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Effects of patient-centered modular secondary prevention in people with acute coronary syndrome

Submission date 24/01/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 24/01/2006	**Overall study status** Completed	
Last Edited 02/11/2022	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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2100

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G03S1204

Study information

Scientific Title
Effects of patient-centered modular secondary prevention in people with acute coronary syndrome

Study objectives
This study aims to test the effect of modular secondary prevention on total blood cholesterol, heart disease risk factors and knowledge in persons who have had an acute coronary syndrome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Central Sydney Area Health Services Human Research and Ethics Committee (CRGH) on 21st May 2003 (ref: CH/62/6/2003-021).

Study design
Single blinded, randomised controlled trial with three groups

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Coronary heart disease and acute coronary syndrome

Interventions
Intervention group will participate in modular prevention including individual risk factor assessment, goal setting and coaching. Control group will continue conventional care by their general practitioner. The standard cardiac rehabilitation group will participate in hospital-based cardiac rehabilitation including six weeks of group exercise and education.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

Proportion of participants with total blood cholesterol less than 4.5 mmol/l.

Secondary outcome measures
Proportion of participants achieving nationally recommended targets for heart disease risk factors, absolute heart disease risk on the lipid risk score and risk factor knowledge

Overall study start date
01/01/2004

Completion date
01/07/2006

Eligibility

Key inclusion criteria
1. Acute coronary syndrome within 12 months of assessment
2. Refusal of invitation to participate in cardiac rehabilitation

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
208

Total final enrolment
144

Key exclusion criteria
Diagnosis of uncontrolled cardiomyopathy, aortic stenosis, arrhythmia, dementia or a terminal illness such as end-stage renal failure

Date of first enrolment
01/01/2004

Date of final enrolment
01/07/2006

Locations

Countries of recruitment
Australia

Study participating centre
10/1-3 Funda Pl
Sydney NSW
Australia
2100

Sponsor information

Organisation
National Heart Foundation of Australia

Sponsor details
Research Division
411 King Street
West Melbourne VIC
Australia
3003

Sponsor type
Charity

Website
http://www.heartfoundation.com.au

ROR
https://ror.org/039d9wr27

Funder(s)

Funder type
Charity

Funder Name
National Heart Foundation of Australia Grant-in-Aid (G03S1204) and a Postgraduate Clinical Research Scholarship for Julie Hila (PC03S1258).

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		09/06/2006		Yes	No
Results article		01/03/2009		Yes	No