

H4RT

Newsletter 2, July 2018

Welcome to the second H4RT newsletter ! We've had no problem finding content for this one – there has been so much progress over the last few months! 😊

1. We now have 25 sites greenlighted and open to recruitment with only five (recently greenlighted sites) not yet recruiting.
2. We have recruited 215 of the required 1,550 participants (14%) – great progress considering it is only 7 months since we began to open sites.
3. Reflecting that, we were delighted to 'pass' our 12-month gateway with HTA.
4. We saw a united response from the renal community to the draft NICE guidelines which included a recommendation on HDF – both the Renal Association and the British Renal Society submitted robust responses challenging NICE's interpretation of the existing evidence and stressing the importance of H4RT.
5. My focus is shifting to ensuring the fidelity of the intervention, i.e. that we are delivering high-volume HDF. Hence the monthly emails about the compliance logs and water quality checks.

Thanks for all your hard work (and patience!!).
Fergus

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

Sunita Procter – Trial Manager

We hope you are enjoying this glorious weather. We are delighted to welcome our new H4RT Lead research nurse **Karen Alloway** who brings a wealth of nursing experience as well as being a GCP trainer. She will keep us on our toes!

We have had a busy few months opening sites. Thank you for travelling to our central training days or hosting them. We currently have 215 patients recruited and are grateful to all site PIs and research nurses who are actively working on the study. The recruitment target is 1,550 so we will be looking for site specific ways to aid recruitment and quality data capture. We would like to work with you closely as a site to optimise recruitment and compliance.

Congratulations to Ipswich, Nottingham, Royal Free, Salford, Bradford, Glasgow, Cornwall, Guy's and St Thomas', Leicester and Sunderland for recruiting to their site target and being in 'green' within the NIHR dashboard and NBT, Barts, Coventry and Manchester for being in 'amber'. Our top recruiter is **Sarah Brand** at Nottingham. Well done for recruiting every month since your site has been open!



It was great to see some of the H4RT site PIs and research nurses at UKKW in Harrogate in June. I enjoyed catching up with you and thank you for coming to the UK Renal Registry stand and saying hello. It was good to do the Harrogate 5k fun run with some of you too.

If you have any questions, as always please do not hesitate to give us a call.



Patients recruited by site

Site ID	Site name	(green-light/ open date)	N=
11	NBT	01/11/2017	26
12	Ipswich Hospital NHS Trust	19/12/2017	15
17	Barts Health	10/01/2018	13
14	N. Midlands NHS Trust	12/01/2018	5
13	Nottingham UH Hospitals	17/01/2018	34
21	Edinburgh	15/01/2018	7
18	Royal Free	22/01/2018	13
16	Salford	30/01/2018	14
25	Coventry	01/02/2018	5
26	East and N. Hertfordshire	02/02/2018	0
20	Bradford	07/02/2018	9
22	Glasgow	07/02/2018	7
30	Cornwall	13/02/2018	4
19	Manchester	16/02/2018	14
15	Newcastle	19/02/2018	4
24	East Kent	02/02/2018	4
29	Guys and St Thomas	07/03/2018	20
23	Leicester	16/03/2018	15
28	Plymouth	11/04/2018	1
32	Sunderland	09/05/2018	1
33	Dundee	16/05/2018	4
35	Kirkaldy	22/06/2018	0
36	South Tees	22/06/2018	0
31	Sheffield	04/07/2018	0
34	Aberdeen	12/07/2018	0
		Total	215



Karen Alloway – Lead Research Nurse



I am really pleased to have been appointed as Lead Research Nurse for H4RT. It's fantastic to be working on such an interesting and important study.

Having worked in research for nearly 18 years, mainly working on mental health studies and managing a research team, I am enjoying having a new challenge. I have been busy over the past 2 months getting up to speed with H4RT and making contact with sites; hopefully you have all seen an email from me introducing myself and offering support. I have also put together a poster about the study to inform clinical staff, which has been emailed out to all sites.

I will be maintaining regular contact with all of the lead RNs; however, I am here to help and if you have any queries or comments do get in touch.

25 sites are now open!



