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Effectiveness of a home-based intervention in increasing level of compliance, and cardiac self-efficacy, and reducing anxiety and depression amongst first-time myocardial infarction (MI) and coronary artery bypass graft (CABG) patients in the first 6 weeks.

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 11/06/2014	**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
RRCC744F DRIVER

Study information

Scientific Title

Study objectives
Does a time structured series of home-based interventions to recently discharged first-time MI and CABG patients, which focus on the encouragement of lifestyle changes related to diet, stress and exercise, have the effect of: raising the patients' level of compliance with the formal cardiac rehabilitation course; raising their self-efficacy for cardiac-related lifestyle change; and reducing the patients' level of anxiety and depression. The study also asks if there are any relationships between these factors, and how they might vary between the MI and CABG groups. The qualitative dimension of the study seeks to explore questions related to the experience of these patients in the immediate post-discharge period, particularly in relation to adjustment within the context of their specific socio-cultural environment.

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. The experimental groups will receive a home-based intervention based on the South Tees Cardiac Rehabilitation document 'A Helping Hand to Heart Recovery', which focuses on lifestyle issues such as diet, exercise and stress management. This intervention will be built around three home visits to the patients in the experimental group at 1, 3 and 6 weeks post-discharge.
2. The control group will receive usual treatment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Compliance with the formal 7-week cardiac rehabilitation course which takes place at 6 -8 weeks post discharge
1. Self-efficacy scores at 1 week and 8 weeks post discharge
2. Anxiety scores at 1 and 8 weeks post discharge
3. Depression scores at 1 and 8 weeks post discharge
4. Descriptive data generated from qualitative interviews which focus on adjustment and lifestyle change

Secondary outcome measures
Not provided at time of registration

Overall study start date
10/01/1999

Completion date
10/01/2001

Eligibility

Key inclusion criteria
Recently discharged first-time MI and CABG patients who are English speaking with no identifiable history of psychiatric illness

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment
10/01/1999

Date of final enrolment
10/01/2001

Locations

Countries of recruitment
United Kingdom

Study participating centre
Tees and North East Yorkshire NHS Trust
Middlesbrough
United Kingdom
TS26 OPT

Sponsor information

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

Sponsor details
The Department of Health
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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