RELAXATION THERAPY

IN CARDIAC REHABILITATION

A randomised controlled clinical trial of breathing awareness as a relaxation method in the rehabilitation after myocardial infarction.

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ONTSPANNINGSTHERAPIE IN DE

HARTREVALIDATIE

A randomised controlled clinical trial of breathing awareness as a relaxation method in the rehabilitation after myocardial infarction.

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The studies presented in this thesis were performed in the Departments of Biofeedback and of Cardiac Rehabilitation in St Joannes de Deo Hospital, Haarlem, The Netherlands

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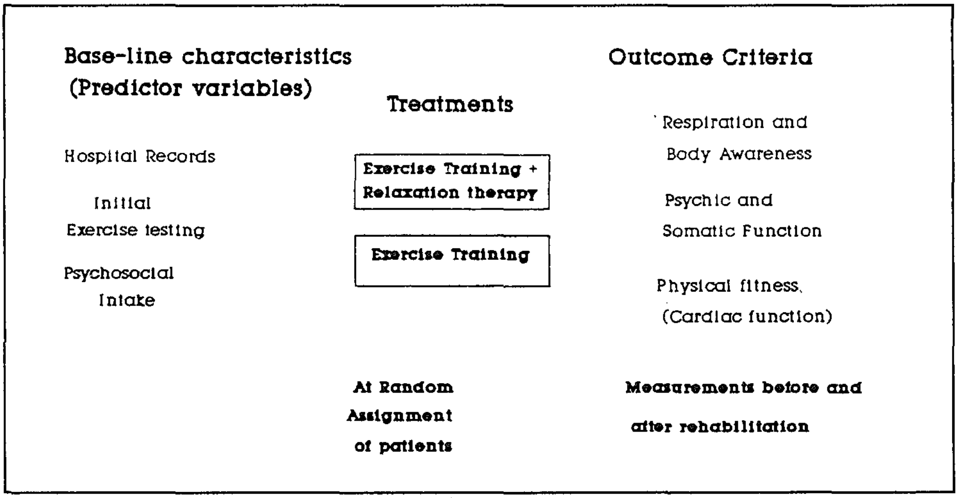

Figure 1.1. Outline of the Study

Chapter 1.

Introduction

Cardiac rehabilitation is often a necessary supplement to medical treatment of patients with acute ischaemic heart disease. Rehabilitation is directed to the functional recovery of the patient, physically as well as socially and mentally. Exercise training is at present the most common component of cardiac rehabilitation. However, most investigators have failed to show that exercise in itself would improve the patient's functional state satisfactorily. Therefore, there is a need to reconsider rehabilitation policy (1). Various authors are in favour of a multidisciplinary or comprehensive approach (2), which enables a differentiation of treatment programmes, tailoring rehabilitation to the needs of the individual patient. We agree with this approach. Rehabilitation is more than exercise training only (3). The question is, what other treatments are there that are feasible and effective. The purpose of this study is to investigate the incremental value of individual relaxation therapy.

In addition to exercise training, other treatment modalities are e.g. psychotherapy, counseling and patient education. They can be effective, but practical implementation may pose some difficulties. One problem is lack of motivation or even resistance of most cardiac patients to psychosocial interventions, in contrast to their enthusiasm for physical exercise (4).

I had an opportunity to develop another method of treating patients, consisting of teaching techniques for tension control and relaxation (5). Those techniques are procedures to induce psychophysiological changes. By relaxation therapy the patient becomes more aware of his body and his feelings and more sensitive to the interaction between physical and psychic events. Awareness is primarily focused on the body, using so-called relaxation "exercises". Thus, relaxation meets the preference of patients for "physical" approaches. However, it opens the way to the "invisible" world of mental and emotional factors, and it may have psychotherapeutic value.

Relaxation techniques are often practised in groups, for instance during or after exercise sessions, or as part of group psychotherapy. In my approach, relaxation therapy is practised on an individual basis and is a treatment in itself. Group sessions are useful to practise relaxation, but they are insufficient for the patient to master relaxation skills, particularly when only few sessions are held. Relaxation therapy requires individual instruction and a minimum of several months of group or home practice, in which the learning process is monitored and supervised (6). As a skills training, it is comparable to the first step in learning how to play a musical instrument. As a therapy, it requires individual guidance to the patient. For cardiac patients, deep relaxation and body awareness are often new experiences. Moreover, the psychotraumatic impact of their recent illness, the presence of stressful circumstances prior to their illness and an inadequate coping strategy can become topics for discussion during the therapy.

Practical constraints (time, money, manpower) limit the extent of treatment. Besides, it is difficult to properly introduce relaxation. Therefore, I developed a shortened and compact method for individual relaxation therapy, using biofeedback-aided muscle relaxation, mental relaxation and instruction in natural breathing. These procedures were effective in inducing relaxation experiences within a few sessions. Relaxation therapy in this way was practised in the Department of "Biofeedback" of the St. Joannes de Deo Hospital, Haarlem, The Netherlands, headed by the author. It contributed to the cardiac rehabilitation programme, which this hospital administered for the region, next to exercise training and psychosocial counseling. Exercise training was the main body of the programme. On average, relaxation therapy covered five to eight individual sessions. Occasionally, group sessions were added. Since 1977, over 700 cardiac patients have received this treatment as part of the cardiac rehabilitation programme. Its techniques are described in detail in the Appendix.

A proper presentation was essential to cope with the resistance which a psychological approach often encounters. For instance, it was important to stress that relaxation was a regular part of the programme and that fitness consisted of both the ability to sustain effort, to rest and to relax. Relaxation was presented as a regular part of a healthy lifestyle. Besides, the attitude of the rehabilitation staff was crucial. In this way, individual relaxation therapy proved acceptable and feasible to most patients.

Literature on relaxation therapy in cardiac patients describes its physical as well as psychological effects. Arousal can be reduced and cardiovascular condition as well as psychological parameters improved. This is in line with the results of studies on relaxation effect on stress-related disorders. To our knowledge however, only one large-scale, controlled study of relaxation in cardiac patients has been performed (7).

In order to assess the value of relaxation therapy, a straightforward programme of physical reconditioning is compared to a more comprehensive treatment, consisting of the same exercise training combined with individual relaxation therapy.

Predictability of the outcome of the different treatments is studied, using base-line clinical data, available at entry into the rehabilitation programme.

The study design is illustrated in figure 1.1. The value of relaxation therapy is assessed by comparing the outcome of the two treatments. Since the patients have been randomly assigned to either of these treatments, differences in outcome can be attributed to the difference in treatment. The outcome criteria are assessed before and after the rehabilitation programme. They are presented in chapters 3 to 5, describing changes in respiration and body awareness (chapter 3), in exercise testing (chapter 4) and in psychic and somatic function (chapter 5) respectively. Besides, a comparison between the two treatments with respect to the occurrence of cardiac events over a longer period of time (2 - 3 years) is described in chapter 6.

Predictability of the outcome is described in chapters 7 to 9. Tailor-made rehabilitation requires that rehabilitation is comprehensive and treatment programmes are differentiated and adapted to the individual. It is crucial therefore to predict what patients will be (un)suitable for what treatment, on the basis of information available at entry into rehabilitation.

Thus, the relationship between baseline characteristics and rehabilitation outcome will be investigated. First, physical outcome is taken as an endpoint for prediction analysis, using the criterion developed in chapter 4. In chapter 7, the relationship between training success and training failure with base-line characteristics is investigated for the entire study population, irrespective of treatment form. Next, predictability of training success is investigated for each treatment (chapter 8). Predictability of the psychic outcome is investigated for the entire population, but in such a way that treatment form is also taken into account (chapter 9). Since in this study patients have been randomly assigned to either of these treatments, differences in the effects of predictor variables may be taken to reflect the nature of the treatments. Thus, relative indications can be detected for exercise training only and for relaxation therapy in combination with exercise training.

These chapters consist of articles which are published or have been submitted for publication. They can be read independently. One of them reports on a part of the study population.

The results of the study are discussed (chapter 10) in the light of the concept of tailor-made rehabilitation. The study is summarised in chapter 11. Details on the relaxation method applied can be found in the appendix.

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Chapter 2.

Conduct and Design

Patients. St. Joannes de Deo Hospital has a regional function in cardiac rehabilitation. Patients from the cardiology departments of the neighbouring hospitals are referred to its rehabilitation centre. Most of these patients suffered an acute myocardial infarction and were able to participate in some physical exercise. They constituted the population of this study. Patients with other cardiac problems, e.g. status after heart surgery or angina pectoris were excluded. Age, gender and severity of infarction were no limitations to rehabilitation and no reasons for exclusion from the study, either.

Only patients with a recent infarction, meaning that the date of hospital discharge was within one month before entry, were admitted to the study. Patients who were referred later, were excluded. Moreover, patients who were referred for relaxation therapy, could not be randomised and were therefore also excluded from the study.

In three intake periods a total of 156 patients, 147 men and nine women, were admitted to the study: March-June 1981, n=32; January-July 1982, n=58; February-November 1983, n=66. Two patients were eligible but refused to participate in the study. The cumulative age distribution is shown in figure 2.1. The median age was 56 (range 36 - 76). Most patients (71%) were employed, 10 of whom (6%) part-time. Classification of infarction size was according to peak serum enzyme level. In most hospitals, an infarction was considered small when the serum glutaminic-oxaloacetic transaminase (SGOT) was elevated but remained below 60 U/l, whereas the infarction was classified as large when SGOT levels had risen over 120 U/l. In 47 patients, the infarction was classified as small, in 49 as medium and in 52 as large. In eight patients serum enzyme levels were not available.

The follow up data reported in chapter 9 concern patients admitted in 1981 and 1982. A fine grain analysis of respiratory variables, described in chapter 3, was made of patients admitted in 1982.

Procedure. At intake at the rehabilitation centre, patients were interviewed by a psychologist or social worker. They were asked to participate in a study designed to assess the effects of the rehabilitation programme. After informed consent, they were randomly assigned by the research administrator to either of the treatments. They completed additional self-administered questionnaires, referring to the situation before their infarction, and an appointment was made for a test of respiratory parameters. On that occasion, questionnaires pertaining to the present situation were completed. The respiratory test and the questionnaires were repeated after the programme was completed.

Clinical baseline data and medical history were obtained from the referring cardiologist. All patients admitted to the study participated in the routine rehabilitation programme, consisting of physical exercise. Graded exercise testing was performed on a bicycle ergometer before and after physical training. A cardiologist tested the patients and he introduced the training programme to them. At the end he discussed the results with them. He was unaware whether the patient received additional relaxation therapy.

Half of the patients were randomly assigned to relaxation therapy in addition to the exercise programme. This therapy took place at a different location. The initial appointment was made by the research administrator. The relaxation therapists did not participate in the exercise programme.

The rehabilitation programme did not have a structured form of patient education. Information was given and questions were answered by each of the rehabilitation team members.

