

Annett Salzwedel | Manfred Nosper | Bernd Röhrig | Sigrid  
Linck-Eleftheriadis | Gert Strandt | Heinz Völler

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# Outcome quality of in-patient cardiac rehabilitation in elderly patients – identification of relevant parameters

Annett Salzwedel<sup>1,2,3</sup>, Manfred Nosper<sup>4</sup>, Bernd Röhrig<sup>4</sup>,  
Sigrid Linck-Eleftheriadis<sup>4</sup>, Gert Strandt<sup>5</sup> and Heinz Völler<sup>1,2,3</sup>

## Abstract

**Background:** Outcome quality management requires the consecutive registration of defined variables. The aim was to identify relevant parameters in order to objectively assess the in-patient rehabilitation outcome.

**Methods:** From February 2009 to June 2010 1253 patients ( $70.9 \pm 7.0$  years, 78.1% men) at 12 rehabilitation clinics were enrolled. Items concerning sociodemographic data, the impairment group (surgery, conservative/interventional treatment), cardiovascular risk factors, structural and functional parameters and subjective health were tested in respect of their measurability, sensitivity to change and their propensity to be influenced by rehabilitation.

**Results:** The majority of patients (61.1%) were referred for rehabilitation after cardiac surgery, 38.9% after conservative or interventional treatment for an acute coronary syndrome. Functionally relevant comorbidities were seen in 49.2% (diabetes mellitus, stroke, peripheral artery disease, chronic obstructive lung disease). In three key areas 13 parameters were identified as being sensitive to change and subject to modification by rehabilitation: cardiovascular risk factors (blood pressure, low-density lipoprotein cholesterol, triglycerides), exercise capacity (resting heart rate, maximal exercise capacity, maximal walking distance, heart failure, angina pectoris) and subjective health (IRES-24 (indicators of rehabilitation status): pain, somatic health, psychological well-being and depression as well as anxiety on the Hospital Anxiety and Depression Scale).

**Conclusion:** The outcome of in-patient rehabilitation in elderly patients can be comprehensively assessed by the identification of appropriate key areas, that is, cardiovascular risk factors, exercise capacity and subjective health. This may well serve as a benchmark for internal and external quality management.

## Keywords

Cardiac rehabilitation, quality management, outcome measures

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## Introduction

German rehabilitation centres are required to pursue quality management and inter-clinic quality assurance (§ 20 SGB Social Law Gazette IX). The implementation of these regulations has been focused thus far on structure and process quality while the demonstration of outcome quality has been largely confined to patient and physician assessments respectively.<sup>1</sup> Valuable methods to determine the rehabilitation outcome, taking into account the severity of disease with functional and/or structural limitations, progression of the disease and cardiovascular risk factors are lacking.

<sup>1</sup>Department of Clinical Pharmacology and Toxicology, Charité (CBF) Berlin, Germany

<sup>2</sup>Centre of Rehabilitation Research, University Potsdam, Germany

<sup>3</sup>Klinik am See, Rehabilitation Centre for Internal Medicine, Rüdersdorf, Germany

<sup>4</sup>Medical Advisory Service of Statutory Health Insurance Funds in Rhineland-Palatinate, Alzey, Germany

<sup>5</sup>Techniker Krankenkasse Hamburg, Germany

## Corresponding author:

Heinz Völler, Centre of Rehabilitation Research, University Potsdam, Am-Neuen-Palais 10, D-14469 Potsdam, Germany.  
Email: heinz.voeller@uni-potsdam.de

The multimodality approach to cardiac rehabilitation (CR) offers a means of improving not only the patients' quality of life but also the prognosis due to consideration to the achievement of target values for cardiovascular risk factors.<sup>2</sup> Additionally, as life expectancy is markedly influenced by physical fitness,<sup>3</sup> one of the major goals of rehabilitation is to enhance physical activity by means of standardized exercise programmes.<sup>4</sup>

The aim of the present investigation was to objectively assess the rehabilitation outcome by consecutive registration of parameters relevant to rehabilitation and sensitive to change.

