The evaluation of a Dutch cardiology Primary Car Plus intervention

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20762

Source
NTR

Health condition

Adult patients (≥18 years) with non-acute and low-complexity cardiology-related health complaints

Sponsors and support

Primary sponsor: Maastricht University
Source(s) of monetary or material Support: The study did not received funding / assistance from a commercial organization. The study is part of the Academic Collaborative Centre on Sustainable Care in Maastricht which is mainly funded by Maastricht University Medical Centre and Maastricht University. This study is as well mainly funded by the Maastricht University Medical Centre and by Maastricht University. In addition, we will receive funding from the non-profit private health insurers CZ and VGZ and the Province of Limburg, the Netherlands. The insurers are funding this project via the cooperative named: 'Versterking Eerstelijn Zuid-Nederland' (VEZN) (translated in English: 'Reinforcing Primary Care South of the Netherlands'). VEZN is a cooperative for project funding, focused on regional projects which aim to keep healthcare sustainable and affordable.
For clarification, the funding sources of this study have also been checked and approved by the Medical Research and Ethics Committee. They approved that there were no competing interests. The funders have no influence on the research; the research is conducted by the independent researchers.

Intervention

Outcome measures

Primary outcome

Triple Aim outcomes:

- Health of the population

- Quality of care

- Healthcare costs

Secondary outcome

A qualitative study that will consist of semi-structured interviews, focus groups and observations. Besides evaluating the process of the introduction of PC+ (e.g. identifying the barriers and facilitators), the aim of the qualitative study is to clarify and explain quantitative results. Therefore, the qualitative study will be based on an adaptive approach; the ultimate design will depend on developments during the research and results of the quantitative study.

Study description

Background summary

Abstract

Background. In an attempt to deal with the pressures on the health-care system and to guarantee sustainability, changes are needed. This study focuses on a cardiology primary care plus intervention. Primary care plus (PC+) is a new health-care delivery model focused on substitution of specialist care in the hospital setting with specialist care in the primary care setting. The intervention consists of a cardiology PC+ centre in which cardiologists, supported by other health-care professionals, provide consultations in a primary care setting. The PC+ centre aims to improve the health of the population and quality of care as experienced by patients, and reduce the number of referrals to hospital-based outpatient specialist care in order to reduce health-care costs. These aims reflect the Triple Aim principle. Hence, the objectives of the study are to evaluate the cardiology PC+ centre in terms of the Triple Aim outcomes and to evaluate the process of the introduction of PC+.

Methods/Design. The study is a practice-based, quantitative study with a longitudinal observational design, and an additional qualitative study to supplement, interpret and

improve the quantitative study. The study population of the quantitative part will consist of adult patients (≥18 years) with non-acute and low-complexity cardiology-related health complaints, who will be referred to the cardiology PC+ centre (intervention group) or hospital-based outpatient cardiology care (control group). All eligible patients will be asked to complete questionnaires at three different time points consisting of questions about their demographics, health status and experience of care. Additionally, quantitative data will be collected about health-care utilization and related health-care costs at the PC+ centre and the hospital. The qualitative part, consisting of semi-structured interviews, focus groups, and observations, is designed to evaluate the process as well as to amplify, clarify and explain quantitative results.

Conclusions. This study will evaluate a cardiology PC+ centre using quantitative and supplementary qualitative methods. The findings of both sub-studies will fill a gap in knowledge about the effects of PC+ and in particular whether PC+ is able to pursue the Triple Aim outcomes.

Keywords. primary care, primary care plus, hospital care, Triple Aim, substitution, referral, cardiology

Study objective

This overall study aims to evaluate the effects of cardiology PC+ centre on the Triple Aim outcomes. The underlying premises of the researchers on the effects of the intervention are that the cardiology PC+ centre will result in an (at least) equivalent health of the population, improved quality of care as experienced by patients and a reduced number of referrals to hospital-based outpatient cardiology care, and hence reduced health-care costs.

Study design

The data will be collected at four different time points, namely at baseline, before the patient has the first consultation with the cardiologist (T0), a week after the first consultation (T1), three months after the first consultation (T2) and six months after the first consultation (T3).

Intervention

Intervention: cardiology primary care plus centre

The PC+ intervention is a cardiology PC+ centre in which cardiologists, supported by other health-care professionals, provide specialist consultations in a primary care setting. Hospital diagnostic tools are available including an ultrasound device, an ergometer and an electrocardiogram (ECG). All GPs in the region participate in the PC+ intervention and are able to refer non-acute and low-complexity patients with cardiology-related complaints to the PC+ centre. Patients who are already diagnosed with cardiology-related health problems by a cardiologist are not appropriate for PC+ and (if needed) they will be treated by the cardiologist in the hospital-care setting. The consultation at the PC+ centre consists of the following diagnostic tests: a blood test, an ECG, an echo and an exercise test. The diagnostic

tests are carried out by multiple health-care professionals, such as nurses, laboratory technicians and physicians, all specialized in cardiology. After the tests the patient meets the cardiologist, who explains the results of the diagnostic tests. The cardiologist sends a comprehensive description of the results of the tests, the diagnosis and his recommendation regarding further treatment (if needed) to the GP. The GP discusses the cardiologist's recommendation with the patient and based on the principles of shared decision-making the GP and the patient discuss the options for further treatment [24]. Moreover, the GP remains clinically in charge of the patient. The further treatment will depend on the results of the tests and the recommendation of the cardiologist; the three overall options are: 1) the patient needs no care (i.e. the patient has no health problems that need further attention), 2) the patient will remain in the primary care setting (the patient needs low-complexity care, e.g. medication) or, 3) the patient will be referred to secondary care (the patient needs specialist care).

Control: hospital-based outpatient cardiology care (care-as-usual)

Hospital-based outpatient cardiology care is considered care-as-usual. All GPs are allowed to refer non-acute and low-complexity patients with cardiology-related complaints to the hospital-based outpatient cardiology care. These patients receive the same care as within the PC+ centre, i.e. the same diagnostic tests carried out by health-care professionals with the same level of expertise. After the tests the patient meets the cardiologist, the cardiologist explains the results and they discuss further treatment (if needed). This underlines a significant difference with the intervention: in the PC+ centre the cardiologist provides only a recommendation on further treatment and the GP discusses the options for further treatment (instead of the cardiologist), i.e. within PC+ the GP remains in charge.

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Eligibility criteria

Inclusion criteria

The study population consists of adult patients (≥18 years) with non-acute and low-complexity cardiology-related health complaints, registered with a GP in the region of the pioneer site. Based on the principles of shared decision-making the GP and the patient will discuss the options for referral which will be either the PC+ centre (intervention group) or the hospital-based outpatient cardiology care (control group). The decision will be based on expertise and experience of the GP, the severity of the complaints of the patient and the preferences of the patient. Less sever, non-acute and low-complex patients should be referred to PC+. At the moment, no specific criteria are included for the referral to PC+. The GP is in charge of referring a patient to the PC+ centre or the hospital-based outpatient cardiology care, i.e. the researchers do not have any influence on the referrals.

Exclusion criteria

Excluded from participation are patients who are already diagnosed with cardiology-related health problems by a cardiologist and patients who have received balloon angioplasty or bypass surgery in the past 18 months. Furthermore, patients with acute health problems who require immediate hospital care and/or patients arriving at the emergency department of the hospital are excluded from participation.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-01-2015
Enrollment:	858
Type:	Anticipated

Ethics review

Positive opinion Date:	09-08-2017
Application type:	First submission

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
NTR-new	NL6451
NTR-old	NTR6629
Other	METC : 15-4-032

Study results