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Published in:
Journal of Psychosomatic Research

Publication date:
2006

Document Version
Publisher's PDF, also known as Version of record

ELSEVIER

Journal of Psychosomatic Research 61 (2006) 1–7

Journal of Psychosomatic Research

Effects of a behavioural intervention on quality of life and related variables in angioplasty patients☆ Results of the EXhaustion Intervention Trial

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Received 13 January 2005; received in revised form 8 September 2005; accepted 20 December 2005

Abstract

Objectives: The EXhaustion Intervention Trial investigated the effect of a behavioural intervention programme on exhaustion, health-related quality of life (HRQL), depression, anxiety, hostility, and anginal complaints in angioplasty patients who felt exhausted after percutaneous coronary intervention (PCI). **Methods:** Seven hundred ten patients were randomized into an intervention group and a usual care control group. The group intervention focused on stressors leading to exhaustion and on support of recovery. HRQL (measured by the MacNew questionnaire), exhaustion [measured by the Maastricht Questionnaire and the Maastricht Interview Vital Exhaustion (MIVE)], anxiety (measured by the State-Trait Inventory), and depression (measured by the structured clinical interview for DSM-IV) were assessed at intake and at 6 and 18 months. Presence of anginal complaints was assessed at 18 months. **Results:** The intervention had a significant beneficial effect on all psychological factors except hostility and on the presence of anginal complaints. The effect of the intervention on exhaustion, as assessed by the MIVE, was modified by a previous history of coronary artery disease (CAD). Gender modified the effect of the intervention on exhaustion and on anxiety, the strongest effect being observed in women. **Conclusions:** The behavioural intervention improved HRQL and related psychological factors. Somatic comorbidity and a history of CAD limited the effect of the intervention.

Keywords: Anxiety; Coronary artery disease; Exhaustion; Depression; Intervention; Quality of life

Introduction

Percutaneous coronary intervention (PCI) constitutes a major achievement in interventional cardiology. However, many patients still feel very tired and easily irritated after PCI. This fatigue state has been labelled vital exhaustion (hereafter: exhaustion). Exhaustion not only has a negative impact on quality of life [1] but also increases the risk of a new coronary event after PCI [2–4].

The EXhaustion Intervention Trial (EXIT) tested the effect of a behavioural intervention on the risk of a new coronary event and on psychological factors in PCI patients who felt exhausted after successful PCI. The effect of the intervention on the risk of a new coronary event has been

☆ The study was supported by the Netherlands Heart Foundation and by The Netherlands Organization for Health Research and Development.

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0022-3999/06/$ – see front matter © 2006 Elsevier Inc. All rights reserved.
doi:10.1016/j.jpsychores.2005.12.008

described elsewhere [5]. This paper reports on the effect of the intervention on health-related quality of life (HRQL), exhaustion, depression, anxiety, and anginal complaints. We hypothesized that the intervention would lead to an improvement in quality of life, and a reduction in symptoms of exhaustion, depression, anxiety, and angina.

Methods

A detailed description of the design of the study has been presented elsewhere [5]. Therefore, the description of the methods is limited to the key characteristics of the study.

Patient selection and randomization

The study was carried out in the university hospitals of Maastricht, Rotterdam, Nijmegen, and in the Catharina Hospital in Eindhoven. Participants were consecutive patients aged 35–68 years, who felt exhausted after successful treatment with PCI. A two-stage procedure was used to ascertain exhaustion. Two weeks after PCI, patients were asked to complete the Maastricht Questionnaire (MQ) [6]. Two items asking for increased irritability were added to the scale. A MQ score of $\geq$14 was used to select patients for the next stage, which consisted of an interview-based assessment of exhaustion. This interview, the Maastricht Interview for Vital Exhaustion (MIVE), consisted of 23 questions [7]. The inclusion criterion for exhaustion was defined on the basis of $\geq$7 positive responses during the interview. Major exclusion criteria were (1) severe somatic or mental comorbidity (e.g., kidney insufficiency or a history of major depression of 3 years or longer); (2) somatization disorder, fibromyalgia, or chronic fatigue; and 3) unsuccessful treatment for a recent depression or panic disorder. A treatment-masked adjudication committee evaluated possible incorrect inclusions.

Once a block of 12 qualifying patients was formed, participants were individually randomized to the intervention group or the usual care control group by a computerized random-number generator. In case less than 12 qualifying patients could be selected within 6 weeks, the computer allocated six patients to the intervention group and the remaining patients to the control group to prevent unwanted delays. All participants gave written informed consent.