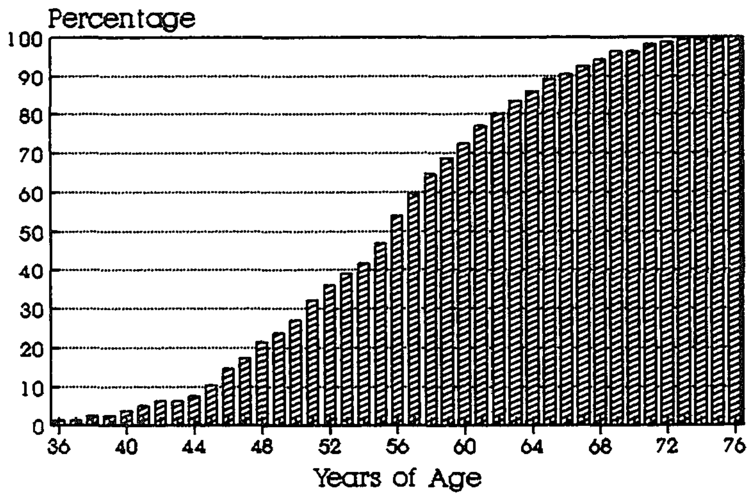

Figure 2.1. Cumulative Age distribution of study population

Exercise training. Exercise training consisted of an interval training on a bicycle ergometer. The programme largely followed the recommendations of a WHO conference on cardiac rehabilitation in Freiburg-im-Breisgau (1968). However, it was shortened from eight to five weeks, whereas the training was intensified, from three to five times a week. Thus, the total number of training sessions remained unchanged. The purpose was to start training soon after hospital discharge and to avoid prolonged rehabilitation, in order not to interfere with the patients' return to work.

Occasionally, patients were not yet fit enough for daily exercise training. In that case, they started with a weekly exercise session of moderate intensity, until they were able to tolerate more intensive exercise. In these patients the total rehabilitation period was increased.

Relaxation therapy. The relaxation therapy, developed at St. Joannes de Deo Hospital, consisted of several techniques, centring around a respiratory technique, taught on an individual basis in six weekly one hourly sessions. The aim was for the patient to become aware of a more relaxed way of breathing, so that he would be able to recognize and elicit this. Thus, the perception by the patient of changes in his body, indicating a more or less relaxed state, was essential. The method differed from most other procedures in various aspects: relaxation was taught individually, a breathing technique was used as a core element, manual handling was important to influence respiration and promote body awareness, relaxation was practised passively (supine) as well as actively (sitting, standing). The relaxation therapists (three psychologists, one physiotherapist and one medical doctor) were trained by the author. A detailed description is given in the Appendix.

Outcome criteria. Obtaining a training effect is a physiological rationale for exercise training in the rehabilitation of cardiac patients. A training effect means that the maximal work load has increased, whereas the cardiovascular response (heart rate, blood pressure) at the same level of effort has decreased: this indicates an improvement in physical fitness. An important implication, for cardiac patients in particular, is that the myocardial oxygen demand for a given work load is reduced, and thus the threshold for the occurrence of myocardial ischemia (chest pain, ST-depression) may possibly be raised.

Exercise testing was carried out routinely at intake into the physical training programme, in order to assess fitness, safety of training and maximal heart rate, from which the individual training heart rate was derived. The same test was performed at the end of the training period, to evaluate whether training had been successful.

Since all patients in this study participated in the exercise programme, measurements of exercise testing were used to assess the training outcome and possible contribution of relaxation. Usually, average changes on pre- and post measurements are compared for each parameter separately. This approach has some important drawbacks. First, an average positive change masks the fact that some patients may not improve or actually deteriorate. Second, an improvement in one parameter does not necessarily mean that training was successful, nor does it exclude deterioration in another parameter. In our view, it was important to identify patients who clearly improved after training, as well as patients who actually deteriorated.

Therefore, a **composite criterion** was constructed (chapter 4), integrating changes in the most important measurements of exercise testing. This results in a **single outcome measure**, indicating a positive change (training success), a negative change (training failure) or no change at all. This criterion served as an overall measure to determine efficacy of exercise, compare the two treatments, and predict the outcome. Thus, the rather arbitrary choice of one parameter as endpoint for predicting the outcome was avoided. An additional advantage of this criterion was that patients who did not complete the training could still be classified on the basis of their reason for stopping. Thus, following the 'intention to treat' principle, outcome could be analysed for all randomised patients.

However, the goal of rehabilitation was not only to improve physical fitness. Exercise is thought to enhance morale and mood, alleviate anxiety and depression, reduce fear of effort and promote the resumption of normal activities. Thus, improved fitness is supposed to have many secondary advantages: fit people feel better. The distinction between primary and secondary effects is important. It implies that training success is not necessarily identical to an improved functional state and rehabilitation outcome cannot be measured by exercise testing alone. I preferred to use self-report measurements by way of questionnaires, to measure subjective improvement and changes in general function. Psychic aspects were represented by scales for well-being, anxiety and depression, whereas more somatic aspects of function were represented by feelings of invalidity, sleeping habits and sleep quality, and functional complaints. Similar to exercise testing, different parameters were used individually, as well as integrated into another composite criterion. This composite score was used to investigate the association of general (psychic) improvement with training and relaxation outcome and it was an endpoint for predicting the psychological outcome.

A respiratory test was introduced to measure changes in respiration and in body awareness, which indicated that the relaxation method had been successful. They were criteria for the immediate goal of the relaxation method. However, the procedure was such that patients in both treatments could be measured and compared. Patients were told that fitness included the ability to rest as well as to sustain effort and that both ends of this continuum had to be measured, in order to assess their condition. Relaxation was not mentioned.

Conclusion. The efficacy of exercise training and relaxation therapy was investigated, using a set of measurements which are specific to the nature of the treatment. In addition, self-report measurements of general (psychic) functions were used to investigate the wider, secondary benefits of the two treatments. In this way the success of rehabilitation for myocardial infarction patients could be estimated in a medical and physiological, as well as psychological sense.

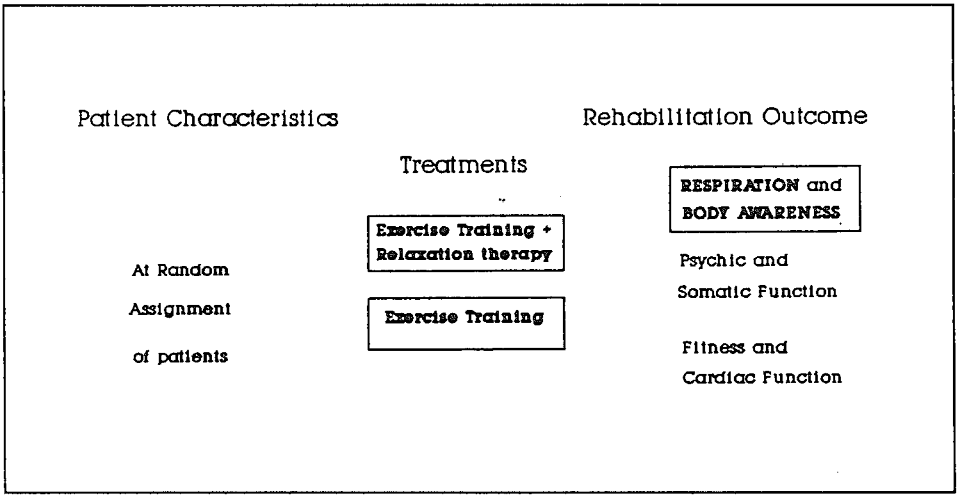

Figure 3.1.
Comparing outcome between treatments: Respiration and Body Awareness

Chapter 3

Breathing Awareness as a Relaxation Method in Cardiac Rehabilitation

Jan van Dixhoorn, MD and Hugo J Duivenvoorden, PhD

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BREATHING AWARENESS AS A RELAXATION METHOD IN CARDIAC REHABILITATION

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INTRODUCTION

Opinions differ as to the feasibility and utility of relaxation therapy for cardiac patients. Although it seems obvious that relaxation is helpful for reducing stress in the recovery period after acute myocardial infarction (1-5), as well as for changing risk behavior (6, 7), its usage in cardiac rehabilitation is limited and variable. Only in West-Germany, it seems, is relaxation offered in all rehabilitation centers, mainly as autogenic training classes (5). In the Netherlands, application for admission is rapidly increasing, up to about 50% for all centers (8). Cardiac patients pose a particular challenge with respect to relaxation. They tend to be skeptical, to prefer strategies that allow them to remain in control, to be impatient and to have little power of self-observation (5, 9). Certainly it is true that relaxation may provoke anxiety and resistance (10). Many professionals involved in cardiac rehabilitation consider it useful for all patients to learn relaxation (5, 11), even though it may have appeal to a minority only. Others assume that only some patients need to learn it (12).

On the other hand, the rehabilitation period is suitable for learning more adequate coping styles. The most popular treatment form, aerobic conditioning, has only a modest psychic effect (1, 13, 14). The aforementioned cardiac patients provide the rationale for behavioral intervention such as relaxation to take place. Certainly, introducing relevant coping styles and motivating patients to utilize them poses a significant challenge to health professionals (9).

An adequate strategy depends as much on the relaxation procedure and technique as on the context of the rehabilitation setting. In St. Joannes de Deo Hospital, Haarlem, The Netherlands, a procedure for individual treatment was developed. It centered around respiration, also using EMG-feedback and general relaxation (15). A randomized controlled trial of this relaxation therapy showed that it improved the overall physical benefit of training, in comparison with only exercise training (16). In particular, the risk of a negative training outcome was diminished by 50% and ST-segment abnormalities, indicating myocardial ischemia, were significantly reduced. A two-year follow-up revealed that patients who learned to relax experienced significantly fewer cardiac events (17). With respect to the psychic benefit of rehabilitation, exercise per se did not result in any psychic change, but the combined treatment of exercise and relaxation increased perceived well-being and reduced anxiety and feelings of invalidity (18).

The nature of the procedure employed was breathing awareness. Most relaxation techniques do not address respiration directly, so as not to disturb its autonomic character by voluntary control. The rationale is, that when one relaxes physically and mentally, respiration becomes optimal. On the other hand, regulating (pacing) respiration modulates the stress response and anxiety (19, 20). Teaching diaphragmatic breathing is effective in reducing stress for various disorders (21-24).

Although reduced arousal certainly affects respiration (25), respiratory *habits* do not necessarily change with general relaxation (26). Simply paying attention to breathing without specific instruction can also disturb it, because of an over-consciousness or by evoking faulty or strenuous habits.

An underlying fact is the dual role of respiration as a voluntary and involuntary function. Breathing may be an indicator of tension but functions as well as a regulator of tension. The problem of breathing technique is how to use the latter potential without disturbing its feedback value as a tension indicator. Therefore, techniques derived from voice and breathing therapy were integrated in general relaxation technique, emphasizing body awareness and passive concentration. This resulted in "breathing awareness" as a relaxation method. Its aim is to elicit a shift in the respiratory pattern towards a more easy and natural pattern while avoiding strain and effortful practice. When successful, this has strong subjective effects and usually lowers respiration rate. This method was applied to cardiac patients, because, as was mentioned earlier, it is for cardiac patients of prime importance to achieve an experience of relaxation within the first sessions of relaxation therapy. A limited number of sessions should be sufficient as a first step to master the basic technique. It is of equal importance to emphasize sensory awareness and to notice bodily signals of tension and relaxation. The majority of the patients are not at all used to being aware of these signals, or on the contrary, to ignoring them. "Feeling well" means "feeling nothing," i.e., there is nothing to complain about. Finally, it is important to present relaxation as a psychologically neutral technique and as part of the normal rehabilitation program.

