

Cardiovascular rehabilitation adapted to transient ischaemic attack and stroke

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

Protocol serial number
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 lifestyle 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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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

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?
Results article	results	01/09/2011		Yes	No
Other publications	pilot study	01/02/2008		Yes	No