Improving patient reassurance through an early intervention prior to exercise stress testing

Submission date	Recruitment status No longer recruiting	Prospectively registered		
25/10/2006		☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
20/11/2006		[X] Results		
Last Edited	Condition category	[] Individual participant data		
02/08/2007	Signs and Symptoms			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Keith Petrie

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives

Providing information about normal findings prior to a exercise stress test will improve reassurance and reduce anxiety about symptoms following the investigation in patients with a negative test result.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by New Zealand Ministry of Health Ethics Committee (ref AKY/04/05/121) on 21 May, 2004.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Symptoms of chest pain

Interventions

Group one: standard information.

Group two: a pamphlet explaining the function and meaning of negative results from the test. Group three: the pamphlet and a brief discussion about what normal results of the test mean.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 1. Patients reported reassurance.
- 2. Levels of worry about their health and belief that something is seriously wrong with their heart, measured immediately following the test and at one month following testing.

Secondary outcome measures

Complaints of chest pain and whether continuing to take cardiac medication.

Overall study start date

01/06/2004

Completion date

31/10/2004

Eligibility

Key inclusion criteria

Patients referred for exercise stress test with negative findings

Participant type(s)

Patient

Age group

Adult

Sex

Not Specified

Target number of participants

90

Key exclusion criteria

- 1. Aged less than 18 years
- 2. Previously diagnosed cardiac pathology
- 3. No symptoms of chest pain
- 4. Undertaking the stress exercise test as part of a pre-surgical medical examination
- 5. Positive exercise stress test

Date of first enrolment

01/06/2004

Date of final enrolment

31/10/2004

Locations

Countries of recruitment

New Zealand

Study participating centre Department of Psychological Medicine Auckland New Zealand 1001

Sponsor information

Organisation

University of Auckland (New Zealand)

Sponsor details

Private Bag 92019 Auckland New Zealand 1001 kj.petrie@auckland.ac.nz

Sponsor type

University/education

Website

http://www.auckland.ac.nz/

ROR

https://ror.org/03b94tp07

Funder(s)

Funder type

University/education

Funder Name

University of Auckland (New Zealand)

Alternative Name(s)

University of Auckland, New Zealand, UoA

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

New Zealand

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:	17/02/2007		Yes	No