

# Cardiovascular rehabilitation adapted to transient ischaemic attack and stroke

<b>Submission date</b> 30/07/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/09/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/01/2012	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
HSR/2007/6

# Study information

## Scientific Title

A randomised controlled trial to evaluate the benefit of a cardiac rehabilitation programme for improving fitness and reducing cardiovascular risk factors in the non-acute ischaemic stroke and transient ischaemic attack populations

## Acronym

CRAFTS

## Study objectives

A comprehensive cardiac rehabilitation programme involving aerobic exercise training, brief life-style intervention counselling and two didactic classes in risk reduction effects a greater change in cardiac risk score (as calculated from blood pressure, lipid profile, age, sex and diabetic status) and healthy lifestyle participation (exercise, diet and smoking cessation) than education classes alone.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from the University of Dublin Human Research Ethics Sub-committee (ref: HREC-19-06-Blake) on the 25th May 2006. This included approval for a qualitative strand currently completed.

## Study design

A single blinded randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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

Stroke, transient ischaemic attack

## Interventions

Over 8 weeks:

Control subjects will attend two one-hour educational session addressing risk factor reduction and lifeskills.

Intervention subjects will attend the two educational classes listed above. In addition they will attend for 16 one-hour aerobic training sessions and will receive brief intervention counselling individually tailored to their lifestyle risk factors and readiness to change on the transtheoretical model.

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome measure**

1. Adherence to the European guidelines for cardiovascular disease prevention in a high risk group as evidenced by the % of smokers, fruit and vegetable intake and habitual exercise, i.e. % taking moderate to vigorous activity greater than three times a week extrapolated from the International Physical Activity Questionnaire
2. Cardiac Risk Score

Baseline measures of the primary and secondary outcomes will be taken on week 1. Reassessment will be conducted on week 10 and at a one year interval.

### **Secondary outcome measures**

1. Physical fitness: VO2 as calculated from a steady state sub-maximal cycle ergometry test
2. Health related quality of life as measured by the Stroke Specific Quality of Life Index, Hospital Anxiety and Depression Scale, Functional Health Status COOP/WONCA Scale
3. Economic evaluation derived from EuroQol-5D

Baseline measures of the primary and secondary outcomes will be taken on week 1. Reassessment will be conducted on week 10 and at a one year interval.

### **Overall study start date**

01/10/2007

### **Completion date**

31/10/2010

## **Eligibility**

### **Key inclusion criteria**

1. Adults of either gender aged greater than 18 years of age who have sustained an ischaemic stroke (confirmed by computed tomography [CT] or magnetic resonance imaging [MRI]) or a transient ischaemic attack (TIA)
2. Cerebrovascular accident [CVA] greater than one year recruited through the community with medical consent
3. CVA less than 1 year with consent of their hospital consultant
4. TIA greater than 3 months with consent of their hospital consultant

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

240

**Key exclusion criteria**

1. Major medical conditions
2. Oxygen dependence
3. Unstable cardiac conditions including angina
4. Uncontrolled diabetes
5. Claudication
6. Acute febrile illness
7. Cognitive impairment
8. Pregnancy
9. Uncontrolled diabetes

**Date of first enrolment**

01/10/2007

**Date of final enrolment**

31/10/2010

**Locations****Countries of recruitment**

Ireland

**Study participating centre**

School of Physiotherapy and Performance Science

Dublin

Ireland

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**Sponsor information**

**Organisation**

Health Research Board (HRB) (Ireland)

**Sponsor details**

73 Lower Baggot Street  
Dublin  
Ireland  
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**Sponsor type**

Government

**Website**

<http://www.hrb.ie>

**ROR**

<https://ror.org/003hb2249>

**Funder(s)****Funder type**

Government

**Funder Name**

Health Research Board (HRB) (Ireland) (ref: HSR/2007/6)

**Alternative Name(s)**

HRB

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

Ireland

**Funder Name**

University College Dublin (Ireland) (ref: Seed Fund SF109)

**Alternative Name(s)**

UCD

**Funding Body Type**

Private sector organisation

### Funding Body Subtype

Universities (academic only)

### Location

Ireland

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Other publications</a>	pilot study	01/02/2008		Yes	No
<a href="#">Results article</a>	results	01/09/2011		Yes	No