The
REVIVED-BCIS2
Newsletter

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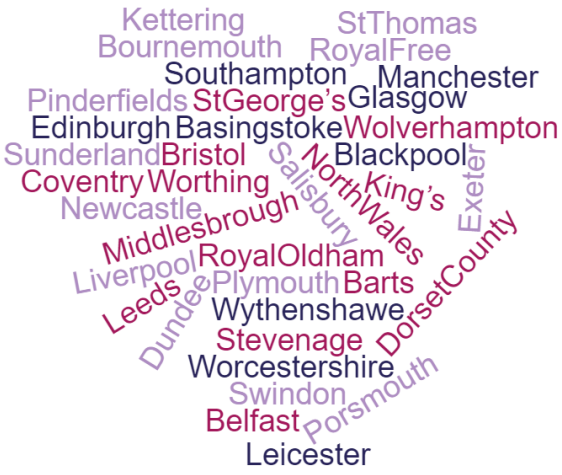
New Year, New REVIVED

What a better way to kick off the new year than with the recruitment of our 500th participant. Well done to the team at Barts Heart Centre for recruiting this milestone participant.

With several new sites on board, fresh faces joining the team, a couple of regional meetings and growing momentum, 2019 will surely be our best year ever.

Last but not least, huge thanks to you all for your hard work and dedication – we would not be where we are today without you all.



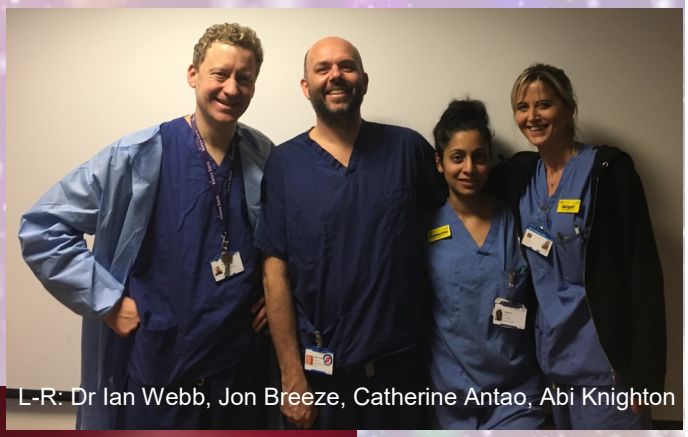
Competition update

In September, we announced a prize giveaway at patient 470, 480 and 490, leading to a bigger prize for patient 500. We are pleased to announce the remaining winners!

The second prize went to Mark, Marion, Marie, Betty and the team at Golden Jubilee National Hospital for recruiting patient 480.

L-R: Betty McPherson, Marion McAdam and Marie Wood

The third prize went to George, Jon, Ian, Jonathan, Catherine, Abi and the team at King's College Hospital for patient 490.


L-R: Dr Ian Webb, Jon Breeze, Catherine Antao, Abi Knighton

And the final prize went to Roshan, Oliver, Bhavik, Dan, Mervyn and the team at Barts Heart Centre for patient 500.


L-R: Dr Bhavik Modi, Dr Dan Jones, Oliver Mitchelmore, Dr Roshan Weerackody and Mervyn Andiapen

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Importance of OMT — by Prof Mark Petrie

REVIVED is nearing the final furlong of recruitment. As it is a heart failure trial, it is essential that we know the benefit of PCI over and above best medical therapy. If PCI is better but our patients are not on the best drugs and devices, the incremental benefit of PCI will be questioned. The cardiology community will want to see the numbers of patients on drugs for heart failure at both baseline and follow up. Patients also deserve best care to improve quality of life and outcomes.

