

Cardiac Rehabilitation: changes in quality of life, fitness and attainment of rehabilitation goals among cardiac patients, during a process-oriented cardiac rehabilitation program

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Abstract

Introduction: Cardiac Rehabilitation significantly (CR) reduces mortality and morbidity and increases the quality of life after a cardiac event, however conventional CR treatments are long, and therefore expensive to serve the increasing demand for CR. At Kennemer Gasthuis (KG) the CR program has been developed into a process-oriented program where content and durations are variable and patient-tailored (adjustable at midterm evaluation). This paper shows how the process-oriented program significantly reduced the length of the CR program for numerous patients, while retaining the good results.

Objective: To provide more insight into what happens in practice in a process-oriented CR program (at KG). Investigate changes in fitness, quality of life and rehabilitation goals it generates, as well as showing more numbers regarding compliance and program duration.

Patients: 3442 patients referred by the cardiologist to the CR program between December 1999 and December 2011, after introduction of the process-oriented program.

Method: The program includes basic CR content: information-, exercise- and relaxation modules, and if required individual guidance. Changes in fitness (watt/HF), quality of life (MPVH-questionnaire) and attainment of rehabilitation goals are measured at start, midterm and end of the program. Analysis is done within two study programs: the 'screening standard program' (SP), including midterm stoppers, and the 'extended standard program' (EP), including patients continuing after midterm evaluation.

Results: Respectively 51% and 27% of all patients are enrolled into SP and EP. Patients in SP show better baseline measurements in all outcome measures. Overall, significant changes in fitness and quality of life were found between the two program groups, whereas patients in SP show a tendency of improving more before midterm evaluation and EP improving more after midterm. In attainment of rehabilitations goals we notice more patients in EP attain their goals compared to SP. Noteworthy is the significantly shorter duration of SP compared to EP: 57.2 vs. 120.6 days.

Discussion and conclusion: The process-oriented approach has reduced duration of CR for several patients, while positive changes in outcome were maintained. Considering growing health-care costs and expected increase of referred patients, a process-oriented program and thus possibility of a shorter program, could be a tool to meet increasing demands for CR.

Recommendations: Process-oriented CR is associated with positive changes in fitness, quality of life and rehabilitation goals. A carefully planned midterm evaluation gives the possibility to significantly reduce the duration of the program, while keeping the good results. Further research will be performed.

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1. Problem Definition and Introduction

Coronary heart disease (CHD) is prevalent and has serious consequences. It is a major cause of mortality (approximately 40.000 deaths in the Netherlands in 2009 [1]), morbidity, decreased quality of life and high healthcare costs. [2] However, continuously improved methods of diagnostics and treatment, and more focus on secondary prevention have significantly decreased the mortality among patients with CHD; from 1972 to 2007 the mortality rates in the Netherlands have decreased by 76%. [1] As a consequence the prevalence of patients surviving a myocardial infarction increases, and it is expected that the number of Dutch patients with CHD will grow by 45% over the next decade. [1,3]

Thus, the need for cardiac rehabilitation (CR) to alleviate the consequences of CHD will increase. Cardiac rehabilitation, either comprehensive or limited to exercise training only, reduces mortality, morbidity and re-hospitalisation. Furthermore, besides the physical benefit, an improvement in quality of life has also been noted. [4,5,6,7] A good quality of life evidently becomes of more consequence as the life expectancy of cardiac patients is constantly improving. Approximately three quarters of patients develop psychological symptoms after a myocardial infarction. Mood problems such as anxiety and depression are known risk factors for coronary artery disease, and also have a negative impact on the recovery process after a cardiac event. [8,9,10,11,12] The addition of relaxation therapy to the physical training program has proven to improve social recovery, mental and physical functioning, as well to reduce the risk of a new cardiac event. [2,13,14] It has also been shown that additional psychological intervention decreases mortality with 54% for at least two years. [15] Noticeable is also that in CR the recovery of a realistic self-confidence and awareness of body limitations is of more significance than simply gaining fitness.

Based on these facts, the CR program in the Netherlands extended into a multi-disciplinary program, with more consideration for secondary prevention.

1.1 Cardiac Rehabilitation in the Kennemer Gasthuis

Annually approximately 3500 cardiac patients are treated in Kennemer Gasthuis (KG). Of these 10-20% (mostly those with CHD) is referred to the CR program.

The CR focuses on four goals: physical, psychological, social and goals concerning risk behaviour [8]. At KG the CR program is also based on these four goals, but as described below the approach on how the program is offered differs from that in other hospitals.

1.1.1 The Re-design, the Process-oriented Program

In 1999 a large "re-design" took place within the CR. The **program-oriented** approach, in which each patient is offered a similar program with an equal duration, was abandoned and a step towards a more personal **process-oriented** approach was taken. The new process-oriented program follows the process of the patient instead of determining the rehabilitation program in advance. Patients are offered the basic CR components (the program modules: exercise, relaxation, information and individual guidance) in which the approach and duration are dependent on the patients' response. Essential is that in the process-oriented approach, content and durations are **variable and thus patient-tailored**.

The idea behind this process-oriented approach is to observe the natural resilience of an individual. One focuses on the patients' natural tendency to recover and one observes whether, and to what extent, that occurs and whether there are factors that interfere, counteract or inhibit it. This method implies a systematic and timely evaluation, which has been added at midterm of the program in 1996, following the recommendations of the first Guidelines for CR. The new design introduced this evaluation as a moment to decide whether to stop or continue the CR program. This is critical to the process-oriented approach. If patients demonstrate a sufficient (training) response to the therapy, they are able to stop CR early and continue the recovery process at home. If there are factors (insufficient physical trainability, social or psychological factors) preventing the recovery response, continued attention and guidance is required (i.e. an extended program). This decision is taken, based on subjective impressions of therapists, the opinion of the patient and clinimetric evaluation. Also, the therapist individually decides the moment of evaluation. The clearer the response of the patient, the sooner the midterm evaluation can take place. [16,17,18,19]

Another element of the process-oriented approach is to expand the scope of treatment modalities in the screening phase (time to midterm evaluation), in order to increase the probability of a positive response. The exercise program offered two options instead of only one. To the exercise on the bicycle ergo meter with ECG monitoring (cycle training), exercise on other fitness instruments, without ECG monitoring, was added (circuit training). In addition, all patients were scheduled for group relaxation sessions as well as an information program.

