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Evaluating the impact of a new nurse led service for people with chronic heart failure who are hospitalised, due to worsening symptoms - a randomised controlled trial

Submission date 31/10/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 28/11/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 19/09/2013	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms Elaine Coady

Contact details
Cardiology Administration
F06 East Wing
St Thomas' Hospital
Lambeth Palace Road
London
United Kingdom
SE1 7EH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RJ1 05/0206

Study information

Scientific Title

Study objectives
Does a nurse led service improve outcomes for people with chronic heart failure? The principal objective is to reduce overall bed days by recurrent hospitalisations which is a common feature of this complex chronic disease. It is anticipated that by introducing a new nurse led service that will educate, monitor and advise patients and their family/carers, clinical deterioration will be noted early and acted upon. The intervention will promote the role of the patient in the monitoring and management of this long term chronic disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The local medical ethics committee approved on the 7th of September 2005 (ref: 05/Q0707/51)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic Heart Failure

Interventions
Nurse intervention will include two visits from the Heart Failure Specialist Nurse or Nurse Consultant during the patients in-patient stay, telephone contact will be made within one week of discharge and the patient will be seen in the nurse-led clinic within 2 weeks of discharge, subsequent nurse-led clinic visits will then continue after this period. The nurse led intervention will include support and education about the disease and treatments and guidance on how to manage at home. This group of patients will be provided with a hand-held record which contains information such as medication list, test results, weight chart etc.

Control: standard care delivery

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Number of episodes of readmission with main diagnosis of heart failure and bed days utilized over a 12 month period.

Secondary outcome measures
1. Use of appropriate medication
2. Self care management strategies
3. Quality of life
4. Patient illness perceptions

Overall study start date
01/11/2005

Completion date
01/11/2007

Eligibility

Key inclusion criteria
Main diagnosis of Heart Failure as demonstrated on echocardiogram - using the European Society of Cardiology guidelines and National Institute for Clinical Excellence (NICE) guidelines.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
170 patients (85 each group)

Key exclusion criteria
1. Patients already exposed to a nurse led heart failure clinic
2. Patients unable to visit the clinic
3. Patients with dementia or other psychiatric disorder
4. Patients with a short anticipated survival (e.g. malignancy)

Date of first enrolment
01/11/2005

Date of final enrolment
01/11/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cardiology Administration
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Guy's and St Thomas' NHS Foundation Trust (UK)

Sponsor details
Counting House
Guy's Hospital
St Thomas Street
London
England
United Kingdom
SE19RT

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Government

Funder Name
Guy's & St Thomas' NHS Foundation Trust (UK)

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