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# Performance Measures for Short-Term Cardiac Rehabilitation in Patients of Working Age

Results of the Prospective Observational Multicenter Registry OutCaRe

Original Research

# Performance Measures for Short-Term Cardiac Rehabilitation in Patients of Working Age: Results of the Prospective Observational Multicenter Registry OutCaRe

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**KEYWORDS**
Cardiac rehabilitation;
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**Abstract** *Objective:* To determine immediate performance measures for short-term, multi-component cardiac rehabilitation (CR) in clinical routine in patients of working age, taking into account cardiovascular risk factors, physical performance, social medicine, and subjective health parameters and to explore the underlying dimensionality.
*Design:* Prospective observational multicenter register study in 12 rehabilitation centers throughout Germany.
*Setting:* Comprehensive 3-week CR.

*Participants:* Patients (N=1586) ≤65 years of age (mean 53.8±7.3y, 77.1% men) in CR (May 2017-May 2018).

*Interventions:* Not applicable.

*Main Outcome Measures:* Feasibility, defined by data availability for ≥85% of patients (CR admission and discharge), and modifiability based on pre-post comparison (statistical significance, with $P$ value<.01; standardized effect size≥.35; change by ≥5% points in categorical variables). In addition, latent factors were identified using an exploratory factor analysis (EFA).

*Results:* Based on feasibility and modifiability criteria, smoking behavior, lifestyle change behavior, blood pressure, endurance training load, depression in Patient Health Questionnaire-9 (PHQ-9), the 5-item World Health Organization Well-Being Index (WHO-5), physical and mental health and pain scale of the indicators of rehabilitation status-24 (IRES-24), and self-assessed health prognosis proved to be suitable performance measures. As a result of the EFA, 2 solid factors were identified: (1) *subjective mental health* including PHQ-9, WHO-5, mental health (IRES-24), mental quality of life, and anxiety and (2) *physical health* including physical quality of life, physical health and pain scale of IRES-24, and self-assessed occupational prognosis. A third factor represents the blood pressure.

*Conclusions:* We provide a small set of performance measures, that are essentially based on 3 latent factors (subjective mental health, physical health, blood pressure). These performance measures can represent immediate success of comprehensive CR and be applied easily in clinical practice.

Cardiac rehabilitation (CR) as a measure of secondary prevention aims to improve different aspects of the underlying cardiac disease. In an intensive and complex multimodal approach, CR addresses medical, physical, social, and psychological conditions, because it comprises medical counseling and prescription of medication, customized exercise training, psychological support, and educational programs to change harmful lifestyle habits. Furthermore, for patients of working age, it provides support in the management of vocational reintegration.[1-3] Hence, CR relates to the biopsychosocial model of the International Classification of Functioning, Disability and Health by the World Health Organization (WHO).[4] The model corresponds to a holistic treatment approach that takes a patient's health condition, body function and structure, individual activities, and participatory ability, as well as environmental and personal factors into account.

The quality assessment of this complex intervention, which is applied to a very heterogeneous patient population, is still a challenge. Currently, several working groups in different countries have developed standards and performance measures to ensure quality in CR.[5-9] Most of them were developed in a sequential process of literature reviews and expert agreements and were related to the structure, process, and outcome of CR as described by Donabedian in his foundational work on quality assessment and assurance in health care.[10]

In Germany, quality assurance programs for rehabilitation were developed and implemented by the German pension insurance mostly for employed patients of working age and by the German National Association of Statutory Health Insurance Funds for patients of older age as requested by German legislators. Both programs are mostly unspecific regarding the medical specialty and focus mainly on the structure and process quality of rehabilitation. For the evaluation of outcome quality, a related research group prospectively examined in an earlier investigation a variety of routinely assessed parameters regarding their suitability as performance measures within a large sample of older patients in German CR. Thirteen parameters in 3 key areas (cardiovascular risk factors, exercise capacity, subjective health) were identified.[11]

Patients of working age were not included in this study. In order to identify performance measures for short-term CR for this patient group, we conducted the Outcome of Cardiac Rehabilitation (OutCaRe) study. In the first step, we performed a Delphi expert survey to consent parameters as potential performance measures.

The aim of this study was to evaluate the expert-approved parameters regarding their suitability as immediate performance measures of short-term comprehensive CR in terms of feasibility and modifiability in clinical routine in patients of working age. In addition, it was our goal to explore the dimensionality and structure underlying the parameters.

## Methods

### Study design and patients

In the first step of the OutCaRe study, we performed a 4-level, web-based Delphi panel with 67 highly experienced experts participating in the consenting round. The experts were physicians (n=51), psychologists (n=7), or sports or physiotherapists (n=9) in leading positions in a CR center

and were members of the German Society for Prevention and Rehabilitation of cardiac diseases.[12] As a result of the Delphi panel, consensus was found on 21 relevant parameters that might serve as performance measures for patients of employable age, including vocational parameters.

In the second phase of the OutCaRe study, which is the object of this publication, we conducted a prospective, observational, multicenter register study. In order to achieve sufficient data representativeness, we planned the recruiting period over 1 year, with an expected participation of 10-20 rehabilitation centers throughout Germany, each enrolling on average 100 patients. The resulting sample size between 1000 and 2000 was considered sufficient to test a number of parameters unknown before the Delphi panel was conducted. Patients younger than 65 years of age, because 65 is the usual retirement age, admitted to CR between May 2017 and May 2018 at one of ultimately 12 participating centers were eligible for enrollment. Exclusion criteria were insufficient knowledge of the German language, early retirement, and lack of patient consent.

## Cardiac rehabilitation

Depending on their assignment diagnosis (eg, acute coronary syndrome [ACS], coronary artery bypass grafting, stable coronary artery disease, valvular disease or surgery, atherosclerotic disease, heart failure) and comorbid disorders, patients received an individually tailored, multimodal in- or outpatient CR program with a usual duration of 3-4 weeks. The program was standardized according to the specifications of the German pension insurance. It included cardiologist counseling, risk-factor modification strategies (eg, patient education on nutritional habits, smoking cessation, physical activity, medication adherence), physician-supervised exercise training and sports therapy (eg, training on a bicycle ergometer, outdoor walking, resistance training, gymnastics), psychosocial interventions (health education and counseling, psychotherapy, stress management in single or group sessions), and vocational assessment and counseling by a physician and a social worker.[13,14] On average, 12 weekly training units and 8 additional counseling sessions were applied.[15]

## Operationalization of parameters to be tested

From the preceding Delphi panel, 21 parameters in the 4 domains of cardiovascular risk factors, physical performance, social medicine, and subjective health were chosen by consensus as potential performance measures for the CR program described above.[12] For the suitability evaluation, the parameters were operationalized using well-described, proven reliable, and valid assessment tools as specified in table 1.

