

Inpatient psychotherapeutic treatment for cardiac patients with depression in Germany: short term results

Stationäre psychotherapeutische Behandlung von KHK-Patienten mit komorbiden depressiven Störungen in Deutschland: Ergebnisse zur kurzfristigen Wirksamkeit

Abstract

The purpose of the PROTeCD (Psychotherapeutic Resource-Orientated Treatment for Cardiac Patients with Depression)-study was to develop and to evaluate a brief psychotherapeutic intervention for rehabilitation in-patients with coronary heart disease (CHD) and depressive disorders. In three cardiac rehabilitation hospitals all patients were screened for mental distress at admission. Patients generally stay for 3 to 4 weeks before being referred to outpatient care.

Method: Those patients with elevated distress were interviewed for mental disorders and took part in the baseline-assessment. Patients diagnosed with a depressive disorder at baseline were randomised into the intervention or the usual care group. Efficacy was assessed at discharge from hospital (short-term). 59 subjects with CHD and co-morbid depressive disorder were randomised into the trial - 27 into the intervention group (IG) and 32 into the usual care group (UC). Patients in the intervention group received 4 to 6 individual psychotherapeutic sessions of 50 minutes each, including patient education and cognitive-behavioural treatment of depression. Outcome measures were depressive and anxiety symptoms in self report and interview.

Results: There was no significant difference between intervention and usual care group in this short-term reduction of depressive symptoms, mental distress and anxiety. However, at discharge the patients still suffer from an increased level of distress compared to the recommended cut off scores of the assessment scales.

Conclusion: Multimodal inpatient rehabilitation reduces depressive and anxiety symptoms in depressed CHD patients in short term independently of an additional psychotherapeutic intervention.

Keywords: coronary heart disease, depression, brief psychotherapy, inpatient rehabilitation, screening

Zusammenfassung

Das Anliegen der PROTeCD (Psychotherapeutic Resource-Orientated Treatment for Cardiac Patients with Depression)-Studie bestand darin, eine psychotherapeutische Kurzzeitintervention für stationäre Rehabilitationspatienten mit koronarer Herzkrankheit (KHK) und depressiven Störungen zu entwickeln und in ihrer Wirksamkeit zu evaluieren.

Methode: In drei kardiologischen Rehabilitationskliniken wurden alle KHK-Patienten zu Beginn ihres 3- bis 4-wöchigen stationären Aufenthaltes in einem Screening zu ihrer psychischen Belastung befragt. Patienten mit einer erhöhten psychischen Belastung nahmen an einem klinischen Interview und der Basisuntersuchung teil. Für diejenigen Patienten mit einer diagnostizierten depressiven Störung erfolgte eine randomisierte Zuweisung zur Experimentalgruppe, die die zusätzliche psychotherapeutische Kurzzeitintervention erhielt, oder zur Kontrollgruppe, die die Standardbehandlung der jeweiligen Klinik erhielt. Zum Zeitpunkt der

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Entlassung der Patienten aus der Klinik wurde die kurzfristige Wirksamkeit der Intervention untersucht. N=59 KHK-Patienten mit komorbiden depressiven Störungen wurden randomisiert - 27 in die Experimentalgruppe und 32 in die Kontrollgruppe. In 4 bis 6 psychotherapeutischen Sitzungen von jeweils 50 Minuten Dauer erhielten Patienten der Experimentalgruppe u.a. Patientenedukation und eine kognitiv-verhaltenstherapeutische Behandlung für Depression. Maße zur Bewertung der Wirksamkeit der psychotherapeutischen Intervention waren Veränderungen in der depressiven und ängstlichen Symptomatik in Selbst- und Fremdbeurteilungsverfahren.

Ergebnisse: Sowohl in der Experimental- als auch in der Kontrollgruppe kam es zu einer Reduktion in der depressiven und ängstlichen Symptomatik im Kurzzeitintervall. Für diese Reduktion fand sich kein signifikanter Unterschied zwischen Experimental- und Kontrollgruppe. Allerdings zeigen die Patienten zum Zeitpunkt der Entlassung weiterhin eine erhöhte Symptomatik im Vergleich zu empfohlenen Cutoff-Werten der eingesetzten Erhebungsinstrumente.

