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THE SENSITIVITY OF OUTCOME ASSESSMENT IN CARDIAC REHABILITATION

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Abstract

This paper examined the thesis that the type of outcome measure is a potential moderating factor in research on the psychological effect of cardiac rehabilitation. It was hypothesized that measures that match to the theoretically prescribed effect of this intervention (i.e., enhancement of subjective health and well-being) are more appropriate to assess change than standard measures of psychopathology. Study 1 examined the differential sensitivity to change of two standard measures (i.e., STAI and SCL90) and one measure that was tailored towards cardiac patients (i.e., Heart Patients Psychological Questionnaire or HPPQ) in a sample of 162 men with coronary heart disease (CHD) who participated in the Antwerp rehabilitation program. At the end of this 3-month program, subjects with a high level of distress at baseline (n=82) reported significantly less change on the STAI / SCL90 scales than on the HPPQ scales (p<.0001), while subjects with a low level of distress at baseline (n=80) only reported a significant change on the HPPQ scales and the SCL90 somatization scale (p<.0001). Thus, the assessment of change was moderated by type of outcome measure and severity of distress at baseline, but in the absence of a control group it is difficult to know what to attribute this change. Study 2 therefore compared 60 men with CHD who participated in cardiac rehabilitation
with 60 men with CHD who received standard medical care alone. Patients in both groups were matched for severity of distress at baseline. Three months after the initial assessment, rehabilitation subjects, but not control subjects, reported a significant decrease in disability and a significant increase in well-being as measured by the corresponding HPPQ scales (p<.0001). Moreover, there was significantly less tranquilizer use in the rehabilitation group than in the control group (p<.05). It was concluded that measures that match to the theoretically prescribed effect of cardiac rehabilitation may actually provide evidence for the psychological effect of this intervention in men recovering from CHD.

The Sensitivity of Outcome Assessment in Cardiac Rehabilitation

Findings from the Medical Outcomes Study indicated that of nine common chronic medical conditions, heart disease had the greatest impact on overall functional status and subjective well-being (Stewart et al., 1989). Consistent with this finding, one of the primary goals of health care for patients with coronary heart disease (CHD) is to improve daily functioning and enhance well-being. This is exactly what cardiac rehabilitation aims at. In addition to medical and surgical therapy, it is estimated that 100,000 patients with CHD participate in rehabilitation programs at a cost of $ 108 million per year (American College of Physicians, 1988). These programs expose patients to activity in gradually increasing doses (behavioral control), arrange for them to see others similar to themselves performing the activity (modeling), and have health care professionals provide information and feedback (cognitive control) (Ewart, 1989). Interventions such as these, which enhance the patient's perception of control, should facilitate recovery from CHD (Krantz, 1980). However, research largely failed to document a psychological effect of cardiac rehabilitation (Blumenthal & Emery, 1988; Langosch, 1988), and there is a risk that cardiac rehabilitation will become a passing vogue if its benefits cannot be demonstrated (Mulcahy, 1991).

Effect of Cardiac Rehabilitation

The medical value of cardiac rehabilitation has only been shown convincingly in recent years. In their meta-analysis of 22 randomized trials of cardiac rehabilitation, O'Connor et al. (1989) observed a 20% reduction in overall mortality and a 25% reduction in cardiovascular mortality for the intervention group compared with the control group. They concluded that cardiac rehabilitation programs may, if fully implemented, save approximately 13,000 lives annually. Two other recent meta-analyses of cardiac rehabilitation trials also showed significant reductions in overall mortality (32% and 24 %) and cardiovascular mortality (38% and 25%) (Bobbio, 1989; Oldridge, Guyatt, Fisher, & Rimm, 1988). These studies corroborate the findings of early meta-analyses which suggested that cardiac rehabilitation may

reduce mortality by about 20-30% (Collins, Yusuf, & Peto, 1984; May, Eberlein, Furberg, Passamani, & DeMets, 1982; Shephard, 1983). Methodological difficulties are inherent in meta-analyses, so that these results may even underestimate the true effect of cardiac rehabilitation on mortality in coronary patients (Oberman, 1989).

In contrast, many studies have not supported the hypothesis that cardiac rehabilitation improves psychological functioning. Naughton, Bruhn and Lategola (1968) found no changes in the Minnesota Multiphasic Personality Inventory (MMPI, Hathaway & McKinley, 1943) profiles of their physically conditioned cardiac patients. Mayou, MacMahon, Sleight and Florencio (1981) did not find significant differences among cardiac rehabilitation and control subjects in psychosocial functioning as rated by a standard psychiatric interview. In a study on 651 men with CHD, Stern and Cleary (1982) observed no differences between the exercise and control groups on the MMPI scales at the six-month, one-year, and two-year follow-ups. Erdman and Duivenvoorden (1983) failed to find a significant decrease in state-anxiety on the State-Trait Anxiety Inventory (STAI, Spielberger, Gorsuch, & Lushene, 1970). Roviaro, Holmes and Holmsten (1984) found that exercise-based cardiac rehabilitation did not influence STAI or Beck Depression Inventory (BDI, Beck, Ward, Mendelson, Mock, & Erbaugh, 1961) scores. Burgess et al. (1987) failed to find a significant effect of cardiac rehabilitation on the Manifest Anxiety Scale (MAS, J. Taylor, 1953) or the Self-rating Depression Scale (SDS, Zung, 1965). Blumenthal, Emery and Rejeski (1988) found that their subjects did not achieve significant changes on STAI or Symptom Check List (SCL90, Derogatis, Lipman, & Covi, 1973) scores after a 3-month rehabilitation period. Oldridge et al. (1991) also failed to observe a positive effect of rehabilitation on STAI or BDI scores.

These negative findings are rather unexpected because cardiac rehabilitation aims at the enhancement of self-efficacy (Bandura, 1982) and control (Carver & Scheier, 1990) as cognitive mediators of stressful events. Evidence in fact suggests that patients with CHD who actively take on the challenge of recovery are better of than their counterparts whose energy goes into focusing on their

emotional distress or trying to suppres it (Scheier et al., 1989). While some patients may focus on feelings of powerlessness, others may view their heart disease as a challenge and an opportunity for growth. In general, these latter patients actively participate in rehabilitation programs because these programs help them to cope with CHD by promoting their sense of control (Krantz, 1980; Rejeski, Morley, & Sotile, 1985). In fact, cardiac rehabilitation provides a direct demonstration of the patient's present capacity and of his/her improvement in performance with time (Thompson, 1988). If control is perceived to be available and subjects have reasonably high outcome expectancies, then high-efficacious subjects experience less subjective distress than low-efficacious subjects (Litt, 1988). Hence, one would expect the increased sense of control regarding CHD to improve the psychological status of patients attending a rehabilitation program. A major problem with research on recovery from CHD is, however, the lack of standardized instruments for measuring outcome variables (Krantz, 1980).

