

H4RT

Newsletter 3, December 2018

What a 2018! This time last year we only had 1 site open and 4 patients recruited and here we are, 12 months later, with 25 sites open and 536 patients recruited! That is a fantastic effort and the result of everyone's dedication to the trial.

We were delighted with the NICE renal replacement therapy guidance and in particular the support of the Renal Association, British Renal Society and Renal Cochrane Group in arguing the need for more evidence of the effectiveness/ safety of high-volume HDF. It has also been great to see Prof Andrew Davenport's embedded 'mechanistic' study 'STITCHED' funded by NIHR EME – he will be in touch soon to see who's interested in taking part. Its all great for renal research in the UK!

Thank you all for your hard work in 2018 and have a great, well deserved Christmas and New Year!!

Dr Fergus Caskey
Chief Investigator of H4RT
Consultant Nephrologist North Bristol NHS Trust

Trial manager - Sunita Procter

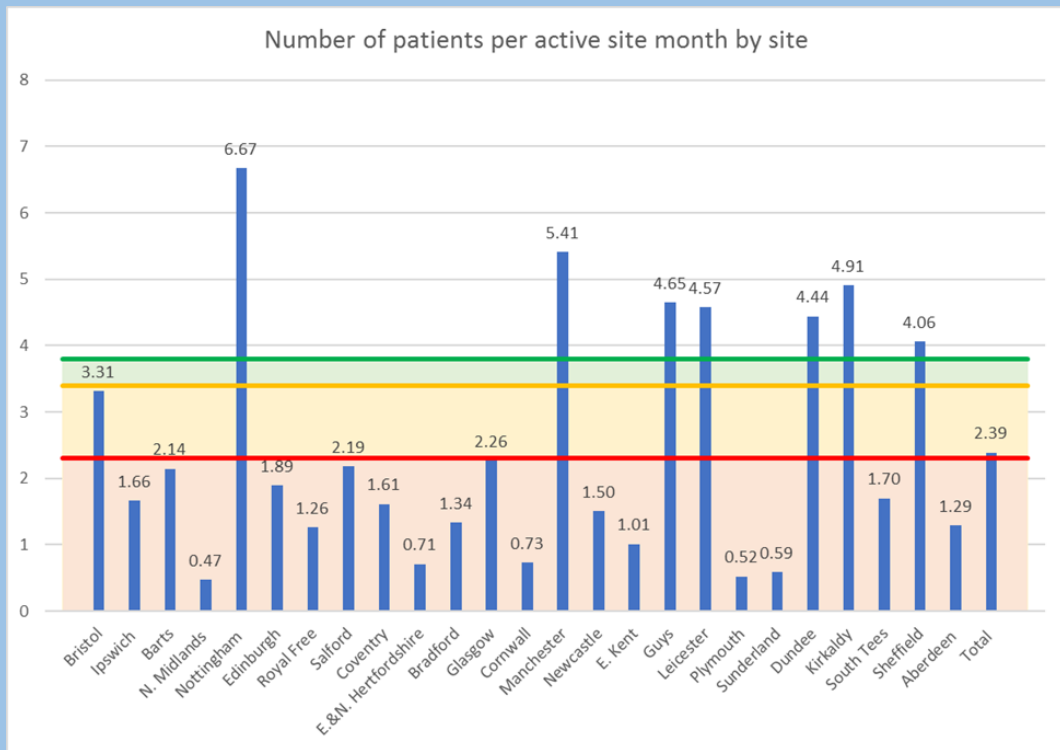
It's been a busy and rewarding year and I am pleased that all of our 25 sites are recruiting patients and we are over a third of the way to our 1550 recruitment target. The central site initiation visits have worked well as we have trained several sites together in different geographic regions – many thanks to the centres who have hosted these training days.

It was great to see so many of you at the research nurse central training day in Birmingham on 1st October 2018. It was an interactive day with invaluable feedback and we have successfully implemented changes to help with compliance and screening.

We have had our Trial Steering Committee, Data monitoring Committee, Trial Management group and Patient advisory group meetings. Many thanks to all our committee members for their expertise, advice, trial oversight as well as encouragement. Substantial amendment 02 received favourable REC and HRA approval in August 2018. All current versions of trial documentation are available on the H4RT website.



The graph shows the number of patients recruited adjusting for the number of months that sites have been open. A special mention to the teams at Nottingham, Manchester, Guys, Leicester Dundee, Kirkcaldy and Sheffield who have recruited every month since being open.



25 sites are now open and recruiting!



Trial Administrator - Nicola Giles

I would just like to thank everyone once again for continuing to send such high quality data to the central H4RT office.

Invoicing

Our current invoicing quarter is September to November 18. For all patients recruited in this period where full datasets (with no queries) have been submitted to the study, we will send you an invoice template for you to forward to your finance department. If you have any patients with outstanding data queries that you are not sure how to resolve, please get in touch.



Lead Research Nurse – Karen Alloway

With 25 sites open for recruitment, I hope to be in contact with you to discuss site specific issues. I am also sending **monthly emails to ALL sites**. Please do let me know if there are things you would like included in these.

We are having regular **research nurse tele-conferences**.

These enable research staff to share their experiences and to discuss any issues they may be experiencing with the focus on encouraging sharing best practice and problem solving. We are running these in smaller groups, which will be focused on sites with potentially similar issues.

Dates for the diary

Groups	Sites	Date	Time
1	Guys Kirkcaldy (Fife) Manchester Salford Edinburgh Newcastle	7 December 2018	14:00 to 15:00
		10 January 2019	10:00 to 11:00
2	Nottingham South Tees Plymouth Cornwall Ipswich Sunderland	7 December 2018	14:00 to 15:00
		10 January 2019	10:00 to 11:00
3	Barts Sheffield Royal Free East Kent Glasgow E&N Herts	18 December 2018	10:00 to 12:00
		18 January 2019	10:00 to 11:00
4	Leicester Aberdeen Coventry Bradford North Midlands Dundee	18 December 2018	10:00 to 12:00
		18 January 2019	10:00 to 11:00

The change to a BSA adjusted target substitution volume for patients on High-volume HDF has raised a few difficulties, but staff are working with their clinical colleagues to achieve these targets. Some of the difficulties are around concerns about dialysis pump speeds/blood flow and use of larger gauge needles. We are encouraging research staff to work with their Principal Investigator to explore ways some of these concerns can be overcome.



Qualitative Researcher – Julia Wade

Thank you to those of you who have continued to forward audio recordings of your recruitment appointments. It is useful to hear these recordings and the issues that patients raise and I will be in touch with you over the next few weeks to discuss these.

We will be sending out an updated ‘**Tips and Guidance**’ document and some ‘**Prompt cards**’ to remind nephrologists to mention the study to patients.

It was great to meet so many of you at the research nurse training day on 1st October and your feedback on how recruitment is going at your centre. Please do continue to get in touch with concerns you have so that we can continue to support you in addressing these.

Screening logs

You should all have received an updated screening and tracker log with data you had already previously entered transferred into the new format. We have two requests to make about these:

1. Some of these had yellow boxes highlighting cells in which data were missing. **Please do leave the yellow highlights** in the spreadsheet when you enter the missing data as this allows us to monitor whether these data have now been entered.
2. **Please do not start a new log for each month** but simply enter the patient activity for the past month into your existing log.

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Documents and information are available on our website <https://www.bristol.ac.uk/population-health-sciences/projects/h4rt-trial> And as always, please feel free to contact us if you have any queries, we are here to help.



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