Treatment

The aim of the treatment was to reduce exhaustion by improving coping with stressors leading to exhaustion and to support recovery by promoting rest and making rest more efficient. Group discussions were used to identify stressors in the family and work domain and to assist patients in coping with these stressors. Recovery was promoted by discussing the minimum and maximum length of resting time, by doing relaxation exercises designed to make rest more efficient [8], by stimulating physical exercise, and by assigning homework. If, for example, two or more patients felt very tired at noon but were reluctant to slow down, these patients were invited to form a "siesta group" and to phone each other at night to discuss whether or not they had taken a nap.

Group discussions were used as the main basis of the EXIT intervention to ensure an optimal match between the needs and demands of the patients and the content of the programme. Counselors acted mainly as facilitators of the group discussions. The programme included treatment for hostility because aggressive coping with stressors belongs to the causes of exhaustion. We used methods developed by Williams and Williams [9] and by Powell [10]. All groups were offered the possibility to meet with a cardiologist, dietician, and a health educator if they wanted to have more information about medical aspects, nutrition, and smoking cessation. These specialists did not lecture but answered questions prepared by the patients. If a patient suffered from major depression and no improvement was observed during the intervention, the patient was suggested to consult the family physician. No individual treatment modalities were used outside the group meetings.

The groups comprised six patients. Partners were encouraged to attend the meetings. Sessions lasted 2 h. As a rule, the meetings started by group discussions and ended by doing one or two relaxation exercises. Counsellors were allowed to skip the relaxation exercises if the patients did not want to stop a discussion. Groups met weekly during the first 10 weeks and once a month during the following 4 months. Usual care consisted of the care regularly given in the four centres. It included routine checkups in all centres and referral to a physical cardiac rehabilitation programme in one centre (Rotterdam).

Assessments

At baseline, data on demographics, medical history, and current medication were recorded. Somatic comorbidity was registered by asking the patients if they had visited a medical specialist in the year prior to PCI and, if so, for what reason. Comorbidity was classified in three categories: diseases meeting the exclusion criteria, chronic painful conditions causing unusual tiredness (e.g., rheumatism) not resulting in exclusion from the trial, and no comorbidity. Quality of life was assessed by the self-administered MacNew Heart Disease Heath-Related Quality of Life Questionnaire, translated by the second author. This questionnaire consists of 24 items that are answered on a 7-point Likert scale, where "1" indicates poor HRQL and "7" indicates good HRQL [11]. Major depression and somatization disorders were assessed according to *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition* criteria by the SCID. Anxiety was assessed by the State-Trait Anxiety Inventory [12]. Hostility was assessed by the State-Trait Anger Scale [13]. Information about previous

cardiac events, indication for PCI, and degree and location of stenoses before and after PCI was obtained from the medical records.

Assessments at 6 months included HRQL, anxiety, and exhaustion (via the MQ). Assessments at 18 months included HRQL, exhaustion (via the MIVE and via the MQ), anxiety, depression, hostility, and the presence of anginal complaints assessed by the London School of Hygiene interview [14]. Because its validity to assess angina pectoris by noncardiologists is debated, the interview was not used to diagnose angina but to identify those who were free from anginal complaints. Patients were considered free from anginal complaints if the following questions were answered negatively: "Have you ever had any pain or discomfort in your chest during last two weeks?", " Have you ever had a pressing or heavy feeling in your chest during last two weeks?", and "Have you ever had a severe pain across the front of your chest during last two weeks?"

Statistical analyses

Univariate *t* tests were performed to identify variables which were associated with one or more of the psychological outcome variables. The effect of the intervention on HRQL, exhaustion, and anxiety was determined by analysis of variance for repeated measures. The effect of the intervention on major depression and anginal complaints was analysed by logistic regression analysis. Age, gender, history of coronary artery disease (CAD), and comorbidity were included as possible effect modifiers on an a priori basis in all main analyses. History of CAD and comorbidity were included as possible effect modifiers in the main analyses because these factors had previously been found to modify the effect of the intervention on cardiac outcomes [5].

Because the randomisation was not successful with regard to HRQL (the mean HRQL scores being lower in the intervention group), the analysis of the effect of the intervention was repeated by regression analyses that included the baseline values of HRQL to control the effect of the intervention on HRQL at 6 and at 18 months for the difference in initial values.

