

# Implementation of the Cardiac Rehabilitation (CR) guidelines by a multifaceted decision support, feedback and outreach visit intervention: A cluster randomized trial.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON28843

### Source

Nationaal Trial Register

### Brief title

CARDSS-II

### Health condition

Guideline implementation; Cardiac Rehabilitation (CR); Health Care Quality, Access, and Evaluation; Feedback and outreach visits.

Richtlijnimplementatie; hartrevalidatie; kwaliteit van zorg.

## Sponsors and support

**Primary sponsor:** Academic Medical Centre (AMC) (Netherlands) (Principal Investigator Niels Peek)

**Source(s) of monetary or material Support:** ZonMw - The Netherlands Organisation for Health Research and Development

## Intervention

### Outcome measures

#### Primary outcome

Guideline adherence in the field of cardiac rehabilitation.

Based on the scores on the different developed quality indicators it will be indicated whether the needs assessment and the therapy indication procedure were carried out in adherence with the guidelines.

We defined adherence at the level of the patient; it implied treating patients who should have been treated and not treating patients who should have been untreated, according to the guideline.

#### Secondary outcome

Improvement on quality indicators in the field of cardiac rehabilitation.

The quality indicators include a) process variables (e.g. frequency with which clinical measurement instruments are employed), b) outcome variables (e.g. changes in patient health status after rehabilitation), and c) structure variables (e.g. presence of precondition to be adherent to CR guidelines).

## Study description

#### Background summary

Implementation of clinical practice guidelines into daily care is hindered by a variety of barriers related to professional knowledge, collaboration in teams and organizations, and practicability of the guidelines. Clinical computerized decision support (CCDS) has been shown to be one of the most effective instruments to improve compliance to practice guidelines by tackling barriers related to professional knowledge. To address other barriers, however, additional interventions are needed. In this study, a continuous multifaceted guideline-implementation strategy was developed which is based on CCDS but extends beyond the professional knowledge barrier. Two additional interventions were designed and embedded with CCDS in a continuous quality improvement framework. First, to address barriers within teams and organizations guideline compliance data are periodically aggregated into feedback reports for care providers. Second, barriers related to practicability of the underlying guidelines are addressed in a guideline-maintenance cycle. A case study in the field of cardiac rehabilitation is presented to demonstrate the feasibility of the developed strategy.

Quality indicators (QIs) are increasingly used to summarize quality of care and to give professionals' performance feedback. We have previously developed a continuous multifaceted guideline implementation strategy that integrates computerized decision support with feedback on QIs and benchmarking. This paper focuses on development of QIs, and presents results of a case study in the field of cardiac rehabilitation. We present a modified Rand method that combines results from a literature search and guideline review with knowledge of an expert and patient panel in an extensive rating and consensus procedure. All sources contributed to the final set of 18 QIs for cardiac rehabilitation.

**Background:** Despite all available evidence of its effectiveness, cardiac rehabilitation and secondary prevention (CRSP) is still insufficiently implemented in current clinical practice. Based on an analysis of implementation problems, recently the Dutch clinical algorithm for the assessment of patient's CRSP needs was revised. The purpose of this paper is to describe the revision process and its results to improve CRSP guideline implementation. **Methods:** The National Institute for Health and Clinical Excellence (NICE) guidelines manual for conducting guideline revisions was followed. Information on the use of the algorithm in practice was collected from electronic medical records and by conducting semi-structured interviews. Next, an expert advisory group identified the problems for use in daily practice and defined the scope for the revision. A multidisciplinary guideline development group subsequently wrote the revised algorithm.

**Results:**

A large variation in assessed patient needs was observed between CRSP clinics. Assessment based on clinical judgement was found to be a source of practice variation and is therefore avoided in the revised algorithm. It was decided to add assessment instruments for anxiety and depression, cardiovascular risk factors, stress, attitude of partner and lifestyle parameters.

**Conclusion:**

The Dutch clinical algorithm for assessing patient needs for CRSP was revised using a combination of

patient data from routine practice, knowledge from academic experts and experience from field experts. The revised algorithm is a practical tool consisting of assessment instruments to improve CRSP guideline adherence in the Netherlands. This algorithm may also be useful for other Western countries to organize their CRSP needs assessment procedure.

## **Study objective**

A multifaceted intervention combining computerized decision support with feedback on quality indicators and educational outreach visits will improve guideline implementation in the field of cardiac rehabilitation.

## **Study design**

1 year

## **Intervention**

We will carry out a multifaceted guideline implementation intervention, consisting of three elements:

1. A CCDS system at the point of care based on the most recent guidelines for CR;
2. Quarterly feedback on quality indicators for CR, and;
3. Educational outreach visits using an online tool to set up a quality improvement plan together with a local quality improvement team.

The first element is particularly directed at internal barriers to guideline adherence on the level of the individual professional in the primary care process (patient care). The second and third element are directed at external barriers on an organizational level in the secondary (logistic) and tertiary (management) care processes.

The effect of the intervention will be evaluated in a multi-center cluster-randomised study with a balanced (2x2) incomplete block design. Cluster-randomisation is chosen to avoid contamination among professionals within the same clinic. There will be two study arms (A and B). Clinics allocated in arm A will receive the intervention directed at improving guideline concordance for the education and lifestyle change therapy; clinics in arm B will receive the intervention directed at improving concordance for the exercise therapy and the relaxation and stress management training.