The questions to be answered are,

1) does relaxation, applied in the procedure outlined above, reduce respiration rate and increase body awareness,

2) do respiration rate and body awareness in turn induce beneficial effects with respect to the total rehabilitation outcome,

3) which respiratory parameters are influenced in particular? (fine grain-analysis)

Table 1. Baseline Clinical Data

Variable	Treatment A		Treatment B	
No. of cases	76		80	
Age (years)	55.4	(8.2)	55.7	(8.1)
Males	71	(93)	76	(95)
Working	50	(66)	51	(64)
Married/with Partner	69	(91)	74	(93)
Size of MI:				
unknown	4	(5)	4	(5)
small	20	(26)	27	(34)
medium	27	(36)	22	(27.5)
large	25	(33)	27	(34)
In-hospital signs of heart failure	14	(18)	13	(16)
Medication on discharge:				
beta blockers	20	(26)	25	(31)
diuretics	27	(36)	20	(25)
anti-anginal	13	(17)	18	(23)
Start of physical training (weeks after hospital dscharge)	4.8	(2.8)	5.2	(2.1)
Exercize testing:				
Maximum work load (watt)	136	(24)	132	(21)
ST-segment abnormalities	24	(32)	20	(25)
Angina pectoris	9	(12)	9	(11)

Data are reported as events and percentages of cases or as means (SD), MI, myocardial infarction.

PATIENTS AND METHODS

Patients

After being discharged from several hospitals, cardiac patients are referred to the regional rehabilitation center at St. Joannes de Deo Hospital, Haarlem, The Netherlands. In three intake periods (1981-1983), a total of 156 myocardial infarction patients were found eligible for the study. They were randomly allocated to two treatment protocols. Patients who were considered to need individual (psychosocial) help in addition to exercise training were excluded. There was no age limit. Table 1 summarizes the clinical data at the time of entry to the trial for the two randomized groups.

Treatment Programs

Rehabilitation consisted of a program of relaxation training in addition to exercise training (Treatment A) or of exercise training only (Treatment B). The exercise training consisted of 5 weeks of interval training, once a day for half an hour, on a bicycle ergometer. Training was done in groups of four patients supervised by two physical therapists. Each patient exercised up to 70% of the maximal heart rate attained at the pre-training exercise test.

Relaxation training was given once a week in six individual sessions of one hour, by five specially trained persons. Three of them were a psychologist, a medical doctor and a physical therapist. Several procedures for active and passive relaxation were employed: EMG feedback of the frontalis muscle was used , 1) as a "mental device" (25) to focus attention for passive relaxation, 2) to give feedback of muscle tension and explain the concept of relaxation, 3) to monitor excess inspiratory effort.

For breathing instruction, attention was directed to respiratory movement (rate, depth, location, ease, regularity). In the supine position, one hand was placed on the lower abdomen, accompanied by the words, "the hand notices what the body does." Next, a technique to influence respiration was applied. Audible lip breathing is an example of this method. It is postulated that this technique stimulates inspiration and diaphragmatic activity, while preventing strain in the throat or chest. Then, attention was again directed towards passively monitoring breathing and the patient was asked to compare the result with the previous condition. The point was made that the primary aim of the technique is to become aware of differences, first in quality of respiratory movement, next in body sensation, and finally in thought, mood and feeling.

The patient learned to observe and elicit a "shift" towards a more easy, free and effortless respiratory pattern, with a smooth rhythm of inhalation and exhalation. The therapist monitored respiration and gave feedback so that inspiration expanded both the lower abdomen and the costal margin. Expiration was moderate and slow. Manual techniques were applied to elicit breathing movements which involved the trunk as a whole and required less effort. This was practiced first in the supine, relaxed position, but later also as the subject was sitting and standing ("active relaxation"). The patient was then asked to practice at home and also when experiencing chest discomfort.

Care was taken to introduce relaxation as a part of the routine rehabilitation procedure and not a means of providing special psychological help. The treatment itself was presented in a neutral fashion. It emphasized the technical and physical aspects of relaxation and its utility in dealing with daily challenges. Also provided was a rationale, in the form of the biofeedback instrumentation, for incorporating the treatment. Finally, breathing "exercises," and the masking of psychological implications also made up the rehabilitation treatment.

Measurements

An appointment was made for the physiological test, at which occasion psychological questionnaires were also completed. All patients performed the graded exercise test at the beginning of the physical training. Both tests were repeated after rehabilitation; the physiological test was also repeated three months later.

Psychological Questionnaires

Before and after rehabilitation the patients completed a set of four psychological questionnaires. They were as follows: first, the Heart Patients Psychological Questionnaire (HPPQ), constructed to measure the well-being of cardiac patients (27), consists of the scales: Well-being (HPPQ-W), Subjective Invalidity (HPPQ-I), Displeasure (HPPQ-D), and Social Inhibition (HPPQ-S). The second type of psychological questionnaire was the STAI, measuring: state and trait anxiety (28). Sleep Quality, measured with a 10-item questionnaire was the third (29). Functional Complaints, a 25-item questionnaire constructed to measure complaints often mentioned by cardiac patients but not typical of angina pectoris was the final form.

Exercise Testing

All patients performed on a bicycle ergometer (Monark) before and after the physical training. The test started with a one-minute period of cycling at 60 cycles a minute without load, then for two minutes at 60 Watts. The test was continued by increasing the workload with 30 Watts every two minutes until symptoms limited the patient to continue or until the physician terminated the test. Exercise-induced signs of cardiac dysfunction (ST-abnormalities, angina pectoris, serious dysrhythmias) were noted and heart rate and systolic blood pressure were measured.

Physiological Test

The test was introduced to the patient as a physiological measurement of the resting condition, in addition to the exercise test which measured the condition during effort. The research assistant was blind to the treatment form of the patient. He did not refer to the relaxation therapy and took care not to make any suggestions with regard to "proper" breathing.

Protocol: after attaching the equipment, the patient remained standing for two minutes. Measurements during the second minute ("standing") were used, after which time the patient was to lie down on the back. Measurements in the second minute of lying down were used ("supine"). Next, the use of mouthpiece and nose-clip was explained and they were attached. After this, the patient was to lie quietly without making physical movements or talking. This lasted six minutes. Measurements in the first ("mouthpiece") and last minute ("quiet") were used.

Body awareness: at the end of the test the patient's self assessment, specifically perceptions concerning the body's state, were recorded. Answers were rated as 1=pleasant, 2=no particular feeling, 3=unpleasant.

Respiration: respiratory movements and heart rate were continuously recorded polygraphically with a Psychophysiograph (ZAK). One band was strapped around the chest at the level of the fifth intercostal space, and one around the abdomen at the umbilical level, both bands containing a transducer which provided stretch dependent voltage changes. This was converted into a recording of chest and abdominal expansion and retraction. Respiration rate per minute was calculated.

Respiratory sinus arrhythmia: a finger plethysmograph was used to measure the pulse, converted by a cardiotachometer in a beat-to-beat recording of heart rate, simultaneous with respiration. Respiratory sinus arrhythnmia was calculated as the mean difference between minimum beat interval during inspiration and maximum interval during expiration for five consecutive respiratory cycles.

Ventilation: using a mouthpiece and nose-clip, air was sampled from the mouthpiece and carbon-dioxide concentration (% volume) was measured with a capnograph (Jaeger). End-tidal carbon-dioxide concentration in the exhaled air was used. Ventilation was measured with a wet spirometer (Lode). Tidal volume registrations corresponded with the amplitude of the simultaneous polygraphic recording of rib-cage and abdominal motion. On the basis of this, tidal volume at the beginning (supine) and the end of the text (quiet) was estimated, and minute volume was calculated.

Method of Analysis

For statistical testing: Student's t-test was used for measurements of a metric level and chi square for measurements of a nominal level. It then followed that the measurements, obtained through exercise testing pre and post training, were integrated into a composite criterion for "training benefit" (TB), trichotomized as follows: a. the patients with doubtful or no change (TB=O), b. the patients who improved (TB=+) or c. the patients who deteriorated (TB=-). The procedure is described in detail elsewhere (16). In short, the measurements were ranked into four levels according to their clinical relevance: 1) signs of cardiac dysfunction, 2) maximum work load, 3) maximum heart rate, and 4) systolic blood pressure response. At each level a patient could be selected for TB=+ or TB=- when a significant change in the particular measurement had occurred. Finally, dropouts were included and classified on the basis of the reason for not completing the program.

The next portion of the evaluation involved psychic outcome. In this report psychic outcome is distinguished in 1) well-being, measured by HPPQ-W; 2) psychic function measured by STAI-S, STAI-T and HPPQ-D, representing anxiety and depression; and 3) somatic function measured by HPPQ-I, sleep quality and functional complaints. For psychic and somatic function, the scores on the questionnaires were standardized and summed-up and the resulting scores were dichotomized in favorable and unfavorable changes.

RESULTS

There were no differences between the two treatments in base-line clinical data as shown in Table 1. Infarction size, classified on the basis of the peak serum enzyme levels, was small in 47 patients, medium in 49 patients and large in 52 patients. In-hospital signs of heart failure occurred in 27 patients (17%). On the average, patients visited the rehabilitation centre during the third week after hospital discharge and underwent initial exercise testing two to three weeks later. Most patients (93%) reached a maximum work load of at least 120 Watts, with an average of 133 Watts, or 89% of the exercise tolerance predicted on the basis of age, gender and height. Forty-five patients (29%) were on beta-blocking medication.

Relaxation Effect

Table 2 shows that average respiration rate, prior to rehabilitation, was about 15/minute and did not differ between treatments. At post-test and at follow-up it decreased to 12.5/minute for Treatment A but was unchanged for Treatment B. The differences were significant ($p < 0.0001$). Figures 1 and 2 show that during the test, respiration rate declined from 17/minute (standing) to 16/minute (lying down) to 13/minute after breathing through a mouthpiece and went back to 14/minute (quiet).

Table 2. Effect of Relaxation Training on Respiration Rate

Average respiration rate	Treatment A n	x̄	(SD)	Treatment B n	x	(SD)	p*
pre-test	73	14.7	(3.7)	7	15.2	(3.6)	ns
post-test	66	12.5	(3.7)	70	15.0	(3.2)	< 0.0001
pre-post difference	65	2.1	(2.8)	69	0.2	(1.9)	< 0.0001
three months follow-up	67	12.6	(3.8)	67	15.2	(3.5)	< 0.0001
pre-follow-up difference	66	1.9	(3.0)	66	-0.1	(2.4)	< 0.0001

* Difference between treatments: Student's t-test, two-tailed

This pattern of a steady decline and a slight increase at the end of the test did not change after rehabilitation. For Treatment A, however, after rehabilitation, all values became substantially lower. The difference with Treatment B was highly significant for all measurements at post-test and at three months follow-up. This means that relaxation induced a stable, more quiet respiratory pattern.

Results of the study also involved the following findings. Before rehabilitation the majority of the patients (Treatment A: 63%, Treatment B: 65%) did not notice anything in particular when asked at the end of the test how they felt their body to be (see Table 3). A small number (Treatment A: 10%, Treatment B: 7%) had unpleasant sensations. After rehabilitation most patients in Treatment A (60%) had a pleasant sensation; this change is significant ($p < 0.001$). Patients in Treatment B felt no change. The difference between the treatments in the post-test situation was significant ($p < 0.01$) and also at follow-up ($p < 0.005$). It means that as a result of

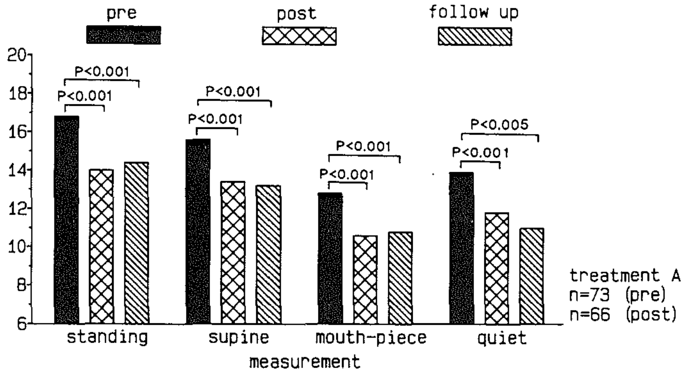

Figure 1. Respiration rate pre-test, post-test and at follow-up for Treatment A.

