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Heart Failure in Older People In Care Homes

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Screening

Participant information sheet

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 measure
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)

Secondary outcome measures
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)

Overall study start date
01/04/2009

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

Age group
Senior

Sex
Both

Target number of participants
Planned sample size: 500; UK sample size: 500

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
England

United Kingdom

Study participating centre
School of Medicine and Health
Durham
United Kingdom
DH1 3HP

Sponsor information

Organisation
University of Durham (UK)

Sponsor details
School of Medicine and Health
Queens Campus
Wolfson Research Institute
University Boulevard
Stockton-on-Tees
England
United Kingdom
TS17 6BH

Sponsor type

University/education

Website
http://www.stockton-on-tees.nhs.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

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	further results	01/02/2013		Yes	No
Results article	results	01/02/2013		Yes	No