As a result of the introduced "re-design" many patients stopped earlier with CR. In the first evaluation patients from the year prior to the introduction (i.e. 1997) were compared to patients following the "re-design" (1999). This comparison showed that the average number of sessions decreased while the overall improvement was maintained in patients who stopped early. [18] Based on the good results the process-oriented CR program was permanently implemented into the KG and has been used for the last 13 years.

1.1.2 Distribution into Study Groups

Based on the content of this process-oriented program, the CR is divided into five study groups. The standard content is exercise and group relaxation. Thus, two main groups are shaped: the **'screening standard program' (SP)** and the **'extended standard program' (EP)**. The former includes patients that, because of satisfactory response, stop after the midterm assessment. The latter are patients who continue the program, with individual guidance if required. In practice the EP can be divided into a screening period (period till midterm evaluation, which predominantly includes group sessions) and an extended period.

In this study we focus less on the three 'rest' groups. First, the **'circuit-training program' (CP)** is for patients who are less trainable and have more co-morbidity. They participate in circuit training only. Second, the **'alternative program' (AP)** includes patients who did not participate in the exercise program, but did other therapy sessions instead. And lastly, the **'no program' (NP)**: herein patients are included who completed the intake module (interview plus first exercise testing) but did not participate in any part of the CR program, hence dropped out.

1.2 Current Developments

In the past decade it has been shown that CR is not only effective for patients with CHD, but also for patients with other heart diseases. This increase of indications for referral, the prolonged survival of heart patients, and aging population expands the patient population for CR. [20,21] Considering the proven effectiveness of CR, the number of referred heart disease patients should ideally be significantly more than the 10-20% whom are currently being referred, also at KG [8]. Thus, there would evidently be far more patients, while the capacity of the rehabilitation centres is limited. If all eligible patients were to be referred, rehabilitation in primary care setting (physiotherapy outside hospital walls) would become necessary and unavoidable.

Since 2004 the Dutch Society of Cardiology developed a decision tree ('decision tree polyclinic needs assessment cardiac rehabilitation') in the guidelines for cardiac rehabilitation to determine which program modules are indicated based on the information given at the intake. The choices are: movement, relaxation, information and lifestyle modules. The decision tree can be made operational by using a software program (e.g. CARDSS). It has been shown that an electronic decision support is suitable for promoting the implementation of the decision tree, as people are more careful with recommendations when using CARDSS than when using paper versions. [8,22,23] The new method is even further focused on establishing patients' needs at intake and to decide upon the content of the subsequent rehabilitation program. This is a clear example of a program-oriented approach. In September 2012 a pilot version of CARDSS is about to be launched at KG, primarily to expand rehabilitation to primary care physiotherapy clinics and to help decide which patients to refer to the rehabilitation centre and which to selected primary care clinics.

It seems appropriate therefore to evaluate the content and impact of the process-oriented approach, of recent years. The knowledge may be used to compare the outcome of the process-oriented approach to the program-oriented approach, in terms of participation in the different program modules, number of sessions, program duration, and of outcome measurements. It may help to predict in the future which patients will benefit from either rehabilitation program.

1.3 Importance and Study Aims

The importance of this research is to provide more insight into what happens in practice in CR in a hospital setting like KG. There are few data on how often certain program modules are followed, which patients follow the modules or not, and to what effect. In comparison to fitness, mortality and morbidity, little is known about the effect CR has on quality of life or attainment of rehabilitation goals.

With more insight we may substantiate the importance of a midterm assessment and subsequent program changes (thus, a process-oriented approach), which in the recent years is performed at KG. This could reduce the duration of the program while retaining the positive outcome. [6,24] Considering growing healthcare costs and the expected increase of referred patients, a process-orientated program with adaptable duration, could be a tool to meet increasing demands for CR.

1.4 Research Questions

The purpose of this research is to gain more insight into participation in and outcome of CR. From here follows the research questions:

1. Which patients followed which program in the CR at KG?
2. What changes occurred in fitness, quality of life and rehabilitation goals, within the two main programs?

After answering the above questions, further research will be done to focus on whether it is possible to predict who will benefit from what program. Which programs of what length are required for which patients? And, who should be treated where?

1.5 Hypothesis

Question 1: Null hypothesis H_0 : the baseline measurements and characteristics of patients within and the content of the programs (SP and EP) are similar to one another. Alternative hypothesis H_1 : the baseline measurements and characteristics of the patients within and the content of these programs differ.

Question 2: Null hypothesis H_0 : changes in fitness, quality of life and attainment of rehabilitation goals, do not differ within the two main study programs. Alternative hypothesis H_1 : changes in fitness, quality of life and attainment of rehabilitation goals, do differ within the two main study programs.

2. Material and Methods

2.1 Design

This is a prospective descriptive study of data from over 3400 patients, collected over the years 1999 to 2011.

2.2 Patient Selection

Inclusion criteria: Men and women of all ages who after hospitalization for a cardiac event were referred to CR by a cardiologist between December 1999 and December 2011 KG. All included patients have entered the program and at least participated in the intake module.

Exclusion criteria: Data of patients following the program for second time or more. The Dutch society of cardiology's guideline for CR gives some contraindications for referral to the program. Some of the mentioned contraindications are: 1) unstable medical phase or 2) not motivated enough, or unconvinced of the importance of cardiac rehabilitation

"The judgment of the cardiologist should be leading with indications and contraindication. When the cardiologist suspects that there are major obstacles interfering with the attainment of physical, mental and social goals and/or promoting a healthy lifestyle, consultation with the patient about specialised rehabilitation care should be considered." [8]

2.3 Data

The data consist of patient treatment data, which are logged into a database as part of the rehabilitation treatment. 3442 patients are included with an average age of 61.6 years. There are 2584 men and 858 women. Reasons for referral are diverse; however most patients have CHD.

2.4 Intervention

The intervention is participation in the CR after the introduction of the "re-design" as previously described.

All patients will receive/are offered an information-, exercise- and relaxation module. If necessary, the program can be extended with individual therapy. At the midterm assessment the therapist, in consultation with the patient and cardiologist, decides whether or not to extend the program.

