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

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

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

Goal-setting and pacing
Standard care
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 healthrelated 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