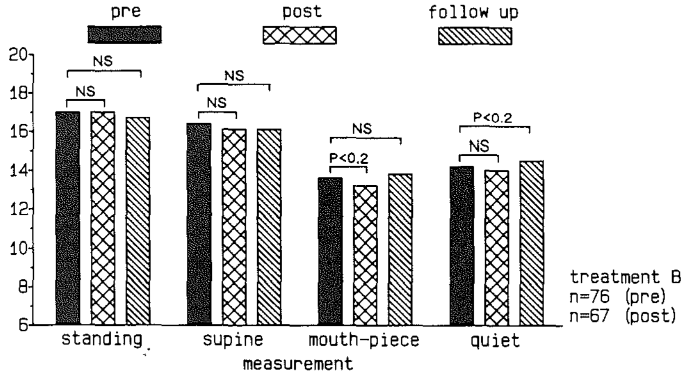

Figure 2. Respiration rate pre-test, post-test and at follow-up for Treatment B.

relaxation training, body awareness increased and physical rest induced more pleasurable body sensations.

Relation of Rehabilitation Outcome To Respiration Rate and *Body Awareness*

The testing procedures produced several outcomes of a significant physical nature. First of all, the composite criterion of training benefit indicated that in Treatment A, 42 patients (55%) improved physically after rehabilitation and 37 patients in Treatment B (46%). Patients were considered not improved when they did not change (Treatment A: 25%,Treatment B: 21%) or deteriorated after training

Table 3 Effect of Relaxation Training on Body Awareness

Body sensation after rest	Treatment A n(%)	Treatment B n (%)	p*
pre-test			
pleasant	16(27)	17(28)	
nothing particular	37(63)	39(65)	
unpleasant	6(10)	4 (7)	ns
post-test			
pleasant	38(60)	23(33)	
nothing particular	20(32)	38(55)	
unpleasant	5 (8)	8(12)	< 0.01
three month follow-up			
pleasant	38(59)	18(28)	
nothing particular	20(31)	39(60)	
unpleasant	6 (9)	8(12)	< 0.005

*Difference between treatment: chi square, df=2, two-tailed

(Treatment A 20%, Treatment B: 33%). Table 4 shows that for both treatments the respiration rate at post-testing was slightly higher with patients who improved physically, in comparison to patients who did not improve. The difference was not significant. Thus, respiratory rate was not related to physical benefit. Positive body awareness had no relation to training benefit either.

The most significant finding related to the psychic nature of the individual was that most patients in Treatment A improved in perceived well-being (HPPQ-W). Those who improved were breathing slower than those who did not improve ($p < 0.05$). Body awareness, however, was only slightly more positive. In Treatment B, well-being only slightly improved after rehabilitation. There was no relationship between improvement and respiration rate or body awareness post-testing.

Importantly, the psychic function (anxiety and depression) showed a positive change in most patients (Treatment A: 69%, Treatment B: 70%). For Treatment A improvement of psychic function had no relation to either respiration rate or body awareness. In Treatment B, patients who improved psychically were breathing faster at post-testing ($p < 0.05$). They did not differ in body awareness from patients who did not improve. Also, the patients' somatic function (sleep quality, feelings of invalidity and functional complaints) showed a positive change (Treatment A: 69%, Treatment B: 60%). Patients in Treatment A who improved somatically tended to breathe slower at post-testing ($p < 0.20$) and had significantly more positive body awareness ($p < 0.02$). This means that somatic improvement was related to the relaxation effect. In Treatment B, patients who improved somatically were breathing slightly faster.

Respiratory Changes: Fine Grain Analysis

Data collected with the physiological test were analyzed for a sub-set of the patients admitted to the study in 1982. Out of 58 patients, post-test measurements were available for 48 (Treatment A: 24, Treatment B: 24).

Estimated tidal volume at the beginning of the test increased for Treatment A from 0.61L to 0.69L (see Figure 3). It decrease in Treatment B from 0.59L to 0.5L ($p < 0.05$). The difference between the treatments was significant ($p < 0.05$). At the end of the test, tidal volume was smaller than at the beginning, particularly for Treatment B, both before and after rehabilitation.

Also, estimated minute volume was 8.0L for Treatment A and 8.5L for Treatment B at the beginning of the test (see Figure 4). It increased slightly for Treatment A and decreased a little for Treatment B after rehabilitation, but not significantly. During the test, minute volume decreased substantially, both before and after rehabilitation, irrespective of the treatment. This means that physical rest clearly reduced ventilation.

Yet another important observation involved estimated effective ventilation. It was calculated as tidal volume minus 0.15L (the average volume of dead air space) times respiration rate. Again, for Treatment A effective ventilation increased (from 5.9L to 6.3L), whereas it decreased for Treatment B (from 6.2L to 5.5L). The difference between treatments was not significant.

Furthermore, end-tidal CO_2 concentration increased significantly in Treatment A from 4.3 (0.5) vol% to 4.5 (0.5) vol% after training ($p < 0.05$). In Treatment B it increased slightly from 4.5 (0.6) vol% to 4.6 (0.6) vol%. The difference between treatments was not significant.

Table 4. Four Outcome Measures, Related to Respiration rate and Body Sensation, for Treatment A and Treatment B.

	Respiration rate at post-test							
	Treatment A				Treatment B			
	n			p*	n			p*
Exercise testing								
improved	38	12.7	(3.6)		35	15.4	(3.1)	
not improved	28	12.1	(3.8)	ns	35	14.6	(3.3)	ns
Well-being								
improved	48	11.8	(3.3)		39	15.1	(2.9)	
not improved	18	14.1	(4.2)	0.03	30	15.1	(3.5)	ns
Psychic function								
improved	43	12.2	(3.6)		46	15.4	(3.1)	
not improved	19	12.4	(3.5)	ns	20	14.0	(2.5)	0.05
Somatic function								
improved	41	11.9	(3.7)		38	15.4	(3.2)	
not improved	20	13.3	(3.2)	0.1	26	14.4	(3.4)	ns

	Body sense at post-test (**)							
	Treatment A				Treatment B			
	n			p*	n			p*
Exercise testing								
improved	36	1.5	(0.7)		35	1.8	(0.6)	
not improved	27	1.5	(0.6)	ns	34	1.8	(0.7)	ns
Well-being								
improved	47	1.4	(0.6)		38	1.8	(0.6)	
not improved	16	1.6	(0.8)	ns	31	1.7	(0.6)	ns
Psychic function								
improved	41	1.4	(0.6)		46	1.8	(0.6)	
not improved	18	1.5	(0.7)	ns	20	1.7	(0.7)	ns
Somatic function								
improved	40	1.4	(0.5)		38	1.8	(0.6)	
not improved	18	1.8	(0.9)	0.02	25	1.8	(0.7)	ns

*Student's t-test, two-tailed;
**1 = pleasant, 2 = nothing particular, 3 = unpleasant

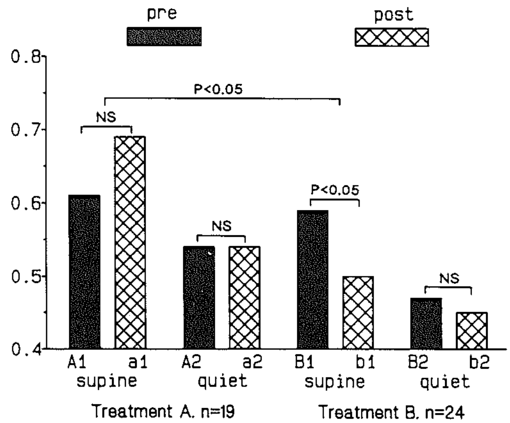

Figure 3. Estimated tidal volume pre-test and post-test for Treatment A and B.

Chest and abdominal motion was also significant. The relative contributions of rib-cage and abdomen to the respiratory movement could be tentatively estimated as being the ratio of the amplitude of the abdominal and rib-cage recording. This ratio was 4.2 for Treatment A and 4.6 for Treatment B at the beginning of the pre-test. During the test it increased for both treatments to 4.5 and 5.0 respectively. This means that abdominal contribution to respiration increased relatively during the test. After training the ratio increased during the test from 5.3 to 5.8 in Treatment A, and in Treatment B from 3.4 to 4.2. Consequently, abdominal breathing had increased in Treatment A but had diminished in Treatment B. The difference between treatments was not significant ($p = 0.14$).

Finally, respiratory sinus arrhythmia was observed (Figure 5). The heart rate variability during slow breathing (6 cycles/minute) both at the beginning and at the end of the test increased for Treatment A after training ($p < 0.005$ respectively $p < 0.02$). For Treatment B respiratory arrhythmia did not change. The difference between treatments was more pronounced at the end of the test ($p < 0.05$) than at the

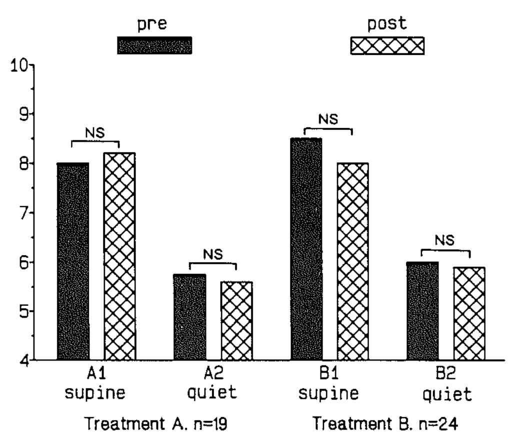

Figure 4. Estimated minute volume pre-test and post-test for Treatment A and B.

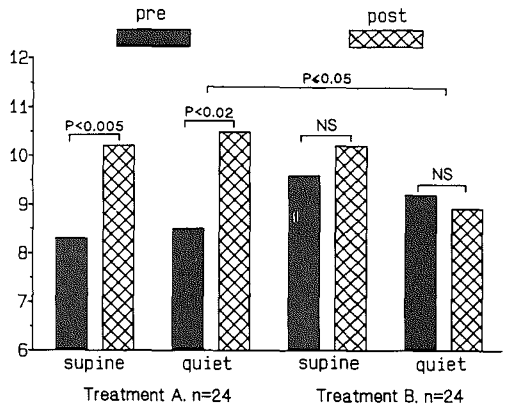

Figure 5. Respiratory sinus arrhythmia pre-test and post-test for Treatment A and B.

beginning ($p = 0.10$). Average variability differed significantly between treatments ($p < 0.04$).

DISCUSSION

Effect on respiration: This study showed that breathing awareness as a relaxation method has been successful in calming respiration and inducing positive body awareness for myocardial infarction patients. Regarding the implications of this result, several points need to be considered. First, the exploratory fine grain analysis on a sub-set of patients showed that a slower respiration rate meant that ventilation became more efficient, because tidal volume increased while minute volume remained practically unchanged. Thus, the proportion of inhaled air used for gas exchange increased, as well as the time for oxygen exchange in the lungs. The increased effective ventilation did *not* result in excess ventilation (hyperventilation), which would have been a negative side-effect (30, 31). In fact, the number of patients with CO_2 below 4.0 vol% dropped from 3 to 1 in Treatment A, whereas it rose from 4 to 6 in Treatment B.