All treatment group comparisons were based on intention-to-treat approach principles. All patients allocated to the intervention group were included in the analyses, irrespective of their compliance. Missing values at 6 and 18 months were replaced by the last observed value. All tests were two-tailed.

Results

Composition of the study population

A total of 4159 patients were approached. Of those who returned the questionnaire, 2258 patients (63%) had a score ≥14. All were invited for an interview, and 1254 (56%) were accepted. "No interest" and "feeling too ill" were the main reasons for refusal. The mean time interval between PCI and the intake interview was 37 days (S.D., 19.3). Of those interviewed, 298 patients were excluded because they did not feel exhausted, 84 patients because of comorbidity, and 62 patients for other reasons; 83 patients did not want to participate. The mean time between the interview and the start of the intervention was 29 days (S.D., 21.4).

After completion of the intervention a list of 19 possible false inclusions was presented to the adjudication committee. The committee accepted the exclusion of 17 patients. Main reasons for exclusion were missing informed consent, comorbidity meeting the exclusion criteria, age <35 years, scheduled for a new coronary intervention before intake, and attending physician disallowed participation. Thus, 710 patients were included in the study (Table 1). The slightly larger number of patients included in the intervention group (366 vs. 344) is caused by the policy to avoid unwanted delays when starting a new intervention group.

Baseline demographic and clinical characteristics of the trial groups are shown in Table 2. The groups were balanced in terms of all medical, demographic, and psychological characteristics except gender and HRQL. Relatively, more women were included in the control group. Therefore, gender was included in all multivariate analyses. At intake, the mean HRQL score in the intervention group was significantly lower than the mean score in the control group (t=2.27; P=.02).

Treatment effects on HRQL

No assessment of HRQL was made in 43 subjects. HRQL was not associated with gender and age. Those with a previous history of CAD had lower HRQL at baseline, at 6 months, and at 18 months (t=2.53, P=.01; t=2.84, P=.01; t=2.43, P=.02, respectively). Comorbidity was not associated with HRQL at entry but strongly associated with HRQL at 6 and at 18 months of follow up (t=1.36, P=.18; t=2.76; P=.006, and t=3.76; P=.000, respectively).

Because the intervention group had lower HRQL scores at entry than the control group, separate analyses were made of the effect of the intervention on HRQL at 6 and 18 months, controlling for HRQL at baseline, age, gender, comorbidity, and history of CAD. Results of the linear regression analyses showed that the intervention had no effect on HRQL at 6 months but improved HRQL at 18 months significantly (t=1.96; P=.05). Although significant, the effect size was modest (Cohen's d=.21).

Treatment effects on exhaustion as assessed by the MIVE

Baseline information was available for all patients. Follow-up data at 18 months were available for 635 patients (89%). MIVE scores at entry were negatively associated with age (r=−.08; P=.05). The mean MIVE scores of women were significantly higher than the mean MIVE

Table 1
Flow chart of patient selection

Approached	4159	
No questionnaire received		575
Not exhausted according to MQ		1326
Invited for interview	2258	
No interest		358
Too Ill, travel distance, or other reasons		646
Interviewed	1254	
Excluded		
Not exhausted		298
Comorbidity		84
Refusal		83
Other reasons		62
Included	727	

	Intervention	Usual care
Lost to follow-up	0	0
Incorrect inclusion	10	7
In main analysis	366	344

scores of men, the mean scores being 13.8 (S.D., 4.0) and 12.8 (S.D., 4.0), respectively (t=2.66; P=.02). Those suffering from somatic comorbidity had significantly higher MIVE scores at entry and at 18 months. The mean exhaustion scores at entry were 14.3 (S.D., 4.5) and 12.9 (S.D., 3.9), respectively (t=2.79; P=.01). Mean exhaustion scores at 18 months were 10.9 (S.D., 6.9) and 7.8 (S.D., 5.9), respectively (t=3.97; P=.00). Patients with a previous history of CAD felt more exhausted at entry than patients in whom the index-PCI was the first coronary event they experienced. Mean values at entry were 13.5 (S.D. 4.2) and 12.8 (S.D. 3.9), respectively (t=2.39; P=.02). A previous history of CAD was not significantly associated with exhaustion assessed at 18 months (Table 3).