2.4.1 Time Path

In principle, two weeks after discharge from the hospital and referral for CR, patients follow an intake module and the first exercise test on a bicycle ergo meter, performed under guidance of the cardiologist (T_0). After that, patients start the relaxation therapy and the physical exercise program.

Within six weeks after the start of the physical exercise program the midterm evaluation (T_1) is done and the results are discussed at the weekly team meeting. Approximately six weeks after this assessment, at the end of the program, the final evaluation (T_2) is held. At this point the midterm stoppers are also evaluated. Three months hereafter there is a follow-up group meeting.

2.4.2 Content of the CR Program

Exercise program

- Cycle training (screening period)
- Circuit training (screening and extended period)

Cycle training: approximately two times per week, for about 30 minutes. Monitoring of heart frequency (HF) and blood pressure (BP) takes place. With each training session there are four participants and two supervisors. The level of effort and limitations are measured by 1) rising of HF at the same wattage, and 2) the ability to continue

talking during exercise (striving for a BORG-score* of 13-14 on a scale to 20). Adjustments are made based on clinical symptoms, BP, HF and subjective experience. *Circuit training (screening period)*: once a week, for about 60 minutes. Eight patients and two supervisors participate in the training sessions. The content of the training is warming up, circuit training and cooling down. Noteworthy is that some patients are given an adjusted circuit-training program without cycle training. These patients have extensive co morbidities and are physically less fit. *Circuit training (extended period)*: circuit training as in the screening periods, but twice a week.

Group relaxation therapy (Van Dixhoorn method): five to six sessions in total with one session per week. The duration is approximately 60 minutes. There are six participants and one supervisor. The supervisor can be a social worker or a physiotherapist and is extensively trained in the method. The relaxation instructions can vary: passive versus active, lying, sitting, standing or moving. The exercises are expected to be practiced at home. If the patient's response is insufficient there is a possibility for individual therapy or to stop the relaxation program.

Information module: four group meetings. Partners are invited to accompany the patient. First a meeting with a cardiologist is held where information about CHD, surgery and medication is given. Second is a meeting with a dietician about healthy diet. Thirdly is a meeting on the role of stress in the recovery after the cardiac event (which is also the first session of the relaxation module). Finally, there is a meeting with a social worker to give information about the consequences and changes. The patients' partners primarily attend this meeting.

Individual guidance

- Individual relaxation therapy (following the Van Dixhoorn method)
- Consult social worker (or clinical psychologist)

2.4.3 Variables

Patient variables: gender, age and diagnosis (divided into five main diagnostic groups, with 11 subgroups)

Program variables: participation (compliance) within different modules, number of treatment sessions per module, program duration (in SP duration of complete program is between T_0 and T_1 , at EP it is between T_0 and T_2) and time between referral and start CR (wait time)

2.5 Outcome Measures

Baseline measurements and changes regarding 1) fitness (exercise test on a bicycle ergo meter, levels of fitness: wattage/heart frequency (HF)), 2) quality of life (by MPVH questionnaire, Medical Psychological Questionnaire for heart patients) and 3) rehabilitation goals. Measurements have been made on three occasions: start (T_0), midterm (T_1) and a final measurement (T_2). The time between these measurements may vary, since the time of midterm and end evaluation is variable.

Fitness is defined as wattage divided by HF (beats per minute). This measure indicates that a rise in wattage and simultaneously a rise in heart frequency does not necessarily mean an improvement in physical capacity, but can also be explained as an increase in motivation to perform better. If certain wattage is achieved with less beats per minute needed, it indicates an improved fitness. Changes in fitness are expressed as a percentage between two time measurements, T_0 - T_1 and T_0 - T_2 .

The **MPVH-questionnaire** measures feelings of wellbeing (MPVH-W), handicap (MPVH-H) and distress (MPVH-D). Minimum and maximum scores for these three subscales are respectively 12-36, 12-36 and 10-30. A high score on the wellbeing scale reflects that the patient is feeling well. In contrast, a high score in MPVH-H and/or MPVH-D indicates that the patient is feeling handicapped and distressed. Changes in quality of life are expressed as a real change (improvement) in score on the MPVH questionnaire between two time measurements, T_0 - T_1 and T_0 - T_2 .

The **rehabilitation goals** are predefined and subdivided into four goal categories: somatic, mental, social and preventive goals. The number of goals within these four categories is respectively five, three, four and four. These rehabilitation goals are defined by the guideline for cardiac rehabilitation [8]. Patients select which goal is applicable to them. Achievement possibilities are: 'sufficiently improved', 'improved', 'not changed' or 'worsen'. A rehabilitation goal is considered as completely attained if it is 'sufficiently improved'. If not, further guidance should be considered. As an outcome measurement, changes in goal attainment are expressed as a percentage of 'sufficiently improved'. In this research we focus on the midterm measurement (T_1) to see if it supports the decision to stop or extend the program.

2.6 Statistics

First data cleaning is performed. Continuous (scale-) variables are tested, by using Kolmogorov-Smirnov. All continuous data in this research is non-normally distributed. Therefore the following non-parametrical statistical

* *Borg RPE-score: subjective scale which represents the patients 'Ratings of Perceived Exertion'. Physiotherapists use the score to identify how much effort is experienced for a particular level of activity. A Borg-score of 13-14 means one experiences the exercise as 'somewhat hard'. The score is also a simple way to estimate heart rate - multiplying the Borg-score by ten gives an approximate heart rate for a certain level of activity.*

tests (for continue and ordinal variables) where used: Mann-Whitney and Kruskal-Wallis. For nominal variables we used chi-square in analysis.

Statistical data analysis is done with use of SPSS version 19.0. Linnaeus institute at KG gives statistical and methodological support if necessary.

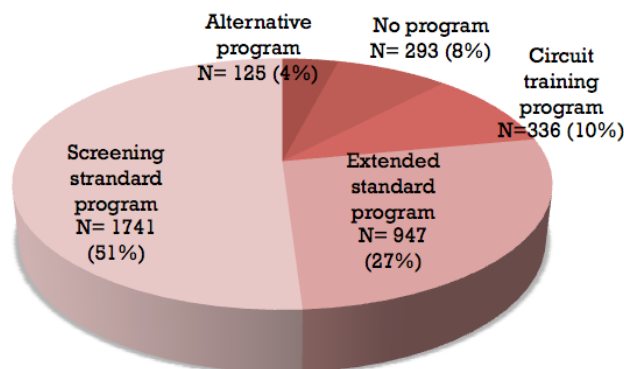
3. Results

3.1 Distribution into Study Groups

3442 patients are included. Figure 1 shows the distribution into the study groups. Over 75% is enrolled into the main two study groups SP and EP (respectively n=1741 and n=947 patients). The two hypotheses will be tested on these two main program groups.