Schlussfolgerung: Unabhängig von einer zusätzlichen psychotherapeutischen Intervention führt die multimodale stationäre Rehabilitation im Kurzzeitintervall zu einer Reduktion psychischer Belastung und depressiver Symptomatik bei KHK-Patienten mit komorbiden depressiven Störungen.

Schlüsselwörter: koronare Herzkrankheit, Depression, Kurzzeitpsychotherapie, stationäre Rehabilitation, Screening

Introduction

During the last years the interaction between depression and cardiac complaints (chest pain, cardiac arrhythmia, and coronary heart disease) has received increased attention (for a review see [1]). Two meta-analyses found an increased risk for developing coronary heart disease (CHD) in physically healthy people with pre-morbid depression [2], [3]. The Odds ratio (OR) was 1.5 (CI (confidence interval): 1.2-1.9) for subjects with depressive symptoms and - after controlling for confounders - 2.7 (CI: 1.6-4.4) for subjects with major depression. Psychiatric disorders are also common in rehabilitation patients [4]. CHD-patients in Germany showed a prevalence of 10% for affective disorders [5]. This is particularly of concern because co-morbid mental disorders have a negative effect on mortality. Compared to CHD-patients having no co-morbid depressive disorder the mortality rate among depressed CHD-patients is two times higher during the following two years after the cardiac event [6].

Psychopharmacological treatment of depression in CHD-patients with selective serotonin reuptake inhibitors (SSRI), especially sertraline, has been shown to be safe and effective [7]. The efficacy of psychotherapeutic treatment, i.e. cognitive behaviour therapy, has been investigated by the ENRICH-study [8]. In a sample of 1343 patients with myocardial infarction and co-morbid depression patients in the intervention group profited more with respect to depressive symptoms than control group patients [9]. However the results of this trial showed no increase in event-free survival in the intervention group

compared to the usual care group. A Canadian working group showed comparable clinical efficacy on depressive symptoms by treating depressed CHD patients with Interpersonal Psychotherapy in an open-label study [10]. The latter results still have to be consolidated in a randomised controlled trial.

Objective and methodology

The present study has the objective to assess the efficacy of an individualized psychotherapeutic or - if indicated - combined psychotherapeutic and psychopharmacological treatment in patients with CHD and depressive disorders. Efficacy of the treatment was assessed by self-report measures (Beck Depression Inventory, BDI [11]; Hospital Anxiety and Depression Scale, HADS [12]) and blinded interviewers (Bech Rafaelsen Melancholia Scale, BRMS [13]).

The study was conducted in three cardiac rehabilitation hospitals in Germany from 23.09.2002 until 31.12.2004. All cardiac patients who agreed to take part in psychological assessment were initially screened for psychological distress, using the HADS. Written informed consent was obtained from all participants prior to the participation in the study. All CHD-patients with a total HADS-score of 17 or higher were interviewed with the Structured Clinical Interview for DSM IV [14]. Patients diagnosed with a unipolar affective disorder, i.e. major depression, dysthymia or with a depressive adjustment disorder, were randomized by closed envelopes into intervention group (IG) or usual care group (UC). UC-patients received standard treatment of the rehabilitation hospitals which consisted

