

Hospital-based versus community-based shared care cardiac rehabilitation after acute coronary syndrome: protocol for a randomized clinical trial

Jannik Buus Bertelsen¹, Jens Refsgaard², Helle Kanstrup¹, Søren Paaske Johnsen³, Ina Qvist⁴, Bo Christensen⁵ & Kent Lodberg Christensen¹

ABSTRACT

INTRODUCTION: Participation in cardiac rehabilitation (CR) is poor although CR reduces morbidity and mortality. One way in which attendance may potentially be improved is by involving municipal health care centres (MHCC) and the patient's general practitioner (GP) to a larger degree in a model of shared care cardiac rehabilitation (SC-CR). Our study tests the feasibility of SC-CR and compares the attendance and effects of SC-CR with the individually tailored hospital-based CR (H-CR) programme.

MATERIAL AND METHODS: After admission for acute coronary syndrome (ACS), patients are randomized to phase II CR which is conducted either as SC-CR or H-CR. During SC-CR, the patient is seen once in-hospital after which the GP takes over. MHCC supports the GP by offering educational intervention regarding smoking cessation, exercise, nutrition and mental health. A total of 208 persons hospitalised due to acute coronary syndrome are to be randomized before hospital discharge.

CONCLUSION. The study aims to examine whether the organisation of SC-CR is feasible and provides the expected benefits.

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stable angina pectoris), patients with heart failure and after bypass or valvular surgery. During the past years, hospitals have been merged into larger units causing inconvenience and extended transportation time for numerous patients. Various countries have tried to respond to this by improving local healthcare in different ways. In Denmark, the responsibility for disease, prevention and rehabilitation has been shifted to the local authorities.

The intention is to promote out-hospital treatment of chronic diseases by utilizing the general practitioner's (GP) profound knowledge of the patient. Cardiovascular disease affects a large part of the population with chronic diseases. Age at first-time MI is increasing [6] and 90% of cardiac patients older than 65 years have at least one additional chronic disease [7]. To meet the challenges of the growing population with chronic diseases and to support the GP, most municipalities have established municipal healthcare centres (MHCCs). The MHCCs provide health education and encourage lifestyle modification through elements of smoking cessation, exercise, nutrition and psychosocial support to patients with chronic diseases such as heart disease, chronic pulmonary disease and diabetes.

Our aim is to compare two models of CR: A shared care model of phase II CR (SC-CR) versus hospital-based CR (H-CR) in ACS in terms of adherence and efficacy.

MATERIAL AND METHODS

Study design

This randomized controlled trial will compare H-CR with SC-CR. SC-CR is based on a model of shared care in which the first visit takes place at the hospital after which responsibility for the subsequent rehabilitation is transferred to the GP. During SC-CR, the MHCC provides courses on smoking cessation, nutrition, exercise training, contributes to disease education and provides psychosocial support. The GP handles pharmacological treatment and general risk factor management. The GP is thus involved earlier and to a greater extent than in the H-CR model.

ACS is confirmed by coronary stenotic or thrombotic lesions. **Table 1** outlines the criteria for study inclusion and exclusion, and **Figure 1** summarizes the design.

PROTOCOL ARTICLE

- 1) Department of Cardiology, Aarhus University Hospital
- 2) Department of Medicine, Viborg, Central Hospital Unit
- 3) Department of Clinical Epidemiology, Aarhus University Hospital
- 4) Department of Medicine, Silkeborg, Central Hospital Unit
- 5) Institute of Public Health, Aarhus University

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Low attendance in cardiac rehabilitation (CR) is a world-wide problem despite the documented benefits of CR in relation to both morbidity and mortality [1]. Studies have shown that only 15-59% of the relevant patients participate in CR [2-4]. Among participants, 50-79% complete the programme [2]. Furthermore, three months after first-time acute myocardial infarction (MI), almost one in three patients displays anxiety, depressive disorders or both, but only one third of these patients receive psychosocial support, whereas approximately 80% adhere to their cardioprotective drugs [5]. Safety concerns and the presumed need for specialization at all levels (physicians, nurses, physiotherapists and dieticians) have so far blocked the introduction of CR at the hospitals in most health care systems. CR is offered to patients with acute coronary syndrome (ACS) (MI and un-

TABLE 1

Inclusion and exclusion criteria in the randomized controlled trial: Hospital-based versus community-based shared care cardiac rehabilitation after acute coronary syndrome.