In the three rest groups, AP contains the smallest number of patients. Noticeable is the relative high number of patients in NP: the dropout rate seems high. Most given explanation for dropout within this study group is lack of motivation (n=79), followed by not-heart-related complaints (n=12) and distance towards the hospital (n=11). Besides a description of demographic, clinical data and baseline measurements, the 'rest group' will not be used for statistical evaluation.

Figure 1: Study groups (number and percentage)



3.2 Comparison of Groups at Baseline

All demographic (age, gender) and clinical data (diagnosis) of all five-study groups is shown in table 1a. The baseline measurements are given in table 1b. In table 1c the baseline measurements for the two main study groups (SP and EP) are shown and statistically tested.

There are several dissimilarities in characteristics between the study groups (table 1a). Median age ranges from oldest (74 years) in CP, to youngest (57 years) in the EP. Furthermore, with 58.3% the number of women is highest in the CP, compared to the lowest number, 18.4%, in the SP. Regarding the distribution of diagnosis within the five study groups, noticeable is the high number of myocardial infarction in both the AP (37.6%) and NP (39.6%). The number of patients with MI in CP is lowest with 25.3%; but instead we here see an evidently higher number of valve operations (17.6%), CABG (26.5%) and heart failure (11.0%). In table 1b, the quality of life baseline measurements spread between 31 (in SP) and 25 (in EP) in wellbeing; implying patients in SP are feeling better as in EP. Feelings of handicap are highest in CP and lowest in SP (30 vs. 24). With a median score of 15, patients in AP are feeling most distressed, whereas patients in SP again feel least distressed.

Comparing SP with EP, age and gender differ slightly but statistically significant between the two main study groups, with EP containing younger patients (median 57 years vs. 61 years), and fewer men (76.7% vs. 81.6%). Between the SP and EP there is no statistical difference in diagnosis. There are clear and highly significant differences in quality of life. Patients in SP have a much better quality of life, with more feelings of wellbeing, and feel less handicapped or distressed. Fitness is 51.3 watt/HF in SP compared to 48.6 watt/HF in EP, this is statistically significant (p-value <0.001), in favour of the SP (table 1c).

Most rehabilitation goals are selected in CP (median 10.5) but in EP the percentage of patients subscribing to goals (compliance) are highest in all four types of goals. As to be expected very few patients in NP set rehabilitation goals. Between SP and EP, patients in the EP set significantly (p-value <0.001) more rehabilitation goals (table 1c).

The time between referral and the start of CR shows little, but significant differences. The median number of days lies between 22 and 27 (Table 1b). In table 1c, we see a difference in wait time between SP and EP of 24 versus 22 days.

Table 1a: Characteristics between study groups

	Screening standard program (N=1741)	Extended standard program (N=947)	Circuit training program (N=336)	Alternative program (N=125)	No program (N=293)
Age, years ¹	61 (22-91)	57 (28-85)	74 (27-88)	66 (35-89)	68 (26-89)
Age groups ²					
- 52 and younger	367 (21.6)	285 (30.1)	8 (2.4)	24 (19.2)	48 (16.4)
- 53-59	392 (22.5)	264 (27.9)	20 (6.0)	20 (16.0)	34 (11.6)
- 60-66	396 (22.7)	206 (21.8)	39 (11.6)	19 (15.2)	48 (16.4)
- 67-73	348 (20.0)	123 (13.0)	98 (29.2)	31 (24.8)	66 (22.5)
- 74 and older	229 (13.2)	69 (7.2)	171 (50.9)	31 (24.8)	97 (33.1)
Gender ²					
- Male	1421 (81.6%)	726 (76.7)	140 (41.7)	78 (62.4)	219 (74.7)
- Female	320 (18.4%)	221 (23.3)	196 (58.3)	47 (37.6)	74 (25.3)
Diagnosis ²					
Ischemic heart disease					
- CABG	394 (22.6)	226 (23.9)	89 (26.5)	22 (17.6)	59 (20.1)
- MI	487 (28.0)	269 (28.4)	85 (25.3)	47 (37.6)	116 (39.6)
- MI + PPCI or PTCA	429 (24.6)	202 (21.3)	41 (12.2)	21 (16.8)	34 (11.6)
- PTCA	97 (5.6)	41 (4.3)	10 (3.0)	7 (5.6)	14 (4.8)
- Angina pectoris	49 (2.8)	33 (3.5)	5 (1.5)	6 (4.8)	8 (2.7)
Heart operation otherwise					
- Valve operation	154 (8.8)	87 (9.2)	59 (17.6)	12 (9.6)	28 (9.6)
- Aorta operation	11 (0.6)	9 (1.0)	4 (1.2)	0 (0.0)	1 (0.3)
- Other heart operation	4 (0.2)	8 (0.8)	0 (0.0)	1 (0.8)	1 (0.3)
Arrhythmia	35 (2.0)	17 (1.8)	6 (1.8)	4 (3.2)	6 (2.0)
Heart failure	78 (4.5)	53 (5.6)	37 (11.0)	4 (3.2)	23 (7.8)
Other	3 (0.2)	2 (0.2)	0 (0.0)	1 (0.8)	3 (1.0)

CABG = Coronary artery bypass graft; MI = Myocardial infarction; PPCI = Primary percutaneous coronary intervention; PTCA = Percutaneous transluminal coronary angioplasty

¹ Continue variables are nonnormally distributed data. Data is presented as the median (minimum-maximum).