Appropriate Measure Selection

Unless one uses finely tuned, sensitive instruments, differences in treatment results between an intervention and a control group may not be reflected in an outcome study (e.g., Kim, Dysken, & Kuskowski, 1992). With reference to this issue, it has been suggested that the instruments that have been used in research on cardiac rehabilitation are not sensitive enough to document a psychological effect (Blumenthal et al., 1988; Roviaro et al., 1984; Stern & Cleary, 1982). Most rehabilitation trials used the STAI / MAS (e.g., Stern & Cleary, 1982), the BDI / SDS (e.g., Oldridge et al., 1991), or the SCL90 / MMPI (e.g., Blumenthal, et al., 1988) to assess anxiety, depression, or multiple aspects of psychopathology.

Although these instruments have proven of value in mental health settings, they predominantly are calibrated to detect relatively large-magnitude elevations in disorder against a normal level of functioning (Depue & Monroe, 1986). Many cardiac patients, however, do not experience problems of psychopathology, but rather experience a significant change in physical health status that affects their life

(Blumenthal et al., 1989). Hence, inappropriate selection of outcome measures may have contributed to the negative findings in this area of research.

Standard measures of psychopathology may not have sufficiently low 'floors' in the context of CHD (e.g., Depue & Monroe, 1986), and may fail to address issues that are relevant to the coronary patient's situation (e.g., Green, 1982). There appear to be two potential problems in assessing the psychological effect of cardiac rehabilitation: nonspecificity (i.e., the measure is too general to detect a significant effect), and measurement of wrong constructs (i.e., the measure is a poor match to variables that should change as a function of the intervention).[1] Although researchers must avoid both pitfalls, the underlying assumption of the present paper is that research on the psychological effect of cardiac rehabilitation is most at fault for choosing measures of the wrong constructs. That is, measures of psychopathology do not operationalize the psychological variables that one expects to be affected by cardiac rehabilitation. There are two reasons why it is theoretically more appropriate to expect less pathologically focused instruments to provide a more sensitive level of outcome assessment in cardiac rehabilitation.

First, most patients with CHD are not psychiatric patients, but predominantly experience decrements in physical health, functional status, and well-being (Blumenthal et al., 1989; Stewart et al., 1989). As a consequence, they tend to worry about their disease and the impact it has on their life (e.g., Frasure-Smith & Prince, 1985). Perceived disability and exaggerated concern with bodily functions are associated with, for example, persistent chest pain complaints (Williams et al., 1986) and failure to return to work (Smith & O'Rourke, 1988) in coronary patients. Most important, measures focusing on common problems of cardiac patients, such as feelings of disability and decrements in well-being, may be more appropriate than traditional measures to provide evidence for the psychological effect of rehabilitation. Conversely, the measurement of well-being by the absence of psychopathology can lead to underestimates of real changes in psychological status as a function of cardiac rehabilitation.

Second, cardiac rehabilitation is not a psychiatric intervention aiming at the reduction of psychopathology, but rather aims at the reduction of long-term disability and the enhancement of well-being (Mulcahy, 1991). The goals of cardiac rehabilitation include optimizing physical conditioning, providing emotional support, treating risk factors for the progression of CHD, teaching health behaviors that improve prognosis, and facilitating a return to occupational activities (Dennis, 1992). Thus, independent of their level of psychopathology, all patients with CHD may potentially experience a beneficial effect of rehabilitation. Interventions that (a) provide appropriate environmental cues for the labeling of physical symptoms (Mechanic, 1972), and (b) enhance perceived control (Pennebaker, Burnam, Schaeffer, & Harper, 1977) should improve self-rated health. Moreover, interventions that (c) promote an accelerated recovery, and (d) address the various issues that each individual patient may worry about, should increase positive affect and decrease negative affect (Carver & Scheier, 1990). Consistent with these propositions, previous research suggests that cardiac rehabilitation subjects may experience more positive self-perceptions (Roviaro et al., 1984), as well as decreased feelings of disability and an increased sense of well-being (Van Dixhoorn, Duivenvoorden, Pool, & Verhage, 1990).

The Present Research

The underlying assumption of this research was that the appropriateness of a potential outcome measure needs to be carefully evaluated for the purpose and setting in which it will be used. This implies that identifying appropriate measures of key constructs is an important factor in research on cardiac rehabilitation. Accordingly, the purpose of the present research was to investigate the hypothesis that measures that match to the theoretically prescribed effect of cardiac rehabilitation may actually provide evidence for the psychological effect of this intervention in coronary patients. For this purpose, the Heart Patients Psychological Questionnaire (HPPQ, Erdman, Duivenvoorden, Verhage, Kazemier, & Hugenholtz, 1986) was used to assess changes in feelings of disability and well-being in adult men with CHD who participated in an outpatient rehabilitation program. As noted earlier, these constructs

(a) are relevant to the coronary patient's situation, and (b) correspond to the psychological impact that cardiac rehabilitation should have. The HPPQ was validated in the Netherlands on a sample of 1,649 cardiac patients. The 12 items of the Disability scale address the discrepancy between the time before and the time after the acute cardiac event, e.g.: "I was able to take on much more work in the past". The 12 items of the Well-Being scale reflect the actual mood state, e.g.: "Lately, I feel relaxed".

The HPPQ does not differ from the more standard measures such as the STAI or SCL90 in terms of specificity but, rather, in terms of match to constructs that ought to change as a function of cardiac rehabilitation. However, I do not suggest that the CHD patient's level of anxiety, depression or general psychopathology is unimportant.[2] On the contrary, evidence indicates that symptoms of depression, for instance, are associated with an increased long-term risk for cardiac mortality or reinfarction in patients with CHD (e.g., Ahern et al., 1990). I merely want to point out that, in addition to assessing where the patient with CHD is in terms of psychopathology, it is also important to assess other relevant psychological constructs that are not tapped by standard measures of psychopathology. That is, psychopathological affective states - albeit being diagnosed and treated in effective rehabilitation programs - are not the primary target of cardiac rehabilitation. Feelings of disability and well-being, however, ought to change significantly as a function of comprehensive rehabilitation in the population of coronary patients as a whole. Therefore, the present research examined the thesis that the type of outcome measure is a moderating factor in research on the psychological effect of cardiac rehabilitation. The focus of study 1 was on the differential sensitivity to change of the STAI, SCL90, and HPPQ outcome measures in a first sample of adult men with CHD. The focus of study 2 was on changes in HPPQ scores as a function of cardiac rehabilitation in a second sample of adult men with CHD.