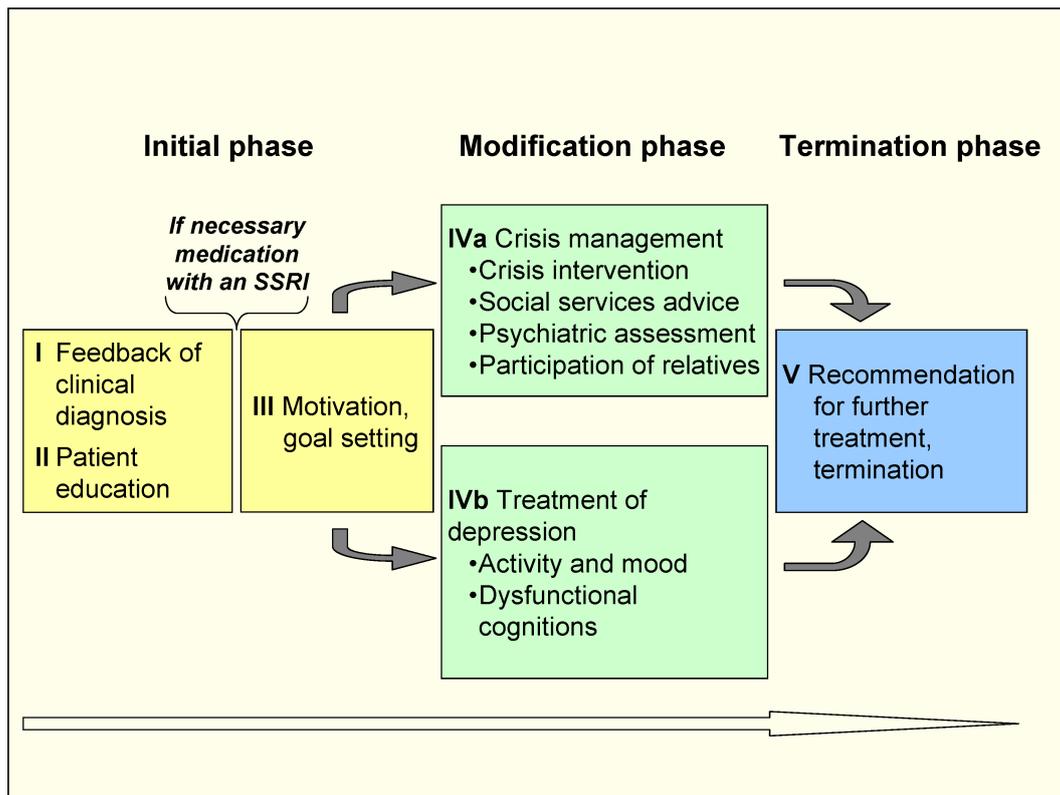


Figure 1: Phases and steps in the treatment of the study patients (intervention group)

of exercise, diet counseling, relaxation and health behaviour education. Participants of the intervention group additionally received the PROTeCD (Psychotherapeutic Resource-Orientated Treatment for Cardiac Patients with Depression)-treatment, which was set up for study purposes. Depressive symptoms and anxiety were assessed before randomisation and at discharge from the rehabilitation hospital, which was approximately three weeks after admission. Ethical approval for the study was given by the local ethics committee of the University Hospital of Freiburg. Data were analysed by SPSS 11.0 using ANCOVAs with baseline data as covariate. The resulting F-value showed the interaction effect between study group and outcome. Missing values in scales were replaced if less than 30% of data were missing by the missing data tool of SPSS, using the remaining items to predict missing values. Missing persons were not replaced by any statistical procedure because of low number of predictors for imputation procedure. Analysis was done by intention to treat. Effect sizes were computed by using the standard deviation at baseline.

Intervention

The intervention consisted of a brief additional psychotherapeutic treatment which was developed for study purposes and delivered to patients with adjustment disorders, dysthymia or mild or moderate depression as primary intervention strategy. Patients with severe depression were treated with a combination of psychotherapeut-

ic and psychopharmacological (sertraline) measures. An overview of the intervention strategies is shown in Figure 1.

As a cognitive-behavioural therapeutic program the intervention pursued three general goals for the patients: 1) Education and provision of written self-help materials about depression and its association with coronary heart disease; 2) Reduction of depression and distress; and 3) Motivation of patients with enduring depression to seek outpatient psychotherapy after discharge from inpatient rehabilitation. The psychotherapeutic intervention was provided by three psychotherapists after training in the procedures and principles of the intervention.