² Number of patients, N (percentage)

Table 1b: Baseline measurements of study groups

	Screening standard program (N=1741)	Extended standard program (N=947)	Circuit training program (N=336)	Alternative program (N=125)	No program (N=293)
Quality of life ¹					
MPVH-W	31 (12-36)	25 (12-36)	26 (12-36)	26 (12-36)	28 (12-36)
MPVH-H	24 (12-36)	26 (12-36)	30 (12-36)	26 (13-36)	26.5 (12-36)
MPVH-D	13 (10-30)	14 (10-30)	14 (10-29)	15 (10-27)	14 (10.28)
Fitness, watt/heartfreq ¹	51.3 (9.2-109.3)	48.6 (10.4-98.6)	31.7 (30.6-79.7) ³	60.3 (27.7-86.4) ³	47.3 (41.7-50.8) ³
Rehabilitation goals:					
Number of participation ²					
- Somatic goals	1633 (93.8)	936 (98.8)	297 (88.4)	37 (29.6)	40 (13.7)
- Mental goals	1050 (60.3)	688 (72.7)	179 (53.3)	21 (16.8)	23 (7.8)
- Social goals	599 (34.4)	460 (48.6)	92 (27.4)	9 (7.2)	10 (3.4)
- Preventive goals	1303 (74.8)	841 (88.8)	229 (68.2)	33 (26.4)	30 (10.2)
Sum of rehabilitation goals ¹	8 (4-14)	9 (5-14)	8 (4-15)	10.5 (6-12)	7.5 (5-9)
Time period, days ¹ (Time between referral and start CR)	24 (1-145)	22 (1-304)	27 (1-132)	26 (2-79)	27 (1-413)

MPVH-W measures feelings of wellbeing; MPVH-H measures feelings of handicap; MPVH-D measures feelings of distress

¹ Continue variables are nonnormally distributed data. Data is presented as the median (minimum-maximum).

² Number of participants, N (percentage).

³ Very small number of measurements in these three groups, respectively 6, 6 and 4.

Table 1c: Baseline measurements between two study groups

	Screening standard program (N=1741)	Extended standard program (N=947)	p-value ^P
Quality of life ¹			
MPVH-W	31 (12-36)	25 (12-36)	<0.001
MPVH-H	24 (12-36)	26 (12-36)	<0.001
MPVH-D	13 (10-30)	14 (10-30)	<0.001
Fitness, watt/heartfreq ¹	51.3 (9.2-109.3)	48.6 (10.4-98.6)	<0.001
Rehabilitation goals			
Number of participation ²			
- Somatic goals	1633 (93.8)	936 (98.8)	
- Mental goals	1050 (60.3)	688 (72.7)	
- Social goals	599 (34.4)	460 (48.6)	
- Preventive goals	1303 (74.8)	841 (88.8)	
Sum of rehabilitation goals ¹	8 (4-14)	9 (5-14)	<0.0001
Time period, days ¹ (Time between referral and start CR)	24 (1-145)	22 (1-304)	0.001

MPVH-W measures feelings of wellbeing; MPVH-H measures feelings of handicap; MPVH-D measures feelings of distress

¹ Continue variables are nonnormally distributed data. Data is presented as the median (minimum-maximum).

² Number of participants, N (percentage).

^P Mann-Whitney

3.3 Participation in CR Program

Participation in exercise is similar for both programs, except for the circuit training that is apparently not followed by all patients in SP. The majority of patients in both programs participate in the relaxation module, whereas a minority follow at least three sessions of the information module. However, patients in EP take significantly better part in the group relaxation-, information-module and individual therapy (table 2a). The same pattern occurs for the mean number of sessions (table 2b). The patients in EP participate significantly more in exercise (11.88 vs. 10.7) and group relaxation therapy sessions (4.46 vs. 3.81). They also have more individual therapy sessions (4.09 vs. 2.96). However, no significant dissimilarity is seen in number of followed information meetings.

As expected the length of the total program in EP exceeds SP unmistakably, with a mean of 120.6 days in EP versus 57.2 in SP, the total program of EP is nearly twice as long. Noteworthy is that duration of the screening period, mean of 55.0 days in EP and 57.2 days in SP, does not differ, statistically significant.

Table 2a: participation; program characteristics between two main study groups

	Screening standard program (N=1741)	Extended standard program (N=947)	P-value ^P
Physical training (total) ¹	1741 (100)	947 (100)	NS ²
- Cycle training	1739 (99.9)	947 (100)	0.297 ³
- Circuit training	1662 (95.5)	946 (99.9)	<0.001
Group relaxation therapy ¹	1509 (86.7)	894 (94.4)	<0.001
Information module ¹ (≥ 3 sessions)	685 (39.3)	422 (44.6)	0.009
Individual therapy (total) ¹	153 (8.8)	242 (25.6)	
- Relaxation therapy	85 (4.9)	142 (15.0)	<0.001
- Consult social worker	81 (4.7)	137 (14.5)	<0.001

¹ Number of participants; *N* (percentage)

² Not tested, participation is constant

³ Not significant

^P Chi-square

Table 2b: number of sessions; program characteristics between two main study groups

	Screening standard program (N=1741)	Extended standard program (N=947)		P-value ^P
		Screening period	Extended period	
Physical training (total) ¹	10.7 ± 3.30	11.88 ± 2.28	10.88 ± 5.49	<0.001 ³
- Cycle training	7.26 ± 2.18	8.02 ± 1.51	1.85 ± 2.56	<0.001 ³
- Circuit training	3.63 ± 1.71	3.95 ± 1.56	9.43 ± 5.25	<0.001 ³
-				
Group relaxation therapy ¹	3.81 ± 1.62	4.46 ± 1.58		<0.001
Information module ¹	2.19 ± 0.96	2.25 ± 1.00		0.138 ⁴
Individual guidance (total) ¹	2.96 ± 1.93	4.09 ± 3.15		<0.001
- Relaxation therapy	3.11 ± 1.82	4.17 ± 2.48		<0.001
- Consult social worker	2.33 ± 1.51	2.91 ± 2.39		0.035
Duration of program ²				
- Total program ⁵	57.2 ± 27.02	120.6 ± 45.00		
- Screening period (T ₀ -T ₁)	57.2 ± 27.02	55.0 ± 20.05		0.575 ⁴
- Extended period (T ₁ -T ₂)		59.4 ± 38.77		

All continue variables are nonnormally distributed data. Data is presented as a *mean ± SD* to give a clear sight on the changes occurring, but tested with nonparametric test.