While parameters of physical performance and cardiovascular risk factors were mostly assessed using established clinical and laboratory diagnostics as well as functional tests, subjective health including depression, anxiety, quality of life, and subjective well-being were evaluated by means of several standardized questionnaires: the Patient Health Questionnaire-9 (PHQ-9), which measures depression on a range from zero (healthy) to 27 (severe degree of depressive symptoms)[16]; the 5-item World Health Organization Well-Being Index (WHO-5) (percentage scale with a range 0-100, suggested cutoff point>50: good well-being; ≤50: reduced well-being)[17]; the German version of the Cardiac Anxiety Questionnaire (Herzangstfragebogen [HAF-17]) (range 0=no anxiety to 4=great anxiety; no cutoff)[18]; the 12-Item Short-Form Health Survey (SF-12) with the physical component summary (PCS) and mental component summary (range 0-100, higher scores indicate a better health state, no cutoff)[20]; and a German questionnaire developed to assess patients' function and health status in rehabilitation (indicators of rehabilitation status-24 [IRES-24]) with subscales for physical and mental health as well as pain (range 0=maximum burden to 10=no burden).[21]

Of the prespecified parameters, the exercise capacity as measured by the cardiopulmonary exercise test was dismissed in agreement with a steering committee consisting of 5 experienced cardiologists. A cardiopulmonary exercise test is not defined as a mandatory standard in German CR, and appropriate equipment is not provided in every CR center. Therefore, the parameter was judged as unfeasible in real-world clinical practice.

## Data collection and data quality assurance actions

All potential performance measures were assessed at admission to and discharge from CR. General data and important confounders were mostly documented at CR admission only (eg, age, sex, education, indication for referral to CR, comorbidities, CR setting and further characteristics of CR, data from last hospital stay). Most of the data were taken from patient records, while the questionnaires as described above were additionally administered to the patients (paper or web based).

The data were documented in a web-based good clinical practice-compliant electronic data capture system (secuTrial[a]) by authorized and personally trained or webinar-trained clinicians and study nurses in the CR centers. Standard operating procedures described in manuals were handed out to the responsible clinic staff. In addition, plausibility checks with lower and upper value limits were programmed for several variables to ensure data quality. Trained members of the research staff continuously supervised the data entry, conducted reasonability checks, and flagged implausible entries, which had to be checked and verified or corrected by the clinic staff. The electronic data capture system documented the complete history of the changes.

## Ethics and registration

The study was approved by the Ethics Committee of the Landesärztekammer Brandenburg (State Medical Association of Brandenburg; registration no. S4(a)/2017) and by the institutional review boards at every participating rehabilitation center. Signed, written informed consent was obtained from all participants. OutCaRe is registered by the German Register of Clinical Trials and the International Clinical Trial Agency (WHO) (registration no. DRKS00011418).

**Table 1** Operationalization of the potential performance measures chosen in the Delphi panel

| Quality Indicators Identified in the Delphi Panel | Operationalization |
|---|---|
| *Cardiovascular risk factors* | |
| 1. Smoking behavior | Question: Do you smoke? (I am currently "smoker," "nonsmoker," "ex-smoker") |
| 2. Lifestyle change motivation | Question: Can you imagine to change your lifestyle because of your disease? ("certainly," "rather yes," "uncertain," "rather not," "certainly not") |
| 3. Systolic or diastolic blood pressure | Standard laboratory assessment |
| 4. LDL cholesterol | Standard laboratory assessment |
| 5. Body mass index | Calculated from measured weight and height (kg/m$^2$) |
| 6. Blood glucose profile | Fasting glucose (standard laboratory assessment) |
| *Physical performance* | |
| 7. Maximum exercise capacity | Measured during stress ECG |
| 8. Endurance training load | As set for exercise training |
| 9. 6-minute walking distance | Measured |
| 10. Painless walking distance | Measured |
| 11. Cardiopulmonary exercise capacity | Was not assessed, as not feasible in real-world clinical practice (according to steering committee) |
| *Social medicine* | |
| 12. Pension desire or motivation for return to work | Würzburger screening, Question 3: Are you currently thinking about filing an application for early retirement? ("yes," "no") |
| 13. Return to work | Assessed at follow-up, not applicable for this analysis |
| 14. Self-assessed occupational prognosis | Würzburger screening, SES (score generated from questions 2-4) |
| | Question 2: Do you believe in returning to your working position after CR? ("yes," "no") |
| | Question 4: How soon after CR do you hope to return to work? ("1 month," "more than 1 month," "never") |
| 15. Work capacity | At admission: Question: Have you been on sick leave before admission to CR? ("yes," "no") |
| | At discharge: evaluated by a physician within the clinical routine social medicine assessments |
| *Subjective health* | |
| 16. Depression | Questionnaire: PHQ-9,[16] WHO-5[17] |
| 17. Heart-focused anxiety | Questionnaire: HAF-17[18] |
| 18. Rating of perceived exertion | Rated on Borg Scale[19] during training |
| 19. Quality of life | Questionnaires: WHO-5,[17] SF-12,[20] IRES-24[21] |
| 20. Subjective well-being | |
| 21. Self-assessed health prognosis | Question: Please estimate your expected state of health in 6 months? ("excellent," "very good," "good," "suboptimal," "poor") |

Abbreviation: ECG, electrocardiogram.

