

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

Submission date 07/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 13/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 26/04/2007	Condition category 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
Dr Richard Holland

Contact details
School of Medicine
Health Policy & Practice
University of East Anglia
Norwich
United Kingdom
NR4 7TJ
+44 (0)1603 593574
r.holland@uea.ac.uk

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

Norwich

England

United Kingdom

NR4 7TJ

+44 (0)1603 591486

l.briggs@uea.ac.uk

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?
Results article	Results	26/05/2007		Yes	No