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Cardiovascular rehabilitation adapted to transient ischaemic attack and stroke

Submission date	Recruitment status	[_] Prospectively registered
30/07/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/09/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/01/2012	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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4

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
4

Sponsor information

Organisation
Health Research Board (HRB) (Ireland)

Sponsor details
73 Lower Baggot Street
Dublin
Ireland
2

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