## Patients and methods

One thousand two hundred and fifty-three consecutive patients were referred by a German health insurance organization to 12 rehabilitation clinics between February 2009 and June 2010 for in-patient rehabilitation after an acute cardiac event.

All patients underwent a standardized in-patient rehabilitation programme with an average duration of 21 days, which included interventions of somatic issues (e.g. physical training), counselling (diet, risk factor management, lifestyle) and psychological support (individual counselling by psychologist and/or group sessions for coping).<sup>5,6</sup>

To identify criteria for outcome quality, their need for improvement and the change achieved in the course of rehabilitation, a uniform documentation structure was developed using the cardiological module of the software known as EVA-Reha®.<sup>7</sup> The contents of the module are derived from guidelines of international medical societies and results of national registries.<sup>1,8-11</sup>

### Documented parameters

In addition to age and gender, body mass index (BMI), waist circumference and living situation as well as education (Table 1) were registered. Impairment groups were divided according to postoperative patients (12 indications: e.g. coronary artery bypass grafting (CABG), aortic/mitral valve replacement, aortic/vascular surgery or pacemakers) and patients treated conservatively or by interventional catheterization (12 indications: e.g. acute coronary syndrome with or without percutaneous coronary intervention (PCI), systolic/diastolic heart failure, aortic aneurysm or heart valve intervention). In addition to the duration of hospitalization in the rehabilitation centre, the hospital length of stay was registered. Cardiovascular risk factors and comorbidities were recorded. The following aspects were registered as additional potential factors

influencing the rehabilitation outcome: complications in the hospital, at the start and during rehabilitation (life-threatening arrhythmia/resuscitation, acute coronary syndrome, stroke, heart, renal or liver failure, impaired wound healing, infections such as pneumonia or pyelonephritis, and blood transfusions). An overview of the documented parameters is given in Table 1.

At admission all patients underwent a 2D/M-mode echocardiography to determine biplane left-ventricular ejection fraction (LVEF) based on Simpson's method<sup>12</sup> Mitral and tricuspid valve insufficiency, systolic pulmonary artery pressure, pericardial and pleural effusions were also documented. Any lung function tests performed during rehabilitation were quantified according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria.<sup>13</sup>

All criteria in which modifications were to be expected during the rehabilitation period were measured at entry and discharge of CR. Heart rate, rhythm and blood pressure were measured at rest (after a five-minute seated rest period) prior to the bicycle exercise stress test, which was performed in 25-watt-steps until exhaustion. The standardized six-minute walking test was performed under the supervision of a qualified sports therapist. The degrees of heart failure and angina pectoris were determined according to the New York Heart Association (NYHA) and Canadian Cardiovascular Society (CCS) classifications, respectively. The patients' lipid profile, haemoglobin, fasting blood glucose and estimated glomerular filtration rate (eGFR, ml/min per 1.73 m<sup>2</sup>) were measured. The patients performed self-assessments of depression and anxiety symptoms on the Hospital Anxiety and Depression Scale (HADS).<sup>14</sup> Somatic health, psychological well-being, and pain were registered on IRES-24 (indicators of rehabilitation status).<sup>15</sup>

### Evaluation of parameters and statistics

The above mentioned parameters, which were documented at admission and at discharge from CR, were examined. Using descriptive statistics the parameters were tested in regard to their sensitiveness to change (comparison between the two time points of measurement), their propensity to be influenced by CR and their objective measurability, in order to determine the rehabilitation outcome. The parameters also had to occur sufficiently often.

