

# H4RT

## Newsletter 1, March 2018

**Welcome to the first H4RT newsletter** - our chance to update you on progress with the trial, activities that are happening and lessons from other sites.

Funding began in May 2017, with six months to get everything set up. Recruitment then began in November 2017, so we are over four months into recruitment! The response has been fantastic, with huge interest from the renal community to do this trial aimed at establishing whether high volume haemodiafiltration is more effective at improving fatal and non-fatal cardiovascular and infection outcomes in people on haemodialysis.

The efficiencies of this “registry trial” are one of its great attractions, but while that has meant stripping out all unnecessary data collection, we need to maintain focus on ensuring achievement and compliance with the allocated treatment arms, i.e. high-volume HDF or high-flux HD. The monthly compliance check is an essential part of this, and we have released working instructions to help the research nurses liaise (with minimal effort) with the dialysis nurses to achieve this. For research nurses that are not from a dialysis background this may look quite technical at first, but if you have any questions, as always please do not hesitate to give us a call!

Thanks again for all your enthusiasm. Welcome to the team!



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

H4RT officially began in May 2017, and what a lot has happened in that time! We obtained Research Ethics Committee and Health Research Authority approval in September 2017, in time to open to recruitment in the first site on schedule.

We have held our first joint Trial Steering Committee (chaired by Prof Jon Townend, Professor of Cardiology in Birmingham) and Data Monitoring Committee (chaired by Prof Duncan Young, Professor in Intensive Care Medicine in Oxford) and our first Patient Advisory Committee (chaired by Mr Bud Abbott). We are very grateful to them and their committee members for all their advice and support in getting the oversight of the trial into really strong shape.

We have held seven central training days and trained 22 sites in England and Scotland. **Thank you** to all of you for travelling to the sites and the host sites. You have made us feel very welcome!



We are really grateful to research and clinical staff in those sites for embracing the trial and sharing the learning with us as we set up and establish this really important and challenging trial. We have 18 sites greenlighted and are recruiting patients or preparing to recruit.

### Sites open so far!



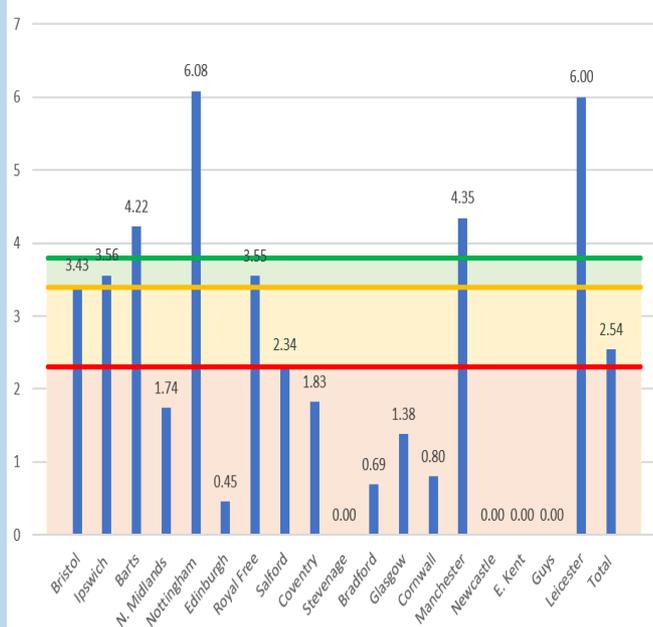
## PATIENT RECRUITMENT

We have recruited 84 patients into the study. We had a busy February when 8 sites were green-lighted. Even the adverse weather conditions – snow, Storm Emma and the Beast from the East did not stop our research nurses recruiting patients into the study.

