Train the trainer

Submission date	Recruitment status No longer recruiting Overall study status	Prospectively registered		
07/09/2005		☐ Protocol		
Registration date		Statistical analysis plan		
14/12/2005	Completed	[X] Results		
Last Edited 20/08/2009	Condition category Circulatory System	[] Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Study website

http://www.klinikum.uni-heidelberg.de/index.php?id=5528

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Acronym

TTT

Study objectives

The intervention will result in a change of the quality of life (Qol) (SF-36, scale physical function) of at least 7% compared to control.

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)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Congestive Heart Failure (CHF)

Interventions

For the control group, a classic state of the art lecture of 1.5-3 hours on heart failure from a cardiologist is used. For the intervention group, an interactive training of 1.5 days plus a refresher course of 1.5-3 hours plus two quality circles (1.5 hours) is planned. Elements of the training apply to the domains of knowledge (guideline), communication (standardized patients), detection and management of psychiatric co-morbidity and organisation of the practice. An interactive format relating to andragogy is chosen. A tool box will be provided consisting of a variety of management algorithms and other helpful tools.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Primary outcome is health related quality of life (Qol) of patients with heart failure measured with SF-36, scale 1 (physical functioning). Change of Qol is measured from T1 to T2.

Secondary outcome measures

Secondary outcomes are the other dimensions: Qol of SF-36, the disease specific Qol (KCCQ), patient perceived quality of care (EUROPEP), readmission to hospital or death due to heart failure (combined), improvement of heart failure according to BNP.

Overall study start date

12/10/2005

Completion date

31/05/2006

Eligibility

Key inclusion criteria

- 1. Objective left- or bi-ventricular heart failure with an ejection fraction of 40% or less (affirmation of the limitation of the heart with echocardiography, no older then six months)
- 2. Age ≥40 years
- 3. Stability of the disease at the point of time of inclusion

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

470 patients, 60 practices with 8 patients per practice

Key exclusion criteria

- 1. Primary valvular heart disease with relevant hemodynamic effects
- 2. Hypertrophic obstructive/restrictive cardiomyopathy (HOCM/RCM)
- 3. Organ transplantation
- 4. Acute left ventricular failure
- 5. Short life expectancy due to a serious concomitant illness
- 6. Impaired mental state that prevents accurate answers to questions
- 7. Addictive disorders with continuing drug abuse despite social, legal or professional conflicts

Date of first enrolment

12/10/2005

Date of final enrolment

31/05/2006

Locations

Countries of recruitment

Germany

Study participating centre Im Neuenheimer Feld 410 Heidelberg Germany 69120

Sponsor information

Organisation

German Federal Ministry of Education and Research (Bundesministerium Für Bildung und Forschung [BMBF])

Sponsor details

Hannoversche Straße 28-30 Berlin Germany 10115 +49 (0)1888 570 Gesundheitsforschung@dlr.de

Sponsor type

Government

ROR

https://ror.org/04pz7b180

Funder(s)

Funder type

Government

Funder Name

German Federal Ministry of Education and Research (Bundesministerium Für Bildung und Forschung [BMBF]) (Germany)

Results and Publications

Publication and dissemination planNot 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	13/08/2009		Yes	No