Setting and procedure

During the 3- to 4-week inpatient rehabilitation the PROTeCD-intervention was delivered as an individual therapy in four to six sessions of 50 minutes each. It consisted of modules which were the same for all participating patients (see Figure 1), but had to be adjusted to the patients' individual needs and knowledge. The treatment began with a feedback on the clinical diagnosis followed by standardized patient education with a brochure (see <http://www.psychologie.uni-freiburg.de/einrichtungen/Reha/behandlu.htm>). Together with the psychotherapist the patient defined individual goals for the intervention. If required, a crisis intervention was part of the treatment. Further treatment steps aimed at modification of dysfunctional cognitions and behaviour, associated with depressive disorders. Before discharge patients were given a

Table 1: Sociodemographic characteristics of the sample

		Intervention (n=27)	Usual care (n=32)	p	
Age (M, SD)		60.81 (11.06)	55.62 (10.05)	.06	
Sex	female	5 (18.5 %)	9 (28.1 %)	.39	
	male	22 (81.5 %)	23 (71.9 %)		
Mental Disorders	MDE	mild	8 (29.6 %)	9 (28.1 %)	.60
		moderate	3 (11.1 %)	3 (9.4 %)	
	MD recurrent	mild [†]	6 (22.2 %)	4 (12.5 %)	
		moderate	1 (3.7 %)	2 (6.3 %)	
	Dysthymia		2 (7.4 %)	4 (12.5 %)	
Depressive Adjustment Disorder		9 (33.3 %)	12 (37.5 %)		
CHD	MI	13 (48.1 %)	21 (65.6 %)	.13	
	CABG	11 (40.7 %)	9 (28.1 %)	.35	
	PTCA	5 (18.5 %)	8 (25.0 %)	.47	
	Unstable Angina Pectoris	2 (7.4 %)	1 (3.1 %)	.51	
	Multiple diagnosis	8 (29.6 %)	10 (31.3 %)		

[†]Severity of current episode

|| lifetime diagnosis

MD=Major depression; MDE=Major depressive episode; MI=Myocardial infarction; CABG=Coronary artery bypass graft; PTCA=Percutaneous transluminal coronary angioplasty; CHD=Coronary heart disease.

written recommendation for further outpatient treatment. Diagnostic and treatment results were communicated to the general practitioner by letter.

Results

5898 patients were treated in the rehabilitation hospitals in the recruitment period (see Figure 2 for a flow chart of patient recruitment). Of 1709 patients who participated in the HADS-screening at admission to inpatient cardiac rehabilitation, 441 CHD patients (25.8%) showed mental distress (HADS ≥ 17). Of these, 268 patients were excluded from the study because they did not consent to a further study participation (N=109), exclusion criteria (i.e. poor general health, language and cognitive deficits; N=96) or other reasons as stated in Figure 2. 173 patients attended the clinical interview. 107 patients did not present sufficient indicators for a depressive disorder or depressive adjustment disorder. Finally 59 patients were randomised into the two groups of the trial (27 IG and 32 UC). At discharge data of 27 IG patients and 28 UC patients were available.

There were no differences between IG and UC with respect to sex, education, professional or marital status, psychiatric disorders, or physical capacity (Table 1). However, IG-patients tended to be older than UC-patients ($p=.06$). The data in Table 1 show, that - as expected - most patients were male. The most common somatic diagnosis in the IG was myocardial infarction in both study groups. About one third of the patients had more than one cardiac diagnosis or procedure. According to the diagnosed mental disorder, every third patient had an

adjustment disorder. The other patients suffered from a depressive episode or dysthymia; no patient had a severe depressive episode at study entry. Therefore none of the randomised patients received additional psychopharmacological medication during inpatient rehabilitation. The mean baseline values of the BDI and the HADS show moderate to severe depressive symptoms or mental distress, respectively. Comparing the subscales of the HADS there is only a small difference between anxious and depressive symptoms. However, both scores are above the proposed cut off score of 11 for anxiety and 9 for depressive symptoms in cardiac patients. The score of the BRMS is quite low indicating a mild depression (values of 0 to 5 indicate no depressive syndrome; values of 6 to 14 indicate a mild depressive syndrome). Patients of the specific intervention group and the usual care group showed comparable depressive symptoms and mental distress. At discharge from rehabilitation a similar decline in self-reported depressive symptoms (BDI), general distress (HADS) and depressive symptoms assessed by interviewers (BRMS) was found in IG and UG (Table 2). No specific efficacy of the psychotherapeutic intervention can be shown. The effect sizes for the whole group with depression range from 0.82 (BRMS), 1.07 (BDI), to 1.95 (HADS sum score). The reduction of anxious symptoms is larger ($d=1.65$) than the reduction of depressive symptoms ($d=0.93$). With regard to the proposed cut off scores of the assessment scales we used (BDI >11 ; HADS D >8 or HADS A >10) the patients showed still moderate distress and depressive symptoms at discharge.

