**Very best wishes for Christmas and the New Year from the Manchester and Liverpool TOPS Team,**

**Bill**

### In this issue

#### Page 1:

**Best wishes for the festive season!**

**Christmas cover at the AC and DCC**

#### Page 2:

**TOPS recruitment update**

**3 year practice recordings**

**Frequently asked questions**

*From all at the Administrative and Data Coordinating Centres, we wish you all the best for the festive season and New Year!*



## Christmas cover: Important information for the time 21st December – 1st January

**The offices at the Administrative and Data Coordinating Centres will close on the 20th December and will reopen on the 2nd January 2014.**

**There will be office cover available on the 27th December for the management of safety reporting (Serious Adverse Events and Unanticipated Problems) and other urgent enquiries.**

**If you have an enquiry requiring a response on the 27th December please either call +44 151 706 4265 (answer phone available) or alternatively email [tracyb@liv.ac.uk](mailto:tracyb@liv.ac.uk)  
Facsimile: +44 151 706 5932 (during Christmas period only)**



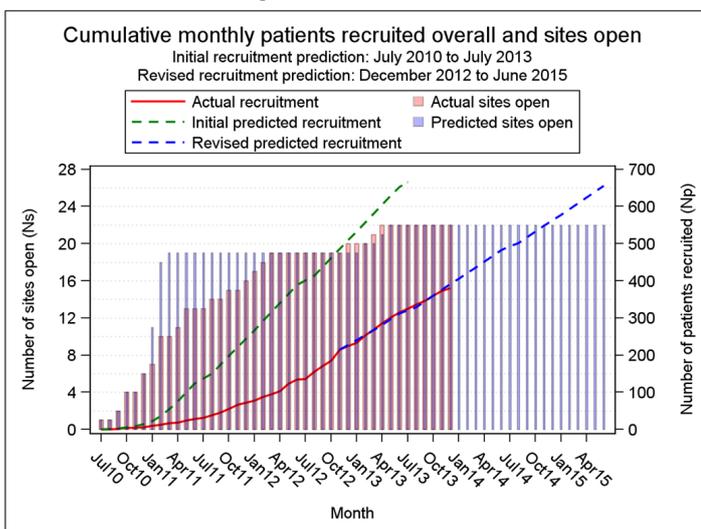
### TOPS Recruitment Update

**381** participants have now been randomised into the TOPS trial.

We are managing to maintain our revised recruitment targets which is an excellent achievement.

Keep up the great work!

#### Recruitment Graph



### 3 year practice recordings

Many thanks to all speech therapists who have sent practice and trial speech recordings to the Data Coordinating Centre to enable feedback from Christina Persson and the Core Speech Group.

Many centres will already be nearing or have completed their first 3 year visit and so we would like to encourage you all to complete your practice recordings as soon as possible.

After sending your practice recording to the Data Coordinating Centre it will get sent to Christina who will watch the recording and get in touch directly with any feedback and tips that might be helpful for the 3 year assessments.

**If you are having problems making your practice Recording or sending it by encrypted USB please contact:**

**Lea Bradshaw at the Data coordinating Centre [tops.trial@liv.ac.uk](mailto:tops.trial@liv.ac.uk)**



### Frequently asked questions

#### Q. What to do if a patient wants to transfer to another centre?

- A. Patients can transfer to another site participating in TOPS if, for example, they move home.

The Site coordinator or Principal Investigator should notify the Data Coordinating Centre in writing, specifying which patient and where they are being transferred to. Copies of participants Case Report Forms will be provided to the new site. The parents will have to sign a new consent form at the new site and until this occurs, the patient remains the responsibility of the original centre.

The new site should send a copy of the new consent form to the Data Coordinating Centre.

#### Q. How do I respond to data queries?

- A. Data queries are questions that are raised often because information is missing, is unclear or is outside of an expected range.

The TOPS data coordinator will send queries to the site coordinator who should print and complete the query forms and **sign and date the form** to confirm who has completed the query. Completed forms can then be emailed back to [tops.trial@liv.ac.uk](mailto:tops.trial@liv.ac.uk) or returned by post or fax to the DCC. However, if you have any problems printing the queries please contact [tops.trial@liv.ac.uk](mailto:tops.trial@liv.ac.uk) and we will arrange to have printed copies of data queries posted to your site.

### TOPS Contact Details

#### Main contact at the Data Coordinating Centre

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