Study 1 : Sensitivity to Change of Outcome Measures

The purpose of study 1 was not to evaluate a cardiac rehabilitation program as such, but rather to examine the sensitivity to change of a number of outcome measures. The following questions were formulated. (a) Is it possible to document the differential sensitivity to change of a number of outcome measures in a sample of adult men recovering from CHD ? To answer this question, a number of measures that have been used in previous research were selected: two standard scales (i.e., STAI and SCL90) and one scale that was designed for cardiac patients (i.e., HPPQ). (b) Does the sensitivity to change of the selected outcome measures differ as a function of the level of distress at baseline? To answer this question, subjects were classified as being initially high or low in distress. The tendency to experience distress is a stable and enduring disposition (McCrae & Costa, 1987; Watson & Pennebaker, 1989). This tendency has also been observed in male CHD patients attending a cardiac rehabilitation program (Denollet, 1991).

Method

Subjects. The subjects were 197 Belgian men with CHD who agreed to participate in the study and who completed the outpatient rehabilitation program of the University Hospital of Antwerp between July 1986 and December 1988. This program includes exercise training, group therapy, and individual counseling. In the 2½ year of data collection, 24 of 221 male patients (11%) dropped out of the program before completing the 3-month rehabilitation period. The mean age of the subjects was 56.2 years (SD 7.7, range 35-79), and indication for participation in the rehabilitation program was acute myocardial infarction (AMI, n=52), coronary artery bypass graft surgery (CABG, n=118), or percutaneous transluminal coronary angioplasty (PTCA, n=27).

Classification of Subjects. Two scales that were not included in the outcome assessment were used to classify subjects according to their level of distress at baseline. A median split on the Trait form of the Dutch adaptation of the STAI (Van Der Ploeg, Defares, & Spielberger, 1980) was used to classify subjects because this scale is a valid measure of stable individual differences in distress (Watson & Pennebaker, 1989). A median split on the Despondency scale of the HPPQ (Erdman

et al., 1986) was also used to classify subjects because the 10 items of this scale reflect the tendency to experience distress in cardiac patients, e.g.: "I tend to be downhearted". Not surprisingly, the STAI Trait and HPPQ Despondency scales correlated significantly in the present sample (r=.80). High-distress subjects (n=82) had STAI Trait scores>36 (M=49.4, SD=8.4) and Despondency scores>15 (M=21.1, SD=3.9). Low-distress subjects (n=80) had STAI Trait scores≤36 (M=29.0, SD=4.3) and Despondency scores≤15 (M=11.8, SD=1.5). Subjects with mixed classifications (above/below median of both scales, n=35) were excluded from further analyses. Level of distress was not associated with medical category (AMI/CABG/PTCA) [$\div^2(2)=1.88, p=.39$].

Outcome Measures. The State form of the STAI (Van Der Ploeg et al., 1980), the Anxiety, Depression, Hostility, and Somatization subscales of the Dutch adaptation of the SCL90 (Arrindell & Ettema, 1986), and the HPPQ Disability and Well-Being subscales (Erdman et al., 1986) were selected as outcome measures. The STAI State is a widely used measure of pleasant as well as unpleasant mood states. The SCL90 is also a frequently used outcome measure which predominantly reflects general distress (Watson, Clark, & Tellegen, 1988). The SCL90 Global Severity Index combines information on number and intensity of symptoms and is a good marker of psychopathology (Blumenthal et al., 1988). The subscales of the SCL90 that had the highest correlation with this index in the present sample were Anxiety (r=.91) and Depression (r=.93). The Anxiety scale reflects symptoms of tension/nervousness, while the Depression scale comprises affective/cognitive symptoms of depression. The Somatization scale of the SCL90 reflects the perception of physical dysfunction. The STAI and SCL90 were selected as outcome measures because several authors have used these standard instruments to measure clinical changes that occur in cardiac patients during rehabilitation studies (e.g., Blumenthal et al., 1988). Unlike the STAI or SCL90, the HPPQ was devised specifically for cardiac patients (Erdman et al., 1986), and measures constructs that ought to change as a function of rehabilitation.

Protocol and Statistical Analysis. On admission to the rehabilitation program, all

subjects filled out the STAI, SCL-90 and HPPQ questionnaires. When discharged from the program (3 months later), they filled out the same questionnaires. Pearson's correlations were calculated and a factor analysis (principal components with varimax rotation) was carried out on the entry data in order to examine the validity of the selected outcome measures. Test-retest correlations were calculated for each of selected outcome measures. Changes in scores were analyzed by repeated measures MANOVAs with initial distress (high/low) as between-subjects factor and outcome measure (STAI/SCL90/HPPQ scales) and time (entry/end scores) as within-subjects factors. Some descriptive characteristics of the selected outcome measures were analyzed in an attempt to clarify eventual differences in sensitivity to change.

Insert Table 1 about here

Results

Validity of Outcome Measures. Significant correlations in the range of .60 to .80 emerged among the State-Anxiety, Anxiety, Depression, and Well-Being scales (Table 1). Likewise, the Somatization and Disability scales correlated significantly in the range of .40 to .60 with most of the other outcome measures. Eigenvalues (>1.0) and scree plot indicated the extraction of one single factor which accounted for 64% of the total variance (Table 1, right side). Clearly, all outcome measures appeared to assess subjective mood and health complaints. Not surprisingly, high-distress subjects reported more mood and health complaints than their low-distress counterparts [Wilk's $\ddot{e}$=0.44,E(5,156)=39.4,p<.0001]. No overall difference on the outcome measures was found as a function of medical category (AMI/CABG/PTCA) [Wilk's $\ddot{e}$=0.94,E(10,310)=0.98,p=.47].

Sensitivity to Change. The test-retest correlations for each of the scales were predominantly in the range of .60 to .70: STAI State-Anxiety (r=.64), SCL90 Anxiety (r=.70), SCL90 Depression (r=.73), SCL90 Hostility (r=.59), SCL90 Somatization (r=.68), HPPQ Disability (r=.64), and HPPQ Well-Being (r=.63). A repeated measures MANOVA with level of distress as between-subjects factor and outcome

measure and time as within-subjects factors indicated a significant distress x measure x time interaction effect [Wilk's ë=0.89,F(6,155)=3.0, p<.01]. This finding suggests that level of distress at baseline (high vs. low) contributes to the psychological changes observed. Since the focus of study 1 was on the ability of various outcome measures to assess change, the measure x time interaction effect was analyzed separately in high distress and low distress subjects. Most important, significant measure x time interaction effects indicated that the selected outcome measures were differentially sensitive to changes in subjects that either experienced high distress [Wilk's ë=0.50,F(6,76)=12.4, p<.0001] or low distress [Wilk's ë=0.57,F(6,74)=9.2,p<.0001] at baseline.