A previous history of CAD modified the effect of the intervention (F=3.81; P=.05). The intervention contributed significantly to the decline of exhaustion in those without a previous history of CAD but not in those who had experienced one or more coronary events before the index PCI (Table 4). Although significant, the effect size was moderate (Cohen's d=.40).

Treatment effects on exhaustion assessed by the MQ

Baseline information of MQ scores was available for all patients. Six-months of follow-up data were available for 649 patients (91%) and 18 months for 642 patients (90%). Baseline MQ scores were not associated with age (r=−.03; P=.45). The mean of MQ scores at baseline was significantly higher in women than in men [(30.2; S.D., 8.6 and 28.7; S.D., 7.4, respectively (t=1.99; P=.05)]. Those suffering from comorbidity had higher MQ scores at baseline, 6 months, and 18 months, the t values being 2.85, P=.00; 2.45, P=.02 and 3.72, P<.00, respectively.

A previous history of CAD was positively associated with higher MQ scores at baseline and at 6 months but not at 18 months, the t values being 3.19, P=.00; 1.95, P=.05; and .20, P=.84, respectively. Gender modified the effect on exhaustion (F=3.26; P=.04). The effect of the intervention was not significant in men but highly significant in women (F=6.75; P<.00). Female patients in the intervention group showed a continuous decrease in exhaustion, whereas female patients in the control condition showed a decrease between baseline and 6 months but an increase in exhaustion between 6 and 18 months. Although significant, the effect size was modest (Cohen's d=.23).

Treatment effect on depression

Baseline information on major depression was available for all patients and at 18-month follow-up of 640 (90%)

Table 2
Medical, demographic, and psychological characteristics on admission by treatment

		Intervention (n=366)		Usual care (n=344)	
Characteristics		n	%	n	%
Indications for PCI	Stable angina	43	12	50	15
	Unstable angina	221	60	187	54
	MI	62	17	63	18
	Post-MI angina	31	8	41	12
	Other reasons	9	3	3	1
Previous	MI	98	27	105	30
	CABG	32	9	32	9
	PCI	76	21	72	21
Significant stenosis in coronary artery after PCI	0	201	55	183	53
	1	99	27	94	27
	2	47	13	46	13
	4	19	5	21	6
Stent implanted		272	74	244	71
Diabetes		50	14	43	13
Smoking	Current	76	21	78	22
	Stopped	252	69	223	65
	Never	38	10	43	43
Major depression		58	16	43	13
Chronic painful condition		49	13	36	11
Medication after PCI	Aspirin	354	97	325	95
	Statin	272	74	256	74
	Beta-blocker	271	74	241	70
	Nitrate	205	56	189	55
	Calcium antagonist	139	38	129	37
	ACE inhibitor	76	21	80	23
	Diuretics	39	11	51	15
	Antidepressants	18	5	22	6
Gender (male)		294	80	256	74
		Mean	S.D.	Mean	S.D.
Body mass index		27.2	4.1	27.3	4.1
Age		53.6	7.2	53.1	7.4
Intake	Exhaustion (MIVE)	13.1	4.1	13.0	4.0
	Exhaustion (MQ)	28.9	7.8	29.2	7.6
	HRQL	110.6	22.8	114.5	21.6
	Trait anxiety	46.7	11.4	45.3	10.4

MI, myocardial infarction; CABG, coronary artery bypass graft; ACE, angiotensin-converting enzyme.

patients. At intake, 58 patients (16%) of the intervention group and 43 patients (12%) of the control group were depressed (χ^2=1.63; *P*=.20). Depression at intake was not associated with age, gender, and a history of CAD. Compared to patients without comorbidity, patients suffering from comorbidity were more often depressed (χ^2=5.28; *P*=.02).

At 18 months, 21 patients (6%) in the intervention group and 29 patients (8%) in the control group were depressed (χ^2=1.96; *df* =1; *P*=.16). Those suffering from comorbidity tended to be more depressed (χ^2=3.19; *P*=.07). Patients with a positive history of CAD were more often depressed at 18 months than patients without previous cardiac events (χ^2=3.94; *P*=.05). No effect modification was observed. The intervention reduced the odds of being depressed at 18 months by 51%, controlling for age, gender, comorbidity, history of CAD, and depression at intake (OR=0.49; 95% CI, 0.26–0.95; *P*=.03). Additional analysis controlling for use of antidepressive medication at intake yielded essentially the same result.

