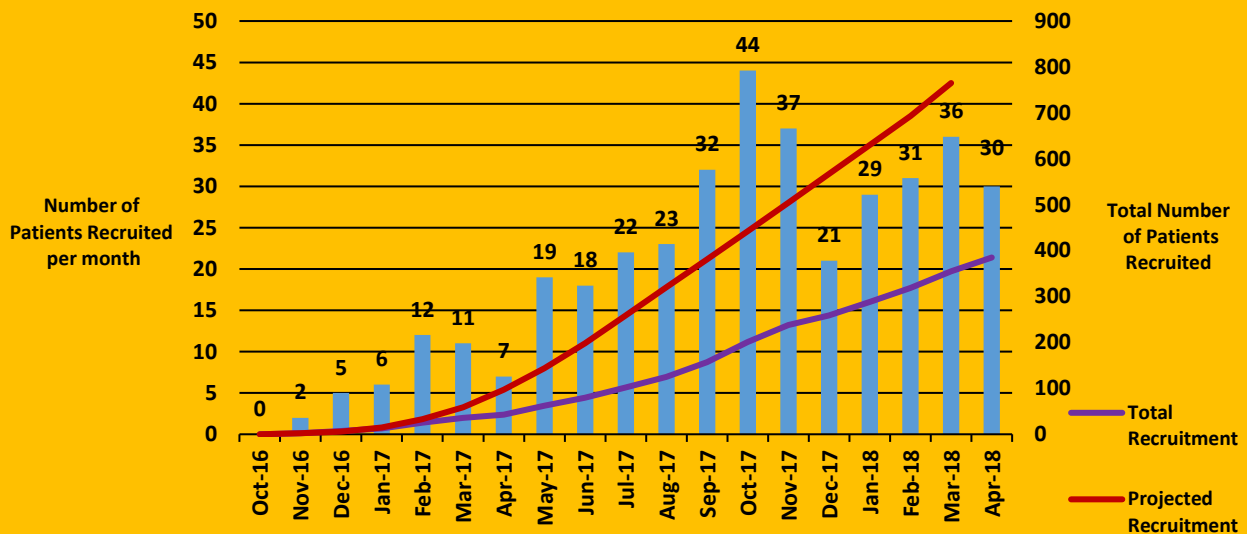


TOTAL RECRUITMENT: 385 PATIENTS!

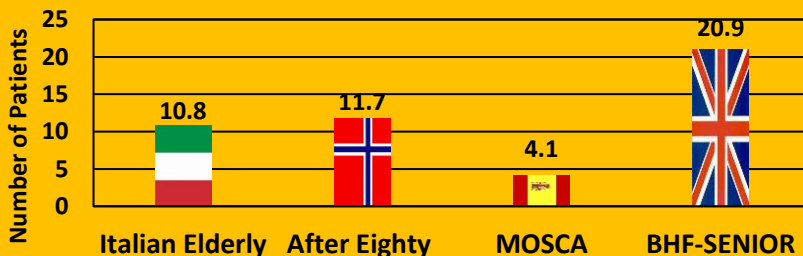

- ♥ Thank you to everyone for your commitment and dedication to SENIOR-RITA
- ♥ We are pleased to announce that **37 sites across the UK** are now open for recruitment - special welcome to our newly opened sites: **Fife, Aberdeen, Royal Oldham, Chel-West and Sunderland**
- ♥ We are in the process of including the remaining **3 new sites (Wigan, Bradford and Sandwell)**
- ♥ Our weekly target is **16-20 patients** and with 40 sites recruiting this is achievable with all your ongoing enthusiasm and support!


UK wide BHF SENIOR-RITA recruitment



- ♥ As you can see currently our recruitment rate is around 50% on target
- ♥ However, it is notoriously difficult to recruit older patients to randomised controlled trials. Nevertheless, **in comparison to previous elderly NSTEMI studies, we are recruiting far more patients per month, thanks to all our incredibly dedicated SENIOR RITA site teams and their commitment!** 😊

Patient Recruitment per Month





Unique features of SENIOR RITA (n=2300) 

Addresses current major burden

- Frailty
- Cognition
- Co-morbidity
- Quality of life
- Cost effectiveness

◆ Impacting Guidelines
◆ Changing practice



- ♥ Following feedback from sites, our main recruitment barriers are **EARLY CLINICAL DECISION-MAKING** and **LACK OF CLINICIAN ENGAGEMENT WITH SENIOR RITA**
- ♥ This highlights that changing **our** attitudes in the management of older patients can make a difference!
- ♥ Let's screen and *interact with eligible patients early and try our best to engage key clinical decision makers* with SENIOR RITA. Things like regular reminders, education sessions and being a prominent presence on recruitment wards may make all the difference

