

EM 8

Rates, Risks and Routes to Reduce Vascular Dementia (R4VaD)				
Start date: 1 Oct 2017			Completion date: 30 Jun 2019	
<p>Overall objective: To recruit a wide range of patients with stroke, presenting in geographically diverse UK hospitals, into a longitudinal study to determine rates of, and risk factors for, cognitive and related impairments after stroke. The work focuses on understanding mechanisms and improving prediction models. This study has also been supported by a grant from a consortium of funders- the Stroke Association, British Heart Foundation and Alzheimer's Society. More broadly, the work builds on an NIHR programme grant supported by the Cochrane Dementia Group</p>				
Deliverables	Milestones	Milestone deadline	Work package dependencies	Person(s) responsible
Objective 1:				
D1.1 Set up the study and initiate patient recruitment	M1.1.1 Gain UK-wide ethical approval	M1.1.1 Complete	none	JMW, Bath, Quinn, Touyz, Werring, Williams, Markus, O'Brien, all of WP8 Vascular EM Group.
	M1.1.2 Make 1 st wave of staff appointments at each centre	M1.1.2 Complete		
	M1.1.3 To set up the applicant centres	M1.1.3 Complete		
	M.1.1.4 Recruit ~100 patients in 5 centres	M1.1.4 Complete		
Objective 2:				
D2.1 Patient data analysed (and written up for publication)	M2.1.1 To present study progress and any available data at the DPUK conference, UK Stroke Forum, or other relevant, in 2019	M2.1.1 Dec 2019		
	M2.1.2 Study data written up for publication	M2.1.2 Jan 2023		
Objective 3:				
D3.1 Involve and set up the study in additional sites	M3.1.1 Set up at least 15 of the additional sites	M3.1.1 Complete		
<p>Updates on delivery against milestones since last report</p> <ul style="list-style-type: none"> To present study progress and any available data at the DPUK conference, UK Stroke Forum, or other relevant, in 2019 (Dec 2019) <p>We have an investigator meeting scheduled for 5th December 2019 at the UK Stroke Forum, Telford. Several team members from Edinburgh (Wardlaw, Backhouse, Brown) will be in attendance and will present the study progress to date.</p>				
<p>Summary of plan to deliver on outstanding work (with dates)</p> <ul style="list-style-type: none"> Our advanced brain imaging and blood pressure monitoring sub studies are in set up and an ethics submission for the substantial amendment will be completed in the next few weeks. We aim to complete set up and begin recruitment to the sub studies by January 2020 We aim to submit our protocol paper for review before December 2019 				
Risks		Mitigation		
1) Low recruitment		1) Recruitment has now reached over 800 participants from 42 active sites and we are on target to reach our goal of 2000 participants by the end of the recruitment window		

<p>2) Incomplete data collection</p> <p>3) Drop out through onerous procedures</p> <p>4) Co-ordination of 1 year follow-ups between 3 centres</p> <p>5) Inadequate funding to respond to the overwhelming enthusiasm and wish to participate in the project from clinicians, researchers and participants alike.</p>	<p>2) Data is being checked regularly for completeness and efforts are being made to chase incomplete forms or address any issues identified.</p> <p>3) We have reviewed the CRF and are removing onerous questions. The CRF has built in stopping points and sites are encouraged to use these to prevent patient fatigue.</p> <p>4) All three follow up coordinators are now in place and are communicating both between themselves and also with the study manager and local sites to ensure the follow ups run smoothly.</p> <p>5) Seek additional funding from other sources.</p>
<p>Team members <u>funded</u> (full or part-time) by DPUK Study manager (R Brown, 0.4 FTE)</p> <p>Team members involved with the project but <u>not</u> funded by DPUK R4VaD study steering committee (J Wardlaw, P Bath, T Robinson and others), recruitment team (E Backhouse, L Fleming and others), programmer (R Dooley), statistician (L Woodhouse)</p>	
<p>Outcomes</p> <p>The R4VaD protocol and SAP papers are being drafted and will be submitted shortly.</p> <p>R4VaD was presented as an ongoing study at the European Stroke Organisation Conference (ESOC), Milan, May 2019. The study will also be presented at UKSF 2019, both at an investigator meeting and as a poster in the ongoing studies category.</p>	
<p>Project narrative</p> <p>We have made significant progress since our last report, recruiting over 800 participants, and setting up a total of 42 sites. We are on track with recruitment and site set up, and have now commenced the annual follow ups for our first few patients. Data completion is being monitored and sub studies are being prepared to commence by the start of 2020.</p> <p>All staff appointments are now in place, including our three annual follow up coordinators.</p> <p>The contribution from DPUK/MRC has been essential in aiding our set up and continued progress with the study.</p>	