Treatment effect on anxiety and hostility

Baseline data on trait anxiety were available for 657 (93%) patients. Follow-up data at 6 and 18 months were available for 642 (90%) and 638 (90%) patients, respectively. Anxiety was not correlated with age. No significant difference in trait anxiety between men and women was observed at any point in time. Anxiety was not associated with comorbidity at baseline but tended to be positively associated with comorbidity at 6 months and was significantly associated with comorbidity at 18 months, the *t* values being 0.56, *P*=.58; 1.50, *P*=.13, and 2.01; *P*=.05, respectively. History of CAD was not associated with anxiety at any point in time.

Results of the analysis of variance showed that the effect of the intervention was modified by gender (*F*=2.82; *P*=.06). Although this interaction just failed to be statistically significant, it suggests a possible meaningful effect modification. Therefore, the analyses were repeated for each gender separately. Results indicated that the intervention had no effect on anxiety in males (*F*=.99; *P*=.37) but reduced anxiety significantly in women (*F*=5.55; *P*=.01). Although significant, the effect size was modest (Cohen's *d*=.30).

Table 3
Mean Exhaustion (MIVE) scores in the intervention and usual care group in those with or without a previous history of CAD

	Intervention		Usual care			
	Mean	S.D.	Mean	S.D.	F	*P*
No history of CAD	*n*=227		*n*=194			
Entrance	12.8	3.9	12.7	3.9	14.54	.00
Follow-up	7.1	5.9	9.0	6.1		
History of CAD	*n*=139		*n*=150			
Entrance	13.6	4.4	13.4	4.0	0.50	.48
Follow-up	8.4	6.4	8.5	6.2		

Table 4
Effect of the intervention in HRQL

		Baseline		6 months		18 months	
	N	Mean	S.D.	Mean	S.D.	Mean	S.D.
No comorbidity							
Intervention	350	110.6	22.8	125.4	26.7	128.3	27.2
Control	317	114.5	21.6	126.5	23.8	127.5	25.7
F=3.89; *df*=2; *P*=.02							
Comorbidity							
Intervention	43	104.3	20.7	119.6	22.7	115.2	26.9
Control	29	116.1	20.8	119.6	21.2	123.4	27.2
F=2.99; *df* =2; *P*=.06							

The intervention did not result in a significant decrease of hostility scores (*F*=2.40; *P*=.12).

Treatment effect on anginal complaints

At 18 months, 334 patients of the intervention group and 307 patients of the control group completed the London School of Hygiene questionnaire to assess angina pectoris. In the intervention group, 164 patients (49%) and 130 patients of the control group (42%) were free from anginal complaints (χ^2=3.07; *P*=.08). History of CAD, age, and gender were not significantly associated with the presence of anginal complaints. Comorbidity was significantly associated with the presence of anginal complaints (χ^2=8.23; *P*=.01). No effect modification was observed. The intervention reduced the odds of anginal complaints by 28%, controlling for age, gender and comorbidity (OR=0.72; 95% CI, 0.53–0.99; *P*=.04).

A total of 298 (81%) patients attended at least nine meetings. Thirty-eight patients (10%) attended fewer than three meetings. Rehospitalization and feeling ill were the main reasons for noncompliance. Compliance was not significantly associated with the effect of the intervention on HRQL, exhaustion, depression, anxiety, and the presence of anginal complaints at 18 months. There did not appear to be any significant difference in the effect of the intervention on HRQL, exhaustion, anxiety, and the presence of anginal complaints at 18 months between centres.

Discussion

The behavioural treatment offered to PCI patients who felt exhausted after successful PCI improved HRQL in the long run, reduced feelings of exhaustion in patients without previous CAD, reduced the odds of being depressed after 18 months, and increased the odds of being free of anginal complaints after 18 months. The intervention reduced anxiety in women both in the short and the long run. However, the effect sizes were modest.

Several factors that limited the effect of the intervention could be identified. First, comorbidity, affecting 12% of the patients, limited the effect of the intervention. Comorbidity

was associated with HRQL, exhaustion, anxiety at 18 months, depression, and the presence of anginal complaints. Most patients classified as suffering from comorbidity suffered from rheumatism of hard or soft tissue. The presence of these conditions restricts the improvement which can be achieved by the intervention used in this study.