Insert Table 2 about here

Table 2 shows the mean entry and end scores, standard deviations, and results of repeated measures MANOVAs with time (entry vs. end) as within-subjects factor for each of the selected outcome measures. High-distress subjects reported a significant change on six out of seven measures (Table 2, left side). This change was, however, greater on the HPPQ than on the standard measures (cf. the significant measure x time interaction). Low-distress subjects did not report a significant change on the STAI State-Anxiety or the SCL90 Anxiety, Depression, and Hostility measures (Table 2, right side). In contrast, they did report a significant change on the SCL90 Somatization and the HPPQ Disability and Well-Being measures. These findings are consistent with the notion that the selection of outcome measures would probably serve as a moderating variable in an experimental or quasi-experimental study of cardiac rehabilitation.

Descriptive Characteristics of Instruments. Low scores at baseline may leave little room for improvement (e.g., Roviaro et al., 1984). Therefore, the frequency distribution of the STAI, SCL90, and HPPQ global scores at baseline was examined. Since these instruments all have a different range of scores, baseline scores with a range of 0-100 were first extrapolated in the following manner: STAI= (State score -

20) / 3 x 5; SCL= total score / 90 x 25; HPPQ = (24 + Disability score - Well-Being score) / 12 x 25.

Insert Table 3 about here

Table 3 shows the frequency distribution and some descriptive characteristics of the extrapolated global scores at baseline for each of the outcome measures.

Repeated measures MANOVAs with instrument as within-subjects factor indicated significantly lower STAI and SCL scores than HPPQ scores at baseline for both high-distress subjects [Wilk's ë=0.10,F(2,80)=341.9,p<.0001] and low-distress subjects [Wilk's ë=0.20,F(2,78)=153.4,p<.0001]. The frequency distribution of the STAI and SCL scores was predominantly restricted to the lowest quartiles. This finding was still more prominent for low-distress subjects: 76% and 100% scored in the lowest quartile of the STAI and SCL, respectively. These findings may help to explain why subjects reported less change on the STAI and SCL90 measures (except for the SCL90 Somatization scale) than on the HPPQ measures.

Discussion

The results of study 1 suggest the differential sensitivity to change of standard measures of psychopathology versus measures that are less pathologically focused. Three months after their initial assessment, coronary patients with a high level of distress at baseline reported a significant change on six out of seven outcome measures, but this change was greater on the HPPQ scales than on the STAI or SCL90 scales. Coronary patients with a low level of distress at baseline did not report a significant change on the STAI or SCL90 emotional distress measures, which is in line with the negative findings of Blumenthal et al. (1988). Although it is tempting to conclude that emotional problems such as anxiety or depression must be present for cardiac rehabilitation to produce psychological benefits, low-distress subjects did report, however, a significant decrease in somatic complaints and disability as well as a significant increase in well-being.

A possible explanation of these discrepant findings is the differential sensitivity to change of the selected outcome measures as a function of the level of distress at baseline. After all, it may be that only high-distress patients find standard distress measures to be useful to describe their psychological status, while outcome measures that are devised for cardiac patients (e.g., HPPQ) or that reflect disease-specific aspects (e.g., perception of somatic symptoms) are more relevant for both high- and low-distress patients. Although the STAI, SCL90, and HPPQ scales seem to tap a common underlying dimension, the subjects of study 1 did evidence much higher

scores on the HPPQ scales at baseline. Consequently, they did report a significantly greater change on the HPPQ scales, while the low STAI and SCL90 emotional distress scores at baseline did not leave much room for improvement (Roviaro et al., 1984). These findings corroborate the notion that scales must have sufficiently low "floors" (Depue & Monroe, 1986).

Clearly, the results of study 1 are consistent with the notion that the STAI and SCL90 may not be sufficiently sensitive outcome measures for either the target population (which is not a psychological clinical population) or the treatment (cardiac rehabilitation). From this perspective it is understandable that the HPPQ might be more sensitive to the intervention because this measure appears to match to the theoretically prescribed effect of cardiac rehabilitation. The absence of a control group is, however, a major problem for the correct interpretation of the results of study 1. Since the research of study 1 was limited to comparison of patients before and after they participated in cardiac rehabilitation, it is difficult to know what to attribute the change. The changes reported may, for instance, reflect regression to the mean or spontaneous recovery, and thus may not reflect clinically significant psychological changes. Therefore, the purpose of study 2 was to investigate the thesis that changes in feelings of disability and subjective well-being as measured by the HPPQ are associated with cardiac rehabilitation.

Study 2 : Disability, Well-Being, and Rehabilitation

The following questions were formulated in study 2. (a) Are changes on the HPPQ Disability and Well-Being scales a function of cardiac rehabilitation ? To answer this question, a control group of CHD patients from a hospital in Kortrijk (a town at ± 100 kilometers from Antwerp) was included. This hospital was chosen because it is located in an industrialized society comparable to Antwerp, while the patients of this hospital have no access to a rehabilitation program. (b) How clinically meaningful are the changes measured ? To answer this question, tranquilizer use was conceptualized as a non-test marker of well-being.

Method

Subjects. The subjects were 120 adult men with CHD who either received standard medical care or participated in a comprehensive rehabilitation program between July 1989 and December 1990. These subjects also participated in a study that was designed to construct a mood scale for cardiac patients (Denollet, in press). The 60 control subjects were selected from a sample of 73 patients: one patient deceased during the trial, three patients did not complete the follow-up questionnaire, and nine patients were excluded from further analyses because they reported an intermediate level of initial distress (i.e., in the 40th-60th percentile range) on the Despondency scale of the HPPQ. High-distress subjects (n=30) had scores>17 (M=21.9,SD=3.2), and low-distress subjects (N=30) had scores<15 (M=12.3,SD=1.5) on the Despondency scale. The mean age of the control subjects was 56.6 years (SD 8.8) and they all had experienced a recent coronary event: AMI (n=30), CABG (n=19), or PTCA (n=11).

The 60 rehabilitation subjects were matched with the control subjects for sex and level of distress at baseline. Thirty high-distress subjects (M=20.6,SD=2.5) and 30 low-distress subjects (M=12.0,SD=1.9) were selected from a sample of 114 male CHD patients who completed the Antwerp rehabilitation program. In the 1½ year of data collection, 11 of 125 patients (9%) dropped out of the program. The mean age of the rehabilitation subjects was 56.0 years (SD 7.5). Indication for rehabilitation was AMI (n=25), CABG (n=29), or PTCA (n=6). Control and rehabilitation subjects were not different with reference to age [F(1,119)=0.15,p=.70] or medical category [$\div^2$(2)=4.01,p=.13].

