

Welcome to the September edition of the safetxt newsletter and hope you all enjoyed the summer.

Congratulations to the centres who recruited their first participants in August which were Sophie Hannay and the team at Chelsea and Westminster, Maryam Nasri at Central London Community, Hannah Gott and the team at Plymouth and Monte Fields and the team at Royal Free.

**159
participants
randomised!**

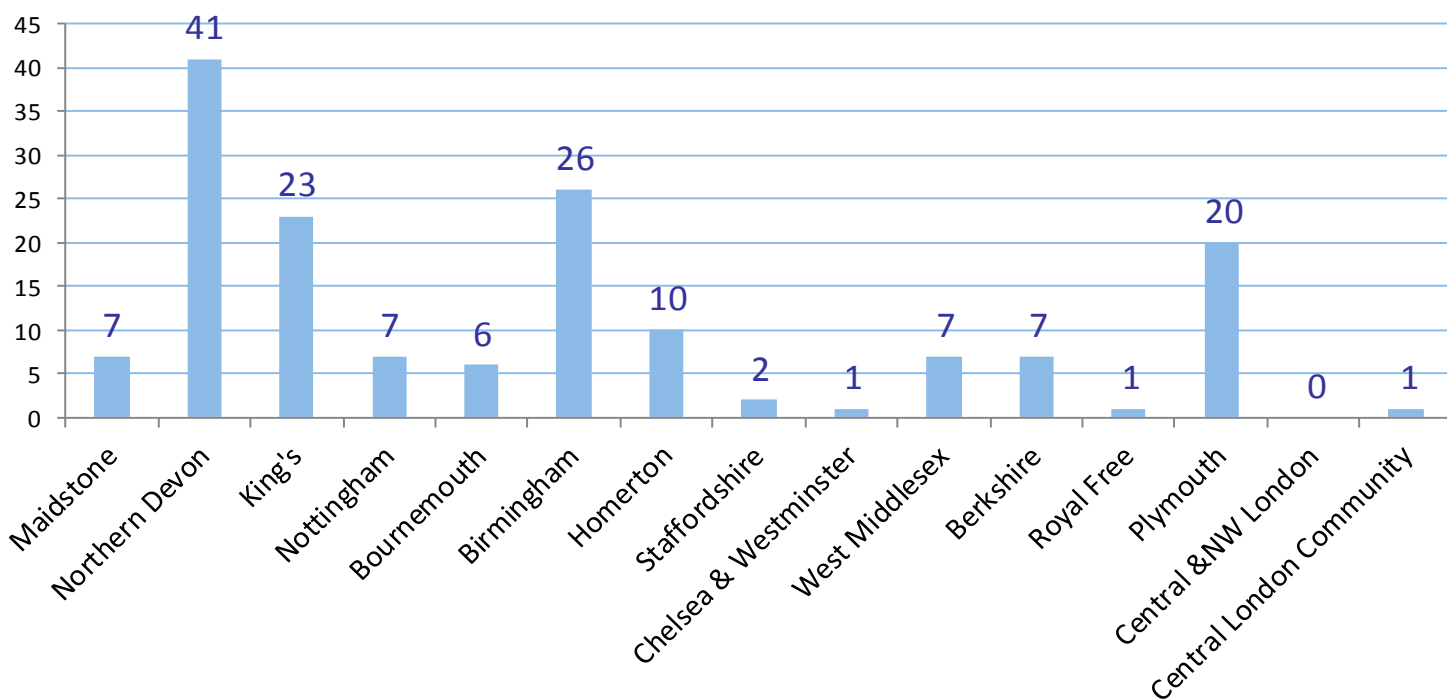
A special congratulations goes to Plymouth Trust who started this month and have recruited 20 participants already.

As you are all aware we said goodbye to Rebecca Matthews at the end of August. We would like to take this opportunity to thank her for all of her hard work on safetxt and to wish her good luck with her new job.

Lauren Jerome will be joining the CTU team on the 5th September to work on the trial and we will feature more about Lauren in an up coming newsletter.

Full approval for amendment 3 has now been received and can be implemented at all of the sites. More information can be found on the next page.

Recruitment Update



Contact Us

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Blue Envelopes

Following some of the site initiation visits there has been some concerns raised about posting out the follow up questionnaires to the participants and what the envelopes will look like. The envelopes are blue and have no franking marks to say they are being posted from LSHTM. The same envelopes were used for the pilot trial and feedback on their use was positive. We have sent out examples of the envelopes to each of the sites so you can show them to any potential participants who raise concerns about this. Please see picture below.



safetxt top TIPS

From Hannah Gott in Plymouth

“Basically I sit next to the Health Advisors here in the SHIP (GUM) looking at the positive list for Chlamydia and Gonorrhoea. Once they have phoned the patients to tell them their results I take the phone and speak to them about the study. If they appear interested I write down their appointment date and time and meet them at the next appointment.”

From Tessa Lawrence in Birmingham

“We leave signs on the staff computers so that they are reminded about the trial and who to look out for. We also print out leaflets for staff with an overview of all of our trials to ensure our staff with all information about the trial and eligibility.”

Amendment 3

Amendment 3 for safetxt was approved by REC on 15th June, and recently received full approval by HRA. This amendment includes changes to the information sheet and consent form to update the information provided and make it easier to understand for the participants.

Current versions:

- Baseline questionnaire V4 23rd May 2016**
- Consent form V5 23rd May 2016**
- Participant information sheet V5 23rd May 2016**
- Participant introduction card V1 23rd May 2016**

Localised versions of these documents have been emailed to all open sites. Open sites have also been posted printed copies along with a version control document. Please destroy all old versions and return the completed version control document to the CTU.

All sites still in set up will have received generic versions. If you would like help with localising these, please get in touch.

Follow up documents have also been approved for use at the CTU but are not required for use at site.

The plan is to submit the next amendment which will include posters for the clinics which we know many of you are keen to receive. There are still a few delays with receiving HRA approval for the amendments but the process is now much improved as they are clearing the back log.