## Statistical analyses

To confirm a parameter as a suitable immediate performance measure, we defined the following criteria: (1) the assessment of the parameter had to be feasible in clinical routine, operationalized as available data sets (at admission to and discharge from CR) for ≥85% of patients. (2) The parameter had to be modifiable during CR, based first on statistical significance ($P$ value $<.01$ for $t$ test for dependent samples, Wilcoxon signed-rank test, or McNemar test) and second on standardized effect sizes (SESs) $\geq.35$[22] for the pre-post comparison or a change of ≥5% points in categorical variables between admission to and discharge from CR. For the SES, we calculated Cohen's d according to Kazis' definition as the mean change found in a variable divided by the standard deviation of that variable at admission to CR to give a more complete and clinically relevant picture of health status change.[23] We interpreted the SES according to Cohen, who defined an effect size of 0.20 as small, 0.50 as moderate, and 0.80 or greater as large.[24]

The selectivity of patients' pre-post changes in continuous parameters was additionally analyzed by comparing the 95% confidence interval (95% CI) and the SD of the mean differences. We assumed for SD values within the upper and lower boundaries of the 95% CI that all patients changed to the same extent, meaning that this parameter would not be an adequate performance measure.

Subsequently, an exploratory factor analysis (EFA) was performed to reveal the dimensionality and data

**Table 2** Baseline characteristics of the study population (N=1586)

| Characteristics | Mean ± SD/n (%) |
|---|---|
| *Sociodemographic data* | |
| Age (y) | 53.8±7.3 |
| Sex (men) | 1223 (77.1) |
| Education | |
| <10th grade | 289 (18.4) |
| Secondary school | 857 (54.8) |
| College/university | 340 (21.7) |
| Living situation | |
| Family/partner | 1219 (78.1) |
| Living alone | 285 (18.3) |
| Employed (n=1562)* | 1387 (88.8) |
| Sick leave before CR (n=1562) | 1124 (72.0) |
| *Cardiac rehabilitation* | |
| Admission to CR | |
| After an acute event | 1320 (83.2) |
| For chronic disorder | 266 (16.8) |
| Setting of CR | |
| Inpatient | 1437 (90.6) |
| Outpatient or day care | 149 (9.4) |
| Duration of CR (d) | 22.9±4.7 |
| Inpatient | 23.5±4.5 |
| Outpatient or day care | 17.3±3.3 |
| Modality of discharge | |
| Regular | 1564 (97.5) |
| Prematurely on patient request | 26 (1.6) |
| Transfer (acute hospital) | 12 (0.8) |
| Death | 1 (0.1) |
| *Indication for referral to CR* | |
| ACS | 630 (39.7) |
| Stable CAD | 307 (19.4) |
| Heart valve surgery | 181 (11.4) |
| CABG | 112 (7.1) |
| Venous disease | 70 (4.4) |
| Cardiac dysrhythmia | 54 (3.4) |
| Diseases of the aorta | 54 (3.4) |
| Arterial hypertension | 50 (3.1) |
| Chronic heart failure | 49 (3.1) |
| Atherosclerosis (incl. PAD) | 38 (2.4) |
| Intervention† | 20 (1.3) |
| Myocarditis, endocarditis, pericarditis | 11 (0.7) |
| Other | 10 (0.6) |
| *Comorbidities* | |
| Arterial hypertension | 1059 (66.8) |
| Chronic ischemic heart disease | 911 (57.4) |
| Hyperlipidemia | 963 (60.7) |
| Diabetes mellitus | 259 (16.3) |
| Heart valve diseases | 133 (8.4) |
| Atrial fibrillation | 129 (8.1) |
| Chronic heart failure | 101 (6.4) |
| Peripheral arterial disease | 89 (5.6) |
| CABG | 87 (5.5) |
| Depression | 76 (4.8) |

**Table 2** (*continued*)

| Characteristics | Mean ± SD/n (%) |
|---|---|
| Chronic obstructive lung disease | 69 (4.4) |
| Kidney disease | 63 (4.0) |

Abbreviations: CAD, coronary artery disease; CABG, coronary artery bypass grafting.
* Further categories for the variable occupational status: in training, housewife/househusband, unemployed, in temporary or early retirement.
† Percutaneous transluminal coronary angioplasty, pacemaker, defibrillator, transplantation.

structure.[25] We hypothesized that there is at least 1 latent variable underlying particularly the questionnaires used to measure subjective health (ie, PHQ-9, WHO-5, HAF-17, scales of the SF-12 and IRES-24). We carried out 2 independent EFAs for both times of measurement (CR admission or discharge) in the same sample (patients with complete data sets). The number of factors retained was based on the scree plot, which is a line graph of the eigenvalues of factors (square sum of factor loadings) ordered from the largest to the smallest. Ideally, after a steep descent the eigenvalues seem to level off—eigenvalues to the left to this bend (*elbow*) are considered significant.[26] For the interpretation of factors, we used the rotation method varimax with Kaiser normalization. We included the Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy and Bartlett's test of sphericity with a KMO index of .50 and a significant result for the Bartlett's test ($P<.05$) affirming the respondent data as suitable for factor analysis.[27] In accordance with Costello and Osborne [28] and Comrey and Lee,[29] a parameter was considered to belong to a factor if the loading was >.32, with at least ≥5 strongly loading parameters (>.5) indicating a solid factor.

Discrete variables were expressed as mean ± SD and categorical variables as absolute values and percentages. All calculations were performed in SPSS version 25.[b]

## Results

### Characteristics of the study population

Of 4938 eligible patients, 1586 patients (mean age 53.8±7.3y, 77.1% men) participated in the study. In 1320 patients (83.2%), CR followed an acute cardiac event (eg, ACS, coronary artery bypass grafting, valvular surgery) (table 2). In this group, patients were admitted to CR on average 16.9±15.6 days after their hospital discharge.

In 90.6% of cases, CR was performed in an inpatient setting with a duration of 23.5±4.5 days. The most common diagnosis was ACS (630 patients, 39.7%), followed by stable coronary artery disease (307 patients, 19.4%) and heart valve surgery (181 patients, 11.4%). The most frequently reported comorbidities and cardiovascular risk factors were

