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Effect of a dual intervention in elderly heart failure patients with cognitive impairment and their caregivers after hospital discharge: a randomized controlled trial

Submission date
15/02/2016

Recruitment status
Stopped

Registration date
01/03/2016

Overall study status
Stopped

Last Edited
19/03/2018

Condition category
Circulatory System

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Heart failure (HF) is a common disease that gets worse over time, is responsible for many hospital admissions and deaths, results in a poor quality of life for the patient and places an economic burden on the health care system. HF happens when the heart becomes unable to pump enough blood around the body at the right pressure. Symptoms include difficulty with breathing and leg swelling. When the part of the heart that pumps blood around the body (the left ventricle) becomes too weak to work properly, the heart failure is being caused by left ventricular systolic dysfunction (LVSD). When the left ventricle becomes stiff, making it difficult for the heart chamber to fill with blood, this is heart failure with preserved ejection fraction (HFPEF). HFPEF may account for up to two-thirds of cases in patients over 70. HF is the final common stage for several diseases more common in aging patients, like hypertension (high blood pressure), valvular heart disease (heart disease involving one or more valves of the heart) or coronary heart disease, but it can also be the result of physical changes due to age itself. HF is most common in older people and is the leading cause of hospitalization and the third cause of cardiovascular death in this age group. Although advanced pharmacological intervention (drug treatments) has improved the prognosis for people with HF, hospital readmission and mortality rates (number of deaths), particularly for hospitalized elderly patients, remain high. There is good evidence that patients with HF and at high risk of being admitted to hospital can benefit from disease management programs (DMP), resulting in fewer admissions to hospital, lower mortality rates, improvements in quality of life and lower medical costs. In these DMPs a case manager provides patients and their caregivers with enough information and support to develop and follow a plan to control HF. However, most studies investigating HF have not included elderly patients with cognitive impairment (for example, trying to remember or learn new things, concentrating or making decisions), despite the fact that this would affect how successful a DMP would be, especially with regard to HF knowledge, self-care, and treatment adherence (sticking with the treatment). This is important because cognitive impairment (CI) is common in elderly adults with HF (more than 25%) and is associated with poor health outcomes, so it is important to determine which interventions (treatments) are beneficial in individuals with

both conditions. This study aimed to test the effectiveness of a DMP in elderly HF patients with CI after being discharged from hospital, involving both patients and caregivers, and its follow-up by a multidisciplinary team.

Who can participate?
Adults over 65, with CI, discharged from hospital after a stay of at least 48 hours for HF, that have a responsible caregiver.

What does the study involve?
The participants are randomly allocated to one of two groups. Both groups will receive medical treatment in accordance with current clinical practice. Those in group 1 (control group) receive the usual care given after being discharged from hospital. Those in group 2 (intervention group) are placed on the DMP after discharge from hospital. The DMP includes, for example, education on the management of HF for both caregivers and patients, monitoring treatments and how the patients is progressing and it also looks at how much of a burden the DMP is placing on the participants caregiver and social network. All participants on the DMP are closely followed-up at a geriatric day-hospital by a multidisciplinary team consisted of a geriatrician (case manager), a nurse and a social worker. The participants are monitored by telephone and also face-to-face visits at the clinic.

What are the possible benefits and risks of participating?
All participants, including controls, are given medical treatment. The principal goals of HF therapy will be to relieve symptoms, maintain or improve the ability of the participants to do everyday activities and quality of life, preserve their independence, and extend survival. There are no known risks to participants.

Where is the study run from?
Hospital of Caceres (Complejo Hospitalario de Cáceres)

When is study starting and how long is it expected to run for?
March 2016 to March 2019

Who is funding the study?
Hospital of Caceres (Complejo Hospitalario de Cáceres)

Who is the main contact?
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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
Effect of a disease management program in elderly heart failure patients with cognitive impairment after a hospital discharge, through a dual intervention in patients and caregivers and its follow-up by a multidisciplinary team, delivered by geriatric day-hospital vs. usual care

Acronym
DUEL-HF (DUal intervention in ELderly Heart Failure patients)

Study objectives
1. A disease management program delivered by geriatric day-hospital and based on a dual intervention in elderly heart failure patients with cognitive impairment and their caregivers after hospital discharge improves event-free survival (defined as any cause readmissions or death)
2. A disease management program based on a dual intervention improves caregiver's knowledge of the disease and management skills
3. An intervention program improves the neuropsychiatric symptoms of patients and caregivers burden.
4. A disease management program reduces sanitary system direct costs associated with heart failure

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee for Provincial Clinical Research, 24/02/2016.

Study design
Single center single-blind randomized controlled study

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Heart failure; Disease management programs; Elderly patients; Cognitive Impairment.