Second, it was found that physical training did not improve respiration. The fine grain analysis showed that patients in Treatment B even tended to breathe more superficially after training. For both treatments, patients with physical training benefit did not breath slower. Thus, contrary to expectation (32), respiration was not inherent to a physical training effect.

Third, the decrease in respiration rate, although highly significant, was modest. When patients are taught to breathe diaphragmatically and asked to perform their skill, respiration frequencies of 4-8/minute would not have been surprising (20,21). In the approach utilized in this study, however, emphasis was less on voluntary skill and more on a shift in the spontaneous respiration pattern. The idea was that a change in the habitual pattern would be more durable. The stability of the results at the three month follow-up confirmed this. The finding has been confirmed even after two years: in 38 patients a registration of respiration was carried out at the follow-up interview Figure 6 shows that respiration rate was still lower for Treatment A, whereas Treatment B showed an unchanged frequency. The difference was highly significant.

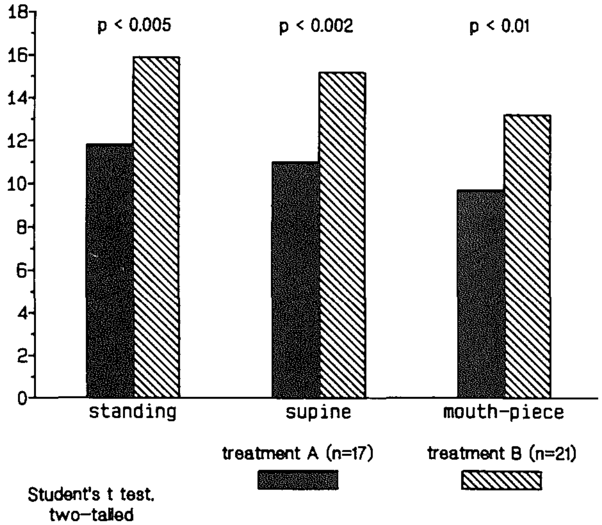

Figure 6. Respiration rate at two year follow-up for Treatment A and B.

Fourth, the study indicated that reducing respiration rate is not an ideal to be achieved. Rather, the express purpose should be to induce a psychophysiological change and to retain the connection of respiration to other physiological and psychological variables (33). The procedure of breathing awareness seemed to have been successful in that respect, because the response of respiration rate to the various phases of the physiological testing (standing, lying down, mouthpiece breathing, quiet) remained unchanged. This means that respiration became more quiet through breathing therapy but was not forcefully controlled and remained a valid tension indicator. Also, respiratory change was not limited to frequency, but included other parameters, e.g., sinus arrhythmia.

However, the interrelation of frequency with other respiratory variables deserves further study, in order to characterize possible changes in respiratory pattern in more detail. For instance, prior to rehabilitation, respiration frequency did not correlate with carbon dioxide. Only after breathing therapy was the expected negative correlation found. This means that breathing awareness strengthened the interrelation of respiratory parameters.

Also, although the relaxing effect of breathing technique is often ascribed to increasing diaphragmatic activity and decreasing upper-thoracic breathing, this seems to be an overly simplistic conclusion. The coordination of the diaphragm with respiratory muscles in the abdomen, the back and in the chest is more important than diaphragmatic strength (34-36). For instance, there was no tendency for upper-thoracic breathing among the cardiac patients (37). Instead, the rib-cage contributed far less to respiratory movement than the abdomen. This tendency was strengthened by the relaxation method, which put emphasis on breathing movement in the lower abdomen. This finding seems paradoxical, considering that efficient breathing involves movement of the whole trunk, including the pelvis, spine and breast-bone (38). It was noted however, that the rib-cage showed small amplitudes, because the chest was rather stiff and usually was wide. In the supine position on the back it became even more fixed. Thus, the absence of gross upper-thoracic breathing did not imply an adequate costo-abdominal rhythm. For that reason, manual techniques were used in various postures to improve the rhythmic expansion and contraction of the whole body under respiration. The technique for home practice started with natural breathing in the lower body, because focusing attention on the chest has a risk of evoking forceful breathing.

Finally, the method employed focused on sensory discrimination of differences in breathing pattern and in bodily tension. The "exercise" was to compare the condition before and after a particular procedure, and to become aware of the difference. Thus, the relatively strong impact of respiratory change was coupled to "passive" awareness and self-observation. It seems that the ability for sensory awareness is the core of all relaxation procedures. The problem was how to introduce this concept to cardiac patients and whether they could tolerate increased sensitivity to inner physical events. When successful, this awareness has the psychological function to reduce anxiety, in particular about the body. Obviously, it is necessary to master the techniques of breathing and relaxation, eventually integrating them into the emotional state.

The outcome of the present study indicated that body awareness had indeed been increased. It should be noted, however, that this concerned a pleasurable experience occurring at the end of the test, i.e., after about 15 minutes. It means that physical rest had become more of a positive experience. Probably a more favorable attitude toward relaxation was induced, rather than the more negative interpretation of the need for physical rest as a sign of weakness. In fact, patients in Treatment A continued taking daytime rests, whereas patients in Treatment B rested less often after rehabilitation. At the two-year follow-up, the treatments still differed in this respect.

The following contentions are therefore justified: that the method of breathing awareness 1) has been effective in changing the habitual respiratory pattern; 2) proved to be a valuable instrument to introduce body awareness and also relaxation.

Two significant factors led to this outcome. First, focusing on breathing "activity," in addition to the feedback signals, made it easier to continue lying down for some time and being passive (25). In case a patient became more restless during passive relaxation (10) the treatment continued with active relaxation, either sitting or standing. Second, the respiratory pattern which resulted from the breathing technique, together with reduced muscle tone (39) induced a "drowsy" state of mind (40,41), which facilitated passive awareness. Practical experience with this procedure showed that it was acceptable to the patients: no one stopped relaxation therapy. After the study, the relaxation procedure was retained as an individual treatment in the rehabilitation. Also, all patients now have one group relaxation session and it is incorporated in the regular physical exercise. In this way, most patients appear to be positive about relaxation.

The rehabilitation outcome can be summarized as follows. Relaxation therapy appeared to improve rehabilitation outcome, as well as respiration and body awareness. The question remains whether the latter effect is instrumental for bringing about an effect on rehabilitation outcome. However, the improvement in patient well-being was clearly related to slower respiration for Treatment A. The effect of relaxation on well-being may therefore be interpreted as partially the result of its influence on respiratory pattern. Improvement in somatic function was related to positive body awareness for patients who learned to relax; they also showed a trend towards slower breathing. Relaxation may have enabled these patients to experience and view their bodies differently, placing different limitations on physical potential. Furthermore, patients in Treatment B improved almost to the same degree, but without concomitant increase in body awareness. Possibly, recovery may have been a different process for them. If that thought is correct, it means that relaxation modifies the influence of rehabilitation on recovery. Another indication for this reality involved the inverse relation between respiration and psychic improvement for Treatment B. A possible interpretation is that, for those patients, heightened activity served as a way to cope with anxiety and depression (42). A kind of masking effect allowed patients to deal with depression.

It is possible that relaxation influences the way in which the patient experiences the rehabilitation, and what he learns from it. There is an enhanced ability to reflect upon lifestyle. The psychological literature on cardiac patients mentions an inability to relax; a preference for activity and resistance to passivity; a need for control and a firm belief in active, effortful coping strategies; a tendency to deny problems and minimize complaints. Cardiac rehabilitation usually addresses these tendencies by focusing on proper aerobic conditioning. The value of breathing and relaxation technique seems to be that it facilitates the ability for the individual to change, and to make rehabilitation more of a learning experience.

Future research is necessary to distinguish patients who were able to learn relaxation from those who could not master the techniques. Inability to relax and to breathe quietly may result from physical handicaps, e.g., intolerance for increased body sensitivity. Also, the motivation of the patient and the relation with the therapist are of importance. An intriguing question involves the degree to which a successful rehabilitation outcome depends upon a potential ability to relax.

SUMMARY

A relaxation method emphasizing sensory awareness and relaxed, diaphragmatic breathing, was introduced into a cardiac rehabilitation program. As compared to a physical exercise program, this method effectively reduced respiration rate and increased pleasant body sensations during physical rest. Simultaneously, ventilatory efficiency increased, hyperventilation was reduced, and heart rate variability increased.

After rehabilitation, slower respiration was associated with a higher level of perceived well-being, whereas positive body awareness signified more adequate psychosomatic function (sleep quality, functional complaints, sense of invalidity). Patients who learned to relax retained the habit of taking a siesta. At the time of a two-year follow-up, respiration rate still persisted to be lower and siesta time was longer than in patients who followed exercise training only.

It is concluded that the method of breathing awareness is suitable to induce relaxation and body awareness for cardiac patients.

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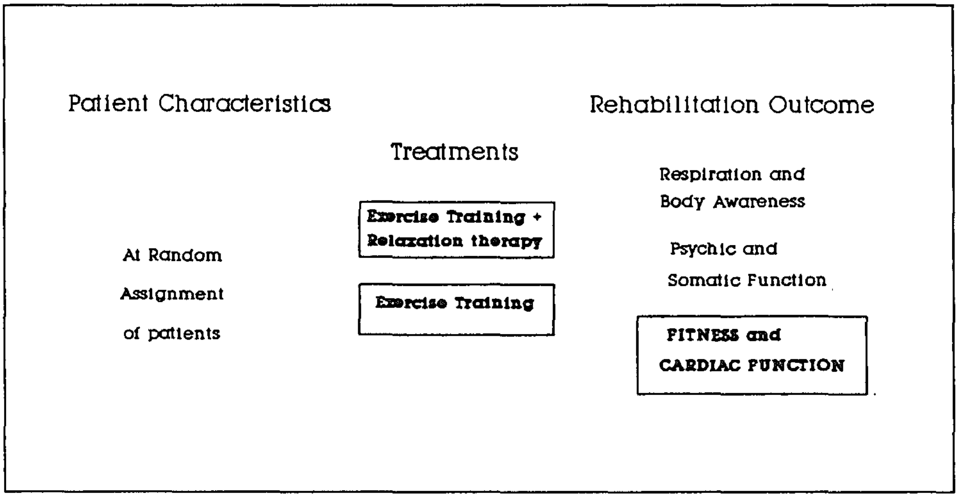

Figure 4.1.
Comparing outcome between treatments: Physical outcome

Chapter 4

Physical Training and Relaxation Therapy in Cardiac Rehabilitation assessed through a Composite Criterion for Training Outcome

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Physical training and relaxation therapy in cardiac rehabilitation assessed through a composite criterion for training outcome

One hundred fifty-six myocardial infarction patients were randomly assigned to either exercise plus relaxation and breathing therapy (treatment A, $n = 76$) or to exercise training only (treatment B, $n = 80$). Effects on exercise testing showed a more pronounced training bradycardia and a remarkable improvement in ST abnormalities in treatment A ($p < 0.005$). A model was developed to integrate the various exercise parameters into a single measure for training benefit. Approximately half the patients showed a training success, with a more positive and less negative outcome in treatment A ($p = 0.09$). The odds for failure were 0.25 for treatment A and 0.51 for treatment B (odds ratio: 2.04; 95% confidence interval, 0.94 to 4.6). Thus the risk of failure was reduced by half when relaxation was added to exercise training. These results indicate that exercise training is not successful in all MI patients and that relaxation therapy enhances training benefit. (AM HEART J 1989;118:545.)