**Table 3** Changes in outcome parameters between admission to and discharge from cardiac rehabilitation

| Parameter | Available Data n (%) | Admission mean ± SD/n (%) | Discharge mean ± SD/n (%) | Difference mean ± SD/diff (%); agreement (%)* | 95% CI | P value[†] | SES |
|---|---|---|---|---|---|---|---|
| *Cardiovascular risk factors* | | | | | | | |
| Smoking behavior[‡] (smoker) | 1501 (94.6) | 568 (37.8) | 273 (18.2) | −19.6%; 79.7% | | <.001 | – |
| Lifestyle change motivation (certain/fairly certain) | 1446 (91.2) | 1139 (78.7) | 1251 (86.5) | 7.7%; 84.2% | | <.001 | – |
| Systolic blood pressure (mmHg) | 1574 (99.2) | 128.8±19.0 | 121.9±14.0 | −6.9±18.2 | −6.0; −7.8 | <.001 | .36 |
| Diastolic blood pressure (mmHg) | 1574 (99.2) | 80.3±11.6 | 75.4±9.2 | −4.9±11.6 | −4.3; −5.4 | <.001 | .42 |
| LDL cholesterol (mmol/L) | 1209 (76.2) | 4.6±2.5 | 3.8±2.2 | −0.8±1.4 | −0.7; −0.9 | <.001 | .32 |
| Body mass index (kg/m$^2$) | 1575 (99.3) | 28.8±5.3 | 28.6±5.1 | −0.2±0.7 | −0.2; 0.3 | <.001 | .04 |
| Fasting glucose[§] (mmol/L) | 135 (52.1) | 8.2±2.7 | 7.5±2.1 | −0.7±2.3 | −0.3; −1.1 | <.001 | .26 |
| *Physical performance* | | | | | | | |
| Maximum exercise capacity[‖] (W) | 979 (61.7) | 110.9±38.1 | 130.9±41.4 | 20.0±28.3 | 18.2; 21.8 | <.001 | .52 |
| Endurance training load (W) | 1479 (93.3) | 48.1±20.5 | 69.1±26.2 | 21.1±20.4 | 20.0; 22.1 | <.001 | 1.03 |
| 6-MWD (m) | 985 (62.1) | 453.0±90.9 | 526.9±91.8 | 73.9±58.7 | 70.3; 77.6 | <.001 | .81 |
| Painless walking distance[#] (m) | 28 (26.9) | 170.8±134.8 | 282.9±205.4 | 112.2±147.1 | 55.1; 169.2 | <.001 | .83 |
| *Social medicine* | | | | | | | |
| Pension desire (yes) | 1430 (90.2) | 250 (17.5) | 228 (15.9) | −1.6%; 91.9% | | .051 | – |
| Self-assessed occupational prognosis (negative) | 1387 (87.5) | 560 (40.4) | 606 (43.7) | 3.3%; 87.3% | | <.01 | – |
| Work capacity[5] (no) | 1159 (98.3) | 1124 (72.1) | 1184 (75.9) | 3.8%; 75.5% | | <.01 | – |
| *Subjective health* | | | | | | | |
| Depression (PHQ-9) | 1403 (88.4) | 6.5±4.9 | 4.5±4.1 | −2.0±3.4 | −1.9; −2.2 | <.001 | .42 |
| Heart-focused anxiety (HAF-17) | 1341 (84.4) | 1.5±0.6 | 1.3±0.6 | −0.2±0.4 | −0.2; −0.2 | <.001 | .31 |
| Rating of perceived exertion (Borg Scale) | 567 (35.8) | 13.1±2.5 | 13.1±2.3 | −0.0±2.6 | −0.3; 0.2 | 1.0 | .01 |
| *Quality of life or subjective well-being* | | | | | | | |
| WHO-5 | 1438 (90.5) | 50.7±25.3 | 68.6±21.3 | 17.9±20.0 | 16.9; 18.9 | <.001 | .71 |
| SF-12 PCS | 1294 (81.3) | 38.8±10.5 | 44.3±9.5 | 5.5±8.3 | 5.1; 6.0 | <.001 | .53 |
| SF-12 mental component summary | 1294 (81.3) | 48.1±11.9 | 54.0±9.1 | 5.9±9.4 | 5.3; 6.4 | <.001 | .49 |
| IRES-24 physical health | 1434 (90.4) | 5.8±2.7 | 7.0±2.4 | 1.1±1.9 | 1.0; 1.2 | <.001 | .43 |
| IRES-24 mental health | 1452 (91.5) | 6.4±2.5 | 7.8±2.1 | 1.4±1.8 | 1.3; 1.5 | <.001 | .57 |
| IRES-24 pain | 1454 (91.6) | 6.2±2.6 | 7.3±2.4 | 1.0±1.9 | 0.9; 1.1 | <.001 | .39 |

**Table 3** (*continued*)

| Parameter | Available Data n (%) | Admission mean ± SD/n (%) | Discharge mean ± SD/n (%) | Difference mean ± SD/diff (%); agreement (%)* | 95% CI | P value[†] | SES |
|---|---|---|---|---|---|---|---|
| Self-assessed health prognosis (excellent/very good) | 1446 (91.1) | 618 (42.8) | 730 (50.5) | 7.8%; 76.2% | | <.001 | — |

\* Agreement (%) refers to the proportion of patients who were in the same category at admission and discharge.
[†] Based on *t* test for dependent samples, Wilcoxon signed-rank test, or McNemar test.
[‡] Patients who quit smoking due to the acute event before subsequent CR were classified as smokers on admission.
[§] In patients with diabetes mellitus, n=259.
[||] During stress ECG.
[#] In patients with peripheral arterial disease, n=108.

arterial hypertension (n=1059, 66.8%), chronic ischemic heart disease (n=911, 57.4%), and hyperlipidemia (n=963, 60.7%). Diabetes mellitus was reported in 259 cases (16.3%) (see table 2).

At CR admission, 606 patients (38.2%) were current smokers, the mean body mass index (BMI) was 28.8±5.3 kg/m$^2$. About three-quarters of the patients (1266, 77.3%) were motivated to change their lifestyle as a consequence of their disease. About 285 patients lived alone (18.0%) and most (n=724, 45.6%) had finished secondary school. The mean maximum exercise capacity was 111±37.9 watts (n=1415) and the mean 6-minute walking distance (6MWD) was 452.5±91.5 m (n=1106). The mean score on the PHQ-9 was 6.5±4.9 points and on the WHO-5 50.4±25.4 percentage points.

