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# Evaluation of a strategy to diminish admissions in patients with heart failure

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| **Submission date**<br>21/09/2009 | **Recruitment status**<br>No longer recruiting | [ ] Prospectively registered<br>[ ] Protocol<br>[ ] Statistical analysis plan<br>[ ] Results<br>[ ] Individual participant data<br>[ ] Record updated in last year |
| **Registration date**<br>06/10/2009 | **Overall study status**<br>Completed | |
| **Last Edited**<br>06/10/2009 | **Condition category**<br>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**
EBM-012008

# Study information

## Scientific Title
Evaluation of a strategy to diminish admissions in patients with heart failure: a randomised controlled open clinical trial

## Acronym
Tele-EMAI

## Study objectives
Patients with heart failure may benefit from at home telemonitorisation of their condition plus multifaceted personalised intervention compared with multifaceted personalised intervention alone.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Local Medical Ethics Board (CEIC Gipuzkoa) approved on the 23rd January 2008 (ref: Acta 01/08)

## Study design
Randomised controlled open clinical trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Prevention

## 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

## Interventions
Control group:
Automated program for opportunity/appropriateness of drug treatment with a personalised and monitored physical activity (aerobic) program. Follow-up telephone calls will take place on day 3 and 6, and every 15 days thereafter by the appointed nurse, and a telephone line and email address will be accessible 24 hours a day.

Intervention group:
As above, plus at home measurement twice daily of transdermal oxygen saturation, temperature, weight, blood pressure, cardiac and respiratory frequency, and in some cases, electrocardiogram (ECG). These measurements are sent by GSM to the hospital team.

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
Measured at the end of the study (see above anticipated end date):
1. Number of admissions
2. Number of emergency department visits

### Secondary outcome measures
Measured at the end of the study (see above anticipated end date):
1. Quality of life (36-item short form health survey [SF-36]) at the beginning and end of the study
2. Perceived quality of medical attention, measured using the Spanish SERVQHOS questionnaire, at the beginning and end of the study

### Overall study start date
20/02/2008

### Completion date
31/12/2009

## Eligibility

### Key inclusion criteria
1. Patients of any gender, aged older than 65 years
2. Heart failure stage III - IV New York Heart Association (NYHA)
3. At least two admissions during the previous year

### Participant type(s)
Patient

### Age group
Senior

### Sex
Both

### Target number of participants
70 patients

### Key exclusion criteria

1. Moderate or severe dementia
2. Physical disability for aerobic activities
3. Refusal to participate

### Date of first enrolment
20/02/2008

### Date of final enrolment
31/12/2009

## Locations

### Countries of recruitment
Spain

### Study participating centre
**Clinical Epidemiology Unit**
San Sebastian
Spain
20014

## Sponsor information

### Organisation
Hospital Donostia (Spain)

### Sponsor details
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### Sponsor type
Hospital/treatment centre

### Website
http://www.hospitaldonostia.org/index2.htm

### ROR
https://ror.org/04fkwzm96

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Hospital Donostia (Spain)

**Funder Name**
Saludnova S.Coop (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