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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Dorothy Frizelle

Contact details

The Department of Clincal Psychology Postgraduate Medical Institute University of Hull Cottingham Road Hull United Kingdom HU6 7RX d.frizelle@hull.ac.uk

Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s))

- 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 preimplantation, post-implantation, and three- and six-month follow-up

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre
The Department of Clincal Psychology
Hull
United Kingdom
HU6 7RX

Sponsor information

Organisation

Medtronic Ltd (UK)

ROR

https://ror.org/00grd1h17

Funder(s)

Funder type

Industry

Funder Name

Medtronic Ltd (UK)

Results and Publications

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