The Antwerp Cardiac Rehabilitation Program. Since the purpose of study 2 was to evaluate the ability of the HPPQ scales to document a psychological effect of the Antwerp rehabilitation program, this program is discussed here somewhat more in detail. Based on two major principles, i.e. an accelerated (10-14 days in-hospital; immediately thereafter on an out-patient basis) and multidisciplinary approach, this program lasts three months and includes exercise training, health education, and individual counseling. The exercise program comprises 36 sessions of one hour each.

During the first 24 sessions (3 x week), patients exercise on different apparatus (bicycle, treadmill, etc.) while being monitored on ECG. The last 12 sessions (2 x week) take place in a sports hall, this time without ECG-monitoring. The psychosocial program comprises six group sessions (2 hours once a week) with patients and spouses, and aims at health education, modification of risk factors, and communication about CHD. Individual psychological and medical counseling is an essential adjunct to these group interventions. This rehabilitation program clearly aims at the enhancement of behavioral and cognitive control (e.g., Krantz, 1980).

Outcome Measures and Statistical Analysis. The Disability and Well-Being scales of the HPPQ were selected as measures of psychological constructs that ought to change as a function of cardiac rehabilitation. Rehabilitation and control subjects completed the HPPQ within six weeks following an acute cardiac event. Three months after the initial assessment (= the end of the program in the rehabilitation group), they filled out again the HPPQ. Changes in scores were analyzed by repeated measures MANOVA with level of distress at baseline (high vs. low) and program (control vs. rehabilitation) as between-subjects factors and time (entry / end score) as within-subjects factor. Crosstabulation was used to analyze the difference in tranquilizer use between rehabilitation and control subjects.

Results

A 2 x 3 MANOVA revealed no difference among control and rehabilitation subjects [Wilk's $\ddot{e}$=0.99,E(2,113)=0.32,p=.73], or among AMI, CABG, and PTCA patients [Wilk's $\ddot{e}$=0.98,E(4,226)=0.44,p=.78] on the Disability and Well-Being entry scores. Comparison of control with rehabilitation subjects, and pooling of patients in one CHD category therefore seemed to be justified. Repeated measures MANOVA indicated a significant program x time interaction effect [E(1,116)=26.57,p<.0001], whereas the distress x program x time interaction was not significant [E(1,116)=1.77,p=.19]. Thus, changes in feelings of disability and well-being were significantly different as a function of cardiac rehabilitation, and this difference was independent of the level of distress at baseline.

Insert Figure 1 about here

As Figure 1 shows, control subjects reported no significant change in disability: from 26.0 (SD 5.9) to 26.9 (SD 6.3) [F=1.85,p=.18], or well-being: from 26.5 (SD 7.4) to 26.7 (SD 8.2) [F=0.04,p=.84]. Conversely, rehabilitation subjects did report a significant decrease in disability: from 25.2 (SD 5.4) to 20.5 (SD 6.3) [F=51.84,p<.0001], and a significant increase in well-being: from 26.1 (SD 7.5) to 30.2 (SD 6.2) [F=31.50, p<.0001] (all dfs: 1,59). Likewise, there was more tranquilizer use in the control group (i.e., 42% of subjects) than in the rehabilitation group (i.e., 22% of subjects) [$\div^2(1)=5.55$,p<.05].

Discussion

An obvious shortcoming of study 2 was the non-random assignment of subjects to control and rehabilitation groups. Albeit technically the best solution to rule out nonspecific effects such as spontaneous recovery and regression toward the mean, randomization is, however, of questionable ethical value in a cardiac rehabilitation setting (Blodgett & Pekarik, 1987a). Accumulating evidence indicates that rehabilitation may be a life-saving intervention in at least one out of five patients with CHD (e.g., Oberman, 1989; O'Connor et al., 1989). This implies that with a randomization design, 12 patients (i.e., 10% of 120 rehabilitation candidates) would have been at risk for premature death in study 2. Moreover, there has been much controversy regarding the degree to which randomization can be relied upon to iron out inequalities between treatment and control samples (e.g., Eysenck & Grossarth-Maticek, 1991). Evidence suggests, for instance, a randomization effect in the sense that cardiac patients assigned to a control condition may become anxious and despondent (Kolman et al., 1984).

Because of these ethical and methodological issues of denying or delaying treatment in a life-threatening disorder such as CHD, a quasi-experimental design was used (Blodgett & Pekarik, 1987b). In order to control extraneous factors which

plausibly could influence treatment outcome, subjects across groups were matched on the dimensions sex and severity of distress. Reliance on matching for severity of distress is especially important, given the moderating effect of the tendency to experience distress that has been observed in patients with CHD (Denollet, 1991; Denollet & De Potter, 1992). The fact that initial analyses failed to reveal pretreatment differences between subjects in the two conditions on demographic or dependent variables suggests the appropriateness of the control group. Nevertheless, the use of a quasi-experimental design requires a much more conservative interpretation of results (Blodgett & Pekarik, 1987a).

With these considerations in mind, the findings of study 2 suggest that changes on the Disability and Well-Being scales of the HPPQ were a function of cardiac rehabilitation. This finding is in keeping with recent research suggesting that CHD patients who participate in a multidimensional rehabilitation program may experience less feelings of disability and a better sense of well-being than patients who participate in exercise training alone (Van Dixhoorn et al., 1990) or than patients who do not participate in formal rehabilitation (Dracup, Moser, Marsden, Taylor, & Guzy, 1991). Furthermore, the significantly lower rate of tranquilizer use in the rehabilitation group corroborates the clinical relevance of the current findings. Most important, tranquilizer use has been related to risk of reinfarction in myocardial infarction patients (Wiklund et al., 1988).

General Discussion

Cardiac rehabilitation needs continuous evaluation (Mulcahy, 1991). However, psychological studies of cardiac rehabilitation are plagued by a number of methodological problems such as small number of subjects, wide variability in rehabilitation programs, and lack of control groups (Blumenthal & Emery, 1988). The present findings suggest that the lack of sensitive outcome measures is a methodological pitfall as well: (a) STAI, SCL90, and HPPQ outcome measures were distinctly different in their sensitivity to change in adult men with CHD, (b) this difference in sensitivity to change was a function of the severity of distress at

baseline, and (c) changes in disability and well-being as measured by the corresponding HPPQ scales were associated with cardiac rehabilitation.

Hence, the major findings of this research support the notion that the fit of the outcome measures to the target population (i.e., coronary patients) and the therapeutic intervention (i.e., cardiac rehabilitation) needs to be carefully considered. As pointed out by Kim et al. (1991), there appears to be a tendency to use familiar instruments to assess changes in psychological functioning. However, since the quality of experimental results depends heavily on the sensitivity of the instruments used, one ought not just take a known standard measure if it is not appropriate. With reference to this issue, the results of study 1 suggest that standard measures of psychopathology may be less appropriate to assess change in cardiac patients. In addition, the results of study 2 suggest that
measures that match to the theoretically prescribed effect of cardiac rehabilitation may actually provide evidence for the psychological effect of this intervention in adult men with CHD. These findings are of interest, particularly in light of the rather mixed evidence that cardiac rehabilitation improves psychosocial functioning (e.g., C. Taylor, Houston-Miller, Ahn, Haskell, & DeBusk, 1986).

