

# Randomised controlled trial and economic evaluation of home-based medication and lifestyle review by community pharmacists for patients with heart failure

|                                        |                                                   |                                                      |
|----------------------------------------|---------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>07/09/2005   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered    |
|                                        |                                                   | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>13/09/2005 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                   | <input checked="" type="checkbox"/> Results          |
| <b>Last Edited</b><br>26/04/2007       | <b>Condition category</b><br>Circulatory System   | <input type="checkbox"/> Individual participant data |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

PG/02/171

# Study information

## Scientific Title

### Acronym

HeartMed

### Study objectives

That home-based medication and lifestyle review by community pharmacists can reduce hospital re-admissions in heart failure patients and improve quality of life.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Not Specified

## Participant information sheet

### Health condition(s) or problem(s) studied

Heart Failure

### Interventions

Home-based medication review and lifestyle advice by community pharmacists

### Intervention Type

Other

### Phase

Not Specified

**Primary outcome measure**

Total number of emergency hospital readmissions at six months

**Secondary outcome measures**

1. Total deaths at six months
2. Total heart failure hospital readmissions at six months
3. Self-assessed quality of life at six months using the EQ-5D and Minnesota living with heart failure questionnaire

Also:

1. Admissions to residential or nursing homes at six months
2. Self-assessed compliance at six months using the Medication Adherence Report scale
3. Self-assessed behaviour change at six months using the European heart failure self-care behaviour scale

**Overall study start date**

01/10/2003

**Completion date**

30/04/2006

**Eligibility****Key inclusion criteria**

1. Adult (over 18 years)
2. Discharged to home or warden controlled accommodation after an emergency admission in the last month with a primary clinical diagnosis of heart failure
3. Prescribed two or more drugs (oral or inhaled) taken on at least a daily basis
4. Norfolk or Suffolk resident

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

306

**Key exclusion criteria**

1. Patients living in residential, nursing homes or long-stay hospitals
2. All patients whose treatment includes planned surgery for ischaemic or valvular heart disease or awaiting heart transplantation
3. All patients with concomitant terminal malignancy.

**Date of first enrolment**

01/10/2003

**Date of final enrolment**

30/04/2006

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre****School of Medicine**

Norwich

United Kingdom

NR4 7TJ

**Sponsor information****Organisation**

University of East Anglia (UK)

**Sponsor details**

University of East Anglia

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**Sponsor type**

University/education

**Website**

<http://www.uea.ac.uk/business>

**ROR**

<https://ror.org/026k5mg93>

**Funder(s)****Funder type**

Charity

**Funder Name**

British Heart Foundation (UK)

**Alternative Name(s)**

the\_bhf, The British Heart Foundation, BHF

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United Kingdom

## 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 | 26/05/2007   |            | Yes            | No              |