

Heart Failure in Older People In Care Homes

Submission date 28/05/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 28/05/2010	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 09/07/2013	Condition category Circulatory System	☐ Individual participant data

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
5037

Study information

Scientific Title
Diagnosing and Managing Heart Failure in Care Homes (HFinCH): a multicentre diagnostic study and therapeutic optimisation trial

Acronym
HFinCH

Study objectives

The purpose of this study is to explore the experiences of diagnosis and treatment of heart failure (HF) for people who are resident in care, and to ascertain the prevalence of HF in a very high risk population, with a view to providing more effective care. The study will provide vital information about the accuracy, feasibility and acceptability of the diagnostic tests used. The study will evaluate the best way of delivering improved healthcare by comparing usual NHS care with a specialist-led service. The study will allow people with heart failure to help inform the development of new and important NHS services that meet patients' needs.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Leeds (West) REC approved on the 3rd November 2008 (ref: 08/H1307/96)

Study design

Multicentre diagnostic study randomised controlled therapeutic optimisation trial

Primary study design

Interventional

Study type(s)

Screening

Health condition(s) or problem(s) studied

Topic: Cardiovascular, Primary Care Research Network for England; Subtopic: Not Assigned, Cardiovascular (all Subtopics); Disease: Cardiovascular, All Diseases

Interventions

Domiciliary Heart Failure Team Care (HFTC) versus Routine Care (RC). RC will consist of test results being communicated to residents and their GPs and/or HF nurse specialists. In addition to routine care, HFTC will involve residents being visited within the home by clinical members of the research team on a number of occasions to have their findings assessed, receive educational advice, discuss options and have their medication reviewed.

Study entry: Other

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Diagnostic phase: the proportion of residents with an incorrect (positive or negative) diagnosis determined by echocardiography
2. Trial phase: proportion of patients receiving an angiotensin converting enzyme (ACE)-inhibitor (or angiotensin receptor blocker [ARB]) and beta-blocker at therapeutic dose (6 months)

Key secondary outcome(s)

Diagnostic phase:

1. Prevalence of HF analyzed as a proportion

2. Proportions where HF has been missed or incorrectly identified
3. Test accuracy (sensitivity, specificity) of NT-Pro BNP, ECG and clinical signs and symptoms for the diagnosis of HF
4. Positive and negative predictive values
5. Acceptability to patients
6. Symptom profiles and quality-of-life (EuroQoL measures)

Trial phase:

1. The proportion of patients dying or being hospitalised for HF (one year)
2. The proportion of patients dying or being hospitalised for any cardiovascular or cerebrovascular event (one year)
3. The net costs of providing the specialist service and change in prescribing (6 months)
4. Changes in use of other CV drugs (6 months)
5. Changes in functional capacity and quality of life (3 months)

Completion date

01/09/2010

Eligibility

Key inclusion criteria

1. Residential/care home managers
2. Residents of residential/care homes in Stockton-on-Tees who are aged 65 years or over, either sex
3. Health care professionals, including a representative sample of GPs, HF nurses, and care home staff, involved in care provision will be invited to participate in interviews

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Key exclusion criteria

Residents with terminal disease

Date of first enrolment

01/04/2009

Date of final enrolment

01/09/2010

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

School of Medicine and Health

Durham

United Kingdom

DH1 3HP

Sponsor information

Organisation

University of Durham (UK)

ROR

<https://ror.org/01v29qb04>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme (ref: PB-PG-0407-13309)

Results and Publications

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	further results results	01/02/2013		Yes	No

[Results article](#)

01/02/2013

Yes

No