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REDUCe

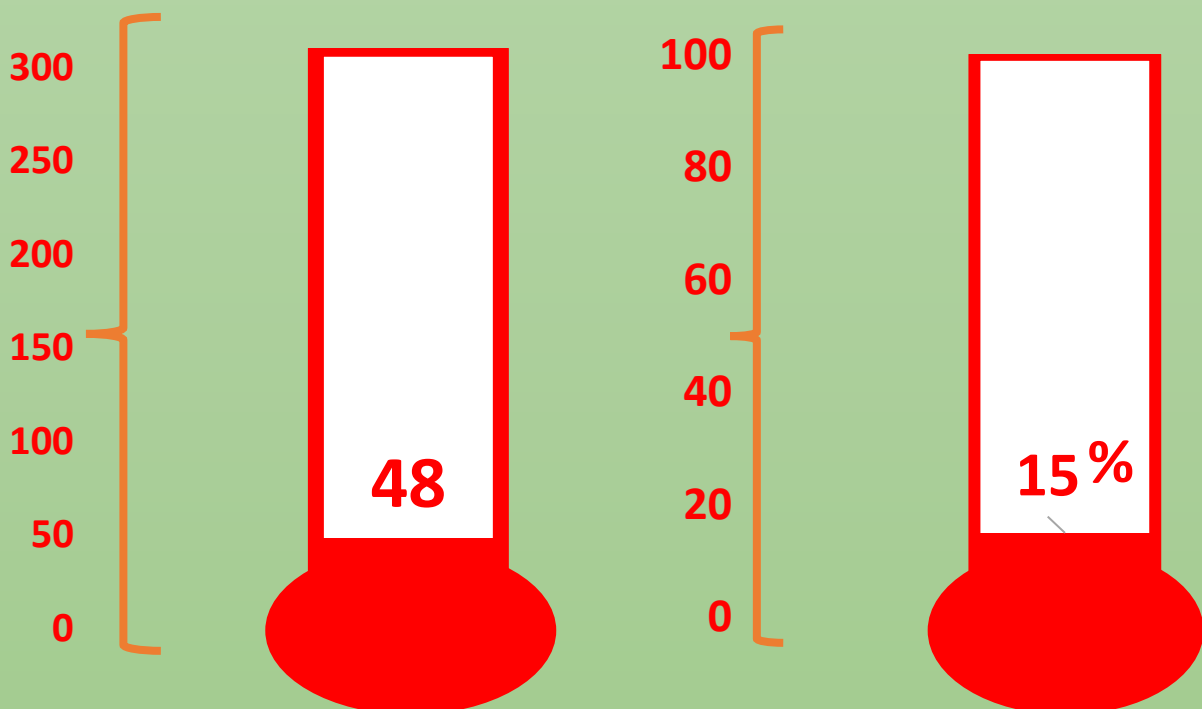
NEWSLETTER ISSUE
#7 – October 2023

REDUCe2

Palliative Long-term Abdominal Drains Versus Repeated Drainage in Untreatable Ascites Due to Advanced Cirrhosis: A Randomised Controlled Trial

RECRUITMENT UPDATE (as of 31st October 2023)

A total of **48** participants have now been randomised.



Congratulations **Hull, Newcastle, Gloucestershire** and **Nottingham** who have all recruited their first patients.



