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Educational intervention to improve knowledge and clinical outcomes for low-literacy patients with congestive heart failure

Submission date 12/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/09/2005	**Overall study status** Completed	
Last Edited 16/08/2011	**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
N/A

Study information

Scientific Title

Study objectives
A heart failure self-management program, designed for use by patients with a variety of literacy levels, would improve knowledge, heart failure-related quality of life, and reduce the combined endpoint of hospitalizations and death.

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)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Heart failure

Interventions
The intervention group received the self-management training. The control group received usual care by their physician.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Combined endpoint of hospitalization or death.

Secondary outcome measures

1. Heart failure-related quality of life
2. Heart failure-related self-management behaviors
3. Heart failure-related knowledge
4. Heart failure-related self-efficacy

Overall study start date
15/11/2001

Completion date
12/04/2003

Eligibility

Key inclusion criteria
Patients aged 30-80 years with heart failure who also took furosemide.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Moderate to severe dementia
2. Terminal illness with life expectancy less than 6 months
3. Severe hearing impairment
4. Blindness
5. Current substance abuse
6. A serum creatinine >4 mg/dl or on dialysis
7. A requirement of supplemental oxygen at home
8. Lacked a telephone
9. Patients who were scheduled to undergo cardiac surgery or awaiting heart transplant

Date of first enrolment
15/11/2001

Date of final enrolment
12/04/2003

Locations

Countries of recruitment
United States of America

Study participating centre
5039 Old Clinic Building, CB#7110
Chapel Hill
United States of America
27599

Sponsor information

Organisation
University of North Carolina (USA)

Sponsor details
5039 Old Clinic Building, CB#7110
Chapel Hill
United States of America
27599

Sponsor type
University/education

Website
www.med.unc.edu

ROR
https://ror.org/0130frc33

Funder(s)

Funder type
Other

Funder Name
Pfizer Health Literacy Initiative (USA)

Funder Name
The Robert Wood Johnson Clinical Scholars Program (USA)

Funder Name

The University of North Carolina Program on Health Outcomes (USA)

Funder Name
Grant no. P30NR03962 from the National Institute of Nursing Research, NIH, to the Center for Research on Chronic Illness at the University of North Carolina (USA)

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	13/03/2006		Yes	No