

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 16/08/2011	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

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Additional identifiers

Protocol serial number

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

Study type(s)

Prevention

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(s)

Combined endpoint of hospitalization or death.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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

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