However, this research provided only preliminary evidence in support of the thesis that the selection of appropriate outcome measures may benefit research on cardiac rehabilitation. That is, I have only examined the superiority of one particular measure (i.e., the HPPQ) over two standard measures (i.e., STAI and SCL90) for assessing the psychological effect of this intervention. More studies using other instruments that would seem to be likely to detect change resulting from cardiac rehabilitation are needed. For instance, measures of psychological constructs such as self-efficacy (e.g., Sherer et al., 1982), self-esteem (e.g., Hoyle, 1991), and well-being (e.g., Denollet, in press) may be appropriate to assess change in patients that participate in cardiac rehabilitation. Note that these measures do not refer to particular contexts or interventions, but that they differ from standard measures of psychopathology in terms of match to theoretically important variables. In terms of specificity, measures such as the HPPQ (Erdman et al., 1986) and the Global Mood Scale (Denollet, in

press) can be situated between the two extremes of utterly idiosyncratic measurement (i.e., specific for a particular medical diagnosis or intervention) and utterly general measurement.

The present paper leaves a number of important questions unanswered. For instance, it would be interesting to see how the research literature would be affected by the proliferation of instruments that would take place if researchers began to tailor-make measures to fit particular interventions. The present results only refer to one medical population in one type of therapeutic setting. Insofar as CHD is an exemplar chronic illness, would these results generalize to other medical populations and other interventions ? With reference to this issue, I do not suspect that we must have separate, tailor-made measures for every medical intervention. It still remains to be seen, however, how many of these measures we do need and how specific they should be. Another issue concerns the degree to which the present results would generalize to female patients with CHD. These patients were excluded in studies 1 and 2 because of the small number of women attending the Antwerp rehabilitation program (±10%), and because of the sex differences in subjective well-being (e.g., Wood, Rhodes, & Whelan, 1989) and coronary morbidity (e.g., Matthews, Davis, Stoney, Owens, & Caggiula, 1991).

Although the focus of this paper was not on intervention per se, this does not mean that research should ignore the fact that the type of intervention is a potential moderating factor as well. Evidence suggests, for instance, that breathing therapy and relaxation may enhance the psychological outcome of exercise training in coronary patients (Van Dixhoorn et al., 1990). CHD is a major killer, and any intervention which promises prevention of its morbidity would seem worthy of replication (e.g., Eysenck & Grossarth-Maticek, 1991). The present research suggests that the development and selection of appropriate outcome measures may serve to corroborate the largely anecdotal observation that patients with CHD feel better following a comprehensive rehabilitation program.

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Author Notes

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Correspondence concerning this article should be sent to Johan Denollet, UZA - Cardiale Revalidatie, Wilrijkstraat 10, B-2650 Edegem, Belgium.

Footnotes

[1] I am indebted to an anonymous reviewer for pointing out this important distinction.

[2] I thank an anonymous reviewer for raising this issue.

Table 1

Intercorrelation matrix and factor analysis of measures that were selected to assess changes in subjective mood/health (N=162)

Outcome Measures		Intercorrelation Matrix *						Factor Analysis †
		Anxiety	Depression	Hostility	Somatization	Disability	Well-Being	Factor I
State-Anxiety	(STAI)	.76	.72	.52	.52	.43	-.73	.85
Anxiety	(SCL90)	-	.86	.59	.66	.41	-.66	.90
Depression	(SCL90)		-	.57	.67	.43	-.67	.90
Hostility	(SCL90)			-	.35	.24	-.42	.65
Somatization	(SCL90)				-	.56	-.58	.78
Disability	(HPPQ)					-	-.59	.64
Well-Being	(HPPQ)						-	-.84
								Eigenvalue= 4.47

Note. STAI denotes State-Trait Anxiety Inventory; SCL90: Symptom Check List; HPPQ: Heart Patients Psychological Questionnaire.
† Principal components with varimax rotation.
* All correlations: $p<.001$, except $r=.24$: $p<.01$.

Table 2

Mean entry and end scores, standard deviations, and repeated measures analyses of variance results for two categories of male CHD patients: high versus low level of distress at baseline (N=162)

Distress Measures	High Initial Distress (N=82)				F †	Low Initial Distress (N=80)				F †
	Entry Score		End Score			Entry Score		End Score		
State-Anxiety (STAI)	48.3	(11.2)	43.6	(11.6)	13.9*	29.8	(6.4)	30.2	(7.5)	0.1
Anxiety (SCL90)	8.7	(6.8)	6.3	(6.7)	15.3*	1.7	(2.1)	1.7	(2.5)	0.0
Depression (SCL90)	15.3	(10.5)	11.3	(11.3)	16.2*	3.4	(3.3)	2.9	(3.6)	1.4
Hostility (SCL90)	3.4	(3.1)	3.3	(3.3)	0.9	0.7	(1.0)	1.0	(1.6)	3.2
Somatization (SCL90)	10.5	(7.0)	7.6	(7.0)	18.3*	5.2	(4.7)	3.4	(4.0)	15.5*
Disability (HPPQ)	28.9	(5.1)	24.3	(6.1)	73.3*	24.3	(5.9)	20.4	(6.0)	37.8*
Well-Being (HPPQ)	20.3	(6.8)	25.8	(8.2)	45.1*	30.3	(4.9)	33.0	(3.8)	23.2*

Note. Standard deviations appear in parentheses. STAI denotes State-Trait Anxiety Inventory; SCL90: Symptom Check List; HPPQ: Heart Patients Psychological Questionnaire.
† Repeated measures analysis of variance with time as within-subjects factor, dfs=1,81 and 1,79 respectively.

***** p<.0001.

Table 3

Descriptive characteristics of the instruments that were used to assess changes in subjective mood/health

	Total Group (N=162)				High Initial Distress (N=82)				Low Initial Distress (N=80)			
	STAI	SCL*	HPPQ†		STAI	SCL	HPPQ		STAI	SCL	HPPQ	
Frequency Distribution of Scores (Quartiles)												
0 - 24	44%	86%	15%		13%	73%	2%		76%	100%	28%	
25 - 49	35%	13%	30%		46%	25%	19%		24%	-	42%	
50 - 74	15%	1%	29%		30%	2%	29%		-	-	29%	
75 - 100		6%	-	16%		11%	-	50%		-	-	1%
Median	28	10	54		45	17	73		15	5	35	
Mean		32.0	13.1	53.0		47.2	19.9	68.0		16.3	6.2	37.6
Standard Deviation		21.7	11.5	25.5		18.7	12.1	21.5		10.6	4.8	19.6

Note. STAI denotes extrapolated State score (range 0-100) of the State-Trait Anxiety Inventory; SCL: extrapolated General Severity Index (range 0-100) of the Symptom Check List; HPPQ: extrapolated Disability/Well-Being score (range 0-100) of the Heart Patients Psychological Questionnaire.