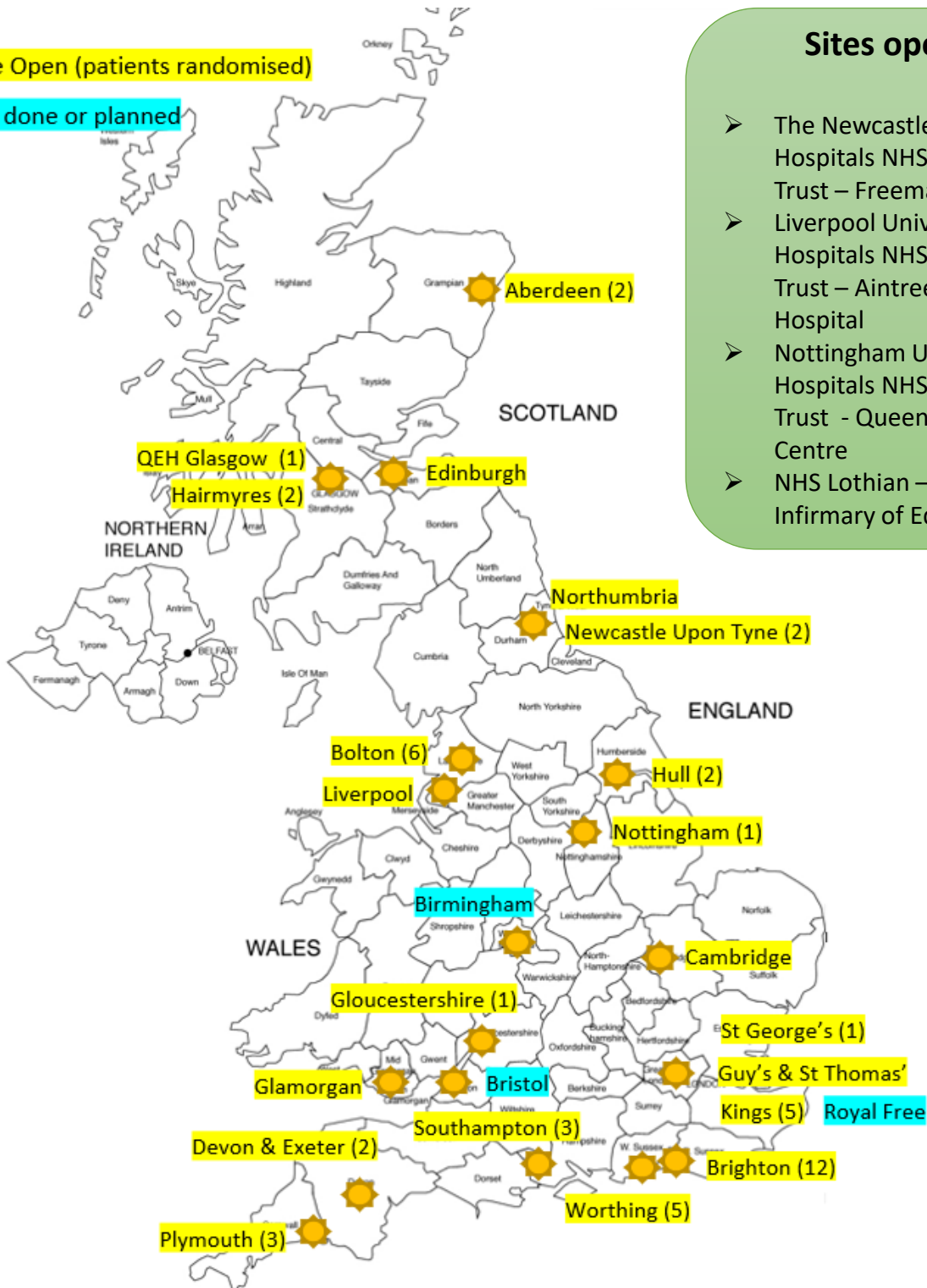
Thanks to all sites who have recruited so far – keep up the fantastic work.



SITE NEWS August, September & October

Site Open (patients randomised)

SIV done or planned



Sites opened

- The Newcastle Upon Tyne Hospitals NHS Foundation Trust – Freeman Hospital
- Liverpool University Hospitals NHS Foundation Trust – Aintree University Hospital
- Nottingham University Hospitals NHS Foundation Trust - Queen’s Medical Centre
- NHS Lothian – Royal Infirmary of Edinburgh



NIHR Associate PI Scheme



The Associate Principal Investigator Scheme is a unique NIHR development opportunity, aimed at any health and care professional who would like to get more involved in research as part of their career.

Staff at 5 sites have signed up to take part in the scheme and some have already completed it.