To quantify the changes the severity of all parameters was categorized in severity classes according to guidelines and recommendations for treatment of cardiac diseases (e.g. Grundy et al.,<sup>10</sup> Mancina et al.,<sup>11</sup> Rabe et al.,<sup>13</sup> Herrmann et al.,<sup>14</sup> Wirtz et al.,<sup>15</sup> Bjarnason-Wehrens et al.<sup>16</sup>). On the basis of these altered severity classes the rehabilitation outcome was rated. For this purpose, for each eligible parameter an

**Table 1.** Registered data

Sociodemographic parameters	Age, gender Educational level Living situation (family/partner, alone, rest home) Level of care Employment
Indication for rehabilitation	Principal diagnosis according to ICD-10 Impairment groups (postoperative and conservative/interventional cases)
Functionally relevant comorbidities	Angina pectoris Heart failure Stroke PAD COPD Chronic back pain Carcinoma Osteoarthritis Rheumatoid arthritis Osteoporosis Others (lung embolism, myocarditis)
Risk factors	Family history of cardiovascular events Arterial hypertension Hyperlipoproteinaemia Diabetes mellitus Smoking BMI, waist circumference
Complications	In hospital, at the start and during rehabilitation
Echocardiography	Left-ventricular function, valvular heart disease, pulmonary hypertension, pericardial effusion
Ultrasound	Pleural effusion
Physical capacity	Resting and exercise stress ECG (rhythm, frequency, blood pressure, exercise capacity) NYHA, CCS and GOLD classes Six-minute walking test
Laboratory	Total cholesterol, HDL, LDL, triglycerides, creatinine, haemoglobin
Subjective health	HADS (depression and anxiety) IRES-24 (pain, somatic health, psychological health)

ICD: International Classification of Diseases; PAD: peripheral artery disease; COPD: chronic obstructive pulmonary disease; BMI: body mass index; ECG: electrocardiogram; HDL: high density lipoprotein cholesterol; LDL: low density lipoprotein cholesterol; NYHA: New York Heart Association; CCS: Canadian Cardiovascular Society; GOLD: Global Initiative for Chronic Obstructive Lung Disease; HADS: Hospital Anxiety and Depression Scale; IRES: indicators of rehabilitation status.

evaluation scheme was developed in which changes during rehabilitation (entry and discharge) were rated as -1 (worsened), 0 (unchanged), 1 (improved) and 2 (highly improved). The classification -1 describes a change to a higher severity class at discharge from rehabilitation, while the classifications 1 and 2 characterize the improvement of one or two degrees of severity. To fulfil the criterion of a clinical relevant change, determined values had to demonstrate a predefined minimal important difference (MID) between the two time points of measurement (pre–post design). The MID defines that amount of change in a parameter that is necessary to justify a change to another severity class (e.g. 5 mmHg for hypertension, two points in HADS).

Parameters with sufficient sensitiveness to change were identified in the effect sizes of pre–post design. In addition, they had to have minimal rates of change of 30%. Changes were rated only for patients who needed a medical intervention (Table 2). Records were analysed of only the patients who stayed longer than 10 days in rehabilitation and were not transferred to a hospital nor those who died ( $n = 1220$ ).

The descriptive analysis of metric data included mention of statistical parameters such as mean and standard deviation; categorical features were shown by mentioning absolute and relative frequencies. According to the study design and the objective of the study the statistical analysis included no comparisons of groups or multivariate analyses.

**Table 2.** Need for improvement, changes at discharge from CR and effect sizes (pre–post design) for chosen parameters

Parameters	Need for intervention (% of patients)	Cut-offs for intervention	Total changes (%)	Effect sizes <i>d</i>
<b>Risk factors</b>				
Arterial hypertension (systolic/diastolic)	35.2	≥ 140/90 mmHg	89.5	0.39/0.35
LDL cholesterol	52.8	≥ 100 mg/dl	69.4	0.37
Triglycerides	33.9	≥ 150 mg/dl	53.0	0.21
<b>Physical performance</b>				
Heart rate (resting)	28.5	<55 and >70, respectively	33.4	0.50
Maximal exercise capacity	96.8	< 150 watts	69.5	0.58
Maximal walking distance	94.5	<550 metres	64.8	0.66
Heart failure (NYHA classes)	37.5	>NYHA I	65.1	/
Angina pectoris (CCS classes)	5.6	From CCS class I	41.3	/
<b>Subjective health</b>				
<b>IRES-24</b>				
Pain	88.4	<8	59.2	0.47
Somatic health	97.2	<8	44.0	0.44
Psych. well-being	95.2	<8	36.1	0.57
<b>HADS</b>				
Depression	31.7	≥7	72.1	0.26
Anxiety	32.3	≥7	61.5	0.23