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Aerobic exercise training is widespread in cardiac rehabilitation. It is intended to increase physical fitness, heighten the exercise threshold for myocardial hypoxia, and prevent disability. Research has been focused primarily on the feasibility of physical training for cardiac patients (safety, indications) and physical effects.[1-4] It appears that exercise is safe, but that the training response is modest.[4-7] This response consists of increased maximal work load, a muting of the heart rate and blood pressure reaction to any given work level, and in turn, a decrease in myocardial oxygen demand.[8-10] However, not all patients can improve their exercise tolerance; some even have a negative training outcome.[4, 9-12] Therefore it is important to differentiate patients with training success from those who failed in training, preferably on the basis of a single outcome measure. To achieve such differentiation requires that a composite criterion be constructed that integrates several parameters into a single outcome category for training benefit. This strategy allows evaluation of cardiac rehabilitation in terms of indications (patients with benefit of training) and contraindications (patients without benefit or with adverse effects). To our knowledge such a composite criterion has not yet been presented.

The role of relaxation and breathing therapy in addition to exercise is investigated in this study. This therapy uses "exercises" as well, but its goals are coordination and awareness.[13, 14] The emphasis is not on work power and performance, but rather on learning how to handle tension and effort. The value of the "coordination-relaxation-flexibility" type of exercise[14] (e.g., yoga, breathing exercises, or active relaxation), has not yet been studied circumstantially in cardiac patients. There are few studies of relaxation therapy in cardiac patients, several of which reported physical benefit.[15-22] To date, the effects of relaxation and breathing therapy as additions to aerobic conditioning, have not been investigated. The question to be studied is whether relaxation therapy has any incremental value to an exercise training program with regard to training outcome.

METHODS

Patients. After discharge from several hospitals, cardiac patients are referred to the regional rehabilitation center at St. Joannes de Deo Hospital, Haarlem, The Netherlands. During a 3-year period, a total of 156 myocardial infarction (MI) patients were eligible for the study. They were

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Table I. Baseline clinical data

Variable	Treatment A	Treatment B	p
No. of cases	76	80	
Age (years)	55.4 (8.2)	55.7 (8.1)	NS
Males	71 (93)	76 (95)	NS
Recurrent infarction	4 (5)	7 (9)	NS
Coronary bypass surgery	1 (1)	2 (2.5)	NS
History of angina >4 weeks' duration	14 (18)	12 (15)	NS
Size of MI:			
Unknown	4 (5)	4 (5)	
Small	20 (26)	27 (34)	
Medium	27 (36)	22 (27)	NS
Large	25 (33)	27 (34)	
Location of MI:			
Anterior	29 (38)	24 (30)	NS
Nonanterior	47 (62)	56 (70)	
Complications of hospital stay: heart failure	14 (18)	13 (16)	NS
Length of hospital stay (days)	18.2 (5.3)	19.6 (6.6)	NS
Postinfarction angina	28 (37)	25 (31)	NS
Medication on discharge:			
beta-Blockers	20 (26)	25 (31)	NS
Diuretics	27 (36)	20 (25)	NS
Antianginal agents	13 (17)	18 (23)	NS

Data are reported as events and percentage of cases or as means (±SD). MI, myocardial infarction. NS, not significant.

randomly allocated to two treatment protocols. Patients who were considered to need individual (psychosocial) help and not only exercise training were excluded. There were no age limits. Table I summarizes the clinical data at entry to the trial for the two randomized groups. Only nine women were referred for rehabilitation.

Measurements. In all patients a graded exercise test was performed on a bicycle ergometer (Monark) before and after the physical training. After an adaptation period on the bicycle, the test started with a 1-minute period of cycling at 60 cycles/min without load, then for 2 minutes at 60 W. The test was continued by increasing the work load by 30 W every 2 minutes until symptoms limited the patient's continuance or until the physician terminated the test. The occurrence of angina pectoris, ST disturbances, or severe arrhythmias were noted in the protocol. The ECG was read by a cardiologist (H.A.S.) for repolarization abnormalities. Most were ST depressions ≥2 mm, horizontal or downsloping, that occurred during or immediately after the test. A (standard) bipolar ECG lead was taken and recorded during the last 30 seconds before the work load was increased. Heart rate was calculated from this recording. Immediately after the test, a 12-lead ECG was recorded. After the patient had rested for 6 minutes, the heart rate was measured. Blood pressure was taken with a mercury sphygmomanometer before the test and at maximum work load.

Design. This was a randomized, controlled clinical trial. To study the incremental effect of a combined treatment of exercise training with relaxation and breathing therapy versus exercise training only, patients had to be randomly allocated to either of the two treatment protocols. Randomization was done after the intake interview for the rehabilitation program after informed consent had been obtained. Patients who needed individual help were referred for relaxation therapy or psychosocial counseling and were excluded from the study. The data were analyzed according to the "intention to treat" principle. The cardiologist supervising the exercise testing was not informed on the treatment of the patient.

Treatment programs. Rehabilitation consisted of a program of exercise training plus relaxation training (treatment A) or of exercise training only (treatment B). The exercise training consisted of 5 weeks of interval training, with exercise sessions once a day for 30 minutes on a bicycle ergometer. Training was done in groups of four patients supervised by two physical therapists. Each patient exercised up to 70% to 80% of the maximal heart rate (Karvonen method) attained at pretraining exercise test.

Relaxation training was given once a week in six individual-hour sessions. The relaxation therapy was done by five specially trained persons (three psychologists, one a medical doctor, and one a physical therapist; they did not participate in the exercise program). Several procedures for active and passive relaxation centered around a respiratory technique were used. The procedures are described in detail elsewhere.[13] In short, electromyocardiographic feedback of the frontalis muscle is used for muscle relaxation and to monitor unnecessary inspiratory effort. The patient learns to observe and elicit a shift in the respiratory pattern so that inspiration expands both the lower abdomen and the costal margin, and expiration is moderated and slow. Consequently, tidal volume increases and the respiration rate decreases, breathing movements involve the trunk as a whole and require less effort. The patient usually feels more quiet and calm (relaxation response). Hyperventilation, if present, decreases. Relaxation is practiced first in the supine, relaxed position, but later also in the sitting and standing positions (active relaxation). The patient is asked to practice daily at home and when experiencing chest discomfort.

Statistical analysis. Statistical tests were performed on the measurements separately by means of nonparametric tests. Wilcoxon's rank sum test was applied to repeated measurements of an ordinal nature, and the Mann-Whitney U test was used for independent samples (treatments A and B). Repeated measurements of a nominal nature were tested with McNemar's test for change, whereas comparisons between independent samples were done with chi square analysis. If the data consisted of more than two categories, the chi square analysis for trends was done.

The composite criterion. To obtain a single measure for overall training outcome, the measurements recorded at exercise testing were considered jointly. A composite criterion for training benefit (TB) was constructed in the form of a set of decision rules to select individuals who exhibit clearly positive or negative change. The purpose was to trichotomize the patients as follows: (1) patients with no or doubtful change (TB = 0), (2) patients who improved (TB = +), or (3) patients who deteriorated (TB = −). The measurements were ranked in a sequence of four levels reflecting their clinical relevance as judged independently by three cardiologists. The most important criteria were applied first, and negative effect had priority over positive effect because the first purpose of any intervention should be not to harm the patient. The decision rules for patient selection were applied sequentially as follows:

1. *Signs of cardiac dysfunction:* (a) exercise-induced repolarization disturbance, (b) exercise-induced angina pectoris, (c) serious arrythmia (groups or runs or multifocal or frequent premature ventricular complexes, bigeminy, or ventricular tachycardia). An individual in whom any of these signs was absent before training, but present after the training, was considered to have a negative effect (TB = −). Disappearance of these signs was considered as a positive effect (TB = +). However, changes in these signs were not used as indicators if relevant medication was changed or maximal work level increased or decreased more than 30 W over the same time period.

2. *Maximal work load.* Reduction of maximal work load was considered as a negative effect (TB = −), and an increase as a positive effect (TB = +), when the change was at least 30 W.

3. *Heart rate.* For comparison, heart rate was measured at similar work loads before and after the training period. The highest work load attained during both exercise testing was used as a criterion. An increase of the heart rate >10% of the initial value was considered a negative training effect (TB = −). Conversely, a decrease of the heart rate >10% of the initial value was considered a positive training effect (TB = +). This criterion was not applied when a change in relevant medication (particularly beta-blocking agents) coincided.

4. *Blood pressure response.* The last measurement was systolic blood pressure at the same work levels. When the blood pressure response during the test after training was >12 mm Hg higher than before training, this was considered a negative effect (TB = −), unless beta-blocking or antihypertensive medication had been stopped. Conversely, when the systolic pressure response was at least 12 mm Hg lower after training, this was considered a training success (TB = +), unless relevant medication had been started.

5. *Dropouts.* Patients who could not be classified on the basis of the previous measurements were considered unchanged (TB = 0) unless they had not performed an exercise test after training. In that case, the reason for the dropout of the rehabilitation program was used to decide whether the outcome was positive or negative with regard to physical recovery or cardiac function. Patients who stopped the training because they resumed their normal daily activity were considered successful outcomes (TB = +); patients who stopped the training for cardiac problems were considered negative outcomes (TB = −); patients who stopped for other reasons were considered neutral with regard to outcome (TB = 0).

Table II. Pretest values and changes in exercise testing for treatment A and treatment B groups

	Pretest *X (SD)*	*Change* *X (SD)*	p^*	
Maximum Watt				
Treatment A	136.4 (23.6)	+7.0 (15.8)	0.01	
Treatment B	131.5 (20.8)	+8.4 (17.1)	0.0005	
Heart rate (beats/min)				
Watt = 0				
Treatment A	88.3 (17.2)	−3.7 (14.0)	0.02	(n = 67)
Treatment B	86.5 (16.8)	−0.7 (11.1)	NS	(n = 72)
Watt = 90				
Treatment A	115.9 (20.4)	−4.8 (10.8)	0.0004	(n = 66)
Treatment B	114.5 (19.2)	−3.4 (10.7)	0.05	(n = 71)
Watt = 120				
Treatment A	130.6 (20.3)	−5.7 (10.8)	0.0001	(n = 62)
Treatment B	130.0 (21.8)	−5.4 (11.7)	0.001	(n = 66)
Watt = 150				
Treatment A	140.2 (22.4)	−6.3 (15.7)	0.05	(n = 28)
Treatment B	142.5 (22.8)	−4.2 (12.9)	NS	(n = 27)
Blood pressure				
Diastolic				
Treatment A	86.0 (9.9)	−0.15 (10.2)	NS	
Treatment B	86.9 (10.3)	−0.75 (10.2)	NS	
Systolic				
Treatment A	131.7 (17.9)	0.39 (14.4)	NS	
Treatment B	128.4 (15.7)	2.1 (14.3)	NS	
Systolic pressure response				
Treatment A	27.0 (17.3)	−0.9 (18.3)	NS	
Treatment B	27.1 (20.0)	1.4 (22.3)	NS	

Treatment A, n = 67, exercise plus relaxation; treatment B, n = 72, exercise only. +, Increase; −, decrease. NS, not significant.
*Significance level: Wilcoxon's rank sum test, two-tailed.