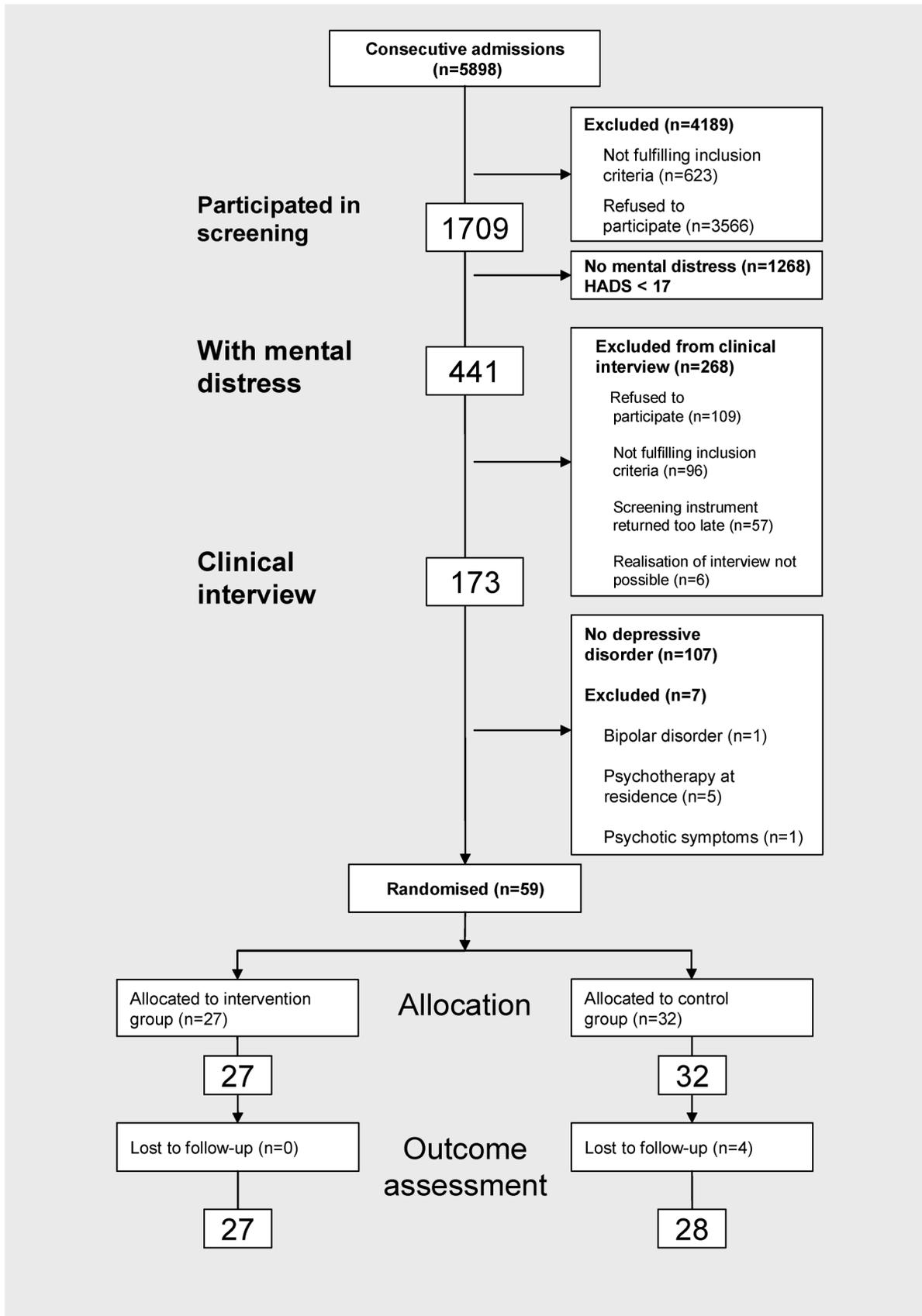


Figure 2: Flowchart of patient recruitment

Table 2: Results in outcome measures of the intervention and usual care group (pre - post comparison)

