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Self-control strategies in chronic diseases [Chronic obstructive pulmonary disease (COPD) and heart failure]

Submission date
04/06/2012

Recruitment status
No longer recruiting

Registration date
10/07/2012

Overall study status
Completed

Last Edited
22/01/2019

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Heart failure and increase in the severity (exacerbation) of chronic obstructive pulmonary disease (COPD) are the most common reasons for hospital admission in the elderly and consume a significant amount of health resources. The aim of this study is to compare two strategies for chronic diseases control during a period of two years, in terms of the number of telephone calls, number of office visits, number of emergency room visits, number of readmissions, mortality and quality of life.

Who can participate?
The study participants are 230 men and women with Chronic Heart Failure or COPD.

What does the study involve?
Over a period of two years participants will be invited to participate in this study and they will be randomly allocated to one of the two strategies.
The first strategy has been carried out in our unit over the past years and consists of a close monitoring with monthly consultations and phone calls, a referring physician in the hospital and a phone number to be used in case of worsening of symptoms.
The second strategy will be a self-control programme. There will be a learning phase aiming at patients recognizing the warning signs and the response to treatment changes. A website will be the contact point between the patient and the hospital staff. On a daily basis patients will answer a questionnaire and through this site clinicians will suggest the necessary treatments. The patient will always have the opportunity to phone the nurse or the doctor if there is any trouble. Thus, patient follow-up and monitoring will be done daily through this web.
At the end of the study we will compare the number of telephone calls, number of office visits, number of emergency room visits, number of readmissions, mortality and quality of life between the two strategies.

What are the possible benefits and risks of participating?
Participants will benefit from greater disease control and possibly a reduction in unnecessary consultations.
Participation in this study does not involve any additional risk.

Where is the study run from?
The study will run from University Donostia Hospital.

When is study starting and how long is expected to run for?
The study will be start at the end of June. Participants will be enrolled on the study for a period of two years.

Who is funding the study?
University Donostia Hospital is funding the study.

Who is the main contact?
Jose Ignacio Emparanza
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled clinical trial of the comparison of two strategies (multifaceted strategy multi-pronged strategy of individualized attention versus a self-control strategy) for the management of patients with COPD and/or heart failure

Study objectives
Training the patient in self-control of their symptoms will decrease the number of calls and number of hits while maintaining the reduction of emergency department visits, readmissions and mortality, compared to that achieved by a multi-pronged strategy of individualized attention, maintaining a good quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Clinical Research Ethics Committee of Guipuzcoa Health Area, May 23, 2012

Study design
Randomized controlled clinical 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
Exacerbation of COPD and heart failure

Interventions
Control Group: Multiple individual attention strategy. This strategy consists of a specific nurse liaison, computer alarms attended by the referring physician, an individualized program of medication, exercise program, a cell of maximum accessibility, a monthly consultation, a monthly phone call every 15 days and if sharpening a query within 24 hours.

Experimental group: self-control strategy. This strategy will assign to each patient a referring physician and a nurse liaison who will conduct a training session to identify warning signs and that through an algorithm allows the patient to make a decision (adjustment of medication, phone call). This algorithm has been developed by medical experts, based on best available scientific evidence. A training simulator will be used, to put the patient in different situations that he might experience during their illness.

The patient will have a website through which respond to a series of questionnaires to assess their clinical situation. After collecting the data for 10 days, establish its baseline. Faced with a deterioration in the patient's baseline, the program detects a warning sign and act by sending an SMS to the referring physician, as well as tell the patient a change in treatment.

The patient also will have a maximum accessibility phone staffed by a nurse from 8:00 to 15:00 and by a physician from 15:00 to 21:00 hours in order to ask questions of and to activate an immediate consultation.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Mortality follow-up to a year
2. Number of telephone calls
3. Number of medical consultations
4. Number of emergency visits for the process
5. Number of readmissions for the same process

Measured everyday during one year.

Secondary outcome measures
Quality of life, EuroQol measured at the beginning and end of the study

Overall study start date
15/06/2012

Completion date
15/06/2014

Eligibility

Key inclusion criteria
1. Patients with heart failure stage II-IV New York Heart Association (NYHA)
2. Patients with acute exacerbation of chronic obstructive pulmonary disease (COPD) from any cause and with one or more hospital admissions in the previous year for the same condition.
3. Patients with heart failure stage II-IV of NYHA and COPD to present more than two severe comorbidities that want to participate.
4. Patients who own a computer with internet access and management practice

Participant type(s)
Patient

Age group
Adult

Sex

Both

Target number of participants
230

Key exclusion criteria
1. Patients with moderate or severe dementia
2. Patients with impaired mobility that prevents them from performing aerobic exercise
3. Patients who refuses to participate

Date of first enrolment
15/06/2012

Date of final enrolment
15/06/2014

Locations

Countries of recruitment
Spain

Study participating centre
Pº Doctor Beguiristain 107-115
San Sebastian-Donostia
Spain
20014

Sponsor information

Organisation
University Hospital Donostia (Hospital Universitario Donostia) (Spain)

Sponsor details
Pº Doctor Beguiristain 107-115
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Spain
20014

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04fkwzm96

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Donostia (Hospital Universitario Donostia) (Spain)

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	05/12/2018	22/01/2019	Yes	No