Type D personality and heart failure: burden of a life threatening cardiac condition in an aging population. A prospective follow-up study.

Published: 18-04-2006
Last updated: 14-05-2024

The objectives of this study are (1) to determine the contribution of psychological factors in the prediction of prognosis, health care utilization, and quality of life (2) to identify biological and psychological mechanisms that can explain the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON30293

Source
ToetsingOnline

Brief title
Type D personality and heart failure

Condition

- Heart failures

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: Nederlandse Organisatie voor Wetenschappelijk Onderzoek (NWO)

Intervention

Keyword: chronic heart failure, prognosis, Type D personality

Outcome measures

Primary outcome

Personality (Type D and hostility) and mood are independent predictive variables. Mediating variables are immunoparameters and psychological variables (self-management and loneliness). Moderators are medical on the one hand (NYHA class, etiology), and psychological on the other hand (positive affectivity, sense of coherence and marital satisfaction). Primairy outcomes are defined as quality of life, health care utilization, and the combined endpoint of mortality and rehospitalizations.

Secondary outcome

The secundary endpoint is defined as cardiac mortality.

Study description

Background summary

Heart failure poses a significant burden on patients, partners and health care. Traditional prognostic risk factors are identified, however little is known about the role of psychological variables.

Study objective

The objectives of this study are (1) to determine the contribution of psychological factors in the prediction of prognosis, health care utilization, and quality of life (2) to identify biological and psychological mechanisms that can explain the influence of predictors, and (3) to identify moderators of psychological risk factors.

Study design

Participants are introduced to the study at consultation of the cardiologist or heart failure nurse. The researcher invites participants to participate in the study. Both patients, as well as partners participate on voluntary base. Data is gathered at baseline, 6, 12, and 18 month follow-up in patients, in partners at baseline and 12 month follow-up.

Study burden and risks

The study is observational, with minimal invasive procedures (blood samples are taken from patients), carried out bij qualified personnel. Furthermore, the study consists of filling out questionnaires. The duration of filling out questionnaires varies between 30 and 60 minutes. Finally, in patients exercise tests are carried out.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients:
Systolic heart failure; LVEF<40%; stable on oral medication during one month; no medical admissions during one month; functional NYHA-class I-III; sufficient understanding of written and spoken Dutch language.;Partners:
Having a relation with the patient and living together, sufficient understanding of written and spoken Dutch language.

Exclusion criteria

Patients:
Age >80 years; myocardial infarction during the month of inclusion; other life-threatening diseases; clinical signs of acute infection; co-morbid chronic inflammatory or auto-immune disease (e.g. Rheumatoid Arthritis); use of substantial anti-inflammatory medication (e.g. cortisol); evident cognitive impairments; chronic severe psychiatric condition (e.g. psychosis).;Partners:
Evident cognitive impairments; chronic severe psychiatric condition (e.g. psychosis).

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-04-2006
Enrollment:	400
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	18-04-2006
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL11118.008.06