

# Investigating changes in brain networks and cognition after heart surgery

<b>Submission date</b> 28/06/2018	<b>Recruitment status</b> Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 08/08/2018	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 03/10/2024	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Cognitive impairment is common after cardiac (heart) surgery, particularly in older people. Up to six in every 10 patients who undergo cardiac surgery have some degree of cognitive impairment six months after their surgery. The mechanisms involved are unclear. Recent research in brain imaging has identified some regions of the brain involved in learning and memory which are working when the brain is "at rest", that is when the subject is not performing an explicit cognitive task. These brain networks, so called "resting state networks", represent the baseline, or default, mode of the brain. Brain imaging studies have shown that when the activity of resting state networks is reduced, patients are more likely to develop cognitive impairment. There is currently limited evidence to suggest whether cardiac surgery causes damage to resting state networks thus leading to cognitive impairment. This study will investigate changes in resting state networks in 20 patients undergoing cardiac surgery with cardiopulmonary bypass (CPB) using functional brain magnetic resonance imaging (fMRI). This study will help doctors to better understand the mechanisms leading to cognitive impairment following cardiac surgery and will aid in the development of preventive strategies and new treatments.

### Who can participate?

Patients aged between 60 and 75 undergoing coronary artery bypass surgery (CABG) with CPB at the Bristol Heart Institute

### What does the study involve?

All patients undergo two fMRI scans and cognitive assessments. The first scan and cognitive assessments take place around 1 week before their heart surgery and the second around 6 weeks after surgery. Each fMRI scan takes about 40 minutes. The cognitive tests take around 45 minutes and assess memory, coordination and levels of attention.

### What are the possible benefits and risks of participating?

There are no direct benefits of participating in this study. This study of the potential role of default mode networks in CPB-related cognitive decline could aid the development of interventions to improve neurocognitive outcomes following surgery, such as cognitive training and physical exercise. There are no associated risks with functional MRI or the neurocognitive assessments.

Where is the study run from?  
University Hospitals Bristol NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?  
April 2018 to March 2020

Who is funding the study?  
Above and Beyond (UK)

Who is the main contact?  
Mr Jonathan Evans  
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## Contact information

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## Additional identifiers

# Study information

## Scientific Title

Investigation of neural mechanisms of COgnitive DEcline after Cardiac surgery with resting state fMRI (CODEC): a pilot study

## Acronym

CODEC

## Study objectives

The primary hypothesis is that default mode network connectivity is impaired following coronary artery bypass graft surgery with cardiopulmonary bypass and correlates with neurocognitive testing.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 03/12/2018, London - Hampstead Research Ethics Committee (Barlow House 3rd Floor, 4 Minshull Street, Manchester M1 3DZ; 0207 104 8345; NRESCommittee.London-Hampstead@nhs.net), ref: 18/LO/2121

## Study design

Single-centre observational study

## Primary study design

Observational

## Study type(s)

Other

## Health condition(s) or problem(s) studied

Cardiac disease/coronary artery bypass grafting

## Interventions

Patients who consent will be required to undergo two functional MRI scans and neuro-cognitive assessments. Patients will have the first scan and neuro-cognitive assessments pre-surgery (1- 8 weeks before surgery date). The second scan and assessments will take place post-surgery (5-10 weeks post surgery date). Each fMRI scan will take approximately 40 minutes. The scans will take place at the Bristol Clinical Research and Imaging Centre. The neuro-cognitive assessment involves tests that assess memory, coordination and levels of attention. As part of the assessment patients will also complete two questionnaires examining current mood/emotional state. Each neuro-cognitive assessment will take approximately 45 minutes.

