

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

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<b>Registration date</b> 03/07/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/12/2008	<b>Condition category</b> 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**

# 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**

The Department of Clinical Psychology

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## **Sponsor information**

**Organisation**

Medtronic Ltd (UK)

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**Sponsor type**

Industry

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**ROR**

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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?
<a href="#">Results article</a>	results	01/01/2009		Yes	No