Please read Dr Veena Ramachandran's from King's College Hospital experience of being involved in this newsletter

There's lots of useful information on their website:
<https://www.nihr.ac.uk/health-and-care-professionals/career-development/associate-principal-investigator-scheme.htm>



Meet the Team

King's College Hospital London

We have now been recruiting to REDUCe2 at King's for over 10 months and have found the journey with our participants challenging but overwhelmingly rewarding.

I have been lucky enough to take part in the associate PI scheme, which has encouraged me to be involved in every step of the trial process from screening and consenting, to undertaking the home visits. Being a small team, we have worked well with recruiting participants and setting up pathways with our radiology and ward teams.

Much of the success of the trial has been down to our research nurse Ane who many of our participants and relatives have come to see as a member of their own family, and a great support in a difficult time in their lives. Needless to say, we have also valued being a part of their journey and the opportunity the trial has given us to speak to patients candidly about death, dying and their wishes.

Quote from one of our recent participants:

"The procedure was similar to being drained with some added surgery to secure the drainpipe. I was comfortable having it done. A little soreness but nothing serious.

The aftercare was to be home district nursing drawing the fluid every two days. This was not very practical, and my family are now working / training with King's to do the drain process at home. This I believe in my case is the best way forward. Very pleased with the process and support so far. This has improved my daily life and I'm feeling positive. I have had no side effects at all, very similar to the two week drain but more practical."

Dr Veena Ramachandran, Clinical Research Fellow in Hepatology



BASL

British Association for the study of the Liver

REDUCe2 Investigator Meeting at the BASL End Of Life Special Interest Group, Bristol - 19th October 2023

Dr Yaz Haddadin, Clinical Research Fellow, attended the meeting and gave a presentation about the study so far. It was well attended by several PI's and Research Staff from some of the sites.

Communication Skills Workshops

As mentioned in the previous newsletter, filming for the workshop videos took place in July and these are currently in the final production stage. Two scenarios were filmed, and they will be used in the workshops as discussion points.

The workshops are planned for Spring 2024.

Qualitative Interviews for Healthcare Professionals

If you or any of your colleagues are interested in taking part in the qualitative interviews, please email the SHORE-C team at shorec-reduce2@sussex.ac.uk

Interviews will be scheduled for a time convenient to you and are open to anyone working on the study – including research nurses, research practitioners, IR Staff, community nurses.



Housekeeping

Data Entry

We have updated the eCRF to gather more data about patient deaths.

If a patient dies, we have added a new section to the Withdrawal page to clarify the reason:

If the 'Main reason for Withdrawal' is '1. Death of Participant' then you will be asked to enter if the event was **Liver-related** or **Not Liver-Related**

Death should never be an Adverse Event / Reaction or Serious Adverse Event / Reaction – it's an Outcome.

Serious Adverse Events (SAEs) / Serious Adverse Reactions (SARs)

Please remember that only SARs need to be reported using the **SAR Form** (V4 15Aug2023). Guidance for completion can be found in the **SAR Reporting Guidance** (V4 15Aug2023).

SARs are serious events that are **Definitely, Probably** or **Possibly** related to the Intervention (LTAD or LVP). Expected SARs are listed in Section 22.2 of the protocol.

Please send SAR forms to: BSCTUsafety@bsms.ac.uk

SHORE-C – Quality of Life Questionnaires and Caregiver CRRS Questionnaires

Please remember to enter these into the SHORE-C database before emailing a copy to shorec-reduce2@sussex.ac.uk



Documents to be sent after randomisation

Please send the following documents to reduce2@bsms.ac.uk via **Secure** email:

- Patient consent form
- Eligibility Checklist – signed by PI / Co-PI to confirm eligibility
- Caregiver consent form (if applicable)
- Expression of Interest forms for the Qualitative Interview for the patient and / or caregiver, if applicable. These will then be forwarded to SHORE-C.

These should be sent within 2 weeks of randomisation.

Next Newsletter will be January 2024



Follow us on X (TWITTER) using [@REDUCe2Study](https://twitter.com/REDUCe2Study) for the latest study news!

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