¹ Number of sessions; *mean ± SD*

² Number of days; *mean ± SD*

³ Training sessions are divided into 'screening period' and the 'extended period'. Statistical testing regards 'screening period'

⁴ Not significant

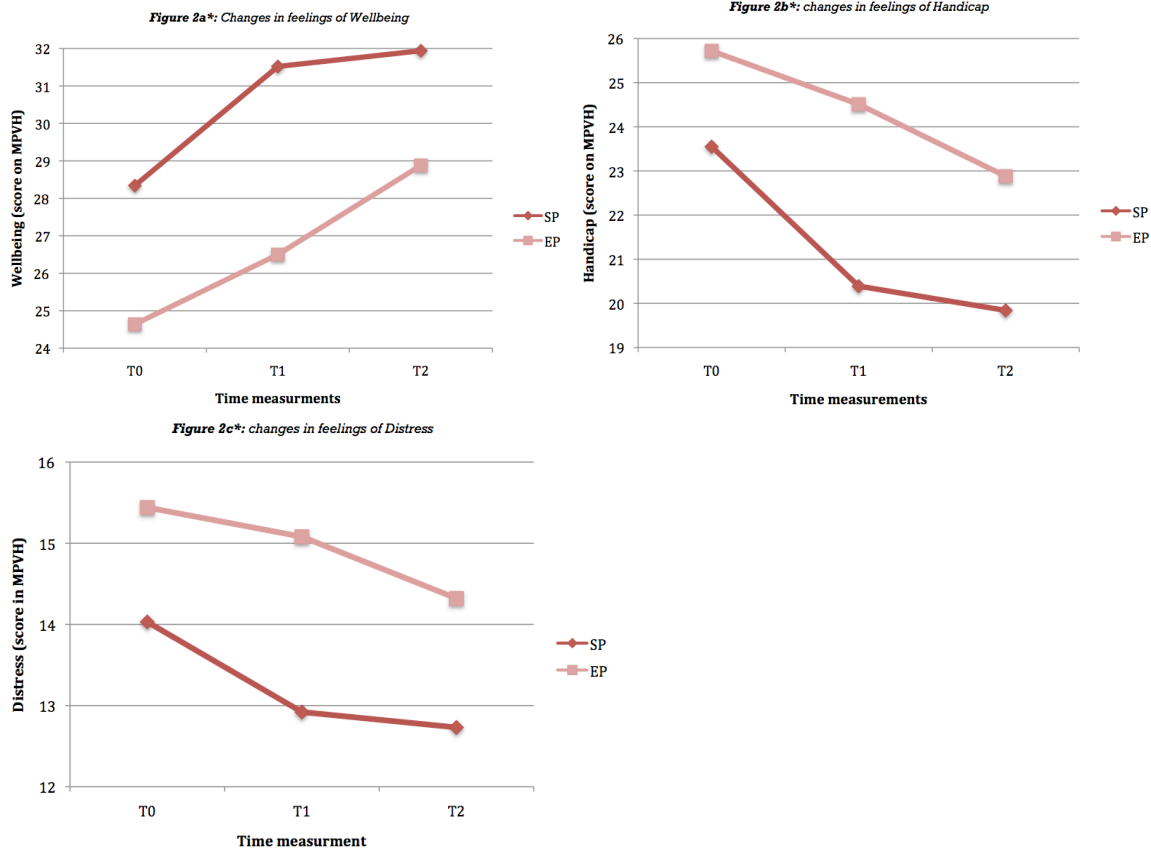
⁵ Duration total program at the screening standard program is the time between T₀-T₁ (screening period)

^P Mann-Whitney

3.4 Changes during CR

3.4.1 Changes in Quality of Life

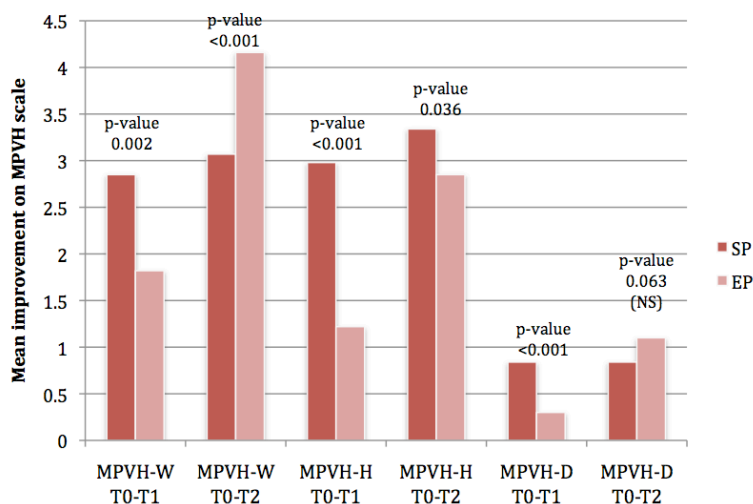
Figure 2a, 2b and 2c illustrate the changes in feelings of respectively wellbeing, handicap and distress, over time. Quality of life is presented as a mean score on MPVH questionnaire on T₀, T₁, and T₂ (number of patients differ at all time measurements). As described above at 3.2, at baseline patients in SP feel better on all three subscales, in comparison to those following the EP. Noteworthy is the curve both programs tend to make. SP shows an initial steeper curve between T₀ and T₁ and remains stable at the final assessment whereas EP tends to make a steeper curve in the extended period (between T₁ and T₂).



* These figures give an example of how quality of life progress's over time within the study groups; therefore analysis (by usage of multivariate GLM) is not preformed on these graphs. Statistics is used underneath (graph 3) to evaluate the increase on MPVH between two study groups, between two time measurements

The mean change values on the MPVH scale are shown in figure 3. The mean change value on MPVH-W shows that between T₀ and T₁, patients in SP show significantly more improvement compared to the patients in EP (2.85 vs. 1.82, p-value 0.002). By contrast EP increases more on MPVH-W scale from beginning to the end (T₀-T₂), thus tends to 'catch up' on SP at the end (3.07 vs. 4.16, p-value <0.001). As to feelings of handicap, SP shows significantly more progress on the MPVH-H scale in both time measurements. As to the distress scale (MPVH-D), SP again significantly improves better in the screening period, but overall improves equally compared to EP. The changes on the MPVH-D scale between T₀-T₂ are not significantly different (p-value 0.063).