For each participating clinic the study period is one year. By using a balanced design both willingness to participate will rise and drop-outs (a problem in the preliminary study CARDSS-I) will be prevented because both arms have their own intervention and serve as each other controls.

#### 1. A CCDS system at the point of care based on the most recent guidelines for CR:

The system will provide patient-tailored advice to professionals during the primary care process of the needs assessment procedure. CR professionals will be stimulated to use the system during clinical interviews with patients in whom rehabilitation needs are assessed, to achieve optimal effect of the decision support. Integration into practitioner workflow is one of the factors that predict success of the CDS system (6). When using the system during the needs assessment procedure, the advice given based on the data entry can immediately be discussed with the patient to set the final rehabilitation program;

#### 2. Quarterly feedback on quality indicators for CR:

Each three months all participating clinics will receive feedback on quality indicators, based on data that is recorded by the system. Feedback reports will include different quality indicators; a) process variables (e.g. frequency with which clinical measurement instruments are employed), b) outcome variables (e.g. changes in patient health status after rehabilitation), and c) structure variables (e.g. presence of precondition to be adherent to CR guidelines). Feedback will be attuned to the research arm concerned: clinics in arm A will receive feedback on quality indicators referring to the education and lifestyle change therapy; clinics in arm B will receive feedback on quality indicators referring to the exercise therapy and the relaxation and stress management training. Both arms will receive feedback on quality indicators referring to the general processes and structures. Each feedback report will compare clinic-specific summary statistics to benchmark values that are based on national averages. In addition, these summary statistics will be compared to statistics from the same clinic during earlier periods to quantify change. Case-mix adjustment will be applied where this is needed. Feedback reports will be presented using an online tool to show a quick overview of all indicators to the users from which they can navigate to pages with more details on each indicator;

#### 3. Educational outreach visits using an online tool to set up a quality improvement plan together with a local quality improvement team:

After feedback reports have been composed, outreach visits will be conducted to increase trust in data quality and to support the clinics with the discussion of their results and the set up of a quality improvement plan. To this end each clinic needs to compose a local quality improvement team including minimally one nurse acting as rehabilitation coordinator, one other discipline and one representative from the management. Main responsibility of this team is to define, implement and monitor a quality improvement plan based on addressed problems from the feedback reports. To support the local teams with this task, outreach visits will be conducted after feedback reports have been sent. During these visits the feedback

reports will be discussed and the local team can select indicators for which they see opportunity for improvement. The online tool in which the feedback reports are shown can also be used to develop a quality improvement plan. For each selected indicator the problem, possible causes, improvement goals and several action items can be recorded during the outreach visit. After four to six weeks a second outreach visit will take place to discuss and support possible problems during the implementation of the improvement plan. When local teams had doubts about the quality and reliability of the data and asked for additional data, this will also be discussed during the second visit.

Three months after the first round of feedback, a new feedback report is composed and spread. The online tool can then be used to discuss the results again and check to what extent the planned improvement goals and action items have been fulfilled. Based on the results improvement goals can be removed (when achieved) or changed (when not achieved but still important) or new goals can be added. During the study period of one year each clinic will receive four feedback reports and four outreach visits. All visits will be facilitated by the same investigator who was a non-medical background; she has been involved in the development of the national CR quality indicator set and has several years of experiences with CR guideline implementation. Having a non-clinician supporting the quality improvement team will make the intervention less intrusive and therefore less threatening to participating clinics.

## Contacts

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## Eligibility criteria

### Inclusion criteria

Clinical level:

All cardiac rehabilitation clinics that electronically collect the items of the minimal dataset and are willing to dispose their data for research are eligible to participate in the study.

Patient level:

All cardiac patients who go through the needs assessment procedure and actual start a CR programme during the study period will be included in the analyses.

### Exclusion criteria

Non; all patients are eligible to be enrolled in the system, as the CR guidelines apply to all CR patients.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-04-2012
Enrollment:	15

Type: Anticipated

## Ethics review

Positive opinion

Date: 19-01-2012

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	NL3097
NTR-old	NTR3251
Other	ZonMW/ METC : 80-82315-98- 08305 / 10.17.1448;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

1. van Engen-Verheul M, de Keizer N, Hellemans I, Kraaijenhagen R, Hasman A, Peek N, Design of a continuous multifaceted guideline-implementation strategy based on computerized decision support. STUD HEALTH TECHNOL INFORM 2010;160:836-840.<br>
2. van Engen-Verheul M, Kemps H, Kraaijenhagen R, de Keizer N, Peek N, Modified Rand method to derive quality indicators: a case study in cardiac rehabilitation. STUD HEALTH TECHNOL INFORM 2011;169:88-92.<br>
3. van Engen-Verheul MM, Kemps HM, de Keizer NF, Hellemans IM, Goud R, Kraaijenhagen



RA, Peek N, Revision of the Dutch clinical algorithm for assessing patient needs in cardiac rehabilitation based on identified implementation problems. EUR J CARDIOV PREV R 2011;ahead of print.