## Intervention Type

Other

## Primary outcome(s)

The change from baseline in default mode network connectivity in the brain post cardiac surgery as assessed by resting state fMRI performed 5-10 weeks post operatively

### **Key secondary outcome(s)**

1. Change from baseline in cognitive ability as assessed by standard neurocognitive tests administered 5- 10 weeks post operatively
2. Length of intensive care unit (ICU)/high dependency unit (HDU) stay. This outcome is assessed during the patient's hospital stay after their surgery.
3. All-cause mortality within 30 days of surgery
4. Clinical outcomes (assessed from surgery until follow up visit 5- 10 weeks post-surgery), defined as:
  - 4.1. Infectious complications i.e. sepsis (defined antibiotic treatment for suspected infection, and the presence of SIRS1 within 24 hours prior to start of antibiotic treatment) or wound infection (ASEPSIS score >20; sternum, leg and arm (if applicable); wounds will be assessed at least once during a participant's hospital stay
  - 4.2. Stroke (validated by CT scanning); assessment of brain imaging (CT or MRI), in association with new onset focal or generalised neurological deficit (defined as deficit in motor, sensory or co-ordination functions)
  - 4.3. ST elevation myocardial infarction accompanied by troponin > 5 ng / ml
  - 4.4. Post-operative acute kidney injury (defined as AKIN criteria stage 1, 2 or 3)
  - 4.5. Respiratory complications i.e. re-intubation, ventilation

The study will also assess the relationship between cognitive decline assessed by the neurocognitive tests (secondary outcome 1) and changes in resting state network connectivity assessed by fMRI (primary outcome).

### **Completion date**

09/02/2021

### **Reason abandoned (if study stopped)**

Lack of staff/facilities/resources

## **Eligibility**

### **Key inclusion criteria**

1. Aged between 60-75 years
2. Electively referred for isolated coronary artery bypass grafting

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Senior

### **Sex**

All

### **Key exclusion criteria**

1. Prisoners and adults lacking capacity to consent
2. Contraindications to MR (implanted electronic devices, metallic foreign bodies,

claustrophobia, body weight >140 kg or waist perimeter exceeding manufacturer's recommendations and others according to manufacturer's recommendations and generally accepted guidelines)

3. Patients with a neurological disorder (e.g. epilepsy, Alzheimer's, dementia and Parkinson's disease)

4. Patients with a diagnosed psychiatric disorder (e.g. schizophrenia, psychosis), drug or alcohol addiction

5. Patients with an already identified as having cognitive impairment (e.g. memory and/or attentional deficits) as defined by psychometric assessment or a preoperative Mini-mental State Examination score < 24. The Mini-mental State Examination will be administered after consent but prior to any of the cognitive assessments or fMRI scan

6. Patients who have previously sustained a stroke, intra-cerebral haemorrhage, acquired brain injury

7. Patients unable to complete the cognitive assessments required for the trial e.g. due to language difficulties, visual or hearing impairment

**Date of first enrolment**

15/04/2019

**Date of final enrolment**

01/12/2020

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**University Hospitals Bristol NHS Foundation Trust**

Marlborough Street

Bristol

United Kingdom

BS1 3NU

## **Sponsor information**

**Organisation**

University Hospitals Bristol NHS Foundation Trust

**ROR**

<https://ror.org/04nm1cv11>

# Funder(s)

## Funder type

Charity

## Funder Name

Above and Beyond (Registered Charity Number: 229945)

# Results and Publications

## Individual participant data (IPD) sharing plan

Current IPD sharing statement as of 11/07/2019:

Anonymised individual patient data (baseline, operative, outcome data and adverse events) will be made available for secondary research, conditional on assurance from the secondary researcher that the proposed use of the data is compliant with the MRC Policy on Data Preservation and Sharing regarding scientific quality, ethical requirements and value for money. Please contact Prof. Chris Rogers ([chris.rogers@bristol.ac.uk](mailto:chris.rogers@bristol.ac.uk)) to discuss any data requests. Data will be made after the study has been closed and the primary publication is out. It will be made available indefinitely. The patient information leaflet which participants consent to explains that we will only share information collected in this study with the participants' agreement. The consent form includes the following question 'I give permission for data collected as part of this study to be used in future ethically approved studies'.

Previous IPD sharing statement:

Anonymised individual patient data (baseline, operative, outcome data and adverse events) will be made available for secondary research, conditional on assurance from the secondary researcher that the proposed use of the data is compliant with the MRC Policy on Data Preservation and Sharing regarding scientific quality, ethical requirements and value for money. Please contact Prof. Chris Rogers ([chris.rogers@bristol.ac.uk](mailto:chris.rogers@bristol.ac.uk)) to discuss any data requests. Data will be made after the study has been closed and the primary publication is out. It will be made available indefinitely. The patient information leaflet which participants consent to explains that data may be provided to researchers running other research studies.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No