Cardiac Care Bridge

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON47539

Source
ToetsingOnline

Brief title
Cardiac Care Bridge

Condition

- Other condition
- Cardiac disorders, signs and symptoms NEC

Synonym
Cardiovascular disease / heart disease

Health condition

In deze studie zullen patiënten met alle cardiologische aandoeningen worden geïncludeerd op zowel de afdelingen cardiologie als cardiothoracale chirurgie

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Cardiovascular risk management, Elderly, Home-based cardiac rehabilitation, Transitional care

Outcome measures

Primary outcome

A composite endpoint of unplanned hospital readmission and mortality up to six

months after randomizaton

Secondary outcome

Readmissions and mortality within three and twelve months after randomization

ADL-functioning

iADL-functioning

Functional capacity

Medication adherence

Anxiety

Depression

Health-related quality of life

Symptom burden

Healthcare utilization (Regular community care, primary care visits, emergency

department visits, hospital readmissions and institutionalization)

Caregiver burden

Study description

Background summary

After an admission for heart disease, patients are at high risk for adverse health outcomes such as readmission and death. In the United States 19.9% of patients with acute myocardial infarction and 24.6% of patients with heart failure (HF) of 65 years and older are readmitted within 30 days after discharge. Within this period, 16.6% and 11.2% of these patients is deceased, respectively. This risk of readmissions and mortality is the highest in the first weeks after the cardiac admission. Risk factors for these adverse outcomes are older age, an unplanned admission in the previous six months, comorbidities and low socioeconomic status. In many patients more health conditions are often present, such as dizziness, impairments in activities of daily living, malnutrition and cognitive impairment. These conditions are also more common in older and cardiac patients and are associated with a higher risk of readmissions, which in turn may result in the onset of new disabilities and death.
In the phase of transitions from one care-setting to another, patients are at risk to adverse health outcomes, e.g. because of medication-related problems, lack of communication between healthcare providers and unmet needs. In addition, after an admission patients are often deconditioned, fatigued and cognitively impaired. These factors increase the risk for readmission and other adverse outcomes. Further, patients need to adopt to new cardiovascular medication regimes and to changes in their lifestyle to prevent for recurrent cardiovascular events. After discharge, the focus is on cardiovascular risk management, often with inadequate attention to wider healthcare needs. In high-risk cardiac patients, this may lead to insufficient medical care, such as to non-attendance of cardiac rehabilitation. This rehabilitation is organized and coordinated by secondary care providers. In primary care, there is no alternative care coordination for patients that currently do not receive rehabilitation in secondary care. As rehabilitation is also effective for these older cardiac patient with high risk of functional loss, there is a need for care coordination and an alternative rehabilitation program in primary care. The transitional care model is developed to ensure continuity of care during inter-setting transitions and to bridge the gap between hospital and other settings, which are aimed at decreasing the risk of adverse health outcomes. We hypothesize that older cardiac patients at high risk of adverse health outcomes, such as functional decline, readmissions and mortality, may benefit from care coordination in the transitional phase.

Study objective

The aim of this study is to examine the effectiveness of a nurse-coordinated Cardiac Care Bridge program consisting of care coordination, cardiovascular risk management and home-based rehabilitation for high-risk cardiac patients of

70 years and older on reducing unplanned hospital readmission and mortality within six months after randomization in comparison to care as usual.

Study design

Single-blind randomized controlled trial on patient-level

Intervention

The intervention starts during the admission for patients randomized to the intervention group (within 72 hours after hospital admission). A personalized, integrated care plan based on identified problems in the CGA will be established by a disease manager together with the patient. The department of geriatrics will be consulted in case of >= 1 identified problem on the psychological domain or >= 5 identified geriatric problems in general. Also other disciplines may be consulted in case of signaled geriatric problems. The integrated care plan will be used during and after discharge.The disease manager will announce the patient by the community care nurse and the primary care physiotherapist (PT). The community care nurse (CCRN) visits the patient during the admission and will receive a detailed discharge summary of the disease manager about the cardiac condition of the patient and the personalized goals established from the integrated care plan.

After discharge, care is continued at home by the CCRN and PT. The intensity of these visits is the highest in the first month after discharge as it is known that in this period patients are at highest risk of functional loss, readmission and mortality. In total, the CCRN will visit the patient four to five times after discharge. On indication, the CCRN may change the week of visit, for example because of changes in health status. If necessary, the patient may always consult the CCRN by phone. Core components of the home visits by the CCRN are the evaluation of the integrated care plan goals, cardiovascular risk management with attention for medication reconciliation, lifestyle promotion and progress in cardiac rehabilitation. The CCRN consults other disciplines if needed. If patients, are readmitted in a participating hospital and ward during the study follow-up of twelve months, they will receive the Cardiac Care Bridge program again from the start.

After discharge, the PT will visit the patient a total of nine times for two times per week for home-based cardiac rehabilitation according to the Dutch multidisciplinary guideline of cardiac rehabilitation. Depending on their functional status, patients will start with functional rehabilitation, focusing on muscle strength and body balance. If patients are able to, the rehabilitation program is intensified by endurance training by a graded exercise protocol. The last rehabilitation visit is made to evaluate the current functional status and to refer patients to additional physiotherapy in primary care or to a cardiac rehabilitation center. The rehabilitation

component of the Cardiac Care Bridge program will not be repeated in case of readmissions during the follow-up period of 12 months. This is due to a limitation in the number of physical therapy sessions in Dutch healthcare insurance policies.

Study burden and risks

We expect that this study will have a negligible risk. As described earlier, home-based cardiac rehabilitation is proven to be as safe as center-based cardiac rehabilitation. Therefore, no extra risks are expected because of the rehabilitation component in this study. All involved healthcare professionals who are not (recently) trained in reanimation, will be offered a reanimation training.

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

- Cardiac patients of 70 years and older
- Admitted to the departments of cardiology or cardiothoracic surgery
- Electively and non-electively
- Admission > 48 hours
- Hisk of functional loss according to the screening-tool for frailty of the Dutch Safety Management Program (screening on ADL-functioning, fall risk, malnutrition and delirium) and/or an unplanned admission in the previous six months
- Mini-Mental Examination Score (MMSE) >= 15

Exclusion criteria

- Congenital heart disease
- Terminal illness: defined as a life expectancy of less than three months, for example because of cancer or terminal heart failure.
-Transferred from or to a nursing home
-Transferred to another hospital not participating in this study
- Unable to communicate in Dutch
- Delirium as confirmed by the treating physician

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-06-2017
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO Date:	13-06-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-09-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-02-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-05-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-08-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-02-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL55636.018.16