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 dataRecord updated in last year

Plain English summary of protocol Not provided at time of registration

Contact information

Type(s) Scientific

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

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