**THE BHF SENIOR-RITA TRIAL SITE LEVEL RECRUITMENT UPDATE
AS AT 30 APRIL 2018**

Site	Principal Investigator	Opened to recruitment	Monthly Site target	Recruited to Date
Aberdeen	Dr Awsan Noman	04-Dec-17	3	3
Ayrshire & Arran	Dr Vera Lennie	22-Mar-17	2	16
Borders	Dr Paul Neary	02-Jun-17	2	1
Dundee	Dr John Irving	13-Nov-17	2	3
Edinburgh	Prof Dave Newby	01-Dec-16	4	10
Fife	Dr Mark Francis	01-Dec-17	1	0
Lanarkshire	Dr Ross McGeoch	30-Mar-17	5	2
Royal Alexandra	Dr Keith Robertson	28-Feb-17	2	4
Basildon	Dr Rajesh Aggarwal	02-Dec-16	1	9
Birmingham	Dr Kaeng Lee	22-Nov-17	2	0
Blackpool	Dr Gavin Galasko	15-Nov-16	2	16
Chelsea & Westminster	Dr Sukhjinder Nijjer	26-Apr-18	5	0
Chesterfield	Dr Justin Cooke	30-Nov-16	2	18
Co Durham & Darlington	Prof Jerry Murphy	23-Jun-17	2	14
Derby	Dr Damian Kelly	22-Sep-17	1	7
East Sussex	Dr Robert Gerber	21-Feb-17	1	6
Epsom & St Helier	Dr Usha Prasad	04-Aug-17	5	2
Gateshead	Dr Ray Meleady	09-Dec-16	4	4
Imperial	Dr Rasha Al-Lamee	22-Aug-17	1	2
Lincoln	Dr Kelvin Lee	27-Jan-17	1	6
Mid-Essex	Dr Gerald Clesham	30-May-17	1	8
Newcastle	Dr Vijay Kunadian	31-Oct-16	8	75
North Cumbria	Dr Louise Buchanan	31-Jul-17	1	4
North Tees	Dr Justin Carter	23-Feb-17	2	37
Northumbria Healthcare	Dr Craig Runnett	27-Mar-17	2	29
Plymouth	Dr David Sarkar	15-May-17	1	9
Royal Berkshire	Dr Charlie McKenna	03-Jul-17	3	2
Royal Free	Dr Roby Rakhit	03-Jul-17	1	5
Royal Oldham	Dr Jolanta Sobolewska	13-Mar-18	3	0
Sheffield	Prof Rob Storey	25-Jan-17	4	22
South Manchester	Dr Hussain Contractor	15-Mar-17	2	16
South Tees	Dr David Austin	02-Dec-16	1	31
South Tyneside	Dr Abdul Nasser	16-Dec-16	0.5	6
Sunderland	Dr Shahid Junejo	15-Mar-18	3	0
Surrey & Sussex	Dr Shrilla Banerjee	02-Jun-17	1	7
Torbay & South Devon	Dr Dirk Felmeden	12-Jun-17	2	5
York	Dr Chris Gale	31-Aug-17	1	6
TOTAL				385

SHOUT OUT SECTION



The Newcastle upon Tyne Hospitals NHS Foundation Trust



North Tees and Hartlepool NHS Foundation Trust



CONGRATULATIONS to our top recruiting team based at the Newcastle Hospitals NHS Foundations Trust (Cardiology Research Team at Royal Victoria Infirmary pictured on the left, Dr. Ifti Haq, Dr. Kristian Bailey, Jenn, Pam and Dr. Danny Chan) – they have now recruited **75 patients overall and 23 patients in 2018!**

They put their success down to:

- ♥ Good relationship between ward staff and research staff
- ♥ Good clinician/Cardiologist engagement
- ♥ Clinical research fellow involvement in recruitment

Here's a **top tip** from our best recruiting site:

*“Explain to patients in layman’s terms that most studies in this area tend to exclude older patients and **emphasise how important SENIOR RITA is and how much we need their help in order to know which treatment for their heart attack is best**”*

– Dr Danny Chan, NIHR Academic Clinical Fellow Cardiology, Newcastle

A massive **WELL DONE** to the SENIOR RITA recruiters at North Tees Hospital (Dr. Justin Carter [PI], Julie, Pam,) – they have now recruited **36 patients in total and 17 patients in 2018**

They put their success down to:

- ♥ Early patient screening
- ♥ Good clinician engagement
- ♥ Regular education sessions and reminder emails about SENIOR RITA

Pictured: Dr. Matt Dewhurst, Pam Race, Julie Gray and Dr. Justin Carter. Thank you team! 😊

Did you know?

