

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

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| <b>Submission date</b><br>15/03/2010   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered    |
|  |   | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>20/04/2010 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input checked="" type="checkbox"/> Results          |
| <b>Last Edited</b><br>04/04/2013       | <b>Condition category</b><br>Circulatory System   | <input type="checkbox"/> Individual participant data |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

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

## **Study type(s)**

Quality of life

## **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(s)**

Measured at 3, 6, and 12 months:

1. Number and duration of hospital admissions
2. Mortality rate
3. Cost-effectiveness

### **Key secondary outcome(s)**

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

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

## **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

Spain

48011

## **Sponsor information**

### **Organisation**

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

### **ROR**

<https://ror.org/00pz2fp31>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

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

# Results and Publications

## 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 | 28/03/2013   |            | Yes            | No              |