Nicola Giles - Trial Administrator

We have now recruited over 200 patients! Thank-you so much for sending me the documents I am continually requesting from you all. The quality of the CRF completion and answers to data queries is very high which helps so much with a large trial like H4RT. You will be pleased to know that the patients recruited between Nov – Jan have been sent their 6 month follow-up questionnaire from the H4RT office and all data entry is done centrally.



HINTS, TIPS AND REMINDERS FOR SITES

Randomisation

When you are using the web system to randomise a patient and it times out, please DO NOT re-enter the details a second time. Please call/email the H4RT study office as we can check if it has worked or not. We have had a few instances when the same patient has been randomised twice!!

The randomisation link is:

<https://www.brtrandomisation.bristol.ac.uk>

Invoicing

Our next invoicing quarter is June till August 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.

Other studies

Patients taking part in other studies can take part in H4RT. Please note that PIVOTAL has now closed (to recruitment and follow up) so we have been told you can recruit PIVOTAL patients to H4RT !!

Julia Wade – Qualitative Researcher

A big thank you to nurses in Ipswich, Nottingham, Manchester, Edinburgh, Glasgow and North Midlands who have gone above and beyond their normal routine and successfully audio-recorded their recruitment discussions with patients – we really appreciate you taking on this extra task in your busy schedule. It has been really helpful that you have been prepared to do so as it has given us insight into what works well in these discussions.

We have been very impressed with the clarity and balance of the information given and we are developing a summary of '**Tips and Guidance**' for discussing the study, which we plan to share with everyone.

Thanks too to the same group of nurses and some PIs who have taken part in interviews which have allowed us to get a picture of how recruitment is organised and managed in different centres. You are clearly working hard to make the study successful. We hope that the information that you have already given us, will now be helpful in supporting other centres.

TIPS AND GUIDANCE FOR RECRUITERS

from the QRI team

Introducing H4RT

Short introduction can include:

- who you are
- name of the study: H4RT
- the study is led by (PI Name)
- that the study is comparing two forms of dialysis: haemodialysis and haemodiafiltration

So, actually, at that stage we don't tend to say that much at all. We just introduce ourselves as the research nurses and we work with Dr {PI NAME} on this study. "We're currently working on a study where we're comparing two different types of dialysis, would that be something you'd be interested in reading a bit more about?" So, we keep it very simple, and most people then say, "Oh yes, that's fine."

Keeping descriptions of HD and HDF balanced

- Highlighting both are safe and used routinely on this unit
- Some units do mainly haemodialysis, some do mainly haemodiafiltration, some do a mixture of both
- Stating very clearly that we don't know which is best
- As a patient you may not notice any difference:
 - Number of visits the same
 - Length of visit the same
 - Same machine and bay (where this applies)

So, at the moment we use both types of dialysis at this unit. Some people are on the haemodiafiltration and some people are on the haemodialysis, the one that you're on. Some units don't do any haemodiafiltration at all, some do all haemodiafiltration and some do a mixture of both, like we do. So, there is a lot of controversy out there. A lot of doctors don't really know whether it's better or not.

It would be a slightly different type of dialysis but using the same machine, the same amount of time, essentially just some of the lines are different and the way it cleans your blood is different.

Giving more detail about treatment

- Both have the same goal: to take the toxins out from your blood.
- Haemodialysis does this with minimal fluid removal and replacement.
- Haemodiafiltration is similar to haemodialysis but also removes and replaces the fluid in your blood.
- We don't know which is better for you:
 - haemodiafiltration may take away the toxins from your blood more effectively (especially if we remove and replace large volumes of water).
 - But it may also remove good proteins from your blood.


General tips

Avoid talking about the 'arm' of the study and talk about 'treatment' instead.

Avoid suggesting that haemodiafiltration is the '*gentler treatment*' or the '*newer treatment*' and keep the comparison neutral: *these are both standard treatments.*

And the final word from an H4RT patient:

'I like the fact that it is helping other people, do you know what I mean? The more you learn - I don't feel like I'm being a guinea pig, I actually feel like the other people will benefit from me doing it.'



Thank-you to all research and clinical staff for your enthusiasm and hard work over the past year.
Have a wonderful summer.

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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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