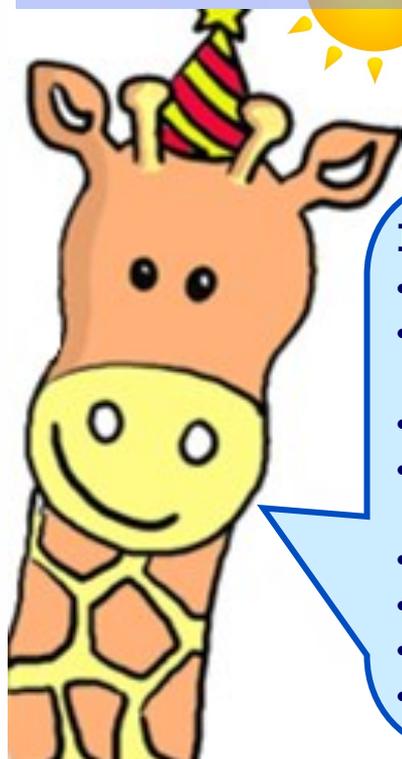




NEWSLETTER

August 2015, Issue 10



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Well Done!

As you know, we completed recruitment on the 21st July.

In total 558 babies have taken part.

Congratulations and thanks to you all!

558

**Participants
Recruited!**

Update: Trial Records

The collection of trial records is making swift progress; the majority of speech recordings received in Liverpool (and checked in Manchester) are of excellent quality: of the 12-months recordings received so far, 95% are of excellent sound quality, and of the 3-year recordings received, 98% passed the sound quality check. Video quality regarding lighting is excellent in 98% and 100% of the recordings checked so far, for 12-month and 3-year recordings respectively. Study models are also now returned at a good rate, with 98% of good or adequate quality.

The TOPS 12-month speech recordings will soon be assessed in a series of "Rating meetings": thirty SLTs from the five countries will start with a calibration/training meeting in November this year. The plan is that the assessment will be done by these SLTs in two batches: during one week in March 2016 and, once the remaining 12-month speech recordings are available, the second batch of recordings will be rated in one week in November 2016.

Protocol Amendment

A TOPS protocol amendment will be submitted shortly, this amendment includes the intelligibility in context assessment at age 5 together with approval to contact local speech and language therapists about local therapy.

We have also clarified each of the outcome measures and how these are assessed. We plan to submit in the UK by the end of August 2015 and for this to be rolled out across international sites pending country specific approvals.



TOPS WEBSITE

Based on your feedback we have now added a link on the TOPS website (www.tops-trial.org.uk) to the case report forms and trial specific guidance documents so that these are all in one easy to navigate space.

Details of how to access the secure site will be sent by email in September

TOPS Renewal Funding

We are currently waiting to hear from NIH regarding the renewal application which includes funding for the conclusion of follow-up and for data analysis.

In the meantime, preparations are under way for the 12-month speech rating calibration meeting, in Manchester in November, costs for which can be fully covered by the current TOPS grant.

Speech Meeting

We had a very successful speech training day on Wednesday 6th May 2015 in Manchester. This meeting was for TOPS speech and language therapists who were unable to make our September 2014 5-year speech meeting and for speech and language therapists new to our team.

5 year speech records:

We are beginning to collect our 5 year outcome data. The first two five year old participants successfully completed speech assessments in Manchester in July. The dates for participant visits are included in the follow up schedules sent to sites but if you are unsure of when to schedule visits please get in touch with tops.trial@liv.ac.uk

Frequently Asked Questions

Q. What should I do if a parent makes a mistake on a consent form?

A. Before sending the consent form to the Data Co-ordinating Centre, ensure that all mistakes are dated and initialled by the researcher, unless a new consent form is completed.

Q. When should I send the surgical photographs?

A. All sites have approval to submit the surgical photographs to the Data coordinating Centre in Liverpool. These should be sent on an encrypted USB in the same way that speech recordings are sent.

Q. When should I withdraw a baby from the trial?

A. The baby should only be withdrawn from the TOPS trial if the parents have withdrawn consent. Otherwise, once randomised, they should be followed up at each of the 12 month, 3 year and 5 year visits. If a child is diagnosed with a syndrome or a developmental delay after randomisation then they should still continue to have TOPS follow up assessments. If you are unsure about whether a participant should be withdrawn from the trial please contact Paul Tate (tops.trial@liv.ac.uk) for advice.



Experiences for the Manchester TOPS Site Coordinator:

Q. Now that recruitment has come to an end, what are your plans to retain research participants in the trial?

A. Manchester: It was explained to families during consent that the trial would run until their child was 5 years old. They will therefore remain involved in the trial and are not aware that recruitment has closed.

Q. What do you consider to be the most enjoyable parts of your job whilst working on TOPS?

A. Working with the families and watching the children develop. It also provided a fantastic opportunity to continue team development although some members may disagree due to lots of emails, from the site coordinator, to everyone requesting availability to see patients and answer data queries!

Q. And your least favourite?

A. Asking team members to answer the data queries!

Q. Are there any parts you wish you had done differently?

A. Use a diary to input each child's randomisation number with data collection timings/birthdays etc. to avoid missing timings, and avoid the use of post-its! Ensure any earlier data queries are

Online training for speech and language therapists -TOPSOT

In May 2015 we launched on-line training (TOPSOT) for speech and language therapists who will be involved in analysis of our 12-month speech data.

TOPSOT allows the speech and language therapists to listen to and rate audio clips of infant vocalizations on-line.

This initiative is the product of work done by Elisabeth Willadsen (from the TOPS core speech group) and her team at Copenhagen, Denmark. The aim of

TOPSOT is to further develop our therapists' specialist skills in assessing the vocalizations produced by 12 month infants and will help prepare them for assessment of our TOPS 12-month speech data in 2016.

If you have any queries regarding the TOPS trial or would just like to get in touch please contact a member of the TOPS trial team at the Administrative or Data Coordinating Centre.

TOPS presentation at European Cleft Conference (ECC 2015):

Bill Shaw presented an outline of the TOPS trial at the European Cleft Conference in Gothenburg (Sweden) in June, and Elisabeth Willadsen described preliminary reports on the reproducibility of 12-month speech ratings.



Contact details

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