NHS England Research Strategy-2018

“To promote the ideal that every patient coming into the NHS is offered an opportunity to take part in research”

NIHR Survey

- ♥ **89% (9 out of 10)** of patients said they would take part in research
- ♥ **95%** said research was important to them that NHS carries our clinical research
- ♥ But how can they take part, if they are not aware of the research project?

Let's offer SENIOR RITA to every eligible patient and change/impact the SENIOR RITA landscape!

SENIOR RITA Recruiting Sites



SITE VISITS

Our chief investigator, Dr Vijay Kunadian, has been visiting some of our recruiting sites across the country

Surrey and Sussex



Surrey and Sussex site led by **Dr. Shrilla Banerjee and Sarah Davies** are committed to SENIOR RITA.

- ♥ They screen for eligible patients every day.
- ♥ The key recruitment promoters include fantastic engagement of cardiac nurses, building rapport with eligible patients, and the use of SENIOR RITA eligibility stickers.
- ♥ The key barriers to recruitment have been early clinician decision and insufficient time to inform patients about SENIOR RITA.
- ♥ Following site visit, several Cardiologists expressed keen interest in SENIOR RITA with a view to offering SENIOR RITA to ALL eligible patients!

Derby Teaching Hospitals



Derby site led by **Dr. Kelly and Marie Appleby** are also very committed to SENIOR RITA.

- ♥ Their recruitment promoters are SENIOR RITA advertising using the BHF heart matters news article, regular education sessions, collaboration with ward staff and research staff and engaging with family members.
- ♥ The barriers to recruitment include early clinical decision, and patient preference.
- ♥ They are addressing this by involving all the clinical team in the trial and also by using visual promoters such as the BBC news piece.

Epsom and St Helier University Hospitals



Epsom and St Helier site led by **Drs Mungi/Prasad and Rosavic** are also very committed to SENIOR RITA.

- ♥ Their recruitment promoters are trial advertising using ward posters, having regular ward-based education sessions about SENIOR RITA and having good communication between the ward staff and research staff.
- ♥ The current barriers to recruitment they face include early clinical decision and family member influence on the patient's decision to participate in SENIOR RITA.
- ♥ With site visit from CI, they have already increased clinician engagement with the study and train more doctors to consent patients

Imperial College Healthcare



Imperial site led by **Dr. Al-Lamee** are also very committed to SENIOR RITA.

- ♥ Their recruitment promoters are trial advertising using ward posters, regular SENIOR RITA reminders in their MDT meetings and regular PI emails to clinicians to remind them about SENIOR RITA.
- ♥ Barriers to recruiting patients at Imperial include early clinical decision, the lack of A+E and AMU facilities onsite meaning early patient contact is difficult and no out-of-hours screening.
- ♥ They strive to increase recruitment by increasing the size of their recruitment team, involving Cardiology Registrars and having PI-led education sessions about SENIOR RITA.

Chelsea and Westminster Hospital



- ♥ We are pleased to welcome our newest site Chelsea and Westminster which is led by **Dr. Nijjer and Marie** (pictured on the left). Their entire team are enthusiastic and we look forward to receiving your first patient. All the best with your recruitment!

Please do let us know if your site would like a visit from Dr Kunadian or another member of her research team to answer any questions you may have regarding SENIOR RITA

To assist newly opened sites and as a refresher to all other sites, please find below information to assist you in conducting this trial

SCREENING:

Each person eligible for SENIOR-RITA, whether or not recruited, must be recorded on the MACRO Screening log: **BHFSRita_Screen**. Screening numbers are 6 digits and in the following format: the first two digits being site number and the next four digits following sequentially starting with 0001. We ask that the screening database be updated as soon as possible after each screening takes place.