## Pre-post changes in outcome parameters

Between admission to and discharge from CR, the proportion of smokers decreased from 37.9% to 18.2% (fully available data, n=1501). The mean BMI changed by −0.22±0.7 kg/m$^2$. The proportion of patients motivated to change their lifestyle as a consequence of their disease increased from 78.7% to 86.5%. The pre-post changes in the physical performance parameters of endurance training load (21.1±20.4 W), painless walking distance (112.2±147.1 m), and 6MWD (73.9±58.7 m) showed the highest SES values, with 1.03, 0.83, and 0.81, respectively. The mean score on the PHQ-9 decreased by 2.0±3.4 points and on the WHO-5 by 17.9±20.0 percentage points. For all discrete parameters, the SD of the mean differences



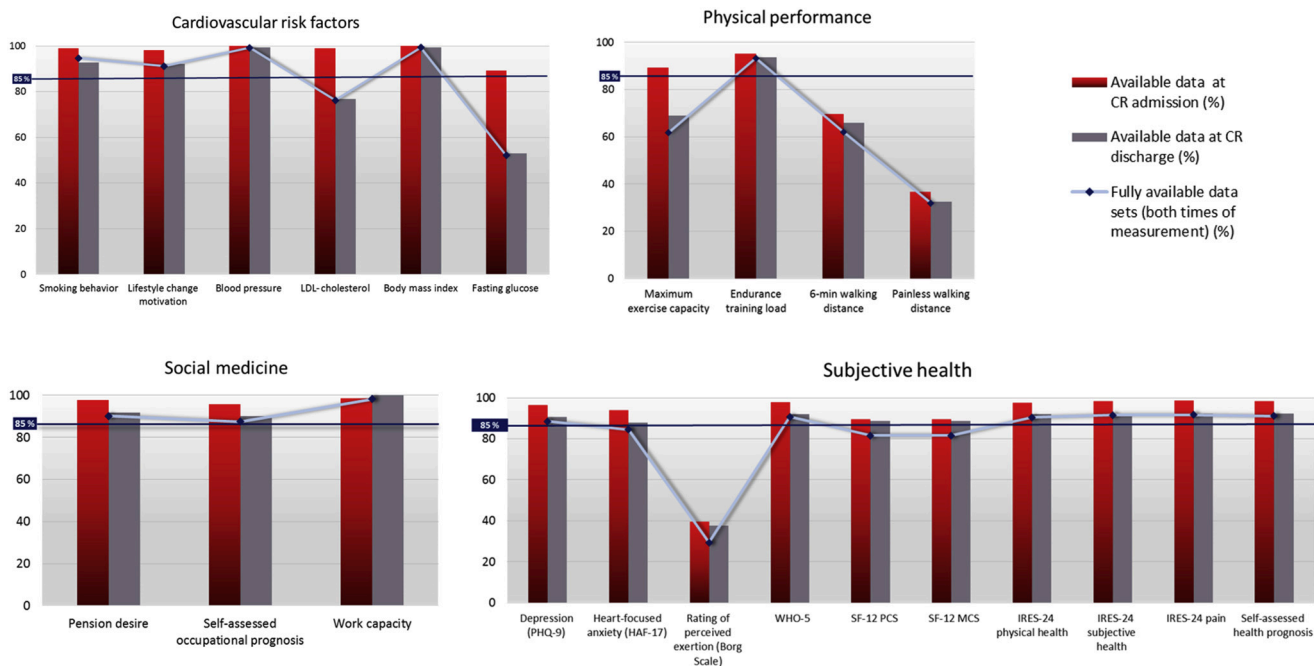**Fig 1** Data availability of outcome parameters of cardiac rehabilitation. Dark blue solid line: threshold for feasibility criteria: fully available data sets (both measurement times) in ≥85% of cases. Abbreviation: MCS, mental component summary.

**Table 4**   Feasibility of data assessment and modifiability of outcome parameters of cardiac rehabilitation—results at a glance

| Parameter | Feasibility of Data Assessment[*] | Modifiability (1): P value $<.01$[†] | Modifiability (2): SES$\geq.35$/change of $\geq 5\%$ points |
|---|:---:|:---:|:---:|
| *Cardiovascular risk factors* | | | |
| Smoking behavior[‡] | ✔ | ✔ | ✔ |
| Lifestyle change motivation | ✔ | ✔ | ✔ |
| Systolic blood pressure | ✔ | ✔ | ✔ |
| Diastolic blood pressure | ✔ | ✔ | ✔ |
| LDL cholesterol | | ✔ | |
| Body mass index | ✔ | ✔ | |
| Fasting glucose[§] | | ✔ | |
| *Physical performance* | | | |
| Maximum exercise capacity | | ✔ | ✔ |
| Endurance training load | ✔ | ✔ | ✔ |
| 6-MWD | | ✔ | ✔ |
| Painless walking distance[‖] | | ✔ | ✔ |
| *Social medicine* | | | |
| Pension desire or motivation to return to work | ✔ | | |
| Self-assessed occupational prognosis | ✔ | ✔ | |
| Work capacity[4] | ✔ | ✔ | |
| *Subjective health* | | | |
| Depression (PHQ-9) | ✔ | ✔ | ✔ |
| Heart-focused anxiety (HAF-17) | | ✔ | |
| Rating of perceived exertion | | | |
| Quality of life or subjective well-being | | | |
|   WHO-5 | ✔ | ✔ | ✔ |
|   SF-12 PCS | | ✔ | ✔ |
|   SF-12 mental component summary | | ✔ | ✔ |
|   IRES-24 physical health | ✔ | ✔ | ✔ |
|   IRES-24 mental health | ✔ | ✔ | ✔ |
|   IRES-24 pain | ✔ | ✔ | ✔ |
| Self-assessed health prognosis | ✔ | ✔ | ✔ |

[*] Data available in $\geq 85\%$ of patients at CR admission and discharge.
[†] Based on $t$ test for dependent samples, Wilcoxon signed-rank test, or McNemar test.
[‡] Patients who quit smoking due to the acute event before subsequent CR were classified as smokers on admission.
[§] In patients with diabetes mellitus.
[‖] In patients with peripheral arterial disease.

exceeded the upper and lower boundaries of the 95% CI (table 3).

## Feasibility of data assessment and modifiability during CR

Smoking behavior, lifestyle change motivation, systolic and diastolic blood pressure, endurance training load, PHQ-9, IRES-24 (physical health, mental health, pain), WHO-5, and self-assessed health prognosis fulfilled the criteria for feasibility of data assessment (fig 1) and for modifiability during CR (tables 3 and 4).

Low-density lipoprotein (LDL) cholesterol, fasting glucose, maximum exercise capacity, 6MWD, painless walking distance in patients with peripheral artery disease (PAD), anxiety on the HAF-17, rating of perceived exertion (Borg Scale), and PCS and mental component summary on the SF-12 failed to meet the feasibility criteria. For these, data were only available for 26.9% (painless walking distance) to 84.4% (HAF-17) of the respective patient groups at both times of measurement (see fig 1) (see tables 3 and 4).