Figure 3: Improvements on MPVH scale



3.4.2 Changes in Fitness

Figure 4 illustrates the changes in fitness over time. Compared to the changes in quality of life, fitness in SP is higher at T_0 , but SP and EP improve equally in the screening period of the program. EP continues the improvement in the extended period, thus improves more during the total program (T_0 - T_2)

Figure 4*: changes in Fitness

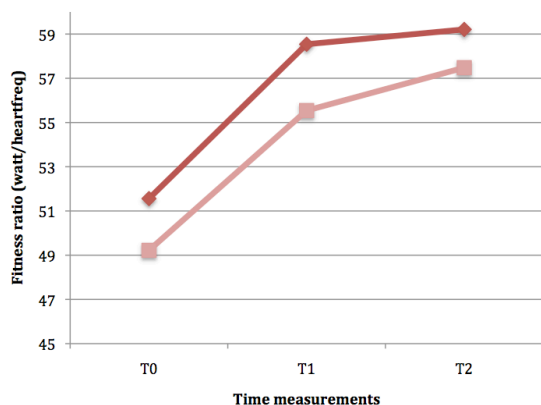
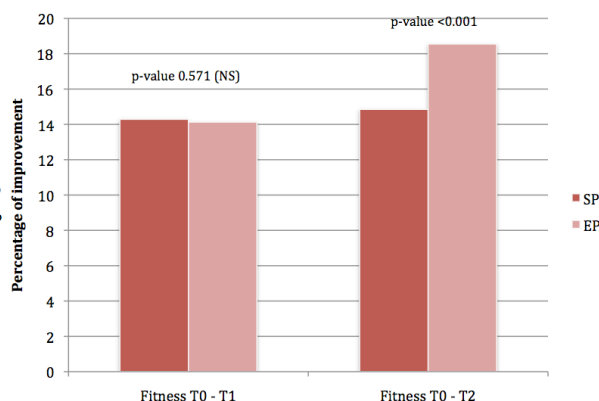


Figure 5: Improvement in fitness



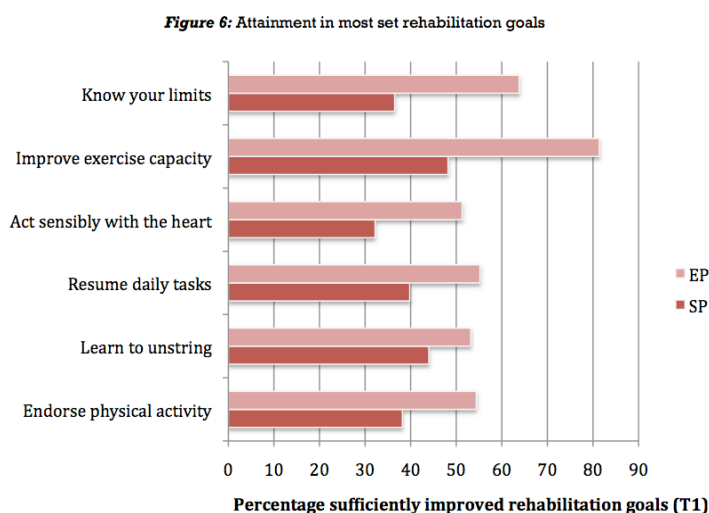
* Figure 4 gives an example on how fitness evolves over time within the study groups; therefore analysis (by usage of multivariate GLM) is not performed in this graph. Statistics is used underneath (figure 5) to evaluate the relative increase in fitness between two study groups, between two time measurements

The mean relative change in fitness is presented in figure 5. At T_1 an increase of 14.3% and 14.1% is seen which implies a similar growth in SP and EP (p-value 0.571). Between T_0 and T_2 , EP shows a significantly higher improvement in fitness (18.6% vs. 14.85%, p-value <0.001).

3.4.3 Attainment of Rehabilitation Goals

In figure 6 the midterm attainment in the five most selected rehabilitation goals is shown. It shows the percentages of sufficient improvement. The idea is that this implies that the personally selected goal is attained completely and no further guidance is required.

It is striking that patients following EP show a significant higher percentage of sufficient improvement in all chosen rehabilitation goals. The percentage varies from 81.4% to 51.3% in EP and 48.2% to 32.2% in SP (p-value <0.001).



4. Discussion and Conclusion

Our results indicate that the process-oriented CR program at KG seems to be paying off. It appears reasonable that patients with good baseline measurements (relatively good quality of life and fitness) are accurately included in the SP program and stop CR early. Patients with less good starting values are rightfully placed in the extended program where limitations are noticed and therefore they receive more attention and individual guidance. Both study groups show a considerable positive change in outcome measures. SP makes the biggest improvement in the screening period, and then seems to be reaching near optimal values, and they remain stable or slightly grow after the midterm assessment. This is important because SP shows a good response to therapy and is able to retain and continue this improvement at home setting. This confirms the essential idea of a process-oriented program. Patients have a natural resilience to recover; the program is developed to see if there are factors inhibiting that recovery process and if so, adjust the program to patients' needs. We can assume that the patients in SP, in consultation with their therapist, tend to make the right decision by stopping CR early. Considering patients in EP, quality of life seems to stay behind in the screening period (T_0 - T_1) comparing to patients following SP, but improves immensely after midterm evaluation (extended period, T_1 - T_2). Therefore we can say these patients rightfully follow the extended program.

The above-mentioned findings show that the CR program at KG is effective. It suggests that a shorter program for some patients is as effective as a longer (extended) program. The duration in EP is more than twice as long as compared to SP. In literature there are speculations that a shorter CR program is possible while retaining CR's excellent effects. [6,24] Though more research about the ideal length of the CR program is needed to confirm these speculations. The increasing prevalence of CHD, decreased mortality rates, aging population and plans on expanding the amount of referrals to the CR program will altogether give an enormous increase in number of patients suitable for CR. Considering this increase and the high-healthcare costs that come with it, a shorter rehabilitation program would be preferable. It might cause more flow into the program and therefore enhance the capacity of CR in hospital setting. Future research will be necessary to investigate the possibility to reduce the duration of the CR program, and hereby keep costs within limits and increase flow.