The effect sizes *d* were calculated according to Cohen for scale variables ( $d = (\text{start-end/pooled standard deviation})$ ). Minimal total changes for chosen parameters were 30%. Cut-offs are adapted from Karoff et al.,<sup>5</sup> Piepoli et al.,<sup>6</sup> Grundy et al.,<sup>10</sup> Mancía et al.,<sup>11</sup> Rabe et al.,<sup>13</sup> Herrmann,<sup>14</sup> Wirtz et al.,<sup>15</sup> Bjarnason-Wehrens et al.,<sup>16</sup> Whelton et al.,<sup>17</sup> Cholesterol Treatment Trialists' (CTT) Collaboration et al.<sup>19</sup>; CR: cardiac rehabilitation; LDL: low density lipoprotein cholesterol; NYHA: New York Heart Association; CCS: Canadian Cardiovascular Society; IRES: indicators of rehabilitation status; Psych. well-being: psychological well-being; HADS: Hospital Anxiety and Depression Scale.

## Results

### Patient characteristics

Of 1253 patients ( $70.9 \pm 7.0$  years; 78.1% were men), 25 (2.0%) had to be transferred to hospitals because of acute medical complications; one patient died. The most common functionally significant comorbidities and risk factors were heart failure, back pain and chronic obstructive pulmonary disease (COPD) (Table 3), but the GOLD class III/IV was rare (<1%). Obesity was recorded for 16.1% of the patients ( $\text{BMI} > 30 \text{ kg/m}^2$ ); more than 95% were retired. A few (2.1%) patients were dependent on professional nursing care.

The most common indication for rehabilitation among patients who had undergone surgery ( $n = 758$ ) was CABG, followed by aortic valve replacement and aortic or vascular surgery. Of patients treated by conservative/interventional means ( $n = 484$ ), the large majority ( $n = 253$ ) had undergone a PCI (Table 3).

Nearly one-third of all patients had experienced a complicated acute medical condition. In hospital, cardiac events such as arrhythmia/resuscitation requiring treatment and decompensated heart failure (>15%)

were as frequent as impaired wound healing, infections and blood transfusions. At the start of the rehabilitation programme wound infections (>5%) were predominant. Decubitus ulcers or MRSA colonization/infection were rare. Atrial fibrillation, a left-ventricular dysfunction ( $\text{LVEF} \leq 40\%$ ), pulmonary hypertension and pericardial effusion were each registered in 12–15% of patients. A severe mitral valve insufficiency was also fairly common (7%).

### Outcome parameters

With regard to the rehabilitation outcome, 13 parameters in three key areas, namely risk factors (blood pressure, low-density lipoprotein (LDL) cholesterol, triglycerides), physical capacity (resting heart rate, maximal exercise capacity, maximal six-minute walking distance, heart failure, angina pectoris) and subjective health (IRES-24: pain, somatic health, psychological well-being; depression and anxiety symptom scores) were identified as being sensitive to change and prone to modification by rehabilitation (Table 2, Figure 1).

Need for intervention and total changes during CR for each parameter are shown in Table 3. The detailed

