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A randomised controlled trial of goal setting and pacing for cardiac patients not suitable for group-based cardiac rehabilitation

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 16/06/2014	**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
RRCC860F WATHALL

Study information

Scientific Title

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

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
Cardiovascular diseases: Heart disease

Interventions
1. Goal-setting and pacing
2. Standard care
3. Attention control procedure

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The primary outcome will be an increase in fitness measured in (METS) using a standardised exercise test. The patients will also keep an activity diary. Other variables to be measured will

include anxiety and depression (Hospital Anxiety and Depression Scale), health beliefs (Illness Perception Questionnaire), this questionnaire has been shown to predict a number of aspects of recovery in post-MI patients, medical co-morbidity, the number of acute events (including hospital admissions), the number of consultations for cardiac reasons, risk factor profile, a cumulative secondary prevention score (using the method of the ASPIRE group), systolic and diastolic blood pressure at rest and following exercise and the EuroQU0L, a measure of health-related quality of life. All of these measures have been validated for use in this patient group and will be piloted during Phase 1 for suitability when other measures may be added.

Secondary outcome measures
Not provided at time of registration

Overall study start date
08/01/2000

Completion date
03/01/2003

Eligibility

Key inclusion criteria
Coronary care patients

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Patients who would normally be offered rehabilitation classes

Date of first enrolment
08/01/2000

Date of final enrolment
03/01/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
94 Huntington Road
York
United Kingdom
YO31 8RP

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive Northern and Yorkshire (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