The parameter of perceived exertion (Borg Scale[19]) also did not meet the first modifiability criterion of a statistically significant change in the pre-post comparison at $P<.01$ ($P>.99$), as did the parameters of pension desire ($P=.051$) and work capacity ($P=.215$).

BMI and self-assessed (negative) occupational prognosis were both available in $>85\%$ of patients and showed statistically significant changes during CR. However, these changes corresponded only to minor effects (SES$=.04$ for BMI, $\Delta$ occupational prognosis 3.3%) and thus did not meet the second modifiability criterion (see tables 3 and 4).

## Underlying structure of tested parameters

For 1087 patients, complete data sets were available for conducting the EFA, in which we analyzed 17 parameters. That corresponds to a subject to item ratio of 64:1, which indicates an excellent sample size for the EFA.[28]

The scree plots indicated a 3-factor solution (fig 2). Based on strongly loading parameters, we interpreted the following components at CR admission: (1) *subjective mental health*
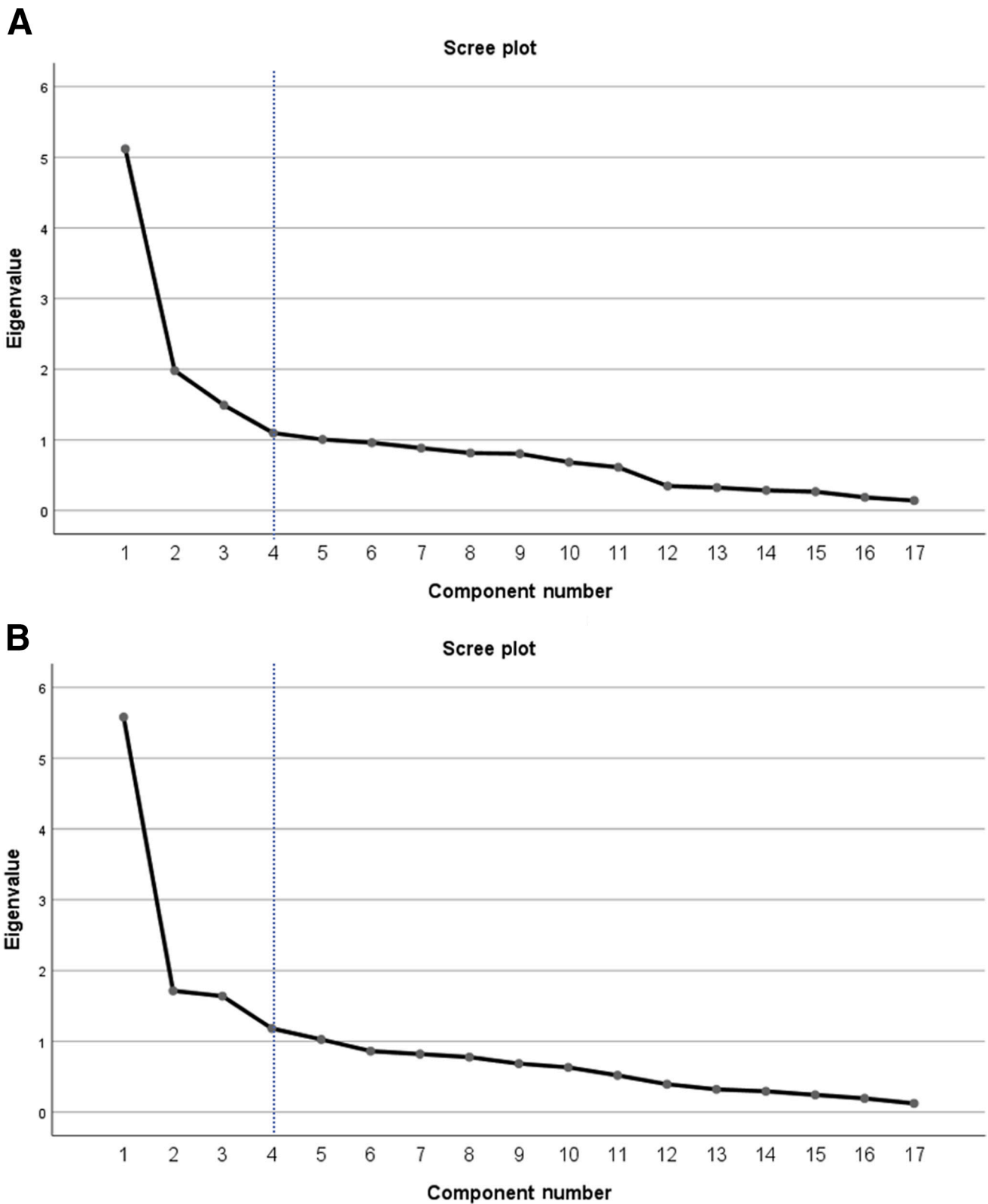
**A**



**B**



**Fig 2** Scree plots for the explanatory factor analyses of parameters measured (A) at CR admission and (B) at CR discharge.

with the mental health scales on both the SF-12 and IRES-24, physical health scale of the IRES-24, depression on the PHQ-9, well-being on the WHO-5, and heart-focused anxiety on the HAF-17; (2) *physical health* with PCS on the SF-12, the physical health and pain subscales on IRES-24, and self-assessed occupational prognosis; and (3) *blood pressure* with systolic

**Table 5**    Results of the EFA: rotated component matrix (n=1087)

| Parameters | Subjective Mental Health | Physical Health | Blood Pressure |
|---|---|---|---|
| *Admission to CR* | | | |
| Smoking behavior | .004 | −.006 | .181 |
| Lifestyle change motivation | .145 | .144 | −.097 |
| Systolic blood pressure | .010 | .105 | .858* |
| Diastolic blood pressure | .039 | .119 | .871* |
| Body mass index | −.103 | −.051 | .499 |
| Endurance training load | .071 | .485 | .103 |
| Self-assessed occupational prognosis | .057 | .639* | −.052 |
| Work capacity | −.170 | .212 | .078 |
| Depression (PHQ-9) | .870* | .178 | .004 |
| Heart-focused anxiety (HAF-17) | .550* | .345 | .001 |
| Quality of life or subjective well-being: | | | |
|   WHO-5 | .844* | .205 | .028 |
|   SF-12 PCS | .194 | .852* | .078 |
|   SF-12 mental component summary | .905* | −.060 | −.013 |
|   IRES-24 physical health | .558* | .607* | −.036 |
|   IRES-24 mental health | .906* | .193 | −.061 |
|   IRES-24 pain | .412 | .671* | .029 |
| Self-assessed health prognosis | .299 | .364 | −.186 |
| *Discharge from CR* | | | |
| Smoking behavior | .128 | .083 | −.061 |
| Lifestyle change motivation | .279 | .092 | −.079 |
| Systolic blood pressure | −.021 | .003 | .868* |
| Diastolic blood pressure | .019 | .043 | .836* |
| Body mass index | −.111 | −.031 | .466 |
| Endurance training load | .090 | .628* | −.006 |
| Self-assessed occupational prognosis | .220 | .624* | −.096 |
| Work capacity | −.103 | .553* | .104 |
| Depression (PHQ-9) | .886* | .093 | −.020 |
| Heart-focused anxiety (HAF-17) | .675* | .235 | −.013 |
| Quality of life/Subjective well-being: | | | |
|   WHO-5 | .854* | .131 | .010 |
|   SF-12 PCS | .427 | .750* | −.019 |
|   SF-12 mental component summary | .850* | −.153 | .005 |
|   IRES-24 physical health | .643* | .529* | −.084 |
|   IRES-24 mental health | .917* | .113 | −.005 |
|   IRES-24 pain | .548* | .559* | −.040 |
| Self-assessed health prognosis | .450 | .163 | −.109 |

NOTE. For this analysis, all parameters as assessed by questionnaires were (re-)coded in the same direction, so that higher values indicate *better health or prognosis*.

  * Parameters loading with ≥.5 are strongly associated with a latent factor: PHQ-9, HAF-17, WHO-5, the mental component summary on SF-12, and the mental health scale on IRES-24 are positively associated with the latent factor of *subjective mental health* at admission to CR.

and diastolic blood pressure (table 5). This detected structure was essentially confirmed for parameters measured at CR discharge. Differences were found for physical health on the IRES-24, which was stronger affected by *physical health* than by *subjective mental health*, and work capacity and endurance training load, which were additional parameters in *physical capacity* at discharge.

The models at CR admission and discharge explained 50.5% and 52.5% of the total variance with KMO=.84 and .86, respectively, and achieved significant results on the Bartlett test (*P*<.001).

## Discussion

OutCaRe is the first German study to identify and evaluate performance measures for immediate effects of multi-component, short-term CR in patients of working age considering the domains of cardiovascular risk factors, physical performance, social medicine, and patients' subjective health. The practice test regarding the feasibility of data assessment and the modifiability of 20 parameters prespecified by a Delphi survey resulted in at least 1 suitable parameter in each of the domains, except social

medicine. Most of the excluded parameters did not meet the feasibility criteria.

## Cardiovascular risk factors

Smoking behavior, systolic or diastolic blood pressure (both well-known risk factors for cardiovascular diseases), and lifestyle change motivation fulfilled all suitability criteria defined by OutCaRe. Smoking has been described as a dominant risk factor for myocardial infarction, with a population attributable risk of 35.7%.[30] Because of the large beneficial effects on morbidity and mortality, smoking cessation is an important goal for patients in CR.[31-33] Patients hospitalized due to an acute cardiac event usually have access to special support services for smoking cessation that end on patients' discharge. This leads to a high relapse rate, with the consequence of higher rates of mortality and major cardiac adverse events.[34] Therefore, delivery of effective smoking cessation treatment during CR is of great importance. As demonstrated in our study, short-term success could be reached, with the proportion of smokers having substantially decreased by 19.6 percentage points. Data were available for 94.6% of patients, indicating that this parameter can be easily obtained. It must be mentioned, though, that the assessment of smoking behavior was based on self-report and therefore has potential for misclassification.[35] Nevertheless, according to our results, smoking behavior has to be considered a relevant performance measure in CR. Arterial hypertension is a predominant risk factor for multiple cardiovascular diseases. It has been shown that a persistent reduction in blood pressure leads to beneficial effects regarding end-organ damage, as well as overall mortality and morbidity.[36,37] In the 2018 European Society of Cardiology/European Society of Hypertension Arterial Hypertension Guidelines,[38] a range of 120-129 mmHg for systolic and 70-79 mmHg for diastolic blood pressure is recommended as the treatment target for hypertensive patients younger than 65 years, which is in line with the 2017 American Guidelines.[39,40]

The assessment of blood pressure can be performed easily, which is reflected by our data that show the highest feasibility rates of all parameters for systolic and diastolic blood pressure (besides the BMI). Systolic blood pressure was already in the target range, while diastolic blood pressure was on the threshold of the objective stated in the guidelines at the time when patients were admitted to CR. Both parameters were modifiable according to our defined criteria, which underlines the effectiveness of risk-factor optimization strategies provided by the CR teams.

## Physical performance

In the OutCaRe study, the endurance training load during bicycle ergometry was an excellent performance measure, with available data for >90% of patients both at admission to and discharge from CR. The parameter was significantly improved in the mean by 21.1 watts—a change with a large effect size according to Cohen's d.[23]

Although recommended by the American Thoracic Society as an important measure for CR, the maximum exercise capacity on the bicycle exercise stress test and the 6MWD did not meet the feasibility criteria due to the high proportion of nonavailable data, particularly at CR discharge.

The same has to be stated for the painless walking distance in patients with PAD, which was only measured in 28 of 108 patients at both time points of measurement, although it is considered a meaningful assessment in patients with PAD.[41,42] Even if our results suggest large short-term effects in agreement with others, we cannot recommend this parameter as a performance measure in the affected patient group.

## Social medicine

Regarding occupation-related parameters, we cannot make a recommendation based on our results. The parameters proposed in the Delphi survey were sufficiently ascertainable in most of the cases. However, they could not be improved to a remarkable extent during short-term CR even though its long-term effects on return to work and work capacity have been found in several studies for different cardiovascular diseases.[43,44]

## Subjective health

In order to measure several aspects of subjective health including depression, anxiety, and health-related quality of life, we included different questionnaires. The PHQ-9, WHO-5, and all subscales of IRES-24 fulfilled the feasibility and modifiability criteria. The HAF-17 and SF-12 failed at the feasibility criteria, although they showed significant improvements. The measured positive effects on subjective mental and physical health during CR are in line with other study results, albeit measured with other instruments or during longer durations of CR.[45-47]

## Underlying data structure

In quality assurance, the burden of data collection should be restricted to the essential information.[48] As hypothesized, several parameters of subjective health and subscales of the questionnaires used are based on 2 latent factors which were interpreted by the authors as *subjective mental health* and *physical health*, respectively. The first comprises depression, anxiety, well-being, as well as mental health and quality of life. The dimension of physical health includes beside physical health and quality of life, endurance training load and the pain subscale of the IRES-24, the self-assessed occupational prognosis, as well as work capacity at CR discharge. With >5 strongly loading parameters in each, these factors are considered solid. The third factor found represents the systolic and diastolic blood pressure and—with less strong loadings—the BMI.

The authors assume that CR programs based on a multimodal approach are suitable to affect these dimensions and consequently the included parameters. Out of these parameters, the PHQ-9, WHO-5, IRES-24, endurance training load, and blood pressure were ascertained feasible and modifiable during CR. We recommend to use these assessments to measure the immediate outcome of a multimodal CR program. It should be noted that the WHO-5

and the PHQ-9 are interlinked as the screening for depression is recommended for the case of worse outcome in WHO-5. Thus, the use of the WHO-5 with only 5 questions may be sufficient for most of the population in CR.[17]

## Compare and contrast

Essentially, German CR standards[2] are in line with international guidelines.[3,5,8,49] Despite regional variation, Supervia et al[50] demonstrated in their review of CR around the globe that a vast majority of CR programs are multi-component interventions containing initial assessment, risk factor management, patient education, and exercise.[50] The median duration of supervised CR globally is 8 weeks with a frequency of 2.5 sessions/week ($\pm$1.3),[50] which is longer yet less intense than in German CR.[15]

Several attempts have been made to measure and compare the quality of CR programs, yet most of them focus on the structure and process of care and few on the outcome.[5–9,51–57] The following studies have to be mentioned regarding the immediate outcome of CR: Austrian colleagues set up a registry with the goal to investigate short-term (phase II, 4-6wk) and long-term (phase III, 6-12mo) effects of outpatient CR. Participants in phase II CR (n=1423) were on average 58.4 years of age ($\pm$11.2y) and 83.9% were men. Similar to our results, the parameters of physical work capacity, blood pressure, glucose, LDL cholesterol (not high-density lipoprotein cholesterol), triglycerides, BMI, waist circumference, and few psycho-cardiological parameters (Hospital Anxiety and Depression Scale depression, MacNew social domain) changed significantly during short-term CR.[56]

In a Canadian CR registry (N=4546, mean age 66.3$\pm$11.5y, 71% men), significant improvements in blood pressure, blood lipids (LDL cholesterol, high-density lipoprotein cholesterol, triglycerides, total cholesterol), BMI, waist, exercise capacity, and depressive symptoms (Hospital Anxiety and Depression Scale depression) were observed. It was stated that data were available for about 90% of the participants at discharge, yet it is unclear whether this applies to all parameters.[55]

In a European study on exercise-based CR, it was stated that exercise capacity during bicycle training was only documented in 28% and 16% of all patients at admission to and discharge from CR, respectively, with a large variety between countries. Exercise capacity improved significantly from 104$\pm$44 to 128$\pm$50 watts.[15] Furthermore, reviews comparing CR with no CR demonstrated significant improvements in the CR group in quality of life[58,59] and smoking abstinence.[60]

Comparing the recent findings to our former investigation in older-aged patients in CR, the changes in parameters during the course of CR achieved nearly similar small to moderate effects for systolic or diastolic blood pressure and LDL cholesterol, as well as parameters of physical performance.[11] Changes in subjective health measured by the IRES-24 were almost identical, while depression and anxiety were less improved in the older-age population. Here, it should be mentioned that different assessment tools (hospital depression and anxiety scale in the former study vs

recently used PHQ-9, WHO-5, HAF-17) were applied. However, full data sets on depression or anxiety for changes in CR in the older population were only available in 33% versus >80% of cases for all applied tools in the younger population.

In summary, available international data regarding changes during CR in patients of working age or older are largely comparable to our results.

## Study limitations

To test the parameters identified in the Delphi panel, we conducted a large multicenter registry. This ensured generalizability of the results and had a great advantage over, for example, the single-site, small-size practice test of indicators by Ohtera et al.[7]

Our study also had some limitations. The measurement of clinical parameters (blood pressure, LDL cholesterol, fasting glucose) and the assessment of all other non-questionnaire parameters were not standardized and could have differed between clinics. Yet, it was our intention to use the parameters as assessed in real-life clinical practice. There was further no quality indicator reliability assessment (eg, interrater agreement) as suggested by Scinto et al[61] for quality indicator testing.[61] Because we used questionnaires with proven reliability and validity from previous studies, this should not be an issue for the parameters assessed by questionnaires. The thresholds for defining feasibility of the data assessment and modifiability of the parameters during CR were arbitrarily chosen, based on contextual considerations.

For logistical reasons, some clinics could not check all CR patients for eligibility and recruited a convenience sample, which might have led to selection bias. Still, our participants were similar to our target population according to statistics on the rehabilitation services of the German pension insurance regarding age and sex (54.1y, 76.0% men).[62]

## Conclusions

Based on feasibility and modifiability criteria as defined by OutCaRe, we provide a small set of potential performance measures within the domains of cardiovascular risk factors, physical performance, and subjective health: smoking behavior, blood pressure, endurance training load, subjective well-being or depression measured by the WHO-5, physical health on the IRES-24, and self-assessed health prognosis. Except of smoking behavior, they were assigned to 3 latent factors *subjective mental health*, *physical health*, and *blood pressure* identified by EFA. The measures proved to be suitable to represent immediate success of comprehensive short-term CR and are applied easily in clinical practice, where the implementation should be supported by accompanying research including a validation study. For the domain of social medicine, ie, occupational parameters, no performance measure could be considered due to a lack of modifiability during 3-week CR.

## Suppliers

a. secuTrial; interActive Systems.
b. SPSS version 25.0; IBM.

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