***** Pearson's r=.91 and r=.93 for the SCL90 Anxiety and Depression scales, respectively ($p<.001$).

† Pearson's r=.86 and r=-.92 for the HPPQ Disability and Well-Being scales, respectively ($p<.001$).

Figure Caption

Figure 1. Changes in mean Disability and Well-Being scores for rehabilitation and control subjects (N=120).

Note. Entry denotes the mean score within six weeks after the coronary event; end: mean score three months after the initial assessment; Disability and Well-Being are subscales of the Heart Patients Psychological Questionnaire (Erdman et al., 1986).

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October 28, 1992

Re: MS #92-024 "The sensitivity of outcome assessment in cardiac rehabilitation."

Dear Professor Beutler,

Thank you for your letter of October 23 concerning my manuscript. Enclosed please find the completed "APA Copyright Transfer" and "Certification of Compliance With APA Ethical Principles" forms.

Needless to say, I am very pleased that my manuscript will be published in *Journal of Consulting and Clinical Psychology*. I hope that you would be kindly willing to consider more of my work for publication in your Journal.

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September 15, 1992

Re: Manuscript #92-024 "The sensitivity of outcome assessment in cardiac rehabilitation."

Dear Professor Newman,

Thank you for your letter of September 3, 1992 concerning my first revision of the above manuscript. I have now attended to the editorial and substantive points that you raised in your letter.

First, the citation "Beck et al., 1961" on page 4 is now replaced by the citation "Beck, Ward, Mendelson, Mock, & Erbaugh, 1961". I checked the citations throughout the manuscript, but I did not find any other incorrect citations. Second, I agree that the use of "moderating factor", in fact, is not correct in the context of the research of Study 1. Therefore, it is now clearly stated that " ... the selection of outcome measures would probably serve as a moderating variable in an experimental or quasi-experimental study of cardiac rehabilitation. " (page 12, first new paragraph, last sentence). I thank you for raising this point.

Needless to say, I am very pleased to have the opportunity to publish my article in *Journal of Consulting and Clinical Psychology*. Please find enclosed the revised original and two copies of the manuscript.

Sincerely,

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August 11, 1992

Re: Manuscript #92-024 "The sensitivity of outcome assessment in cardiac rehabilitation."

Dear Professor Newman,

Thank you for your interesting and useful comments on the above manuscript. I am convinced that the manuscript is now improved by the revision you recommended, and I appreciate that you would be willing to consider this revision for publication in *Journal of Consulting and Clinical Psychology*.

I am in agreement with most comments and therefore I have corrected the paper in a fashion that deals with the various issues raised by you and your referees. On the basis of your suggestions, I have decided to reframe the conceptualization of my paper by focusing on the issue of appropriate outcome assessment in the context of cardiac rehabilitation. Accordingly, " ... in medical settings" is deleted in the title, and is now replaced by " ... in cardiac rehabilitation". I agree that I am not providing an adequate test of the outcome assessment issue for all medical problems or settings, and that the present research only refers to one medical population in one type of therapeutic setting. Therefore, the introduction is now framed more modestly, focusing on the assessment of the psychological effect of cardiac rehabilitation.

The issue of appropriate measure selection is now stated with less modesty in the introduction, pages 6 and 7. The second paragraph on page 7 now clearly states that the fit of the outcome measures to the target population and the therapeutic intervention needs to be carefully considered. Furthermore, the psychological effect that cardiac rehabilitation should have is now discussed more in detail on page 4, last paragraph and page 6, last paragraph. Mention is now made of the fact that cardiac rehabilitation " ... aims at the reduction of long-term disability and the enhancement of well-being (Mulcahy, 1991)" (page 6, last two lines).

It is now clearly stated that " ... measures of psychopathology do not operationalize the psychological variables that one expects to be affected by cardiac rehabilitation " (page 6, lines 10-12). Accordingly, reference is made to the fact that " ... measures that match to the

theoretically prescribed effect of cardiac rehabilitation may actually provide evidence for the psychological effect of this intervention in coronary patients " (page 7, second paragraph, lines 6-8).

The style of the American Psychological Association is now used in the revised manuscript. The margins are 3-4 cm top, bottom, left and right, there now is a running head, the title is included on the first page of the manuscript, the word "Introduction" is now omitted, positions of tables and figures are correctly noted, and the format of the headings are now in APA format.

This revision does not include a reproduction of the HPPQ items in an appendix because this would, in fact, involve copyright problems. I agree that reversing the order of studies one and two might detract from the primacy of the current study 1. I therefore decided to maintain the current order of the studies. My responses to these and other comments of the reviewers are detailed in the attached sheets.

I hope that this revision meets the various points raised by you and your referees, and that you therefore would be willing to accept my paper for publication in *Journal of Consulting and Clinical Psychology*. Please find enclosed 3 copies of the revised manuscript.

Sincerely,

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Responses to Comments of Reviewer # 1.

Thank you for your interesting comments and suggestions that enabled me to further strengthen the paper. I am most grateful for pointing out the distinction between nonspecificity and wrong constructs as two potential problems in assessing the psychological effect of cardiac rehabilitation. I agree that this distinction is a very important one, and I have revised my paper to be more theoretically based by focusing on this issue in the context of cardiac rehabilitation.

The introduction now describes more in detail the psychological impact that cardiac rehabilitation should have (page 4, last paragraph and page 6, last paragraph). I agree that extant research is most at fault for choosing measures of the wrong constructs rather than measures that are too general. This is now clearly stated in the introduction section, page 6, lines 4-10. Mention is also made to the fact that " ... measures of psychopathology do not operationalize the psychological variables that one expects to be affected by cardiac rehabilitation " (page 6, lines 10-12), and to the fact that " ... measures that match to the theoretically prescribed effect of cardiac rehabilitation may actually provide evidence for the psychological effect of this intervention in coronary patients " (page 7, second paragraph, lines 6-8). This theoretically prescribed effect of cardiac rehabilitation is now referred to as " ... the reduction of long-term disability and the enhancement of well-being " (page 6, last two lines).