RESULTS

A total of 156 patients were admitted to the study (treatment A, n = 76; treatment B, n = 80). Baseline clinical data are shown in Table I. There were no differences between the two treatments. Three patients had previous coronary artery bypass grafting (CABG), 11 patients experienced recurrent infarction, and 26 patients had a history of angina pectoris. Infarction size was classified on the basis of the peak serum enzyme levels according to the standards of the participating hospitals. In most hospitals, an infarction is classified as small when the serum glutamic-oxaloacetic transaminase (SGOT) level is elevated, but remains below 60 U/L, whereas the infarction is classified as large when SGOT levels rise above 120 U/L. The infarction was classified as small in 47 patients, as medium in 49 patients, and as large

Table III. Signs of myocardial ischemia during stress testing: Repolarization disturbances on ECG (ST-T segment)

	Treatment A			*Treatment B*		
	After training			*After training*		
Before training	*Absent*	*Present*	*Total*	*Absent*	*Present*	*Total*
Present	12	12	24	4	16	20
Absent	42	1	43	47	5	52
Total	54	13	67	51	21	72

McNemar's test: $p < 0.005$, two-tailed; not significant

Table IV. Overall outcome of training based on composite criterion for training benefit

	Treatment A	*Treatment B*
TB = + (Success of training)	42(55%)	37(46%)
TB = 0 (No change)	19(25%)	16(21%)
TB = − (Failure of training)	15(20%)	27(33%)
Total	76(100%)	80(100%)

TB, Training benefit.
Linear chi square: 2.85, $df = 1$, $p = 0.09$, two-tailed.

in 52. In eight patients the enzyme levels were not available. In-hospital signs of heart failure (hypotension, cardiothoracic ratio >50%, pulmonary congestion) were present in 27 patients (17%). Assessment of ventricular function was not performed routinely in the participating hospitals. The average patient's hospital stay lasted almost 3 weeks. Postinfarction angina was present in one third of the patients in the study.

Exercise testing: Univariate analysis. A total of 139 patients completed the rehabilitation program (treatment A, $n = 67$; treatment B, $n = 72$). The initial values and the changes after training are shown in Table II. There were no significant differences in exercise parameters between the treatments before rehabilitation.

Maximum work load increased for both treatments to a small degree [treatment A: 7.0 W (5%; $p < 0.01$); treatment B: 8.4 W (6.4%; $p < 0.0005$)]. For treatment B, initial work load was slightly lower and the increase more pronounced; the difference between the two treatments was not significant. Most patients regained the pretest work level after training. Only 39 of 139 patients (28%) had a greater maximum work load (treatment A, 18; treatment B, 21). Conversely, seven patients (treatment A, 4; treatment B, 3) ended the test period with a lower maximum work load.

Average heart rate. For both treatment groups, the average heart rate at similar work levels was lower after training. There was a trend for more pronounced training bradycardia in treatment A compared with treatment B at most levels of effort; the difference did not reach significance. If a reduction of more than 10% of the initial value is used as a cutoff point, heart rate at maximum work level decreased for 22 patients, two of whom reached a lower work level after training. Thus 20 patients (14%) experienced a significant training response in maximum heart rate (treatment A, $n = 8$; treatment B, $n = 12$). When the same cutoff point is applied, maximum heart rate increased in 18 patients, 10 of whom reached a higher work level. This means that eight patients (6%) had a negative training effect in this respect (both treatments, $n = 4$).

Blood pressure. The average changes in blood pressure were negligible. There was neither an effect of training nor an additional effect of relaxation on systolic or diastolic pressure. Resting systolic blood pressure increased slightly in treatment B. The systolic blood pressure reaction to effort did not change on average. However, with a cutoff point of a change >12 mm Hg, the blood pressure reaction was reduced in 34 patients; in three of them work level also diminished. Thus 31 patients (22%) had a positive training effect in this respect (treatment A, 13; treatment B, 18). However, blood pressure increased in another 34 patients, 11 of whom also reached higher work level. This means that 23 patients (17%) had a negative training effect (treatment A, 9; treatment B, 14).

Cardiac dysfunction. With respect to signs of cardiac dysfunction, Table III shows that repolarization disturbances in the ECG during the initial stress test were present in 44 patients (treatment A, 24; treatment B, 20). These were mainly ST-T depressions; in five patients, exercise induced ST elevations. After training, ST abnormalities disappeared in half the cases in treatment A, whereas it appeared anew in only one patient ($p < 0.005$). In treatment B, ST disturbance disappeared in four patients and appeared in another five patients. The difference between treatments was significant ($p < 0.02$). Angina pectoris during initial stress testing was present in 18 patients (nine in both treatment groups). It was present in 12 patients (six in both treatments) at the posttraining test. In treatment A, angina pectoris disappeared in four of nine patients, but appeared in one patient. In treatment B, angina disappeared in six of nine patients, but appeared in three others. The changes after training are statistically not significant, probably because of the small number of patients. There was no difference between the two treatments. Serious arrhythmias were present in 14 patients (treatment A, 5; treatment B, 9); three of them were complex. Major change occurred in only one patient in treatment B (i.e., complex arrhythmia was present at the posttraining test where none existed at the pretraining test). There was no change in antiarrhythmic medication.

Exercise testing: Composite criterion. The overall outcome based on all measurements results in a trichotomy: the patient can have a success or failure of exercise training, or no change. Table IV and Figs. 1 and 2 show the outcome for both treatment groups. Four test criteria are considered sequentially: cardiac dysfunction, maximum work load, maximum heart rate, and systolic blood pressure response. In addition, the 17 patients who dropped out of the program are classified according to the reasons for not completing the training. Two patients felt good enough to resume full activity and did not complete the training; they are considered successful outcomes (TB+: $n = 2$; both in treatment A). Nine patients had to stop the program because of cardiac problems; these are considered to have a negative outcome (TB = –; $n = 9$; treatment A, $n = 3$, treatment B, $n = 6$): three patients had coronary bypass operation, two developed arrhythmias (one was later readmitted to the hospital), three patients were readmitted to the hospital for unstable angina pectoris, and one patient died. Six patients stopped the training for noncardiac reasons. These patients were considered neutral with regard to outcome (TB = 0: $n = 6$; treatment A, $n = 4$; treatment B, $n = 2$). Five of the six patients had physical problems that prevented training (chronic lung disease, hepatitis, complaints of hip, lower back, and knee, respectively) and one had social reasons. Thus, according to the "intention to treat principle," all randomized patients are classified.

The flowcharts (Figs. 1 and 2) show that for each of the subsequent criteria, several patients were selected with a positive change, but a small number were also selected because of a negative effect. Approximately half the patients completed the training successfully (treatment A, 42 patients (55%); treatment B, 37 patients (46%). Conversely, training failure occurs in a substantial number of patients: 15 patients in treatment A (20%) and 27 patients in treatment B (33%). Nineteen patients (25%) in treatment A and 16 patients (21%) in treatment B showed no change. The overall training outcome is shifted slightly more to the positive side for patients in treatment A than for patients in treatment B. However, the difference between the two treatments was not significant at the 5% level (chi square, 2.85, $df = 1$, $p < 0.09$, two-tailed test for differences).

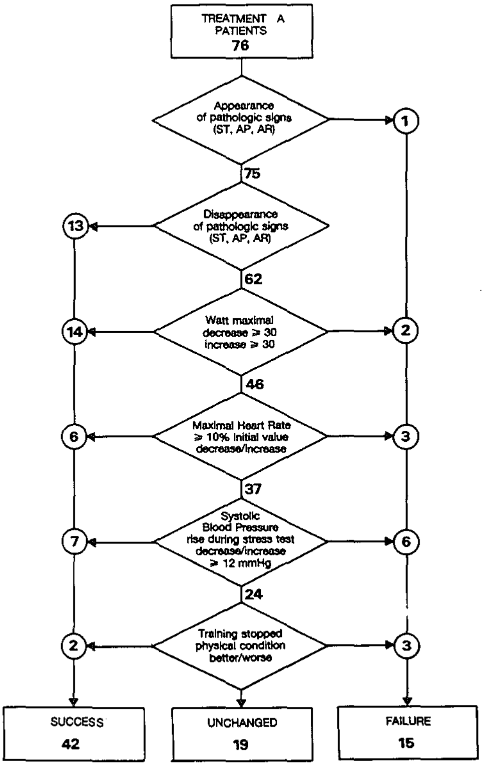

Fig. 1. Training benefit for patients in treatment A group: Exercise + relaxation.

DISCUSSION

Relaxation effect. A 5-week daily exercise program for patients soon after myocardial infarction resulted in a modest training response: maximum work load increased, and heart rate at a given work level was reduced significantly. There was no clear evidence of an incremental effect of relaxation therapy on these measurements separately. However, training bradycardia was more pronounced at all levels of effort for patients who were taught to relax. In accordance with other studies,[21, 23] relaxation was found to decrease resting heart rate significantly, whereas exercise did not. Exercise-induced signs of cardiac dysfunction remained stable during rehabilitation, except for a substantial decrease of ST abnormalities in patients who received relaxation therapy. A similar result was found in cardiac patients in an earlier study by Kavanagh[18] and in normal subjects at high cardiac risk more recently by Patel et al.[24] It is remarkable that relaxation influences myocardial ischemia. If

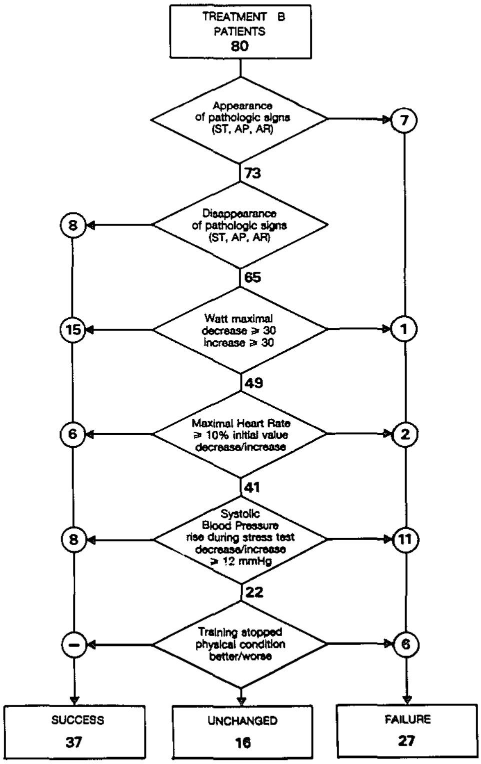

Fig. 2. Training benefit for patients in treatment B group: Exercise only.

this finding is replicated, it will be of clinical significance and may also have prognostic implications.[25] This suggestion is empirically supported in a follow-up study in which relaxation was shown to reduce the number of cardiac events during a 2-year period, particularly readmission to the hospital for unstable angina pectoris or CABG.[26]

However, when the average outcome for two treatments is compared, important information may be missed. The result made on the basis of the composite training criterion demonstrated that a "modest" training response masks the fact that some patients clearly benefit, whereas others do not benefit or even deteriorate. Physical training was effective in only approximately half the patients. A substantial number of patients had a negative outcome. The proportion of success versus failure of training was more positive for patients who received breathing and relaxation therapy. The reduction of training failure in particular is intriguing. The odds for failure were 15/61 (0.25) for treatment A, and 27/53 (0.51) for treatment B. The odds ratio for a negative outcome was 2.04 (95% confidence intervals, 0.94 to 4.6). Thus relaxation and breathing therapy reduces the risk of failure by half.