**Table 3.** Patient characteristics (n = 1253)

Variable	N	%
Age (years)	70.9 ± 7.0	
Gender (m/f)	978/274	78.1/21.9
BMI (>30 kg/m <sup>2</sup> )	202	16.1
Waist circumference (female >88 cm, male >102 cm)	479	43.6
Living situation (family/partner)	994	79.3
Education (>secondary school)	523	41.8
Retired	1201	95.8
Level of care I, II (SGB Social Law Gazette IX)	26	2.1
Indication		
Postoperative	758	61.1
CABG	406	53.6
Aortic valve replacement	97	12.8
Aortic surgery	83	10.9
Mitral valve replacement/reconstruction	82	10.8
Conservative/interventional	484	38.9
PCI	253	52.3
ST elevation myocardial infarction	73	15.1
Other cardiac disease	43	8.9
Risk factors		
Arterial hypertension	1044	83.3
Hyperlipoproteinaemia	990	79.0
Positive family history	530	42.3
Diabetes mellitus	302	24.1
Smokers	60	4.8
Ex-smokers	513	40.9
Comorbidities		
Angina pectoris	39	3.1
Heart failure	114	9.1
Stroke	68	5.4
PAD	81	6.5
COPD	105	8.4
Back pain	148	11.8
Carcinoma	84	6.7
Osteoarthritis, rheumatoid arthritis, osteoporosis	148	11.8
Others (lung embolism, myocarditis)	152	12.1

BMI: body mass index; CABG: coronary artery bypass grafting; PCI: percutaneous coronary intervention; PAD: peripheral artery disease; COPD: chronic obstructive pulmonary disease.

changes of systolic blood pressure levels are demonstrated as a pre–post representation in Figure 2. Improvements and deteriorations for all identified parameters are presented in Figure 1.

## Discussion

A detailed description of the patient population, taking functional and structural limitations into account, revealed 13 parameters that could be used to determine

the rehabilitation outcome. These could be divided into the key areas of risk factors, physical capacity and subjective health (Figure 1). In these parameters, improvements were achieved on average in 51% of cases, in at least 31% (resting heart rate) to at most 77% (arterial hypertension). However, risk factors and parameters of subjective health worsened in approximately 12% of patients.

## Risk factors

Independently of the underlying cardiovascular disease, the achievement of target blood pressure values (<140/90 mmHg) signifies a favourable prognosis. Even in advanced age, in hypertensive patients a reduction of blood pressure by 5 mmHg is associated with a 14% reduction in the rate of stroke and a 7% reduction in mortality rates.<sup>17</sup> In the present study, blood pressure could be improved in more than three-quarters of patients who required optimization of this parameter (35%). This rate is similar or even superior to data reported in other large registries.<sup>18</sup>

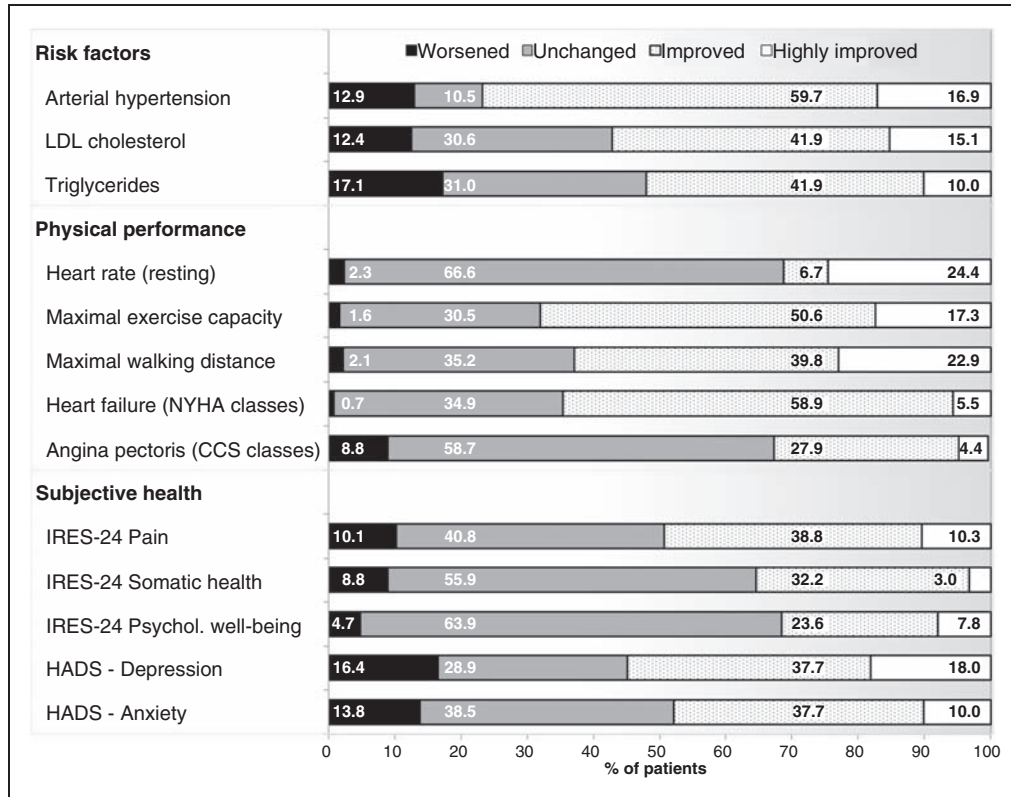
In our investigation the large majority of patients were referred for rehabilitation in the presence of pre-existing atheromatosis, which concerned the aorta and the peripheral vessels in addition to coronary arteries (Table 3). The prognostic significance of achieving target values for LDL cholesterol is independent of the affected vascular region<sup>19</sup> and age.<sup>20</sup> LDL cholesterol required intervention in nearly every second patient. Improvements were achieved in more than one-half of the patients, but failed to fulfil the expectations derived from comparisons with other observational studies.<sup>8,9</sup>

