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Primary care-based telemonitoring for home care patients with heart failure and chronic lung disease

Submission date 15/03/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/04/2010	**Overall study status** Completed	
Last Edited 04/04/2013	**Condition category** Circulatory System	

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
N/A

Study information

Scientific Title
Evaluation of a primary care-based telemonitoring intervention for home care patients with heart failure and chronic lung disease: a randomised controlled trial

Acronym
TELBIL project

Study objectives
Home care patients with heart failure and chronic pulmonary disease may benefit from a primary care-based telemonitoring intervention which could result in a reduction of hospital admissions, duration of the hospitalisations and mortality. We postulate that home telemonitoring may improve the quality of life of these patients in a way that is cost-effective and acceptable to patients and health care professionals.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethics Committee for Scientific Research (CEIC, Basurto Hospital, Bizkaia, Spain) approved on the 16th December 2009

Study design
Randomised controlled open 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
Heart failure and chronic pulmonary disease

Interventions
Intervention group:
Telemonitoring will consist of daily patient self-measurements of respiratory rate, heart rate, blood pressure, transdermal oxygen saturation, weight and body temperature. Additionally, the

patient will complete a qualitative symptom questionnaire daily using the telemonitoring system. After a local intelligent analysis the abnormal measurements, suggesting clinical alarm, will be sent by GPRS to the primary care team responsible for the care of each patient. Routine telephone contacts will be conducted every fortnight.

Control group:
Patients receive the standard care consisting of periodic medical examinations. The frequency of the medical examinations will vary depending on the clinical, social and family situation of each patient. In addition, the general practitioner or nurse will see or call the patient on demand in the event of a deterioration in the medical condition.

The physicians and nurses responsible for the care of the patients in the control and intervention groups have received specific training in the early detection and management of acute decompensations prior to the start of the study.

The total duration of intervention and follow-up for both intervention and control group is 12 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Measured at 3, 6, and 12 months:
1. Number and duration of hospital admissions
2. Mortality rate
3. Cost-effectiveness

Secondary outcome measures
Measured at 3, 6, and 12 months:
1. Number of emergency department visits
2. Number of home visits
3. Number of primary care visits
4. Number of specialist care visits
5. Number of telephone contacts
6. Number of acute heart or respiratory decompensations
7. Quality of life (EQ-5D questionnaire at baseline and after 3, 6 and 12 months of follow-up)
8. Patient and professional satisfaction with the telemonitoring technology using validated questionnaires (after 3 months of follow-up)
9. Medication changes

Overall study start date
01/02/2010

Completion date
01/06/2011

Eligibility

Key inclusion criteria
1. Home care patients aged over 70 years of any gender
2. Heart failure and/or chronic pulmonary disease
3. At least two hospital admissions during the previous year (with at least one of the admissions due to the above mentioned diseases)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60 - 80 participants (in total)

Key exclusion criteria
1. Residents in nursing homes
2. Paediatric patients (younger than 14 years of age)
3. Refusal to participate in the study
4. Frequent users of specialist healthcare services (i.e., rehabilitation, haemodialysis, frequent visitors to hospital day-care centres, etc.)
5. Terminal illness with life expectancy less than 6 months
6. Cognitive impairment

Date of first enrolment
01/02/2010

Date of final enrolment
01/06/2011

Locations

Countries of recruitment
Spain

Study participating centre
Comarca Bilbao de Atención Primaria
Bilbao
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48011

Sponsor information

Organisation
Basque Government (Spain) - Department of Health and Consumer Affairs

Sponsor details
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Sponsor type
Government

ROR
https://ror.org/00pz2fp31

Funder(s)

Funder type
Government

Funder Name
Basque Government (Spain) - Department of Health and Consumer Affairs

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	28/03/2013		Yes	No