PROTOCOL AND CONSENT FORMS

Following Substantial Amendment 4, all sites should be operating to **Protocol v2.0 14th December 2017** and using the following versions of Information Sheets/Consent forms:

Participant Information Sheet & Participant Consent Form England v1.2 27th November 2017

Consultee Information Sheet & Consultee Declaration Form England v1.2 27th November 2017

Participant Information Sheet & Consent Form Scotland v1.3 27th November 2017

DOCUMENTS TO BE SUBMITTED TO THE NCTU

For each randomised participant, the following information will be collated:

- ♥ Participant or Consultee Consent form
- ♥ Eligibility criteria form
- ♥ Participant Contact details form
- ♥ Carer Contact Sheet (if applicable)

The above documents should be transmitted by **secure fax to the NCTU on 0191 5800987**. Should participating centres not have access to a fax machine, these documents will need to be sent as an **encrypted password protected file** via email to seniorrita.support@newcastle.ac.uk. The password should be sent in a separate email.

EQ-5D-5L QUESTIONNAIRES – 30 DAY AND 3 MONTH

The 30 day and 3 month questionnaires are sent to the participants by the SENIOR-RITA support team, NCTU. The data on the returned forms is entered by the NCTU on to MACRO.

SERIOUS ADVERSE EVENTS

Due to the nature of the study population (high-risk older patients with multiple co-morbidities) only serious adverse events which are causally (possible, probable or definitely) related to the study intervention (coronary angiography and/or PCI) **occurring within 7 days of the procedure** will be reported in **patients randomised to the invasive arm** only.

Events occurring in participants randomised to the **optimal medical therapy** will not be reported as SAE but will be recorded as an **outcome measure** in the eCRF.

SAE forms should be faxed to 0191 5800866 or emailed to soho66seniorrita@newcastle.ac.uk

RANDOMISATION SYSTEM

Site staff with access to the NCTU Randomisation Service are able to reset their passwords themselves. On the Log In page there is a 'Forgotten your password?' link that will request the users email address and then ask them to click **RESET PASSWORD**. A reset link will be sent to the users email account where they are requested to enter their email address and a new password. Please note the user is required to change their password within 15 minutes of receiving the email.

TRAINING LOGS

All new site staff must undertake study specific training and this must be recorded on the training log. A copy of this training log together with a current signed and dated CV, GCP certificate, and updated and authorised delegation log must be forwarded to the SENIOR-RITA support team. Training logs for all existing staff following implementation of SA4 must also be forwarded to the NCTU.

MACRO DATABASE AND DATA ENTRY

Please ensure all data is entered onto MACRO in a timely manner. We periodically raise batches of DCR's so you need to check MACRO on a regular basis for missing data and DCR red flags.

- ♥ For any questions where the data was not available, right click the mouse and select 'change status' then 'not available'. This will prevent this question from being flagged as missing.
- ♥ In order to close a DCR after you have resolved the query simply right click on the DCR you have responded to and select 'respond to DCR' – you will then be able to place a comment on the DCR and clarify how the DCR has been addressed in the dialog box. Select OK and close the DCR browser before saving the subjects visit page. After the data has either been changed, verified or marked as 'not available' the red flag will change to blue. A member of the NCTU will then be able to check all blue responded to DCR's and close them. Unless they are showing as blue flags, we are not aware that you have responded.

EMAIL ADDRESSES

We note that a few sites have been changing over to **nhs.net** email addresses. Please will you let us know if your email address has changed recently.

REMINDERS

SENIOR RITA INVESTIGATOR MEETING DURING THE BRITISH CARDIOVASCULAR SOCIETY CONFERENCE



Please mark your diaries for the **SENIOR-RITA Investigator Meeting** Tuesday 5th June 2018 10am to 12 noon during the British Cardiovascular Society Conference Stanley Suite, Midlands Hotel, Manchester. Agenda to follow soon.

We will hold workshops sharing best practice on recruitment.

Please remember to keep checking The SENIOR-RITA website for daily updates

<https://research.ncl.ac.uk/seniorrita/>

Also, don't forget to follow us on Twitter [@SNR_RITA_Trial](https://twitter.com/SNR_RITA_Trial)

Here is the link to the BHF Heart Matters news on the SENIOR RITA Trial

<https://www.bhf.org.uk/heart-matters-magazine/research/heart-attack-treatments-for-older-patients>

Be sure to check our weekly updates on Monday mornings and answers to FAQs

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Telephone: 0191 208 4591 or 0191 208 3825

E-mail: seniorrita.support@newcastle.ac.uk Clinical Queries: 0191 282 6710

Database queries e-mail nctu.database.support@newcastle.ac.uk