

Evaluating the benefits of an advice and relaxation tape given during acute myocardial infarction (MI).

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/09/2009	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

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

RM103

Study information

Scientific Title

Study objectives

To determine if an advice and relaxation tape given to patients within 12 hours of admission to hospital with acute myocardial infarction would reduce anxiety and depression and lead to improved cardiac knowledge and rehabilitative outcomes.

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)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Cardiovascular diseases: Heart disease

Interventions

1. A specially developed audiocassette with relaxation instruction and advice and information - to be listened to as often as the patient wished and taken home on discharge.
2. An audio cassette of music chosen by the patient from a selection of different musical genres.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Coronary risk factors
 - 1.1. body mass index
 - 1.2. smoking
 - 1.3. behaviour
 - 1.4. cholesterol
 - 1.5. blood pressure
2. Physiological status
 - 2.1. heart rate
 - 2.2. blood pressure
3. Psychological status
 - 3.1. anxiety
 - 1.2. depression
4. Cardiac misconceptions

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/10/1997

Completion date

01/03/1999

Eligibility**Key inclusion criteria**

Patients admitted to a coronary care ward with acute MI.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

243 (added 17/07/09)

Key exclusion criteria

Patients regarded by medical staff in the CCU as being too ill to take part in the trial.

Date of first enrolment

01/10/1997

Date of final enrolment

01/03/1999

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Department of Health Sciences

York

United Kingdom

YO10 5DQ

Sponsor information

Organisation

Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Cardiovascular Disease and Stroke National Research and Development Programme (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2002		Yes	No