Triglycerides are a major component of the metabolic syndrome in connection with obesity, a large waist circumference and diabetes mellitus. This parameter – influenceable by healthy diet and physical exercise (two essential modules of the rehabilitation programme) – could be improved in every second patient who required optimization of his/her condition, and is similar to the outcomes of other investigations.<sup>8,21</sup>

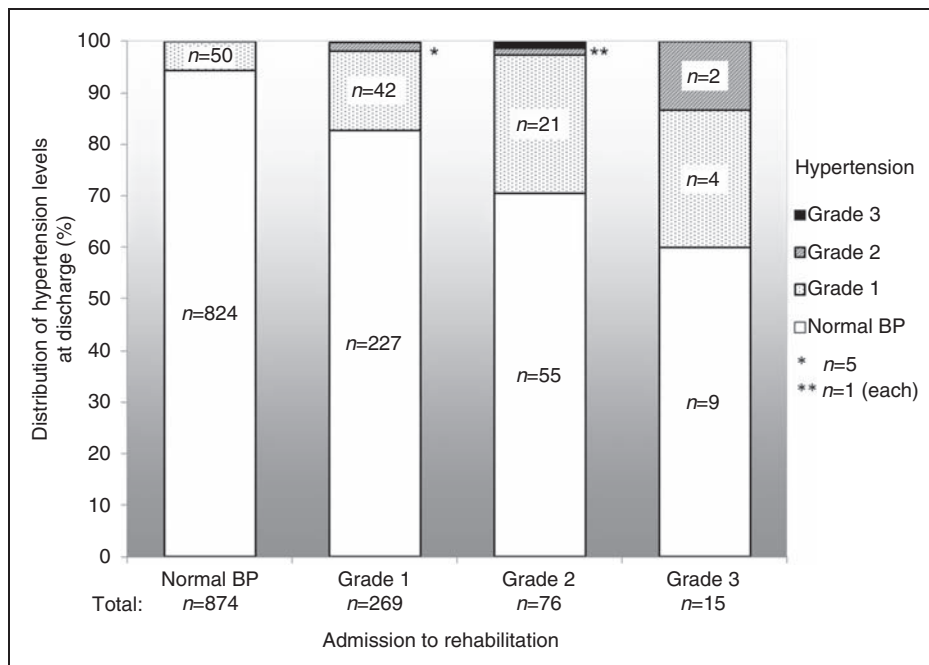
Other risk factors, such as overweight, a large waist circumference and smoking, prognostically associated with a high cardiovascular risk, cannot be altered to a clinically relevant extent in three weeks. These parameters were identified as unsuitable to determine the rehabilitation outcome.

