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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Prevention

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed
No

Age group
Senior

Sex
All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration