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ORIGINAL ARTICLE

No impact of an extensive social intervention program on return to work and quality of life after acute cardiac event: a cluster-randomized trial in patients with negative occupational prognosis

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Abstract

Objectives To examine the effectiveness of extensive social therapy intervention during inpatient multi-component cardiac rehabilitation (CR) on return to work and quality of life in patients with low probability of work resumption after an acute cardiac event.

Methods Patients after acute cardiac event with negative subjective expectations about return to work or unemployment ($n=354$) were included and randomized in clusters of 3–6 study participants. Clusters were randomized for social counseling and therapy led by a social worker, six sessions of 60 min each in 3 weeks, or control group (usual care: individual counseling meeting by request). The return to work (RTW) status and change in quality of life (QoL, short form 12: Physical and Mental Component Summary PCS and MCS) 12 months after discharge from inpatient CR were outcome measures.

Results The regression model for RTW showed no impact of the intervention (OR 1.1, 95% CI 0.6–2.1, $P=0.79$; $n=263$). Predictors were unemployment prior to CR as well as higher anxiety values at discharge from CR. Likewise, QoL was not improved by social therapy (linear mixed model: ΔPCS 0.3, 95% CI − 1.9 to 2.5; $P=0.77$; $n=177$; ΔMCS 0.7, 95% CI − 1.9 to 3.3; $P=0.58$; $n=215$).

Conclusions In comparison to usual care, an intensive program of social support for patients during inpatient cardiac rehabilitation after an acute cardiac event had no additional impact on either the rate of resuming work or quality of life.

Keywords Social work · Cardiac rehabilitation · Return to work · Quality of life · Acute coronary syndrome · RCT

Introduction

For patients recovering from an acute coronary event including myocardial infarction or myocardial revascularization, besides their medical progress, societal and occupational reintegration has a significant prognostic value as well. The patients' ability to return to work (RTW) plays a key role in social outcome because of its substantial impact on quality of life.

Occupational prognosis following a cardiac event depends on multiple medical and non-medical factors. The severity of left ventricular dysfunction, residual ischemia, physical fitness, and existing comorbidities all influence successful RTW, as does the gender and educational level of the patients (Bhattacharyya et al. 2007; Osler et al. 2014). In addition, psychosocial factors such as depression, lack of social support in the patient's environment, and strenuous

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working conditions (e.g., shift work, physically demanding work, or high performance pressure) are negatively associated with the rate of successful occupational reintegration (Dreyer et al. 2016; de Jonge et al. 2014; Biering et al. 2012). Even after participating in a multimodal rehabilitation program, a negative subjective occupational prognosis could remain a determinant for non-resumption of work, as a Norwegian study in musculoskeletal and mental disease patients (Aasdahl et al. 2018) as well as own data (Salzwedel et al. 2019) suggest.

Likewise, work insecurity or occupational stress may lead to an increased risk of coronary artery disease (CAD) progression (Virtanen et al. 2013; Aboa-Eboulé et al. 2007). Moreover, social isolation and lack of social support are associated with a significantly poorer health prognosis for patients with CAD (Barth et al. 2010). The combination of low socio-economic status and ongoing psychological stress has a negative impact on the course of cardiovascular disease. Therefore, it is essential to identify patients with psychosocial issues after an acute cardiac event and provide them with meaningful social supports (Lazzarino et al. 2013; Frasure-Smith et al. 2000).

To date, there have been no adequately validated models supporting occupational reintegration in the post-acute phase following a cardiac event (O'Brien et al. 2017). Cardiac rehabilitation (CR), which generally starts within 14 days of hospital discharge in Germany, failed to show robust effects on RTW rates (Deutsche Rentenversicherung Bund 2018).

The aim of this study was to evaluate an extended social therapy group intervention focused on individual requirements during CR for patients with a poor occupational prognosis to determine its effects on patients' work resumption and health-related quality of life.

Methods

Design and participants

The investigation was conducted between November 2013 and April 2015 as a prospective, cluster-randomized controlled study at two German rehabilitation centers. Eligible patients were assigned to CR after an acute cardiac event including an acute coronary syndrome (ACS), coronary artery bypass grafting (CABG), or heart valve surgery and were of working age between 18 and 65 years. An additional inclusion criterion was a reduced likelihood of return to work after CR, assessed with the Würzburger Screening test (clinic version) at admission to CR. This questionnaire is a standardized instrument that documents patients' subjective occupational prognosis or current unemployment and estimates the likelihood of return to work with acceptable sensitivity (84%) and specificity (82%) (Löffler et al. 2008). Patients who had been unemployed for longer than a year were excluded from the trial.

Cardiac rehabilitation

Cardiac rehabilitation was conducted in well-established, privately operated rehabilitation centers located on the outskirts of Berlin and in Brandenburg county, respectively, which accommodate additionally gastroenterological, hematologic-oncological and angiological diagnostic groups.

Standardized multimodal 3-week inpatient CR started within 14 days of hospital discharge for all study participants. The intensive structured program included physician counseling plus a supervised individualized exercise training program, consistent risk factor management, patient education for secondary and tertiary prevention of CAD, psychological support, and extensive counseling on life style adjustment (Karoff et al. 2007).

Interventions

The study intervention was conducted in addition to the regular program during CR by specially trained social workers/social educators. Social workers are important contact persons dealing with individual problems regarding occupational, social and financial restitution after acute illness both in employed and retired patient populations. The given intervention was performed after extended instruction of clinic-based social workers. It was comprised of three specific modules in six 60-min sessions. These sessions were mandatory for the study participants of the intervention group. The intervention program was held in small groups of 3–6 participants for optimized individualization of problem solution. Lectures as well as group and individual work educated each rehabilitant about their social welfare benefit rights and options for occupational reintegration. Furthermore, health-promoting behaviors and individual personal and environmental resources were addressed. All included contents are demonstrated in Table 1.

The control group obtained the customary social therapy offerings in CR, which consisted of social work counseling meetings on an as-needed basis (usual care). These meetings were offered by the same social workers who also performed the intervention program.

Randomization process

Eligible patients were informed about the study content in groups of up to six persons after admission to the CR. The informational meetings took place at most once weekly. Upon giving informed consent, the patients were randomized to intervention or control group as a cluster of at

Table 1 Content of the interventional model

Module 1 Information on social-legal rights	Financial assistance (transitional and sickness benefits, supplementary payments) Disabled Persons Act (compensation for employed individuals) Application process (as needed, how to overcome inhibitions)
Module 2 Occupational capacity/health behavior	Subjective estimation of capacity (social-medical assessment, patient's own impressions) Occupational reintegration (stepwise reintegration, in-company integration management) Services to help participation in work life (options and, if necessary, communication to rehab counselors) Health behavior (setting personal goals, dismantling barriers, implementation in daily working life)
Module 3 Promoting social competency	Networking (network analysis and formation) Social support (awareness and activation of resources) Communication training (conversational analysis, communication techniques) Taking personal responsibility (knowing one's strengths, coping strategies)

least three and up to six participants. The randomization sequence was generated using software from the participating biometrics institute and managed at the study sites by a study nurse. Participants were grouped and social workers allocated to groups (clusters) before randomization took place. Thus, the group assignment was unknown to either the social worker or the patient in advance or during the informational meetings. Patients were allocated into the intervention and control group, respectively, after the informational meetings and only after all group members decided on their study participation.

Blinding, patient safety, ethics

Given the type of intervention—active group therapy—blinding was not possible. The risk to the patients resulting from the intervention was rated as minimal. Patients were only enrolled in the study after giving written informed consent. The study was reviewed and favorably evaluated by a vote of the Ethics Committee of Potsdam University (No. 26/2013).

Data collection

Sociodemographic variables including age, sex, living situation, educational level, job-related information (employment, training, type and difficulty of the last job), CR indication, relevant comorbidities, and cardiovascular risk factors were obtained from the patients' medical records. In addition, physical performance (6-min walking distance, maximum exercise capacity on bicycle ergometry), clinical–functional data (2D echocardiographic left ventricular ejection fraction, blood pressure, heart rate, New York Heart Association (NYHA) classification, laboratory test results), as well as the patients' psychological burden [Hospital Anxiety and Depression Scale (HADS, score range 0–21)] were collected at admission and discharge from CR. Health-related quality of life data (Physical and Mental Component Summary (PCS, MCS; score range 0–100) in Short-Form-12) (Morfeld et al. 2011) and Forms of Social Support (F-SozU K-14; score range 1.0–5.0) (Fydrich et al. 2007) were documented by the social worker or study nurse.

Follow-up and outcome measures

Three and twelve months after discharge from CR, information on occupational activity (e.g., employment, disability, unemployment, retirement), SF-12, and Work Ability Index (WAI; score range 7–49) (Hasselhorn and Freude 2007) were queried via postal mail. Occupational reintegration 1 year post-CR and changes in health-related quality of life on the SF-12 between discharge and 1 year after CR were used as outcome measures in this study. The vital status of patients who could not be reached by mail was determined through the resident registration office.

Statistics

Based on previously collected routine data, we assumed a 50% rate of return to work in the control group. To show a moderate effect (effect size Cohen's $d = 0.4$ corresponding to an odds ratio increase of 2.24 or an absolute 19% increase to 69% for return to work) with a power of 80% for two-sided $\alpha = 0.05$, 105 patients were required per group. However, to offset an assumed cluster effect of ICC = 0.02 (intra-cluster correlation coefficient, chosen according to experience with similar studies) and an expected loss-to-follow-up of 25%, the case number was set at a minimum of $2 \times 156 = 312$ study participants in 52 small groups.

The statistical analysis is based on the full analysis dataset containing the available data from all randomized patients who did not withdraw consent. Missing values were not replaced, i.e., were handled by case-wise deletion in the analyses. The analysis was conducted based on linear

two-level random-intercept models, which enable explicit representation of cluster effects. For the metric outcome measures, mixed linear regression analyses were used, and for occupational reintegration, mixed logistic regressions. Unadjusted and adjusted intervention effects are reported. The adjustment procedure was specified in the study protocol. For each outcome, in addition to the intervention and to the respective baseline measurement, a set of 10–13 clinically meaningful covariates were pre-defined. Of each of these covariate sets a subgroup was selected through backwards elimination with P values below 0.05 considered as significant. Only the selected covariates were used for adjustment of the intervention effect and are presented together with the unadjusted effect as forest plots. Cluster effects were tested in comparison to a linear model without cluster as random effect using the corresponding maximum likelihood test.

Calculations were done in SPSS Version 23 or STATA 15.1.

Results

Patient characteristics and the cardiac rehabilitation process

A total of 363 patients were included in the study and randomized in 89 clusters. Nine patients withdrew their consent, so that we were able to evaluate the baseline data of 354 patients (Fig. 1).

At admission to CR, no significant differences were determined between the intervention and control group ($n=167/187$) with respect to sociodemographic, anamnestic, medical, or functional parameters. Only the average Body Mass Index was lower in the intervention group than the control group (Table 2).

Enrolled patients were mostly male with an average age of 51 years. At the time of the cardiac event, 67% of the patients were employed, a quarter was unemployed. The prevalent indication for rehabilitation was CAD with ACS or CABG (70%), and in 75% of the cases, this was an initial event (Table 2).

A relevant proportion of the study population had comorbid orthopedic (20%) or psychiatric (16%) diseases. In addition, a notable finding was an increased anxiety level,

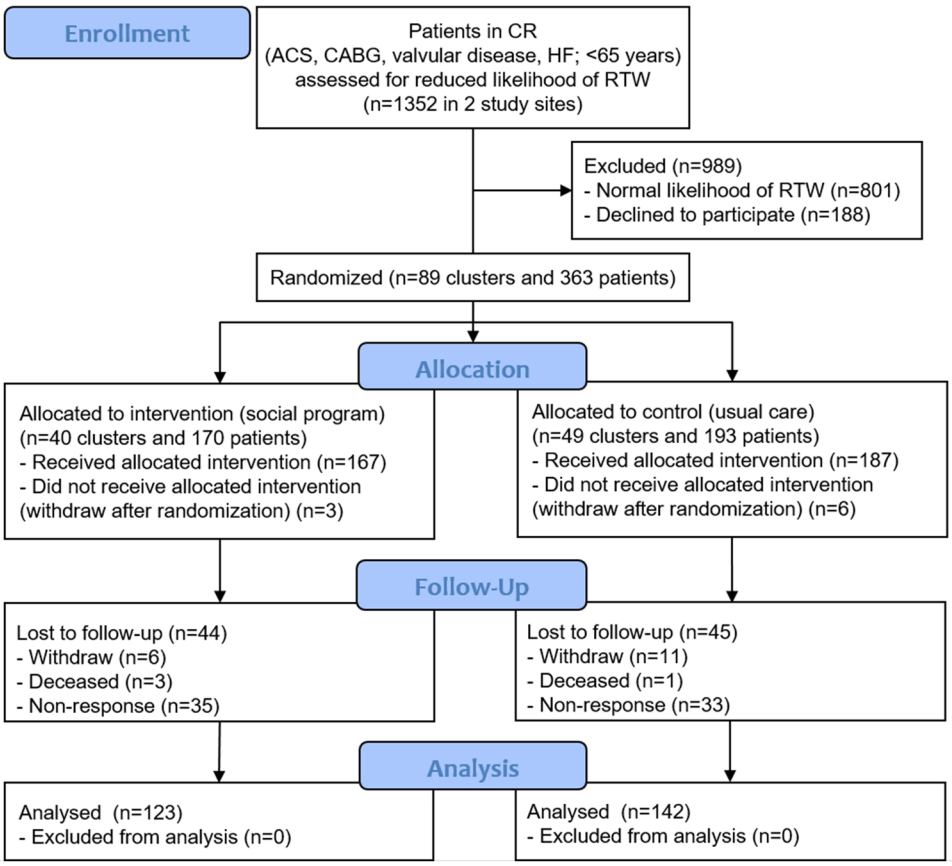

Fig. 1 CONSORT diagram of the patient flow through recruitment and study process. *CR* cardiac rehabilitation, *ACS* acute coronary syndrome, *CABG* coronary artery bypass graft, *HF* heart failure, *RTW* return to work

Table 2 Patient characteristics at admission to cardiac rehabilitation

Parameter	Intervention ($n=167$)	Control ($n=187$)	Total ($n=354$)	P
Sociodemographic data				
Gender (male)	128 (76.6%)	137 (73.3%)	265 (74.9%)	0.45
Age (years)	51.7 ± 6.6	51.6 ± 6.9	51.6 ± 6.8	0.95
Marital status (partnership)	117 (70.1%)	124 (66.3%)	241 (68.1%)	0.51
BMI	27.7 ± 4.9	29.0 ± 6.2	28.4 ± 5.7	0.04
Schooling completed < 10th grade	31 ($n=164$, 18.9%)	30 ($n=185$, 16.2%)	61 ($n=349$, 17.4%)	0.51
Occupational situation				
Sick leave before cardiac event (< 3 months)	114 ($n=151$, 75.5%)	115 ($n=171$, 67.3%)	229 ($n=322$, 71.1%)	0.13
Employed	112 (67.1%)	125 (66.8%)	237 (66.9%)	0.97
Officially unemployed	48 (28.7%)	47 (25.1%)	95 (26.8%)	0.51
Salaried/civil servant	101 ($n=166$, 60.8%)	119 ($n=185$, 64.3%)	220 ($n=351$, 62.7%)	0.54
Physically demanding work	46 ($n=165$, 27.9%)	44 ($n=178$, 24.7%)	90 ($n=343$, 26.2%)	0.53
Rehabilitation indication				
CAD (MI. PCI/CABG)	120 (71.9%)	124 (66.3%)	244 (68.9%)	0.26
Valvular disease	18 (10.8%)	23 (12.3%)	41 (11.6%)	0.67
Heart failure (ICD/CRT)	13 (7.8%)	16 (8.6%)	29 (8.2%)	0.80
Other	16 (9.6%)	24 (12.8%)	40 (11.3%)	0.97
Initial event	122 ($n=167$, 73.1%)	139 ($n=184$, 75.6%)	264 ($n=351$, 75.2%)	0.91
Comorbidities				
Orthopedic/rheumatic	36 (21.6%)	36 (19.3%)	72 (20.3%)	0.85
Psychiatric	30 (18.0%)	28 (15.0%)	58 (16.4%)	0.45
Risk factors				
Smoker	94 ($n=153$, 61.4%)	92 ($n=172$, 53.5%)	186 ($n=325$, 57.2%)	0.15
Diabetes mellitus	38 ($n=166$, 22.9%)	33 ($n=185$, 17.8%)	71 ($n=351$, 20.2%)	0.24
Hypertension	133 ($n=166$, 80.1%)	138 ($n=185$, 74.6%)	271 ($n=351$, 77.2%)	0.23
Psychosocial parameters				
HADS-anxiety score	7.6 ± 4.4 ($n=146$)	7.6 ± 4.3 ($n=165$)	7.6 ± 4.3 ($n=311$)	0.97
HADS-depression score	6.9 ± 4.2 ($n=144$)	6.8 ± 4.1 ($n=165$)	6.8 ± 4.1 ($n=309$)	0.69
F-SozU: K 14	56.3 ± 28.7 ($n=156$)	53.4 ± 29.5 ($n=161$)	54.8 ± 29.1 ($n=317$)	0.37
F-SozU: NENUNT	12.7 ± 7.9 ($n=156$)	13.7 ± 7.9 ($n=156$)	13.2 ± 7.9 ($n=312$)	0.32
F-SozU: NENBEL	1.5 ± 1.8 ($n=156$)	1.7 ± 1.9 ($n=156$)	1.6 ± 1.9 ($n=312$)	0.47
SF-12: PCS	37.0 ± 6.9 ($n=144$)	37.6 ± 7.6 ($n=151$)	37.3 ± 7.2 ($n=295$)	0.49
SF-12: MCS	45.8 ± 11.6 ($n=144$)	44.5 ± 11.4 ($n=151$)	45.1 ± 11.5 ($n=295$)	0.35
Functional parameters				
NYHA class III/IV	12 ($n=164$, 7.3%)	12 ($n=180$, 6.7%)	24 ($n=344$, 7.0%)	0.91
Max. exercise capacity (W)	98.0 ± 48.2 ($n=159$)	99.0 ± 35.4 ($n=174$)	98.5 ± 41.9 ($n=333$)	0.87
6-min walking distance (m)	371.6 ± 89.6 ($n=142$)	380.7 ± 89.3 ($n=150$)	376.3 ± 89.4 ($n=292$)	0.39

Data are presented as mean ± standard deviation (SD) and as absolute values and percentages, respectively. P values were obtained from Student's t tests and Chi^2-tests of two-level random-intercept models, respectively

BMI body mass index, *CABG* coronary artery bypass graft, *CAD* coronary artery disease, *CRT* cardiac resynchronization therapy, *F-SozU* questionnaire on social support, *HADS* Hospital Anxiety and Depression Scale, *ICD* implantable cardioverter-defibrillator, *K 14* short form of the questionnaire on social support, *MCS* mental component summary in SF12, *MI* myocardial infarction, *NENBEL* mentions of stressful persons (Part B, F-SozU), *NENUNT* mentions of supportive persons (Part B, F-SozU), *NYHA* New York Heart Association, *PCI* percutaneous coronary intervention, *PCS* physical component summary in SF-12

persisting in 23% of the patients until the discharge from CR (Table 3). An elevated depression score was noted in 17% of patients at discharge from CR, although in both domains of the HADS, the average score was decreased during CR stay (anxiety 7.6 ± 4.3 points at admission vs. 6.6 ± 4.5 points on discharge; depression 6.8 ± 4.1 points at admission vs. 5.8 ± 4.4 points at discharge) without group differences in both variables.

Both the physical and mental subscales of SF-12 showed notable improvement over the course of CR, again without

Table 3 Psychosocial and functional parameters: changes during cardiac rehabilitation and values at discharge

Variables	Intervention ($n=167$)	Control ($n=187$)	Total ($n=354$)	P
Changes during CR				
HADS				
Anxiety level	−1.2 ± 2.9 ($n=117$)	−0.7 ± 3.2 ($n=133$)	−0.9 ± 3.1 ($n=250$)	0.19
Depression level	−1.4 ± 2.7 ($n=116$)	−1.0 ± 3.5 ($n=133$)	−1.2 ± 3.1 ($n=249$)	0.36
SF-12				
PCS	2.2 ± 7.9 ($n=128$)	2.1 ± 6.5 ($n=138$)	2.2 ± 7.2 ($n=266$)	0.88
MCS	3.3 ± 10.1 ($n=128$)	3.7 ± 10.0 ($n=138$)	3.5 ± 10.0 ($n=266$)	0.70
Values at CR discharge				
HADS				
Anxiety level	6.3 ± 4.6 ($n=126$)	6.9 ± 4.4 ($n=144$)	6.6 ± 4.5 ($n=270$)	0.31
Anxiety level > 10	30 ($n=126$; 23.8%)	32 ($n=144$; 22.2%)	62 ($n=270$; 23.0%)	0.76
Depression level	5.7 ± 4.1 ($n=126$)	5.9 ± 4.7 ($n=144$)	5.8 ± 4.4 ($n=270$)	0.76
Depression level > 10	17 ($n=126$; 13.5%)	28 ($n=144$; 19.4%)	45 ($n=270$; 16.7%)	0.21
SF-12				
PCS	39.5 ± 8.1 ($n=137$)	39.6 ± 7.2 ($n=145$)	39.5 ± 7.6 ($n=282$)	0.89
MCS	49.1 ± 11.4 ($n=137$)	48.2 ± 11.4 ($n=145$)	48.7 ± 11.4 ($n=282$)	0.54
Social support				
F-SozU K14	56.6 ± 30.5 ($n=149$)	56.6 ± 29.1 ($n=152$)	56.6 ± 29.7 ($n=301$)	0.98
F-SozU NENUNT	13.2 ± 7.4 ($n=147$)	14.0 ± 8.4 ($n=145$)	13.6 ± 7.9 ($n=292$)	0.48
F-SozU NENBEL	1.7 ± 2.3 ($n=147$)	1.8 ± 2.0 ($n=145$)	1.8 ± 2.2 ($n=292$)	0.93
Functional parameters				
Max. capacity (W)	118.8 ± 45.4 ($n=139$)	118.2 ± 49.6 ($n=150$)	118.5 ± 47.5 ($n=289$)	0.84
6-min walking distance (m)	471.8 ± 77.1 ($n=125$)	468.6 ± 91.1 ($n=135$)	470.1 ± 84.5 ($n=260$)	0.76

Data are presented as mean ± standard deviation (SD) and as absolute values and percentages, respectively. P values were obtained from Student's t tests and Chi^2-tests of two-level random-intercept models, respectively

CR cardiac rehabilitation, *F-SozU* questionnaire on social support, *HADS* Hospital Anxiety and Depression Scale, *K 14* short form of the questionnaire on social support, *MCS* mental component summary in SF12, *NENBEL* mentions of stressful persons, *NENUNT* mentions of supportive persons, *PCS* physical component summary in SF-12

statistically significant differences between groups. The intervention group achieved a discharge score of 39.5 ± 8.1 points on the PCS; the control group achieved a score of 39.6 ± 7.2 points on the PCS, and 49.1 ± 11.4 points versus 48.2 ± 11.4 points on the MCS. The index of social support reported by the study participants (F-SozU) already matched results in general population at admission to CR (Fydrich et al. 1999). Here once again, no group differences were demonstrated over time.

Follow-up and outcome measures

A total of 265 patients (88 clusters) responded to the follow-up survey 12 months after CR. Taking into account four deceased patients, the response rate was 76%. Multilevel analysis showed a greater chance of non-response for patients who were younger ($P=0.007$), had a lower educational level (< 10 years of school, $P=0.040$), were unemployed prior to the CR ($P=0.004$), had a lower sick leave prior to the cardiac event (< 3 months, $P=0.15$), NYHA Class III/IV ($P=0.007$), and who were smokers ($P=0.013$). However, no association could be demonstrated with the study intervention. There was no cluster effect as well: no training group had a collective tendency for non-response.

A total of 115 patients (43.7%) were employed 12 months after CR, with no significant differences between the intervention and the control group (IG 51 (42.1%) vs. CG 64 (45.1%), $P=0.829$). About 15% of patients in both groups had filed applications for occupational rehabilitation (e.g., non-medical offers to enable reintegration such as occupational retraining or education). A similar proportion was receiving sickness benefits, and one in ten was receiving disability pension benefits. About 23% of the patients had applied for disability pension benefits and/or were unfit for work (24%) or unemployed (25%) 1 year after discharge from CR. Overall, 40% of participants in both groups had experienced a change in their occupational situation.

The only significant differences between the two groups were related to health behavior. More participants in the intervention group showed persistent nicotine consumption than in the control group (IG 26.2% vs. CG 15.1%; $P=0.027$). In addition, the proportion of patients who

participated in a CR program phase III (heart sports group) was greater in the intervention group (IG 42.9% vs. CG 30.7%; $P = 0.044$). In both groups, 70% of participants reported physical activity of more than 90 min per week (Table 4).

In multivariable analysis, work resumption 1 year after discharge from CR was not influenced by the intensive social intervention (Fig. 2). Instead, it showed a negative association with pre-existing unemployment and high anxiety levels at the end of CR. Each of these variables was associated with a reduction of the likelihood of occupational reintegration by 80%.

With respect to the health-related quality of life, a higher WAI 3 months after CR and a higher performance on the bicycle ergometry at the end of CR were each associated with a significant improvement in somatic quality of life after 12 months, whereas a higher PCS and higher anxiety scores on HADS at discharge from the rehabilitation clinic had a clear negative impact (Fig. 3a). However, the study intervention had no effect on the change in physical and mental quality of life. Mental quality of life only had a negative association with higher MCS values at discharge and elevated anxiety scores (Fig. 3b).

No significant intraclass correlations were found between clusters, neither for work resumption nor for PCS nor MCS. This means that there are no indications in the data for outcome differences between training groups. Neither training groups of better nor of worse performance could be identified.

Discussion

The present study failed to demonstrate any effect of an extensive social intervention program on occupational reintegration or health-related quality of life 1 year after cardiac rehabilitation for patients with a negative occupational prognosis. High anxiety levels at discharge from CR proved to be a negative predictor for both outcome measures, while higher physical and mental quality of life were associated with a larger PCS decrease in the course after CR. The latter is suggestive of the regression to the mean phenomenon. It is conceivable that the achieved gains in quality of life made during CR are abraded by stressors and challenges in the patients' everyday life. However, it is a common effect that higher baseline values of a modifiable variable lead to lower outcome values due to the inferior potential of enhancement.

From clinical perspective, the majority of the study population had CAD and premature arteriosclerosis, with a burden of risk factors that included a high rate of smokers and diabetics, confirming results of large registries (Virtanen et al. 2013; Reibis et al. 2012). In addition, it is not surprising to find higher anxiety and depression levels in comparison to the general population (Breeman et al. 2015).

This constellation of psychosocial factors is incompatible with achieving behavioral change through an intervention time-limited to 3 weeks—regardless of intensity (Whooley et al. 2008; Parashar et al. 2006; Kuhl et al. 2009). In particular, high levels of anxiety are associated with a significantly lower rate of compliance with recommendations for reduction of cardiovascular risk factors during the early months after a myocardial infarction (Kuhl et al. 2009). Stopping smoking is a specific life style change that is not adequately achieved. Overall, our findings confirm the results of a previous qualitative analysis in which aspects of life style change were clearly of great relevance in a comparable patient population. However, environmental and personal obstacles were barriers to implementing such much-needed changes in life style (Schulz-Behrendt et al. 2017). As 70% of the interview statements in this study demonstrate, the patients focused predominantly on physical aspects, especially on improving their health status, to overcome their illness.

At the same time, it is evident that anxiety and depression are each negative predictors of occupational reintegration following a cardiac event (Söderberg et al. 2015; O'Neil et al. 2010). A recent study confirms the association between disease-specific workplace-related anxieties, unfavorable psychosocial working conditions and occupational reintegration (Söderberg et al. 2015). Although multimodal rehabilitation in Germany is built upon the bio–psycho–social model of the International Classification of Functioning, Disability and Health (ICF) (World Health Organization 2001), it seems that psychological factors, especially in a social or occupational context, are not being adequately addressed in CR. In the social therapy study intervention as well, it appears that psychological components did not receive sufficient attention.

Similarly, none of our interventions is adequate to address pre-existing unemployment. Both psychological stress and pre-existing unemployment would presumably require long-term multimodal counseling, although at least in relation to depression, positive effects on quality of life have been shown from short-term psychotherapy after myocardial infarction (Roncella et al. 2013).

The social therapy intervention was conducted in the setting of cardiac rehabilitation. The standardized CR program for patients in Germany after an acute cardiac event is characterized by its high therapeutic intensity. On average, 12 weekly training units plus 8 additional counseling sessions are conducted in just a 3-week period (Benzer et al. 2017). In addition, patients with coronary heart disease routinely undergo an extensive training program, including a series of medical lectures and interdisciplinary seminars designed to impart knowledge about medical principles, an adapted lifestyle, and therapeutic compliance (Meng et al. 2014). This

Table 4 Occupational parameters, health behavior and self-assessed health status at 3- and 12-month follow-up

Variables	Intervention ($n=141$)	Control ($n=155$)	Total ($n=296$)	P
Three-month follow-up				
Occupational parameters				
Employment	34 ($n=140$; 24.3%)	35 ($n=155$; 23.0%)	69 ($n=292$; 23.6%)	0.77
Current sick leave	79 ($n=140$; 56.4%)	81 ($n=151$; 53.6%)	160 ($n=291$; 55.0%)	0.71
Disability pension	5 ($n=139$; 3.6%)	11 ($n=151$; 7.3%)	16 ($n=290$; 5.5%)	0.17
Unemployment	39 ($n=139$; 28.1%)	40 ($n=150$; 26.7%)	79 ($n=289$; 27.3%)	0.72
Change in occupational situation	47 ($n=136$; 28.1%)	42 ($n=152$; 27.6%)	89 ($n=288$; 27.3%)	0.26
Psychosocial scores				
WAI				
F-SozU K14	53.7 ± 28.2 ($n=141$)	51.3 ± 28.9 ($n=153$)	52.5 ± 28.6 ($n=294$)	0.47
F-SozU NENUNT	13.1 ± 7.6 ($n=134$)	13.4 ± 8.0 ($n=150$)	13.3 ± 7.8 ($n=284$)	0.76
F-SozU NENBEL	1.7 ± 2.9 ($n=134$)	1.7 ± 2.0 ($n=150$)	1.7 ± 2.5 ($n=284$)	0.91
SF-12: PCS	40.2 ± 8.2 ($n=140$)	40.5 ± 7.9 ($n=151$)	40.4 ± 8.0 ($n=291$)	0.60
SF-12: MCS	48.6 ± 11.1 ($n=140$)	47.0 ± 11.3 ($n=151$)	47.8 ± 11.2 ($n=291$)	0.24
Health behavior				
Smoker	38 ($n=138$; 27.5%)	24 ($n=150$; 16.0%)	62 ($n=288$; 21.5%)	0.02
CR program phase III	72 ($n=137$; 52.6%)	66 ($n=149$; 44.3%)	138 ($n=286$; 48.3%)	0.18
Physical activity	107 ($n=137$; 78.1%)	118 ($n=148$; 79.7%)	225 ($n=285$; 78.9%)	0.33
Self-assessed health status				0.91
Better	63 ($n=138$; 45.7%)	69 ($n=151$; 45.7%)	132 ($n=298$; 45.7%)	
Worse	16 ($n=138$; 11.6%)	17 ($n=151$; 11.3%)	33 ($n=298$; 11.4%)	
Equally	59 ($n=138$; 42.8%)	65 ($n=151$; 43.0%)	124 ($n=298$; 42.9%)	
Variables	Intervention ($n=123$)	Control ($n=142$)	Total ($n=265$)	P
12-month follow-up				
Occupational parameters				
Employment	51 ($n=121$; 42.1%)	64 ($n=142$; 45.1%)	115 ($n=263$; 43.7%)	0.83
Current sick leave	24 ($n=119$; 20.2%)	39 ($n=142$; 27.5%)	63 ($n=261$; 24.1%)	0.18
Disability pension	13 ($n=120$; 10.8%)	14 ($n=141$; 9.9%)	27 ($n=261$; 10.3%)	0.88
Unemployment	34 ($n=121$; 28.1%)	32 ($n=141$; 22.7%)	66 ($n=262$; 25.2%)	0.34
Change in occupational situation	50 ($n=120$; 41.7%)	56 ($n=141$; 39.7%)	106 ($n=261$; 40.6%)	0.77
Psychosocial scores				
WAI	23.4 ± 10.4 ($n=114$)	24.8 ± 10.9 ($n=125$)	24.2 ± 10.7 ($n=239$)	0.31
F-SozU K14	52.8 ± 30.7 ($n=121$)	51.5 ± 30.1 ($n=141$)	52.1 ± 30.4 ($n=262$)	0.72
F-SozU NENUNT	12.4 ± 7.0 ($n=119$)	12.9 ± 7.8 ($n=137$)	12.7 ± 7.4 ($n=256$)	0.61
F-SozU NENBEL	1.5 ± 1.9 ($n=119$)	1.4 ± 2.0 ($n=137$)	1.4 ± 2.0 ($n=256$)	0.80
SF-12: PCS	41.6 ± 8.3 ($n=118$)	41.4 ± 9.4 ($n=141$)	41.4 ± 8.9 ($n=259$)	0.76
SF-12: MCS	46.8 ± 10.3 ($n=118$)	46.5 ± 11.4 ($n=141$)	46.6 ± 10.9 ($n=259$)	0.817
Health behavior				
Smoker	32 ($n=122$; 26.2%)	21 ($n=139$; 15.1%)	53 ($n=261$; 20.3%)	0.03
CR program phase III	51 ($n=119$; 42.9%)	43 ($n=140$; 30.7%)	94 ($n=259$; 36.3%)	0.04
Physical activity	80 ($n=114$; 70.2%)	92 ($n=132$; 69.7%)	172 ($n=246$; 69.9%)	0.94
Self-assessed health status				0.78
Better	52 ($n=120$; 43.3%)	62 ($n=142$; 43.7%)	114 ($n=262$; 43.5%)	
Worse	18 ($n=120$; 15.0%)	25 ($n=142$; 17.6%)	43 ($n=262$; 16.4%)	
Equally	50 ($n=120$; 41.7%)	55 ($n=142$; 38.7%)	105 ($n=262$; 40.1%)	

Data are presented as mean ± standard deviation (SD) and as absolute values and percentages, respectively. P values were obtained from Student's t tests and Chi^2-tests of two-level random-intercept models, r, respectively

CR cardiac rehabilitation, *F-SozU* questionnaire on social support, *MCS* mental component summary in SF12, *NENBEL* mentions of stressful persons, *NENUNT* mentions of supportive persons, *PCS* physical component summary in SF-12, *WAI* work ability index

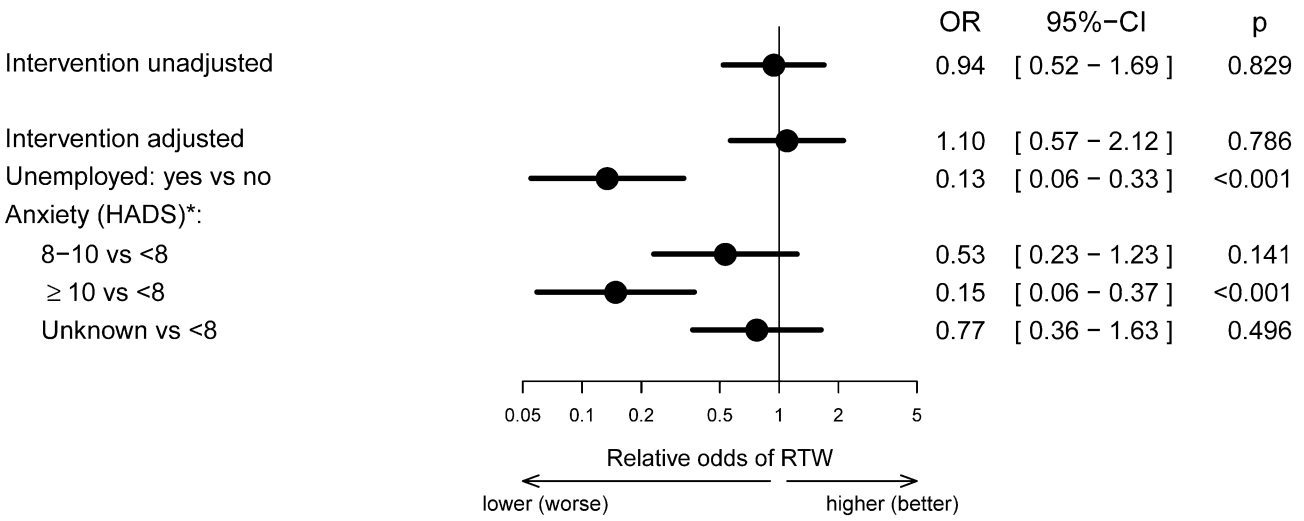

Fig. 2 Predictors of return to work at 12 months' follow-up ($n = 263$). *At discharge from cardiac rehabilitation; *CI* confidence interval, *HADS* Hospital Anxiety and Depression Scale, *OR* odds ratio, *RTW* return to work

CR-type may aptly be described as an intensive intervention. Given this intensity, 6 additional 1-h scheduled meetings with training units on social and occupational themes may strike the patients in the intervention group as being an excessive demand, all the more so given that over a third of coronary patients in rehabilitation facilities have diminished cognitive performance capacities (Salzwedel et al. 2017).

Limitations

Several limitations are to be considered in the present study. First, the study was underpowered to demonstrate small effects which might nevertheless be of relevance to the patients, or to differentiate between strata of similar work load or similar professional orientation. In particular, bigger studies are required for the important binary endpoint 'return to work'. A post hoc power analysis that used the observed effect on return to work resulted in a required sample size of 9–10,000 patients in 1500–1600 training groups to reach a power of 80%. Second, there was neither control for manifest psychiatric diagnoses nor did they constitute explicit exclusion criteria. Moreover, in the assessments of subjective well-being (e.g., HADS and SF-12), there was missing data in approx. 15–25% of the cases. In addition, there was no differentiation based on the severity of the myocardial infarctions that had occurred although it is a known predictor of RTW. The effects of the intervention may have been negatively affected by this. In addition, because of the planned weekly informational meetings for the study, we cannot exclude the possibility of some exchange among patients in different clusters on study-relevant themes. In addition, there was no documentation of the utilization by participants in the control group of individual social work counseling sessions.

Conclusion

An extended social therapy counseling and training program during cardiac rehabilitation after an acute coronary syndrome and/or CABG failed to improve the likelihood of occupational reintegration 1-year post-discharge and did not improve health-related quality of life, compared to patients receiving per-request individual counseling. Given the patients' severe psychosocial stress, we assume that patients may experience an overload of therapies and content in this early setting after index event. Further studies should determine the optimal quantity and structure of individualized medium-term psychosocial interventions that directly address the individual occupational situation. Hereby, a positively influenced work resumption or quality of life can be expected.

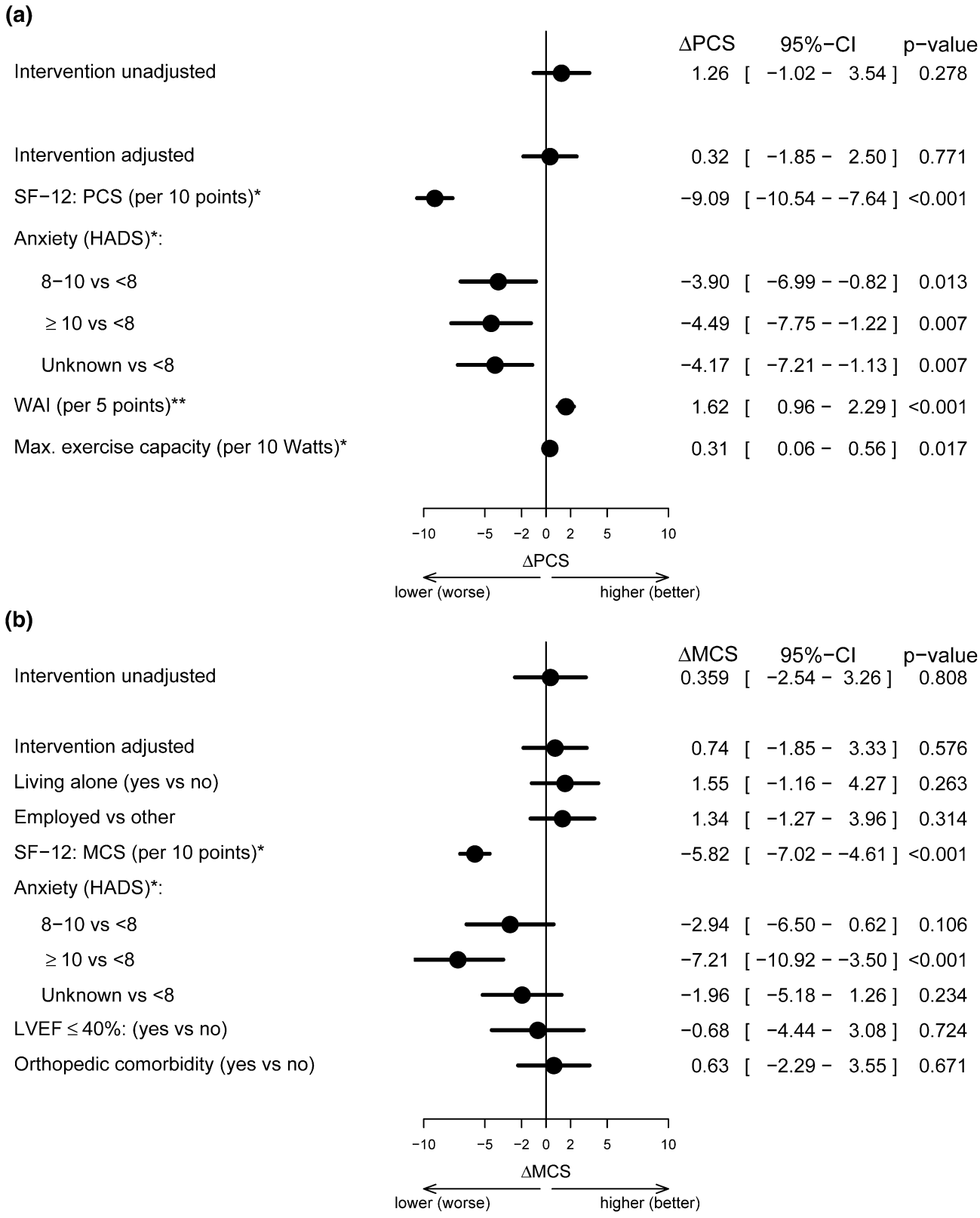

Fig. 3 Predictors of changes in quality of life between discharge from CR and 12 months' follow-up (unadjusted $n=216$, adjusted PCS $n=177$, MCS $n=215$). **a** PCS, physical component scale of the SF-12. **b** *MCS* mental component scale of the SF-12; *at discharge from cardiac rehabilitation, **at 3 months after discharge from cardiac rehabilitation; positive values (right side of *x*-axis) indicate an improvement of ΔPCS/ΔMCS; *CI* confidence interval, *HADS* Hospital Anxiety and Depression Scale, *LVEF* left ventricular ejection fraction, *OR* odds ratio, *WAI* work ability index

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All the procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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