Inclusion criteria

Admission due to acute coronary syndrome with angiographically documented coronary thrombosis or stenosis

No prior CR

Residents in the municipalities of Aarhus, Viborg, Silkeborg, Skive, Skanderborg, Favrskov, Syddjurs and Samsø, who are allocated to Aarhus University Hospital, Viborg Hospital or Silkeborg Hospital.

Age 18 to 80 years at admission

Accept of both hospital-based CR and shared care CR before randomization. Written informed consent

Exclusion criteria

MI on non-thrombotic basis (Type II MI)

Lack of physical or mental ability to participate in CR

Ejection fraction $\leq 40\%$ evaluated by echocardiography

Resuscitation after cardiac arrest if need of ergotherapy after discharge

Unable to understand and write Danish without help

Any other disease leading to severe disability including pulmonary disease ($FEV_1 < 1$ l/s), neurological disease (cerebrovascular insult), severe kidney disease (uraemia, serum creatinine > 300 micromol/l, hepatic cirrhosis or cancer

CR = cardiac rehabilitation; FEV_1 = forced expiratory volume in 1st second.; MI = myocardial infarction.

Randomization

Written informed consent is obtained during admission followed by a subsequent computer randomization which is stratified by hospital to ensure equal distribution of H-CR and SC-CR in each hospital. Patients refusing participation are offered H-CR.

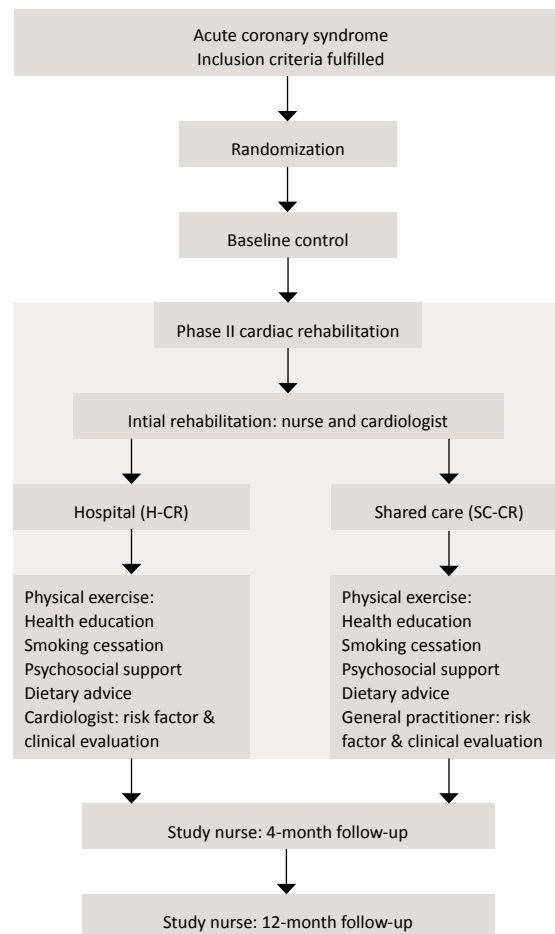
Study course*Project controls*

During admission, questionnaires dealing with background information and lifestyle issues (smoking, diet, physical exercise and alcohol) and for male patients also erectile dysfunction issues using the validated 5-item International Index of Erectile Function [8] are completed. A Global Registry of Acute Coronary Events (GRACE) score is obtained at discharge [9]. The questionnaires on lifestyle and background have previously been used as part of a population-based questionnaire survey for mapping health and prevalence of chronic diseases in the Central Danish Region [10].