## Physical capacity

According to the ICF classification, mobility is a major determinant of participation.<sup>22</sup> Thus, for many elderly patients the goal of rehabilitation is to prevent



**Figure 1.** Identified parameters of rehabilitation outcome and sensitivity to change (%).  
 LDL: low-density lipoprotein; NYHA: New York Heart Association; CCS: Canadian Cardiovascular Society; IRES: indicators of rehabilitation status; Psychol.: well-being: psychological well-being; HADS: Hospital Anxiety and Depression Scale.



**Figure 2.** Changes in systolic hypertension levels during rehabilitation (%).  
 BP: blood pressure; hypertension grade 1, 2, 3 according to international classification.<sup>11</sup>  
 Missing values in 12 (1.0 %) cases.



dependence on long-term nursing. Furthermore, physical fitness improves coordination and thus prevents falls, enhances cognition and reduces cardiovascular risk factors and consequent morbidity and mortality.<sup>3,23,24</sup> As tachycardia is a negative predictor heart rate can be improved by exercise and is associated with life expectancy.<sup>25</sup> In the present study every third patient had an excessively high heart rate. As improvement was achieved in just 31%, there is a need for further optimization.

The six-minute walking test is an evaluated measure of physical capacity. The walking distance as well as the level of performance on the bicycle exercise stress test are associated with prognosis.<sup>3,26</sup> In our study, nearly three-quarters of patients were able to perform the exercise stress test and the six-minute walking test. This variable clearly called for improvement, which could be achieved in nearly two-thirds of the patients. Thus, one may anticipate a better prognosis in the large majority of patients.<sup>24</sup>

Symptoms of heart failure and angina pectoris can also be positively influenced by physical exercise<sup>27,28</sup> and may therefore be regarded as parameters of outcome quality.

### Subjective health

Quality of life has been a principal factor in the outcome measurement of CR and has been largely based on subjective data provided by patients and physicians. While controlled investigations showed rehabilitation to exert a positive impact on anxiety and depression symptoms,<sup>29</sup> an average of only a small positive trend is recorded in our observational study, in accordance with studies that also show no significant improvement in HADS during CR.<sup>30</sup> However, it is worthwhile to consider the differentiated analysis of the individual evaluation categories (Figure 1). In addition to improvements in approximately 50%, up to 16.4% of the patients experienced deterioration.

The extent to which appropriate measuring instruments were used to register subjective health is not clear. IRES-24 has been evaluated in patients with musculoskeletal diseases.<sup>15</sup> The McNew test or EuroQol could have been used more specifically for patients with cardiovascular diseases. In particular, a German version of the currently evaluated EuroHeartQol may ensure a more valid assessment of subjective health.<sup>31</sup>

### Out-patient rehabilitation, long-term results

The recent European CR Inventory Survey (EUCRIS) revealed a broad range of CR regimes across European countries concerning type (50% in-patient as well as half of the patients attending out-patient CR), length

(3–4 weeks versus 12–16 weeks) and mean focus of therapy (exercised based versus comprehensive counselling).<sup>32</sup> Therefore, the question arises of whether the identified outcome parameters in our study can be transferred to out-patient CR. One can assume that additional variables of rehabilitation outcome, such as smoking or obesity, could be optimized during a long-term period. But data comparing in- and out-patient CR so far are sparse and showed no different long-term results, although patients in the in-patient setting were older and often in a postoperative situation.<sup>18,33,34</sup>

### Limitations

This multicentre study was initiated by a German health insurance organization (Techniker Krankenkasse) as part of quality assurance for in-patient CR in elderly, mostly retired patients. Objective, verified statements regarding long-term results and outpatient rehabilitation cannot be drawn from this study.

### Conclusion

In the present study of elderly patients we were able to identify 13 parameters in three key areas (risk factors, physical capacity and subjective health) as indicators of in-patient rehabilitation outcome. Although it seems to be justified to transfer the results into the out-patient setting, further studies with a long-term follow up, especially in younger patients, are needed in order to develop a uniform instrument of evaluation for outcome quality, which will then permit comparisons between rehabilitation centres.

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### Conflict of interest

None declared.

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