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Cost-effectiveness of a management program after hospital discharge in older patients with heart failure

Submission date
19/12/2011

Recruitment status
No longer recruiting

Registration date
27/01/2012

Overall study status
Completed

Last Edited
28/10/2022

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Heart failure (HF) occurs when the heart becomes unable to pump blood efficiently. Symptoms include difficulty with breathing and leg swelling. HF is the final result of several diseases more common in aging patients, such as high blood pressure, but it can also be the result of changes associated with age itself. Although new drug treatments have improved outcomes for heart failure patients, hospital readmission and death rates, particularly for hospitalized elderly patients, remain high. There is good evidence in patients with HF and high risk of hospitalization that multidisciplinary strategies based on coordination and continuity of care, disease management programs (DMPs), can reduce hospitalization and death rates, improve quality of life and lower overall medical costs. In these DMPs a case manager provides patients and their caregivers with sufficient information and support to develop and comply with a plan to control HF. However, most clinical trials in HF have excluded elderly patients with significant functional impairment, multiple illnesses and living in a nursing home. We aimed to assess the cost-effectiveness of a management program after hospital discharge in elderly patients with HF with any of these conditions.

Who can participate?
To take part you need to be aged over 65 and have been discharged home or to a nursing home without medical staff after a hospital stay due to HF of at least 48 hours.

What does the study involve?
Participants were randomly allocated to one of two groups. While one group received the DMP, consisting of a comprehensive hospital discharge planning and close follow-up at a geriatric day-hospital, the other group received the pre-existing routine of post-discharge care. After hospital discharge, the patients were managed in accordance with current clinical practice. In general, this meant that the patient was treated and followed by their primary care physician. Both groups received medical treatment in accordance with current clinical practice and were followed-up for 12 months.

What are the possible benefits and risks of participating?
All participants received medical treatment. The main goals of the HF treatment were to relieve symptoms, maintain or enhance functional capacity and quality of life, preserve independence, and extend survival. The goals of the DMP program were to reduce hospitalization and death rates, and improve quality of life and also lower overall medical costs. There were no known risks to participants.

Where is the study run from?
The study was conducted with patients of the Caceres Health Area after hospital discharge in a single center (Complejo Hospitalario de Cáceres) (Spain).

When is the study starting and how long is it expected to run for?
The study ran from March 2007 to November 2010.

Who is funding the study?
Regional Government of Extremadura (Spain) and European Union (FEDER).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Cost-effectiveness of a disease management program after hospital discharge in older patients with heart failure delivered by geriatric day hospital versus usual care

Study objectives
1. A disease management program delivered by geriatric day hospital improves event-free survival (defined as any cause readmissions or death) in older patients with heart failure after hospital discharge
2. A disease management program for older patients with heart failure after hospital discharge delivered by geriatric day-hospital is cost-effective
3. An intervention program improves health-related quality of life and functional status for elderly patients with heart failure

Ethics approval required
Old ethics approval format

Ethics approval(s)
Clinical Research Ethics Committee, Caceres, 23/02/2006, ref: CE 23022006

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Heart failure in the elderly

Interventions
Intervention group:
The disease management program (DMP) had four main components:
1. Educational intervention on management of heart failure to improve patient and caregiver's knowledge of the disease and self-management skills
2. Monitoring and improvement of therapy according to international guidelines
3. Monitoring of clinical status and comorbidity
4. Monitoring changes in functional and mental status, and social network

The intervention program consisted of two phases.
In the first phase, prior to discharge the multidisciplinary team (which consisted of a geriatrician [case manager], a nurse and a social worker) assessed and had an in-depth interview with the patient and caregiver or family members. Later the patients and their families received a formal education session about the disease by the nurse using a teaching manual.
During the second phase, regular follow-up was scheduled. The first contact with the patient was by telephone in the second day after hospital discharge. The first visit occurred in the geriatric day-hospital 10 days after discharge. Future visits were agreed according to the patient s clinical and treatment needs, but minimum controls were established at months 1, 3, and 6 after hospital discharge. The case manager was available for consultation during working hours by phone contact number. Patients were instructed to contact in case of doubts or signs of worsening.

Control group:
Patients assigned to usual care received the pre-existing routine of post-discharge care. After hospital discharge, the patients were managed in accordance with current clinical practice. In general, this meant that the patient was treated and followed by their primary care physician. An outpatient visit by the geriatrician was planned at 12 months after discharge.

Follow-up began with the index admission and ended 12 months after discharge or in case of the patients death.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Estimated event-free survival, defined on the basis of time to first event (any cause readmission or death) at 1 year. KaplanMeier survival curves will be constructed to assess differences in deaths or readmissions between groups and compared using the log rank test. Data for all event-free patients will be censored on study day 365. Event-free survivals will be tested with the Cox proportional hazards method.
2. Cost-effectiveness analysis. We will estimate costs from a societal perspective and will be included medical and non-medical costs. The effectiveness will be expressed in Quality-Adjusted Life Years (QALY) and will be calculated from the data of the Health Related Quality of Life (HRQL) obtained from the generic EuroQol-5D questionnaire.

Secondary outcome measures
1. Evaluate health-related quality of life:
For health-related quality of life, the Minnesota Living With Heart Failure Questionnaire (MLWHFQ) score at baseline and 12 months will be calculated for each group in the trial. The effect of the DMP on quality of life will be estimated as the difference between groups in the change in MLWHFQ scores during the study.
2. Functional status:
Assessed as ability to perform basic activities of daily living, the Barthel index (BI) score at baseline and 12 months will be calculated for each group in the trial. The effect of the DMP on functional status will be estimated as the difference between groups in the change in BI scores during the study.

Overall study start date
02/03/2007

Completion date
30/11/2010

Eligibility

Key inclusion criteria
1. Patients aged over 65
2. Discharged home or to a nursing home without medical staff after a hospitalization due to heart failure of at least 48 hours of hospital stay (determined according to the European Society of Cardiology guidelines)

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
56 patients had to be included in each group to detect at least a 30% relative reduction at 12 months in the outcome of events in the intervention group

Total final enrolment
117

Key exclusion criteria
1. Planned discharge to a long-term care facility or nursing home with medical staff
2. Severe dementia or other serious psychiatric illness
3. Confined to bed
4. Anticipated survival of less than 6 months
5. Foreseeable follow-up problems such as residence outside the hospital catchment area
6. Refusal to participate

Date of first enrolment
02/03/2007

Date of final enrolment
30/11/2010

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Nuestra Señora de la Montaña
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Sponsor information

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Sponsor type
Hospital/treatment centre

Website
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Funder(s)

Funder type
Government

Funder Name
Regional Government of Extremadura (Spain) ref: GR10127

Funder Name
European Regional Development Fund [Fonds Européen de Développement Régional (FEDER)]

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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		06/06/2018	28/10/2022	Yes	No