

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

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

**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

Spain

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?
<a href="#">Results article</a>	results	28/03/2013		Yes	No