











Newsletter 5, December 2019

BREAKING NEWS!

NIHR have given us a great Christmas present this year – funding for an extension to recruitment to end March 2021!

This gives us all a little more time to reach our target to of 1,550 and have the power to detect a difference of at least 20% in cardiovascular or infection outcomes.

To hit this, sites need to average 58 recruits (i.e.

1,550 recruits across 27 sites), and 4 have managed this already – Nottingham, Bristol, Manchester and Guy's and St Thomas'. Several others are getting close! Thank you all!! The CRN encourages easily achievable recruitment targets, but we hope you will to support H4RT by recruiting beyond your CRN target. Is there another satellite unit you

could recruit in? Are you getting new HDF-capable machines? It would be great if we in the UK could answer this question about HDF.

Have a great Christmas and New Year!



Dr Fergus Caskey

Chief Investigator of H4RT Consultant Nephrologist North Bristol NHS Trust

Trial Manager - Sunita Procter

A special thank you to our 27 sites: you have recruited 952 patients - 61% of our overall target and a great achievement of which you can be really proud. Another 598 patients are now needed to reach our 1550 patient target, show how HDF and HD compare and potentially change practice for kidney dialysis across the UK. We had a busy year, including our successful Investigator Meeting on 1st May 2019. We had invaluable input from Dr Sandip Mitra on achieving high volume HDF which has already changed practice at some sites. It was useful to connect with sites and share insights into different approaches to recruitment.

Please SAVE THE DATE 1st April 2020 when we have another Investigator meeting

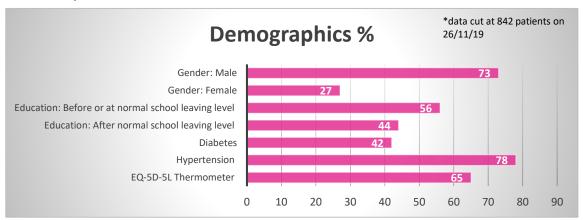
at a beautiful venue in **Bristol**. There is a great line up of speakers including our keynote from Professor of Surgery, Jane Blazeby who will be sharing her insights and experiences of what makes a difference when motivating teams at trial sites and recruiting patients to challenging surgical trials.

I hope you all can take a well earned rest over the Christmas break.

Patient Demographics

We have an active Patient Advisory Group who meet annually and provide input. At our last meeting in March 2019 the members suggested that it would be useful to have a few percentages to show the basic demographics of H4RT patients recruited to the trial.





Patients recruited by site			
SITE ID	Site name	Open date	N=
11	North Bristol Trust	01/11/2017	96
12	E. Suffolk and N. Essex	19/12/2017	23
17	Barts Health	10/01/2018	46
14	North Midlands Trust	12/01/2018	13
13	Nottingham	17/01/2018	107
21	Edinburgh	15/01/2018	34
18	Royal Free	22/01/2018	25
16	Salford	30/01/2018	43
25	Coventry	01/02/2018	21
26	East and North Herts	02/02/2018	26
20	Bradford	07/02/2018	16
22	Glasgow	07/02/2018	24
30	Cornwall	13/02/2018	17
19	Manchester	16/02/2018	75
15	Newcastle	19/02/2018	24
24	East Kent	02/02/2018	20
29	Guy's and St Thomas'	07/03/2018	69
23	Leicester	16/03/2018	55
28	Plymouth	11/04/2018	12
32	Sunderland	09/05/2018	6
33	Dundee	16/05/2018	41
35	Fife	22/06/2018	30
36	South Tees	22/06/2018	35
31	Sheffield	04/07/2018	30
34	Aberdeen	12/07/2018	38
37	Portsmouth	08/04/2019	19
27	Liverpool and Broadgreen	17/06/2019	7
*data at 16/12/19		Total: 952	

It has taken team work and dedication from all our sites to recruit nearly 1000 patients to this important trial.

We have sites open in the North, South, East and West and have more sites expressing an interest in joining the study. This is exciting as we go into 2020.





Karen Alloway - Lead Research Nurse



It has been a pleasure supporting you all in working on this incredibly important study for our dialysis patients. I would like to thank all 27 committed sites for recruiting nearly 400 patients this year and getting us closer to our overall target of 1550.

We are now on the home stretch and if all sites aim for an average of 3 recruits per month we can reach this important milestone by March 2021.



We have been able to demonstrate that patients are willing to participate, no matter which dialysis treatment they are currently on, with high recruitment happening at sites where units are delivering HDF routinely as well as those where HD is the routine treatment.

We decided to change the monthly teleconference to a clinic where you can dial in to access support around any issues you may be experiencing regarding compliance and recruitment. We do appreciate that everyone is busy so we will be available for the whole hour, but you can phone in at any time during that hour.

We hope the monthly news email helps you to feel supported in running the study at your site and provides ideas for increasing recruitment and achieving compliance. If there are any suggestions of things that we can do to provide extra support to sites we would like to hear from you.

Trial Administrator - Nicola Giles

As always, a huge thank-you to all for keeping on top of the patient data. It is of great help to us that it is such good quality.

Invoicing

Our current invoicing quarter is September to November 2019. For all patients recruited in this period where full datasets (with no queries) have been submitted to the study, we will have sent 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.



Key Contacts:	
Chief Investigator	Dr Fergus Caskey Email: <u>Fergus.Caskey@bristol.ac.uk</u>
Trial Manager	Dr Sunita Procter Telephone: 0117 928 7286 Email: <u>Sunita.Procter@bristol.ac.uk</u>
Project Administrator	Mrs Nicola Giles Telephone: 0117 331 3913 Email: Nicola.Giles@bristol.ac.uk Email: h4rt-study@bristol.ac.uk
Lead Research Nurse	Mrs Karen Alloway Telephone: 0117 414 8110 Email: <u>Karen.Alloway@nbt.nhs.uk</u>
Research Aministrator at NBT	Ms Lucy Hanson Telephone: 0117 414 8112 Email: <u>Lucy.Hanson@nbt.nhs.uk</u>
Qualitative Researcher (QRI)	Dr Julia Wade Telephone: 0117 928 7362 Mobile: 07847 618455 Email: julia.wade@bristol.ac.uk

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.

Follow us on
Twitter: @H4RT_UK

NIHR | National Institute for Health Research

Funding Acknowledgement: This project was funded by the National Institute for Health Research HTA programme (project number 15/80/52). 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.