Scale	Intervention N = 27		Usual Care N = 32		ANCOVA †	
	admission M (SD)	discharge M (SD)	admission M (SD)	discharge M (SD)	F (df)	p
BDI N = 48 (n=25; n=23)	19.04 (6.39)	12.34 (7.69)	21.25 (5.43)	15.29 (7.65)	.322 (1)	.57
BRMS N = 46 (n=21; n=25)	9.78 (4.11)	6.24 (5.15)	8.66 (3.75)	5.72 (3.54)	.044 (1)	.84
HADS-A N = 50 (n=27; n=23)	11.78 (3.00)	7.42 (4.21)	13.16 (2.52)	8.29 (3.67)	.003 (1)	.96
HADS-D N = 50 (n=27; n=23)	11.30 (3.10)	7.41 (4.17)	11.42 (3.67)	7.92 (3.30)	.309 (1)	.85
HADS sum N = 50 (n=27; n=23)	23.07 (4.02)	14.83 (7.59)	24.58 (4.51)	16.21 (6.49)	.159 (1)	.69

† F-Value shows the interaction effect of study group by time in relation to outcome measure.

|| Different sample sizes result from missing data at one point of assessment. Only patients with data at both assessments were included in the analysis.

Discussion and conclusions

In short term, an additional psychotherapeutic intervention introduced into cardiac rehabilitation seems to be no more effective than the standard interdisciplinary care provided by the rehabilitation hospitals. During standard inpatient rehabilitation depressive symptoms were reduced in patients with coronary heart disease. The observed effect sizes were comparable to other psychotherapeutic treatments of longer duration and higher intensity. Already published studies about depression or anxiety in cardiac rehabilitation in Germany showed a comparable reduction of distress during inpatient treatment [15]. This effect may be caused by unspecific psychosocial interventions and exercise which show benefits on depressive symptoms in cardiac patients [16]. Follow-up studies showed an increase of distress six months after the inpatient intervention with almost the same scores like at the study entry [17], [18]. Preliminary analysis of follow-up results showed this effect also in this study population, especially in the usual care group [19]. A more continuous psychotherapeutic intervention would be helpful for stabilising those patients in out-patient care.

The patients treated in our study reported more depressive symptoms than in comparable U.S.-studies [9]. This may be due to a selection bias, resulting from the fact that the patient recruitment took place in inpatient rehabilitation hospitals, whereas the U.S.-studies refer to all patients after a CHD event. We found that one out of three patients with elevated mental distress was suffering

from a depressive disorder. Increased anxiety levels were also rather common in the depressed patients. This was also shown in a large sample of in-patients in a cardiac rehabilitation hospital who showed elevated depression and anxiety scores compared to the general population, especially in patients between 50 and 60 years of age [20]. The majority of the patients in our study suffered from a first episode of a major depression or an adjustment disorder. None of the patients received additional psychopharmacological medication which is contrary to the international situation. About two thirds of depressed CHD patients received medication at baseline [10] in a comparable clinical situation in North America.

One major problem of randomised controlled trials in psychotherapy is the number of drop-outs in the usual care or waiting list condition. Also in our study more patients in the usual care group dropped out from the study than in the intervention group. This may be caused by the refusal of additional support by the investigators, which in turn may have mortified the usual care patients. Further analyses of our data will focus on the drop-outs and on the usual care group to investigate the treatment usually received by depressive CHD patients in rehabilitation hospitals. Another focus will be to look for predictors of responding and non-responding patients.

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