The initial project visit in the hospital is 1-2 weeks after discharge. Visit two is after four months of follow-up (at five months, if bypass surgery is performed due to delay on rehabilitation), and visit three is after 12 months of follow-up. The questionnaires used for assessing quality of life (QoL) are validated for cardiac patients. The following are used: The Short Form Health Survey (SF-12) [11], HeartQoL [12] and the EQ-5D, which can estimate quality-adjusted life years [13]. The Patient Assessment of Chronic Illness Care (PACIC) instrument is used to assess the chronic care [14]. The Hospital

FIGURE 1

Study design for the randomized controlled trial: Hospital-based versus community-based shared care cardiac rehabilitation after acute coronary syndrome.



Study nurse visits: Observational and non-interventional. Results of ambulatory blood pressure measurement, exercise test and blood samples are reported to the physician in charge of rehabilitation

Anxiety and Depression Scale (HADS), which is a validated score system on anxiety and depression, is obtained six weeks after discharge and at visit two and three[15]. The information obtained is listed in **Table 2**.

Initial in-hospital rehabilitation visit (all patients)

All patients visit the rehabilitation nurse who outlines the course plan and assesses the patient's mental status. A clinical assessment by a cardiologist is done immediately after an ergometer bicycle test. If the patient performs without having angina or an adverse event, training outside the hospital is acceptable. If the patient is randomized to SC-CR, a standardized letter is sent to the GP and to the MHCC conveying information on the shared care model, prescribed medicine, optimal individualized treatment goals and a standard plan for the

GP follow-up visits. The course of H-CR is outlined in **Appendix 1** and the course of SC-CR is outlined in **Appendix 2**.

Study outcomes

The primary outcome is adherence to the CR programme measured as a composite of the participation in the various elements of CR, a modified version of Wurgler [16]:

- Smoking cessation course, if smoker
- Dietary advice
- Exercise training
- Clinical assessment by a doctor
- Patient education
- Individual talks with health staff (nurse, physiotherapist, dietician)

Participation in one element is defined as 50% attendance or more.

Full participation is participation in all elements, i.e. six of six if smoker and five of five if non-smoker. Most participation is equivalent to one element missing. Partial participation is two elements missing, whereas limited rehabilitation is defined as three elements or more missing. Secondary outcomes include measured changes in bike exercise test, 24-h ambulatory blood pressure measurement (ABPM), weight, abdominal circumference, cholesterol levels, fasting blood glucose and haemoglobin A1C. Secondary outcomes also include reported changes in: lifestyle, health-related QoL (HeartQoL, SF-12, EQ-5D), anxiety and depression level, readmission and major adverse cardiovascular events (death, MI, stroke) and assessment of support in chronic illness care with PACIC.

Ethical considerations

The study is conducted in accordance with good clinical practice and the ethical standards described in the Helsinki Declaration.

The Central Denmark Region Committees on Biomedical Research Ethics and the Danish Data Protection Agency have approved the study protocol. Clinical Trials ID: NTC 01522001.

Safety aspects

The risk of adverse events (AE) in supervised exercise training is low in patients with ACS. Danish guidelines state that team size should allow the physiotherapists to observe each participant.

Furthermore, staff involved in physical exercise should be trained in basic heart lung rescue and the physiotherapist should be trained in cardiac symptoms. All AEs are registered.

Assessment methods

Information on primary outcome will be registered from patient records and attendance lists. Information on MI and readmissions will be obtained through interviews and checked against hospital records. Secondary outcome measures are obtained by the project nurse. Data are collected as part of standard procedures, including interview, questionnaire, clinical examination, blood tests, bike exercise tests and 24-h ABPM. Patients who drop out are contacted twice by phone and, if possible, an interview is conducted in cases where further attendance is refused.

Sample size

We aim to include 208 patients within a maximum inclusion period of 20 months. Patients will be randomized

 **TABLE 2**

Outline of data at the three project controls in the randomized controlled trial: hospital-based versus community-based shared care cardiac rehabilitation after acute coronary syndrome.