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

The intervention program consists of two phases:
1. First phase: prior to discharge the DMP multidisciplinary team, consisting of a geriatrician (case manager), a nurse and a social worker assesses and has an in-depth interview with the patients and their caregivers. Later the patients and their caregivers receive formal education session about the disease using an information manual explaining details regarding the disease, such as diet, weight control, exercise, lifestyle, and medication, as well as how to recognize cardiac decompensation symptoms, following the guidelines of de ESC. The educational session is adapted to the degree of cognitive impairment (CI) of the patient and it is focused in the caregiver. In addition, the case manager provides information to the caregiver about the process of CI, their symptoms and their management. As support material they will be given an informative manual on HF and manual control recommendations of psychological and behavioral symptoms related to CI.
2. Second phase: regular follow-up is scheduled. Nurse contact each patient, via telephone, 48 hours after the hospital discharge, to record any problems. After 10 days, the team examines the patients/caregivers in the geriatric day care hospital (GDCH), using educational reinforcements and evaluating for possible cardiac decompensation.
The subsequent follow-ups occur at the GDCH, 1 and 3 months after the hospital discharge. During these programmed sessions, the team assesses the patients/caregivers for treatment compliance, reinforces the health education, and assesses the ability of the patients/caregivers to fulfill the recommendations; in addition, the prescriptions and doses are adjusted according to clinical guidelines. The global therapeutic regime and comorbidities are reevaluated by considering possible changes in the functional, cognitive, affective, and social capacities in the patient. At 2nd month, the geriatric doctor contacts each caregiver via telephone to reinforce health education and to evaluate for possible cardiac decompensation and control of neuropsychiatric symptoms. Furthermore, the team provides the contact number of the case

manager who is available on a morning schedule (from 09:00 to 14:00 hours) for consultation regarding the study. Each patient receives attention in the GDCH or via telephone when he or she requires an unscheduled evaluation for clinical decline due to a medical problem.

Control group: Patients assigned to usual care receive the preexisting routine of post-discharge care. After hospital discharge, the patients are managed in accordance with current clinical practice. In general, this means that the patient is treated and followed by their primary care physician.

Follow-up begins with the index admission and ends 6 months after discharge or in the event of death of the patient.

Intervention Type

Primary outcome measure
Event-free survival, defined as the time elapsed until the first readmission or until death of the patient for any cause during the study period. The hospital readmissions (total and HF-related) and mortality (total or HF-related) are accounted for. For event-free patients, the data were censored on the last day of the study. The event-free variable is tested using the Kaplan-Meier survival curve and the log-rank test. A sequential survival analysis is performed, using the Cox model, to determine if the treatment of the patients is an independent event predictor after adjustment for other relevant covariables.

Secondary outcome measures
1. Caregiver's knowledge of the disease (HF) and management skills, using a 15-question scale developed by DeWalt et al (Patient Education and Counseling 55 (2004) 78–86) and management skills, assessed using the European Heart Failure Self-care Behaviour Scale (EHFScBS). Scales scores at baseline and 6 months will be calculated for each group in the trial estimating the effect of the DMP as the difference between groups
2. Adherence to treatment, assessed via interview and Morisky-Green test score at baseline and 6 months
3. Change during the study in control of neuropsychiatric symptoms, assessed using the Neuropsychiatric Inventory Questionnaire (NPI-Q) scores at baseline and 6 months
4. The effect of the DMP on caregiver burden, estimated as the change in the Caregiver Burden Interview during the study
5. Cost analysis, assessed via the difference between groups in sanitary system direct costs

Overall study start date
01/03/2016

Completion date
01/03/2019

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
Consecutive patients diagnosed with acute HF and discharged from the Geriatric Service of the Cáceres Hospital Complex (Spain) are included. The patients are diagnosed according to the

criteria of the European Society of Cardiology and must have:
1. A hospital stay of more than 2 days
2. A responsible caregiver

After inclusion and exclusion criteria are reviewed, patients/caregivers will be asked if they would be willing to take a cognitive screening test and potentially participate in the study. If cognitive impairment is present they will be included in the study after patients and caregivers to sign informed consent.

Participant type(s)
Mixed

Age group
Senior

Sex
Both

Target number of participants
Based on our previous study (González-Guerrero JL et al. J Am Geriatr Soc. 2015;63:1950-1), the sample size was calculated assuming an event-free rate of 45% in the control group. With our intervention, this percentage was reduced by 20% (two-sided alpha=0.05 and beta=0.80). To perform this calculation, each group required 84 patients.

Key exclusion criteria
1. Terminal patients (with an expected survival of less than 6 months)
2. Bedridden patients
3. Patients with severe dementia (Global Deterioration Scale grade 7) or other serious psychiatric disease
4. Patients who were impossible to follow up
5. Patients in retirement homes
6. Patients or caregivers who refused to participate

Date of first enrolment
21/09/2016

Date of final enrolment
20/09/2018

Locations

Countries of recruitment
Spain

Study participating centre
Hospital of Caceres (Complejo Hospitalario de Cáceres)
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
http://www.areasaludcaceres.es/

ROR
https://ror.org/01mhgyv56

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The results of this project will be presented in national and international congresses and published in high-impact journals.

Intention to publish date
01/03/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date