DRUGS for heart failure

What is best medical therapy for heart failure? All patients who meet the inclusion criteria should be on:

- An ACE inhibitor (e.g. enalapril) or an angiotensin II inhibitor (e.g. candesartan) or an ARNI (sacubitril/ valsartan)

  AND
- A beta blocker (e.g. bisoprolol or carvedilol)

  AND
- A mineralocorticoid receptor antagonist (e.g. spironolactone or eplerenone)

If patients are not on these drugs classes (1-3), then please ask your heart failure team or yourselves why? There are some reasons not to start patients on these drugs, but they should be documented.

DEVICES for heart failure

What devices should my patients receive?

- CRT

  Patients with wide QRS complexes (QRS >140ms-1 on their ECGs) should also have cardiac resynchronisation implanted.

- ICD

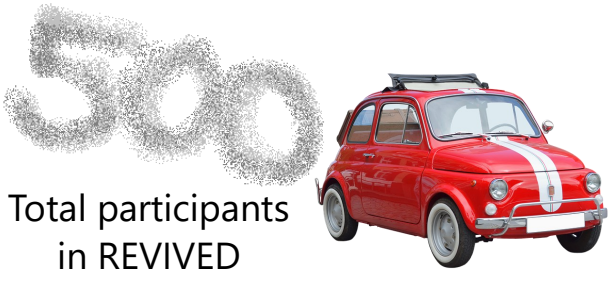
  All patients should also be considered for an ICD. They all have low EFs and coronary artery disease so have a guideline-recommended indication for ICDs. Some will be too old, too frail or have other reasons for not implanting but ICDs should be considered.

The easiest way for research teams to optimise drug and device therapy is to refer to local heart failure teams (cardiologists and nurses). Also, ask yourselves these simple questions at the patient's next REVIVED follow-up visit.

With a big push from all over the next year, REVIVED will be the pre-eminent trial of PCI in heart failure.

Prof Mark Petrie, Consultant Cardiologist, Golden Jubilee National Hospital

REVIVED 2018 in numbers



500

Total participants in REVIVED

112

Total participants recruited in 2018

25 (out of 33)

Sites recruited at least one participant

19

Number of sites that met their quarterly target (at least once) in the past year

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Classification of Adverse AEs – Serious or not?

We have recently had a few queries about whether an event is serious or not. In REVIVED, we use the HRA/REC definition of a serious adverse event:

In non-CTIMPs, a serious adverse event is defined as an untoward occurrence that:

Results in death

Is life-threatening

Requires hospitalisation or prolongation of existing hospitalisation

Results in persistent or significant disability or incapacity

Consists of a congenital anomaly or birth defect

Is otherwise considered medically significant by the investigator

All assessments of seriousness, in addition to those of effectiveness and causality, should be made by the PI or someone delegated that task on the Delegation Log.

Contact the REVIVED CTU if you have any questions about recording and reporting adverse events and we will be very happy to help.

New starter

Welcome to Bristol Heart Institute, who opened to recruitment in December. It was wonderful to meet the team and wish you success in your endeavours!

Myth busters

We wanted to further clarify a few potential misunderstandings about REVIVED processes.

Can patients who do not have confirmed ischaemia be recruited into the trial?

Yes, so long as the patient meets all the inclusion criteria and none of the exclusion criteria, they are not required to have any ischaemia confirmed to be recruited into the trial. Identifying ischaemia is encouraged where possible, but it is not required for the trial.

If we are using an echo scan to confirm the qualifying EF, can we submit that as the baseline scan?

It depends.

If the qualifying EF is from an echo scan (either TTE or resting stage of DSE) within the past 6 months, then that scan can also be submitted as the baseline echo.

If the qualifying EF is from an echo scan (either TTE or resting stage of DSE) between 6-12 months or from a cardiac MRI, then a new echo scan should be done at or soon after randomisation and submitted as the baseline echo.

How long do we have following randomisation to book in the PCI procedure for the patient?

There is no time limit between randomisation and the PCI procedure, but we do recommend that it be scheduled in as soon as possible.

Contact the REVIVED Clinical Trials Unit

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