Data	Baseline	4 months	12 months	Distribution	Analysis ^a
Test and measurements					
NYHA class & CCS class	X	X	X	paired	ΔWilcoxon
Height and weight	X	X	X	paired	Δt-test
Medication	X	X	X		χ ² -test
Abdominal circumference	X	X	X	paired	Δt-test
24-hour ambulatory blood pressure measurement	X	X	X	unpaired	t-test
				paired	Δt-test
Peripheral blood pressure		X		unpaired	t-test
Bicycle ergometer test	X	X	X	paired	Δt-test
Blood samples	From admission	X	X	unpaired	t-test
				paired	Δt-test
Questionnaire					
Lifestyle (diet, smoking, exercise, alcohol)	X	X	X	paired	ΔWilcoxon
Hospital Anxiety and Depression Scale	6 weeks	X	X	unpaired	Mann-Whitney
Health-related quality of life (SF-12, HeartQoL, EQ-5D)	X	X	X	unpaired	Mann-Whitney
Patient Assessment of Chronic Illness Care		X	X	unpaired	χ ² -test
Erectile dysfunction – males only	X		X	unpaired	Mann-Whitney
				paired	Wilcoxon
Attendance in CR		X			χ ² -test
Impression of CR (satisfaction, delay, relatives)		X		unpaired	Mann-Whitney
From patient files					
Attendance		X		unpaired	χ ² -test
Rehospitalization	X	X	X	unpaired	χ ² -test
Major adverse cardiovascular events	X	X	X	unpaired	χ ² -test

CCS = Canadian Cardiovascular Society; CR = cardiac rehabilitation; EQ-5D = EuroQoL 5-dimensions questionnaire; H = hospital; HeartQoL = heart quality of life questionnaire; NYHA = New York Heart Association; SC = shared care; SF-12 = short form health survey 12-item. All analyses compare groups SC and H.

A) All analyses compare groups SC and H.

Cardiac rehabilitation:
A composite of various
elements.



for H-CR and SC-CR. The included patients are expected to be equally distributed between the two participating hospital units. Based on how CR is conducted, four subgroups with around 50 participants each can be established; the participating centres will include H-CR Aarhus, H-CR Viborg/Silkeborg, SC-CR Aarhus and SC-CR Viborg/Silkeborg.

Power calculations

Based on information from the Danish Heart Association, 35% of the candidates for rehabilitation are expected to participate in most of the rehabilitation in the Central Denmark Region [16]. We hypothesize that SC-CR will improve the attendance rate by 20 percent point to 55%. The expected sample size will enable us to identify such an increase in the attendance rate with a power of 0.80 and a two-sided p -value < 0.05 . The share of patients who drop-out /withdraw is expected to be 10%. A participation rate of 55% is considered realistic as a previous Danish study has reported that 58.5% of all patients participated fully or partially in CR at the hospital [5].

Statistical analysis

Data analysis will be performed according to the intention-to-treat principles. If a patient is rejected from the SC-CR model for medical reasons at the first rehabilitation visit, he or she will be recorded as having been excluded. If a patient regrets participation before the baseline rehabilitation control visit, he or she will be recorded as having withdrawn. Patients lost to follow-up will be recorded as dropouts. Difference between the SC-CR and H-CR groups in terms of primary endpoint attendance will be analyzed using the χ^2 test.

The last two columns of Table 2 show the distribution and expected analysis of the data. Parametric data will be analyzed by student's paired t -test and non-parametric data by the Wilcoxon signed rank test. Between the four subgroups, H-CR Aarhus, H-CR Viborg/Silkeborg, SC-CR Aarhus and SC-CR Central, two-way and one-way ANOVA analysis for paired and unpaired parametric data will be used. Non-parametric data will be analyzed by Friedman's test for paired data and Kruskal-Wallis' test

for unpaired data. Non-normally distributed data will be transformed prior to the statistical analysis.

Trial registration: Clinical Trials ID: NTC 01522001

DISCUSSION

Increasing attendance in CR is a challenge. We aim to investigate whether phase II CR can be conducted in primary care (GP and MHCC) by comparing the results obtained here to what is achieved in-hospital. Depending on the patient, leaving the hospital environment earlier than normally could have a positive effect. Our study may help elucidate this and may guide the strategic decisions.

CR is recommended for all patients with ACS in Denmark. Healthcare is shifting towards earlier hospital discharge and more follow-up in primary care. More chronic diseases and cancer tasks are shifted to the GP and the MHCC. These strategic changes have already been implemented in some Danish regions even though it is unknown whether this is feasible and advantageous.

