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Is the cardiac model of rehabilitation is more effective than standard care in reducing cerebrovascular risk factors post-transient ischaemic attack?

Submission date 08/07/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/09/2009	**Overall study status** Completed	
Last Edited 01/08/2013	**Condition category** Circulatory System	

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
RHM MED0832; PRF/08/04

Study information

Scientific Title
A single centre phase II feasibility study evaluating if the cardiac model of rehabilitation is more effective than standard care in reducing cerebrovascular risk factors post-transient ischaemic attack

Acronym
Ex4TIA Study

Study objectives
Providing a cardiac model of rehabilitation (exercise and lifestyle strategies) for people within one month of a transient ischaemic attack (TIA)/minor stroke will improve their physiological status and reduce their vascular risk as defined by the cardiovascular and cerebrovascular score. We will ask the following questions:
1. Does the intervention produce significant physiological changes associated with atherosclerotic disease?
2. Does the intervention enhance lifestyle changes more effectively than standard care?
3. Do the patients perceive any benefit from the intervention in relation to standard care?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Southampton and South West Hampshire Research Ethics Committee (B) approved on the 16th April 2009 (ref: 09/H0501/46)

Study design
Single centre exploratory single-blind two group randomised controlled phase II feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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

Cerebrovascular disease - transient ischaemic attack/minor strokes

Interventions
Although a single centre study, this trial is registered for ethical purposes as a two site study as recruitment occurs in a different site (Acute Hospital Trust) to the intervention (Primary Care Trust).

Intervention group:
Cardiac Rehabilitation Programme (Exercise and Lifestyle Education). Participants will have baseline data collected within 1 month of their cerebrovascular event following which they will then be randomised to standard care or standard care and cardiac rehabilitation with endpoint data collection 5 months subsequently. The intervention is an existing standard NHS cardiac rehabilitation programme consisting of Phases 2 - 4:
Phase 2 = risk stratification, education, family involvement and support
Phase 3 = structured exercise & education sessions
Phase 4 = patient directed continuation of the exercise component and the long term maintenance of individual goals

Control group:
Standard care.

All participants primary and secondary outcomes (with the exception of the qualitative interviews) will be recorded at the same time. Participants will have initial baseline measures recorded within one month of their cerebrovascular event (TIA/minor stroke). All participants will then continue for a five month period with standard care (routine TIA investigations and pharmaceutical treatments along with a short piece of lifestyle advice) or standard care and the intervention. All participants will return for endpoint data collection in the fifth month after initial baseline data collection. A number of patients will then be randomly selected (estimation 20) to be interviewed in order to gain a subjective analysis of their views regarding standard care and the cardiac model of rehabilitation.

Intervention Type
Other

Phase
Phase II

Primary outcome measure
Cardiac Risk Score: an algorithmic score that assesses the future risk of cardiac events based on age, sex, smoking status, resting blood pressure, diabetic status, total cholesterol and high-density/low-density lipoprotein cholesterol. Measured at baseline and 5 months.

Secondary outcome measures
Measured at baseline and 5 months:
1. Biomarkers (C-reactive protein, fibrinogen)
2. Cardiovascular Disease Score: similar to the Cardiac Risk Score but allows for the identification of cerebrovascular risk
3. Exercise frequency: self-reported
4. Exercise capacity: maximal oxygen uptake (VO2) estimation derived from the Astrand-Rhyming cycle ergometer test (for participants not taking Beta Blockers)
5. Obesity: body mass index (BMI) and Waist-to-Hip ratio

6. Diet: quantity of fruit and vegetables consumed daily
7. Mood: Hospital Anxiety and Depression (HAD) score
8. Quality of Life: 36-item short form health survey (SF-36)
9. Qualitative analyses - purposive sampling of up to 10 participants from each arm with thematic analyses of semi-structured interviews

Overall study start date
20/07/2009

Completion date
20/10/2010

Eligibility

Key inclusion criteria
1. Diagnosis (within 1 month of incident) of:
1.1. TIA - resolution of symptoms less than 24 hours of onset (not suspected patent foramen ovale [PFO]), or
1.2. Minor stroke - National Institutes of Health Stroke Scale (NIHSS) score less than 3
2. Lives within geographic locality (GP postcodes)
3. Independently mobile (can use stick but no falls within 2 months)
4. No significant visual/speech impairment
5. Cognitive capacity to undertake group exercises (no apparent dementia)
6. Able to give verbal and written consent
7. Aged greater than 18 years, either sex
8. Considered medically fit for exercise (Canadian Angina score and SIGN 2002 guidance)
9. No previous experience of cardiac rehabilitation
10. No current or recent participation in research

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
1. TIA of suspected patent foramen ovale (hole in heart) origin with no other significant vascular risk factors
2. Live outside of the area covered by Southampton Cardiac Rehabilitation Team
3. Aphasia or other communication problems affecting ability to consent or to understand information given

4. Apparent dementia or significant cognitive impairment (mini-mental test [MMT] score less than 7)
5. Previously undertaken cardiac rehabilitation
6. Involved in current research or have recently been involved in any research

Date of first enrolment
20/07/2009

Date of final enrolment
20/10/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Rehabilitation Research, MP 886
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Sponsor information

Organisation
Southampton University Hospitals NHS Trust (UK)

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Sponsor type
Hospital/treatment centre

Website

http://www.suht.nhs.uk/home.aspx

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Research organisation

Funder Name
Physiotherapy Research Foundation (UK) (ref: PRF/08/04)

Funder Name
Private Physiotherapy Education Foundation (UK)

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?
Results article	results (patients' experiences)	01/09/2013		Yes	No