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Evaluation of a self-help, home-based comprehensive rehabilitation programme for Implantable Cardiac Defibrillator patients

Submission date 16/05/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/07/2007	**Overall study status** Completed	
Last Edited 11/12/2008	**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

MREC/03/2/053

Study information

Scientific Title

Acronym
ICD-Plan Trial

Study objectives
To assess the effectiveness of a rehabilitation programme (the Implantable Cardiac Defibrillator [ICD]-Plan), for patients undergoing implantation of a cardiac defibrillator.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the London Multicentre Research Ethics Committee (MREC) on the 17th November 2003.

Study design
A prospective multicentred, intention-to-treat cluster randomised controlled trial of implantation centres to intervention or control.

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
Cardiac disease rehabilitation

Interventions
The ICD Plan:
Healthcare staff in the intervention centres participated in a half-day training session delivered by a clinical psychologist. Training utilised a mixed format utilising presentations, case studies, role-playing and scenarios. The training addressed a number of issues including risk factors and their reduction, the psychology of cardiac disease, cardiac concerns and misconceptions, goal setting and pacing, the over-activity and rest cycle, self-management of anxiety and low mood, basic breathing and relaxation techniques and basic principles of cognitive-behavioural therapy.

The ICD Plan consisted of three patient held booklets, a goal-setting diary and relaxation tape or CD:
1. The first booklet was given to patients whilst awaiting implantation. It dealt with common fears experienced by patients prior to surgery. These were identified from consultation with ICD patients themselves, healthcare staff and the research literature and explained the device. It targeted the ICD concerns that have been shown to lead to increased disability and anxiety and depression and introduced relaxation and better breathing to help patients cope with the stress of surgery and ICD implantation
2. The second booklet was a short one for relatives and carers detailing how they could help
3. The third booklet explained the best way to get back to normal and avoid further problems. It was a cognitive-behavioural rehabilitation programme in self-help form. The Facilitator and the patient, and when possible the family discussed the patients rehabilitation needs and set some simple initial goals
4. The goal setting diary was structured to be 12 weeks in length. The manuals are a self-help plan and can be worked through at the patients own pace

The patient and facilitator made contact three more times to discuss progress and set new goals.

Control:
Patients in the control group received care as usual.

Both groups also received a written information booklet by the British Heart Foundation (BHF) on how to manage ICDs. This booklet is available in the public domain.

Both intervention and control group received follow-up at the same time intervals using the measures. These time intervals were:
1. Pre-implantation questionnaire
2. Post-implantation questionnaire
3. Three-month follow-up questionnaire
4. Six-month follow-up questionnaire

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Anxiety and depression, the primary outcome, was measured using the Hospital Anxiety and Depression Scale (HADS). HADS is a 20-item instrument with two subscales measuring anxiety and depression with higher scores indicating greater psychological morbidity. A score of eight or more on either subscale indicates borderline case-ness for anxiety or depression. This was measured at pre-implantation, post-implantation, and three- and six-month follow-up.

Secondary outcome measures
1. Health related quality of life was measured using the 12-item Short Form health survey (SF-12), measured at pre-implantation, post-implantation, and three- and six-month follow-up
2. Changes in the functional status of the sample was measured using the physical limitations subscale of the Seattle Angina Questionnaire (SAQ), measured at pre-implantation, post-implantation, and three- and six-month follow-up
3. Data on the number of shocks and ICD storms (three or more ICD shocks in any 24 hour

period) in the six months following implantation were provided by the electrophysiologist at each centre
4. Service utilisation was measured using self-completed questionnaires developed for the measurement of health economic events in randomised controlled trials, measured at pre-implantation, post-implantation, and three- and six-month follow-up

Overall study start date
01/12/2003

Completion date
31/01/2005

Eligibility

Key inclusion criteria
1. Men and women aged 18 years or more
2. Due to receive an ICD
3. Provided consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
188

Key exclusion criteria
1. Angina pectoris, Canadian Cardiovascular Society (CCS) class III and IV
2. New York Heart Association (NYHA) functional class IV
3. Cognitive impairment (judgement by clinician)
4. Inability to participate in a regular rehabilitation program at discharge
5. Inability to understand English
6. Exercise limitations due to clinical conditions not related to Coronary Artery Disease (CAD)
7. Known exercise-induced tachyarrhythmias
8. Cardiomyopathy associated with haemodynamic obstruction
9. Any major non-cardiac condition, that would adversely affect survival during the duration of the study
10. Patients unlikely to comply to the study and/or follow-up visits (including abuse of any substances)
11. Participation in a concurrent investigational research study or cardiac rehabilitation programme

Date of first enrolment
01/12/2003

Date of final enrolment
31/01/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Sponsor information

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Medtronic Ltd (UK)

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Medtronic Ltd (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	01/01/2009		Yes	No