Reference is also made to the notion that " ... measures of psychological constructs such as self-efficacy (e.g., Sherer et al., 1982), self-esteem (e.g., Hoyle, 1991), and well-being (e.g., Denollet, in press) may be appropriate to assess change in patients that participate in cardiac rehabilitation " (page 19, second paragraph, lines 7-10). It is also pointed out that these measures do not refer to particular contexts or interventions, but that they differ from standard measures of psychopathology in terms of match to theoretically important variables.

I agree that the issue of whether standard measures used to assess psychopathology in psychiatric populations are appropriate for research on "normal" individuals is a very thorny one, and that this issue, in fact, may detract from the intent of my research. For these reasons, I have decided to omit this issue in the revised manuscript.

Regarding your suggestion to include the items of the HPPQ in the manuscript, I have decided not to do so because this would involve copyright problems. However, your point that the difference between the HPPQ and more standard measures is not the specificity of items is well taken. It is now stated that " The HPPQ does not differ from the more standard measures such as the STAI or SCL90 in terms of specificity but, rather, in terms of match to constructs that ought to change as a function of cardiac rehabilitation." (page 8, second paragraph, lines 1-3). Moreover, it is now stated in the general discussion section that in terms of specificity, measures such as the HPPQ and the Global Mood Scale (Denollet, in press) can be situated between the two extremes of utterly idiosyncratic measurement and utterly general measurement (page 19, second paragraph, last four lines).

The information of Table 1 (page 11) is discussed less in detail. I decided to maintain the order of the studies one and two because reversing the order of studies one and two might detract from the primacy of the current study 1. Study 2 is, in fact, a validation study of the HPPQ that provides further evidence for the thesis that " changes in feelings of disability and subjective well-being as measured by the HPPQ are associated with cardiac rehabilitation " (page 14, second paragraph, last three lines).

In the general discussion section, it is now clearly stated that " ... this research provided only preliminary evidence in support of the thesis that the selection of appropriate outcome measures may benefit research on cardiac rehabilitation " (page 19, second paragraph, lines 1-3). Furthermore, I have pointed out that I have only examined the superiority of the HPPQ over the STAI and SCL90 for assessing the psychological effect of cardiac rehabilitation, and that more studies using other instruments are needed (page 19, second paragraph, lines 3-10). Mention is also made to the fact that the present results only refer to one medical population in one type of therapeutic setting, and that it remains to be seen that these results would generalize to other medical populations and other interventions (page 20, first paragraph, lines 4-7).

The style of the American Psychological Association is now used in the revised manuscript. The margins are 3-4 cm top, bottom, left and right, there now is a running head, the title is included on the first page of the manuscript, the word "Introduction" is now omitted, positions of tables and figures are correctly noted, and the format of the headings are now in APA format.

Admittedly, the present paper leaves a number of important questions unanswered. I agree that it would be interesting to see how the research literature would be affected by the proliferation of instruments that would take place if researchers began to tailor-make measures to fit particular interventions. This is now stated in the general discussion section (page 20, top of the first paragraph). Mention is also made to the fact that I do not suspect that we must have separate measures for every medical intervention. But then, of course, much more research is needed in order to determine how many of these measures we do need and how specific these measures should be.

I hope that these modifications may provide an appropriate answer to the important issues that you have indicated, and I am convinced that your numerous suggestions have helped me a great deal to produce a manuscript that is stronger and more focused than its previous draft.

Responses to Comments of Reviewer # 2.

The STAI and SCL90 were selected as outcome measures in study 1 because several authors have used these standard instruments to measure clinical changes that occur in cardiac patients during rehabilitation studies (e.g., Blumenthal et al., 1988). This is now clearly stated in the method section (page 10, second paragraph, lines 14-17). The HPPQ was selected as an outcome measure because this scale taps two psychological constructs (i.e., perceived disability and subjective well-being) that ought to change as a function of rehabilitation. Accordingly, it is now stated that " the STAI and SCL90 may not be sufficiently sensitive outcome measures for either the target population (which is not a psychological clinical population) or the treatment (cardiac rehabilitation). From this perspective it is understandable that the HPPQ might be more sensitive to the intervention because this measure appears to match to the theoretically prescribed effect of cardiac rehabilitation." (page 14, second paragraph, lines 1-6).

I agree that the present research only refers to one medical population in one type of therapeutic setting. Therefore, the introduction now focuses on the assessment on the psychological effect of cardiac rehabilitation. As a consequence, " ... in medical settings" is deleted in the title, and is now replaced by " ... in cardiac rehabilitation". Nonetheless, I think that the multidisciplinary nature of comprehensive cardiac rehabilitation is quite relevant to the implementation of psychological interventions in medical settings.

Responses to Comments of Reviewer # 3.

Thank you for your helpful comments on my paper. Needless to say that I agree that the issue of treatment outcome assessment in both medical and psychiatric settings is an important one. My responses to your comments and suggestions are detailed in the following sections.

I am most grateful for pointing out that, in addition to assessing where the patient with CHD is in terms of psychopathology, it is important to assess other relevant psychological constructs that are not tapped by standard measures of psychopathology. I agree that the coronary patient's level of anxiety, depression or general psychopathology is also important in the context of morbidity and even mortality (e.g., Ahern et al., 1990). This now clearly stated in the introduction section (page 8, second paragraph, lines 3-10).

A description of the HPPQ Despondency scale (such as those given for the two other HPPQ scales) is now provided in the method section of study 1 (page 9, third paragraph, lines 6-10).

It is now stated that "Significant correlations in the range of .60 to .80 emerged among the State-Anxiety, Anxiety, Depression, and Well-Being scales (Table 1). Likewise, the Somatization and Disability scales correlated significantly in the range of .40 to .60 with most of the other outcome measures. ... Clearly, all outcome measures appeared to assess subjective mood and health complaints." (page 11, second paragraph, lines 1-7).

The results section of study 1 now provides test-retest correlations for each of the selected outcome measures: "The test-retest correlations for each of the scales were predominantly in the range of .60 to .70: STAI State-Anxiety (r=.64), SCL90 Anxiety (r=.70), SCL90 Depression (r=.73), SCL90 Hostility (r=.59), SCL90 Somatization (r=.68), HPPQ Disability (r=.64), and HPPQ Well-Being (r=.63)." (page 11, third paragraph, lines 1-4) Test-retest correlations for the HPPQ scales in study 2 were in the same range.

Since low scores at baseline may leave little room for improvement (e.g., Roviaro et al., 1984), the frequency distribution of the STAI, SCL90, and HPPQ global scores at baseline was examined. However, these instruments all have a different range of scores. Therefore, baseline scores with a range of 0-100 were first extrapolated for the STAI, SCL90, and HPPQ scales. This now clearly stated in the results section of study 1 (page 12, third paragraph, lines 1-5).

I hope that these responses may provide an appropriate answer to the important issues that you have indicated.