ISRCTN98675639 https://doi.org/10.1186/ISRCTN98675639

Netherlands Heart Foundation Coordinating Study Evaluating Outcomes of Advising and Counselling in Heart Failure

Submission date	Recruitment status	[_] Prospectively registered
19/07/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/07/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/01/2021	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.hartfalen-coach.nl/

Contact information

Type(s)
Scientific

Contact name
Dr T. Jaarsma

Contact details
University Medical Center Groningen (UMCG)
Department of Cardiology
P.O. Box 30.001
Groningen
Netherlands
9700 RB
+31 (0)50 3613429
T.Jaarsma@thorax.umcg.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Netherlands Heart Foundation Coordinating Study Evaluating Outcomes of Advising and Counselling in Heart Failure

Acronym
NHS-COACH

Study objectives
1. To determine the effectiveness of two interventions (basic support (A&Cb) versus intensive support (A&Ci) compared to care as usual in chronic heart failure (CHF)-patients on time to first major event (heart failure [HF], hospitalisations and death), quality of life and costs
2. To determine the role of underlying mechanisms (knowledge, attitude, skills, behaviour, compliance) in the effectiveness of the two interventions (A&Cb versus A&Ci)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Heart disease, heart failure

Interventions
Patients in the intervention group 1 (A&Cb) will receive extra visits to outpatient clinic where they will visit the HF nurse. Education according to guidelines starts during hospital phase.

Behavioural strategies will be used to improve compliance. In addition, patients are instructed to contact the HF nurse if there is a change in the patient's condition or if there are any problems related to HF needing assistance of a health care provider.

Patients in intervention group 2, (A&Ci) are provided with more intensive advising and counselling. Patients in this group will receive support similar to that of intervention group 1, to which further support is added: patients in this group will be seen each month during the course of the study by the HF nurse. In the first month, telephone calls are made weekly and at least one home visit is made within 10 days. The nurse consults a multidisciplinary team at least once to optimise her advice for each patient. This team will consist of a physiotherapist, dietician and social worker.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Time to first event (HF readmission and death)

Secondary outcome measures
1. Number of readmissions
2. Quality of life
3. Costs
4. Compliance
5. Knowledge
6. Attitude
7. Skills
8. Self-care behaviour

Overall study start date
01/01/2002

Completion date
01/01/2007

Eligibility

Key inclusion criteria
1. Hospital admission for symptomatic chronic heart failure, established by the cardiologist
2. Evidence for structurally underlying heart disease
3. >18 years of age

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1050

Total final enrolment
958

Key exclusion criteria
1. Are enrolled in clinical trials requiring additional visits to research health care personnel
2. Restrictions that render the patient unable to fill in the data collection materials
3. Have undergone invasive cardiac intervention within the last six months (percutaneous transluminal coronary angioplasty [PTCA], coronary artery bypass graft [CABG], hypertensive crisis [HTC], valve replacement) or planned to have such a procedure the following three months
4. Have been evaluated for heart transplantation

Date of first enrolment
01/01/2002

Date of final enrolment
01/01/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Groningen (UMCG)
Groningen
Netherlands
9700 RB

Sponsor information

Organisation
University Medical Center Groningen (UMCG) (The Netherlands)

Sponsor details
PO Box 30001
Groningen

Netherlands
9700 RB

Sponsor type
University/education

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Charity

Funder Name
Netherlands Heart Foundation (NHS) (Nederlandse Hartstichting)

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	27/04/2010	06/01/2021	Yes	No