**A massive WELL DONE to everyone.**

Site ID	Site	Recruited	Greenlighted on
11	Bristol	16	01/11/2017
12	Ipswich	11	19/12/2017
17	Barts	10	10/01/2018
14	N. Midlands	4	12/01/2018
13	Nottingham	13	17/01/2018
21	Edinburgh	1	15/01/2018
18	Royal Free	7	22/01/2018
16	Salford	4	30/01/2018
25	Coventry	3	01/02/2018
26	Stevenage	0	02/02/2018
20	Bradford	1	07/02/2018
22	Glasgow	2	07/02/2018
30	Cornwall	1	13/02/2018
19	Manchester	5	16/02/2018
15	Newcastle	0	19/02/2018
24	E. Kent	0	23/02/2018
29	Guys	0	07/03/2018
23	Leicester	6	16/03/2018
	<b>Total</b>	<b>84</b>	

Number of patients per active site month by site



## PILOT PHASE PROGRESSION CRITERIA

Our pilot phase runs for 6 months and ends in April 2018.

To proceed to the full trial we need to have 17 sites actively recruiting. We are delighted to have already met this first milestone with 18 sites open for recruitment.

Our target recruitment for each site is 3.2 – 3.8 patients per active site month.

We already have 8 sites meeting this recruitment per active site month target.

**CONGRATULATIONS** to Bristol, Ipswich, Barts, Nottingham, Royal Free, Salford, Manchester and Leicester.



## QuinteT Recruitment Intervention (QRI)

The QRI team is here to support you with recruitment and we are pleased that recruitment has started well. We get most rapid insight into recruitment at your site from the Screening log & Tracker or by speaking to research nurses, so please do forward the logs or get in touch if you think you see problems with recruitment emerging. Those of you who have **audio-recorders**, please continue to record your consultations, as these are extremely useful for helping us to understand how patients are responding to the study. Remember to forward contact details of patients who decline participation in H4RT and are happy to talk about their experience of discussing the trial in a telephone interview. Anything you want to discuss about recruitment? Please do get in touch: [Julia.wade@Bristol.ac.uk](mailto:Julia.wade@Bristol.ac.uk) or 0117 928 7362 or 07847 618455

## Hints, tips and reminders for sites

The Screening log and tracker was developed with the help of our QRI team to help us understand recruitment. Please remember to send these to Nicola each month.

**We are monitoring compliance at the sites at the end of each month. Remember to send in your monthly HD/HDF compliance and Water Quality log. Nicola will send you a reminder each month to send them to the H4RT office.**

Please do let us know if there are any site specific issues we can help you with to recruit patients into the trial. We understand that all sites work slightly differently and we can work together to find a solution.

If a patient is randomised to HDF, add the working instructions for HDF in their folder – this is a guidance document to try to help if needed but local SOPs should also be used for troubleshooting.

After the patient has consented to take part and completed the baseline CRF, remember to ask them to complete the baseline Questionnaire before randomisation.

We have the H4RT study PROTOCOL and have provided the study SOPs/flow charts on the website.

<https://www.bristol.ac.uk/population-health-sciences/projects/h4rt-trial/>

Please check the **version control log** stored there to ensure that you are using the correct versions of study documents. We will always let you know when our documents are updated.

### Key Contacts:

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We are really looking forward to working with you all over the course on the trial. Please feel free to contact us if you have any queries, we are here to help.



Follow us on  
Twitter: @H4RT\_UK



**Funding Acknowledgement:** This project was funded by the National Institute for Health Research HTA programme (project number 17/SC/0391). **Department of Health Disclaimer:** The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HTA programme, NIHR, NHS or the Department of Health. **BRTC Acknowledgement:** This study was designed and conducted in collaboration with the Bristol Randomised Trials Collaboration (BRTC), a UKCRC Registered Clinical Trials Unit (CTU) in receipt of National Institute for Health Research CTU support funding. **REDCap Acknowledgement:** Study data is collected and managed using REDCap (Research Electronic Data Capture, Harris PA, et al. J Biomed Inform. 2009 Apr;42(2):377-81) hosted at the University of Bristol. **Sponsorship:** The study is sponsored by North Bristol NHS Trust.