A review examining factors influencing attendance in CR programmes after referral concluded that attendance is highly influenced by social factors. Greater involvement of the patients and their families and a focus on social mechanisms might increase CR attendance and thus the rate of success [17]. A high CR attendance may have long-term benefits. An Australian study with 14 years of follow-up including 281 CR attenders showed a mortality risk of more than a factor two for "< 25% attenders" compared to "> 75% attenders" (odds ratio (OR) = 2.57, 95% confidence interval 1.04 to 6.38) [18].

Limitations

It is not technically possible to perform complete study nurse blinding, but the study nurses are instructed not to intervene. Should any problem occur, patients are referred to their CR staff.

Numerous trials studying adherence to CR suffer from selection bias, because those who are socially vulnerable (unemployed persons, less educated persons and singles), the elderly and women are less likely to attend [19]. The uncertainty of the new SC-CR model might result in rejection from potential participants.

We chose to include patients with ACS and an ejection fraction of at least 40% not to conflict with the hospital heart failure clinic set-up. Heart failure patients would probably benefit the most from CR, but in this context we have chosen a low-risk group with potentially lower rehabilitation benefits.

Finally, CR is performed slightly differently in the hospitals and in the MHCC with both individual and group-based CR. However in all cases CR includes exercise training, health education, psychosocial support, dietary advice, smoking cessation and clinical assessment.

Perspective

Primary care in which the GP is assisted by the MHCC and where they together perform most of CR can potentially strengthen the focus on the social and contextual factors – and may possibly serve as the cornerstone in the support of the increasing population of chronic patients as these shift towards a healthier lifestyle and may hence allow for an improved prognosis in the recovery from ACS.

APPENDICES

Appendix 1

Continued hospital-based cardiac rehabilitation (H-CR)

In all three hospitals, exercise training is given as two weekly one-hour group sessions during 12 weeks. Apart from this, there are some differences between the three hospitals.

H-CR is tailored individually in Silkeborg and Aarhus. This implies individual one-to-one sessions with a clinical dietician and a rehabilitation nurse regarding psychosocial support and education on disease prevention.

In Viborg, patients are offered two individual sessions with a rehabilitation nurse for psychosocial support. The remaining educational sessions including dietary advice are group based and given two hours once weekly for eight weeks.

HADS is obtained six weeks after discharge by the rehabilitation nurse. The cardiologist explores the cause if the score is eight or above in either anxiety or depression. The phase II H-CR is concluded by the cardiologist with a clinical examination, a status on cardiovascular risk factors, a check-up on the prescribed medicine and advice on future control at the GP.

Appendix 2

Continued shared care rehabilitation (SC-CR)

SC-CR is primarily group-based, but in the beginning of the course individual sessions are given by a nurse, a physical therapist or a clinical dietician to establish a personal relationship and to introduce the patient to the healthcare centre. In Aarhus, a five-week course with weekly two-hour lessons on cardiovascular health issues, cardiovascular disease and risk factors is given by a nurse. The clinical dietician then continues with a five-week course with two-hour sessions containing both theoretical and practical cooking instructions. Physical exercise supervised by a physiotherapist is given either twice weekly for ten weeks or once weekly for twenty weeks. The MHCC course is concluded with an individual evaluation.

In the other MHCC, the course is group-based and includes patients with different diagnoses (heart disease, chronic obstructive pulmonary disease or diabetes). Two-hour sessions are given weekly for eight weeks. Six of these lessons cover health and disease is-

sues. The remaining two lessons cover dietary advice.

Exercise training is one hour twice weekly for 12 weeks.

HADS is obtained six weeks after discharge at the MHCC. If the score for either anxiety or depression rises above eight the patient is instructed to turn to the GP and the GP is alerted directly from the MHCC.

The phase II SC-CR is concluded at the GP with a clinical examination, a status on cardiovascular risk factors, a check-up on the prescribed medicine and a plan for future control.

CORRESPONDENCE: Jannik Buus Bertelsen, Department of Cardiology, Aarhus University Hospital, 8000 Aarhus C. Denmark. E-mail: jannibert@rm.dk

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