

Development of an optimal screenings package for psychosocial problems in patients with Cardiac Diseases

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The primary objective of this study is to develop a short and feasible screening package which is specific and sensitive to detect psychosocial problems in patients with CD.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational non invasive

Summary

ID

NL-OMON31854

Source

ToetsingOnline

Brief title

Psychosocial Screening in patients with Cardiac Diseases

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym

Cardiac Diseases; Heart Diseases

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Nederlandse Hartstichting

Intervention

Keyword: Anxiety, Cardiac, Depression, Psychosocial, Screening

Outcome measures

Primary outcome

Psychosocial problems;

- impaired well being
- anxiety
- depression
- distress
- lack of social support

Secondary outcome

NA

Study description

Background summary

The number of patients with a cardiac diseases (CD) is increasing. These patients are confronted with severely debilitating physical consequences of their disease, such as fatigue and limited vital capacity. However, a cardiovascular event also confronts patients with changes in other areas of life such as psychological, social, and relationship functioning. Literature shows that patients experience feelings of anxiety, depression, and/or distress. Heightened levels of psychosocial burden have an impact on adaptation to the disease and on quality of life outcomes. Distress and depression also independently predict adverse cardiac events. Based on these findings one can conclude that there is a need to provide care for distressed CD patients. Unfortunately, within the current standard medical care, not much attention is being paid to the psychosocial burden experienced by patients with CD. A first step towards structural psychosocial care for CD patients would be to screen these patients on psychosocial functioning. Yet, at this moment, there is no short and feasible instrument available for the Dutch situation.

Study objective

The primary objective of this study is to develop a short and feasible screening package which is specific and sensitive to detect psychosocial problems in patients with CD.

Study design

A cross-sectional study

Study burden and risks

The burden of patients consists of;

- the completion of a few short computerized questionnaires (15 minutes), after visiting the cardiologist or specialized nurse. Computer assistance will be available.
- a subsample of these patients (with a score on the Well-being Screenings List between 24 and 58) will be asked to participate in a semi-structured interview, which will take place at the hospital or at home (max 45 minutes).

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;

1) visiting the outpatient clinic of the department of Cardiology (a cardiologist or specialized nurse),

2) age ≥ 18 ,

3) willing to give informed consent prior to completion of the questionnaires.

Exclusion criteria

patients not being able to speak or read the Dutch language

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 03-07-2008

Enrollment: 400

Type: Actual

Ethics review

Approved WMO

Application type:

First submission

Review commission:

METC Universitair Medisch Centrum Groningen (Groningen)

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

NL22939.042.08