Another matter to discuss is the time between referral and start of the program (wait time). In our figures wait time varies between a median of 22 and 27 days within the five study groups; considering the recommended 30-day waiting time benchmark [25,26] this is all right. Wait times are generally considered acceptable by patients, but perhaps they might also be a reason for dropout. We noticed that in AP and NP there are considerable more patients with a primary myocardial infarction. These patients have not been exposed to complex treatment and have a tendency to recover rapidly. Within AP and NP wait time is 26 and 27 days. Taking into account their usual rapid recovery, a wait time of 26-27 days might be considered too long for those patients to participate in the physical training or to attend at the CR program at all. The Canadian cardiovascular society has presented a number of wait time benchmarks, considering a patients diagnosis; for MI patients, wait-time is preferable between 7-30 days. PPCI patients have an ideal waiting time of 2-7 days. CAGB and valve operations have a wait

time benchmark of 21-30 days, due the recovery time after surgery. [25] If wait time can be adjusted to a patient's diagnosis, dropout might be reduced. Besides wait time, there are other motives for dropout like distance to the hospital, lack of motivation plus cardiac - or other non-cardiac complaints. In this study there were 293 patients in NP (dropouts). By expanding CR, using the primary care setting, the number of dropouts might decline. Another possibility to widen access and participation could be home-based cardiac rehabilitation; for example the fragile, less trainable or elderly can take advantage of cardiac rehabilitation without leaving the house. It also appears that home-based CR versus clinical CR has no difference in outcome measures with low risk patients. [27,28]

Comparability of study groups: this study shows dissimilarity at baseline within the five study groups. The distribution in age for example can be explained. Oldest patients are represented in CP; this is to be expected, since elder patients tend to be less fit and have more co-morbidities compared to younger patients. In contrast, the youngest patients are included in EP. They might have more difficulties adapting and coping with CHD. Work- and family related problems are also most likely to be noticed in EP; therefore an extended program with additional guidance is more often required. Noticeable is that with elderly patients the CR program consists mainly of supervised exercise and counselling, whereas with younger patients modification of risk factors is of more importance, combined with physical training. [21] Furthermore, the proportion of women is highest in CP. Women tend to suffer from heart disease at an older age and have more extensive co-morbidities with it, like hypertension, diabetes and obesity. [29,30] Besides, women are more likely to have concerns about pain and fatigue while exercising, therefore a less heavy program (without cycle training) seem appropriate. [30] In CP we also see more patients with heart failure. Since especially these patients are less trainable, they are rightfully included in CP.

The last matter to discuss is the unexpected outcome in attainment of rehabilitation goals. Goal setting is an established strategy used to change health behaviour but it also influences a patient's motivation to participate into the treatment program. [31] Our results confirm this influence. In EP patients choose the most rehabilitation goals, as well as participate best within the program by loyally attending all treatment modules. However our results also seem to show a discrepancy between program and goal achievement. In SP fewer patients sufficiently improved their rehabilitation goal. If a rehabilitation goal is not sufficiently improved, the goal is not attained and further guidance in achieving that goal is to be expected. Therefore we assumed the percentage of attainment to be higher in SP than in EP, since patients in this program stop CR at midterm. Unexpectedly, our results show the contrary; goal setting and attainment is higher in EP. Ideally patients set optimistic, yet realistic goals, which will contribute into changing health behaviour and also maintaining it. Goal setting is generally a result of discussion between therapist and patient. But patients can also be tempted to set rehabilitation goals due to social pressure to please a therapist/cardiologist. Perhaps patients in SP set rehabilitation goals but are actually not motivated enough to obtain them. There is less goals self-efficacy (which is the regulator function (competence) in goal pursuit (Bandura theory)), and this interferes in goal attainment. [32] A higher self-efficacy enhances the amount of effort that will show when faced with obstacles. Another possible explanation is that patients in SP tend to be more critical. Because baseline measurements are high, less room for improvement is achievable. However, patients in EP have more room for improvement and they are therefore possibly easily satisfied. Noteworthy is the thought that during CR patients develop a higher threshold for declaring their goal to be attained. Patients can adjust their expectations during the program as a result of the program. This suggests that goal setting at the start of a intervention (CR) may not be as useful as goal setting some time after entry into the CR program so patients can make more realistic goals. [33] It appears that there is a difference in objective (fitness, proved validity of MPVH-questionnaire) and subjective goals (goal setting). Both are relevant, but are both valid as an outcome measure in rehabilitation. It is said that the validity of self-identified activity goal attainment as a measure of the efficiency of CR is unclear and might give misleading results, due to the growing expectations during a CR program. [33] - The most relevant explanation for the misleading results noted in this research is the patients' interpretation of the term 'sufficiently improved'. It is plausible that patients consider the term 'improved' as the attainment of the rehabilitation goal, whereas 'sufficiently improves' can be mistaken for 'moderately improved'. This consideration is confirmed by comparing changes in the measurements: patients who say they are improved show more improvement than patients who declare themselves 'sufficiently improved'. Checking the percentage of 'not changed' plus 'worsen', it appears that in all five most chosen rehabilitation goals this percentage is quite small, but relatively highest at EP. This confirms that they do not stop but continue treatment. In the future therapists will have give more attention to the patient's interpretation of certain terms to see whether this hypothesis of misinterpretation is correct.

4.1 Limitations

Regardless of the interesting results, this study only shows significant changes in fitness and quality of life between patients in SP and EP, but it cannot yet confirm the actual effect of the programs. Therefore more research (controlled trials) is required. Analysis in this research limited itself to univariate testing, whereas multivariate statistical testing is necessary. A fellow student will follow-up this study, to determine the true effect and to explore whether certain determinants can be discovered to explain the effect of CR at KG; is the effect of this process-oriented CR program due to program factors (participation, duration and success of the different programs; SP vs. EP) or patients factors (gender, age, diagnosis, or baseline measurements).

Interfering factors: information bias is that the patients' interpretation of particular terms used in setting and attainment of rehabilitation goals might be confusing and give misleading results. Patient characteristics are not equally distributed among the five study groups. Selection bias is not taken into account in this research, and has not been corrected for. In the follow-up study this will be considered.

4.2 Recommendations

The process-oriented CR program seems to be effective. Patients seem to follow the right program suited for their needs. Further research within KG will be done to determine its effect. Future research is of importance to evaluate effects of CR in a short versus a long program to see for which patients the length of CR can be reduced. This might suppress high healthcare costs in the future and creates more capacity for CR in hospital setting.

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