Second, "History of CAD" limited the effect of the intervention on exhaustion as assessed by the MIVE. The intervention reduced exhaustion in those without a previous history of CAD but had no effect on exhaustion in those with a previous history of CAD. Exploratory analyses suggest that the lack of effect occurred mainly in those with a long-lasting history of CAD. Sixty-nine patients (10%) had experienced two or more cardiac events before the index PCI. This group was characterized by a higher prevalence of a poor left ventricular ejection fraction (χ^2=3.43; P=.06). This subgroup was not only more exhausted at entry; they also had felt exhausted during a longer period of time. Thirty-five percent of those without a cardiac event before PCI or with a single event had felt exhausted for more than 1 year before PCI. Forty-eight percent of those with two or more cardiac events had felt exhausted for more than one year (χ^2=4.16; P=.04). Changes in mean exhaustion scores were significantly lower in those who had felt exhausted for more than one year. Therefore, it is not unlikely that the effect modification by "history of CAD" has to be partially attributed to the presence of a subgroup with a serious and long-lasting history of CAD.

The effect of the intervention may also have been limited by the fact that exhausted patients only were invited to participate in the study. Exhaustion is strongly correlated with HRQL. At 18 months, HRQL correlated −0.71 with exhaustion as assessed by the MIVE and −0.81 with exhaustion as assessed by the MQ. Changes in HRQL correlated strongly with changes in exhaustion scores (r=.56; P=.00), suggesting that exhaustion is a major determinant of HRQL. Exhaustion was found to be rather stable over time. Fifty-four percent of the patients in the control group (which reflects the natural course of the disease) still felt exhausted at 18 months. This high stability is suggestive of irreversible neurohormonal and/or behavioural changes. It still has to be determined why exhaustion is so stable over time. However, it is safe to assume that the determinants of the stability of exhaustion also belong to the major determinants of HRQL. Intervention programmes, which also include nonexhausted patients, may obtain stronger effects on HRQL than those reported above.

Gender was found to modify the effect of the intervention on exhaustion (as assessed by the MQ) and on anxiety. The strongest effect was observed in women. Although the interaction between intervention and gender just failed to be statistically significant, the data are suggestive of a real effect of modification, especially because this observation corresponds with observations made by O'Farrel et al. [15] and by Toobert et al. [16]. We speculate that the difference in the effect of the intervention on exhaustion, as assessed by the MQ, and on anxiety is associated with differences in inhibition or differences in the ability to open up because the treatment relied strongly on group discussions.

The intervention reduced the odds of depression significantly. The significant effect on major depression is remarkable because treatment of depression did not form part of the intervention. Patients who remained depressed were advised to contact their general practitioner. How many patients followed this advice and, if they did, what kind of treatment was given by the general practitioner is unknown. We speculate that the support given by the group discussions, especially, contributed to the decline of depression in the intervention group.

Caution is needed in interpreting the data on anginal complaints because no assessment of anginal complaints was made at baseline. It cannot be ruled out that the difference between the intervention group and the control group observed at 18 months is fully or partly due to differences at baseline. Therefore, the data suggest but do not prove that the intervention had a beneficial effect on anginal complaints.

Because aggressive coping belongs to the causes of exhaustion, treatment of hostility was part of the programme. Changes in hostility were found to correlate positively with changes in exhaustion (r=.26; P=.00). However, the intervention did not result in a significant decrease of hostility scores. Strengthening this part of the intervention may enlarge the effect of the intervention on HRQL and exhaustion.

The four participating centres perform about 80% of all angioplasties in the southern half of The Netherlands. Although one centre (Rotterdam) referred all patients to a physical rehabilitation programme, no significant differences in any of the outcome variables were observed between centres. Therefore, it is unlikely that the internal validity was limited by the fact that the participants were referred to a physical rehabilitation programme in one centre. The results of the EXIT study can be generalized to all Dutch cardiologic centres. The same observation makes it also less likely that the modesty of the effect sizes of the intervention is caused by the absence of physical training as part of the program. However, the external validity of the EXIT study decreases over time because of the rapid improvement of cardiologic intervention techniques.

The EXIT study demonstrated that intervening on exhaustion improves HRQL, exhaustion, anxiety, and depression. However, the magnitude of the effect was modest. Forty-eight percent of all patients had either a positive history of CAD or suffered from a chronic painful disorder. Thus, half of all patients suffered from a somatic condition, which limits the effect of a behavioural intervention, as used in this study on HRQL and other psychological characteristics. These limiting factors have to be taken into account when evaluating the effects cardiac rehabilitation has on the mental state of PCI patients.

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