Outcome differences can be interpreted as an effect of relaxation because the patients had been randomly assigned to either of the two treatments. There were no differences in clinical baseline characteristics or exercise parameters that might explain the results. Therefore it can be concluded that relaxation and breathing therapy has incremental value to exercise training for improvement of exercise tolerance. The study does not determine the effect of relaxation without exercise.

The study was not designed to investigate possible mechanisms by which relaxation therapy might exert its effect. In future studies, several options deserve consideration. First, relaxation may influence sympathetic reactivity[15, 23, 24] and thus reduce the risk of effort,[7] especially for the "overzealous" patient.[18] Second, breathing therapy in particular may affect hypocapnia, which results from hyperventilation.[27] Carbon dioxide is a potent vasodilator and can modulate coronary blood flow.[28, 29] Third, a slow respiratory pattern promotes parasympathetic activity,[30] (e.g., respiratory sinus arrhythmia), which counteracts sympathetic reactivity. Considering that cardiac and respiratory activity are linked physiologically, for instance, in nervous regulation in the brain stem, the breathing component of the relaxation technique may have special relevance. Respiration is also connected mechanically to cardiac activity, for instance, via its effect on venous return as well as via thoracic mobility.[31] Finally, silent ischemia appears to be linked to psychologic processes, particularly denial.[32] Consideration of these factors in future studies may help to distinguish those patients who might benefit from a particular type of relaxation therapy.

Single outcome category: Success vs failure. To our knowledge a composite criterion for assessing success or failure of exercise training has not yet been presented. The rationale for such a criterion is that it results in a single outcome category, reflecting success or failure of training for the individual patient. This allows evaluation of cardiac rehabilitation in terms of indications (expected benefit of training) and contraindications (expected adverse effects). Exercise testing provides the proper measures for physical training. However, a positive outcome is not necessarily a result of training. The natural recovery after myocardial infarction may contribute to it as well.[33] Nevertheless, differences in exercise tolerance after sufficiently intensive training are usually considered as a training response. Absence of this response implies that training was not successful. Similarly, a negative outcome might be caused by progression of ischemic heart disease. Conversely, progressive training effort may provoke symptoms and increase risk.[7, 34] This training failure is partly preventable, as the reduction of negative outcome by relaxation in this study demonstrates. Thus the failures or dropouts provide essential information on the unsuitability for the particular treatment.[35]

Exercise testing yields several measurements, both continuous and dichotomous, and their clinical importance varies. They may show disparate results. To reduce this number of measurements, combinations can be made, for example, the rate-pressure product or the work level where cardiac dysfunction appears (angina threshold or ST threshold). The purpose of our strategy was to develop a model to integrate the measurements in a single classification of overall outcome. The basic idea is to rank the various parameters of exercise testing in order of importance. In the case of MI patients, signs of cardiac dysfunction (ST abnormalities, angina pectoris, complex arrhythmias) were considered to be of primary relevance. Priority was given to negative changes, because treatment should first of all exclude any harm, *primum non nocere*. The level at which a change is scored was high. For instance, only serious arrhythmias are included.

The next three steps concern changes in parameters of physical fitness: maximal work load, heart rate, and systolic blood pressure, in this order. The cutoff levels were higher than those used for univariate comparisons.[36] For instance, the minimal change in work load is 30 W, corresponding with a substantial degree of improvement or deterioration (about 22%). Heart rate and blood pressure effects were compared in the third and fourth step for the common highest work level at pretraining and posttraining test. The criterion was intended to be a measure of overall physical effect or recovery; it includes change in fitness, provided that cardiac dysfunction does not change. The underlying concept was that fitness cannot compensate for dysfunction.

Implications for rehabilitation policy. The model results in a single trichotomous outcome measure, which seems to be a sufficiently sensitive and realistic criterion for the purpose of evaluation. An "in between" category of "no change" allows one to focus on either indications (benefit vs no benefit) or contraindications (failure vs no failure) for training. Because cardiac rehabilitation programs are rather expensive and involve a certain risk, much effort could be saved when the likelihood of benefit could be predicted on the basis of initial data.[36] A composite criterion, resulting in a single outcome measure, would be a valid end point for prediction and subsequent patient selection.

However, the absence of physical benefit does not necessarily mean that rehabilitation is useless. It does not imply absence of social or psychologic benefit. Patients without training effect may still benefit from rehabilitation. In fact, there is little evidence for the assumption that physical fitness is associated with well-being and improved mental health, or is instrumental for social recovery or reduction of anxiety or depression.[37] Nevertheless, although physical criteria are obviously insufficient to evaluate rehabilitation, they are crucial to evaluate whether the choice of exercise as a treatment was appropriate. Rehabilitation should be tailored to the individual need. Patients without training success may possibly benefit from other treatment modalities. When the likelihood of training success is low, one option is to concentrate treatment on behavioral intervention such as information, education, counseling or risk-factor modification. This study suggests three other options. One is to provide relaxation and breathing therapy, either on a one-to-one basis or in groups. Another is to integrate this relaxation therapy in exercise training (e.g., as part of the warming up and cooling down). Finally, the exercise itself may be changed to the flexibility-coordination-relaxation type,[14] as in yoga,[38] or in awareness through movement,[39] and active relaxation. The outcome of this study suggests that this may result in physical benefit for some patients who do not have success with exercise training per se.

Breathing and relaxation therapy provide a different viewpoint on exercise. As Hellerstein has noted,[40] exercise training is an established treatment, but currently "there is a plethora of repetitive exercise programs in cardiac research that are devoid of original hypotheses." It may be time to differentiate qualitatively the content and aim of exercise in such a way that patients with low probability of training success may still benefit from rehabilitation.

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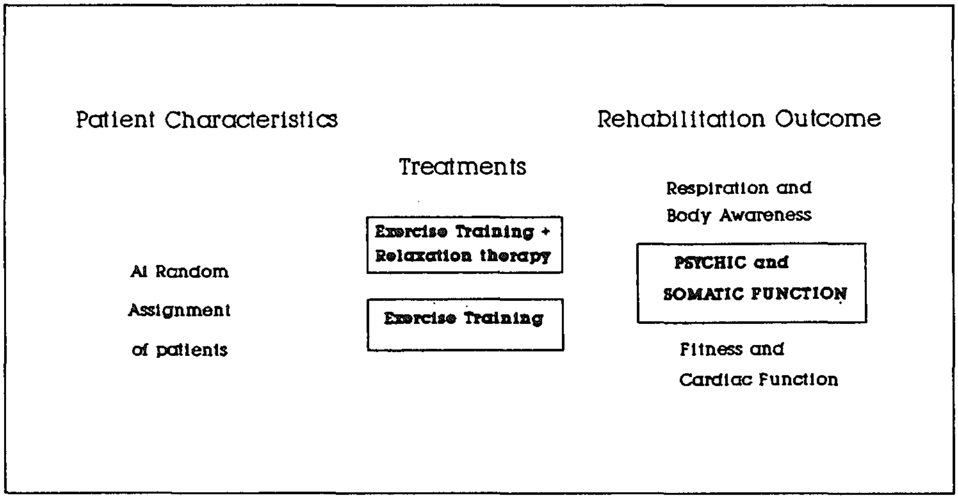

Figure 5.1.
Comparing outcome between treatments: Psychic outcome

Chapter 5

Psychic Effects of Physical Training and Relaxation Therapy after Myocardial Infarction

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PSYCHIC EFFECTS OF PHYSICAL TRAINING AND RELAXATION THERAPY AFTER MYOCARDIAL INFARCTION

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Abstract—The psychological impact of exercise training and relaxation therapy was investigated in 156 myocardial infarction patients. They were randomly assigned to either exercise plus relaxation and breathing therapy (Treatment A: $n = 76$) or exercise training only (Treatment B: $n = 80$). Patients in Treatment A improved on three out of eight psychological measurements (anxiety, well-being, feelings of invalidity). No change was demonstrable in Treatment B. The difference between the treatments was significant for wellbeing ($p < 0.005$).

Physical outcome, measured by exercise testing was positive in about half of the patients (Treatment A: 55%, Treatment B: 46%). A negative outcome occurred less in Treatment A ($p < 0.05$). Training success was not associated with psychic benefit. The association differed for the two treatments. It was concluded that exercise training was effective for some but not for all cardiac patients, and that a psychic effect of exercise could not be demonstrated. Relaxation therapy enhanced physical and psychic outcome of rehabilitation.

INTRODUCTION

CARDIAC rehabilitation studies often report psychological benefit of physical training: patients are highly motivated and they feel more self-confident [1–5]. Psychological measurements, however, do not always support those findings [2, 4]. In six controlled studies [2, 6–10] a variable and modest psychic effect of exercise for coronary patients was found. Moreover, increased physical fitness is not consistently associated with psychological benefit [7, 9, 11–13]. Although physical training is frequently used [14], the questions arise whether exercise is an adequate treatment and whether it is crucial to obtain a physical training effect. Possibly, the psychological value of rehabilitation depends more upon other factors, for instance the social context of a programme [7, 11, 15] or on the interaction of exercise with a more psychological treatment [12, 16].

In this study the effect of relaxation and breathing therapy in addition to physical training is investigated. Several studies have demonstrated psychic effect of relaxation therapy in cardiac patients, as a part of a behavioural treatment [8] or as an independent treatment [17–21]. Some authors consider it useful for all patients to acquire relaxation skills [21, 22], others assume that only some persons need to learn it [23]. The utility of this therapy is seen in its explicit psychophysiological nature. It is acceptable to cardiac patients, because it utilizes movements and 'exercise', but the emphasis is on learning more adequate ways of handling tensions and efforts, and on experiencing inner quiet. Thus, the combination of exercise and relaxation may induce greater or different psychic changes than exercise only.

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The questions to be studied are first, whether exercise training or relaxation therapy improve psychic functioning, and if so, whether relaxation therapy has any incremental value to exercise as a sole treatment; second, whether psychic benefit is associated with a successful training outcome and if so, whether this association differs between the two forms of treatment.

PATIENTS AND METHODS

Patients

Cardiac patients are referred after discharge from several hospitals, to the regional rehabilitation center at St. Joannes de Deo Hospital, Haarlem, The Netherlands. A total of 156 myocardial infarction patients were eligible for the study and were randomly allocated to two treatment protocols. Patients who needed individual (psychosocial) help in addition to exercise training were excluded. There were no age limits. Median age was 56 yr, ranging from 36 to 76 yr. Only nine women were referred for rehabilitation. Table I summarizes the clinical data at entry to the trial for the two randomized groups.

Procedure

In order to study the incremental effect of relaxation and breathing therapy, patients were randomly allocated to either of the two treatment protocols. Randomization was done after the intake interview for the rehabilitation programme and after informed consent. Patients who needed individual help were referred for relaxation therapy or psychosocial counselling and were excluded from the study. Graded exercise testing was performed, and self-administered questionnaires were completed by the patients, before and after rehabilitation.

Measurements

Psychological questionnaires. (1) The Heart Patients Psychological Questionnaire (HPPQ), constructed to measure the well-being of cardiac patients [24], consists of four scales: (a) well-being, 12 items (score range 12–36) including e.g. 'I feel at ease nowadays', I feel healthy'; (b) subjective invalidity, 12 items (score range 12–36) including e.g. 'I could do a lot more work formerly', 'I don't have enough stamina'; (c) displeasure, 10 items (score range 10–30), including e.g. 'I'm often out of sorts without knowing why'; (d) social inhibition, six items (score range 6–18), including e.g. 'I don't like having a lot of people around me'. All answers have to be given on a three-point scale: true/?/untrue. (2) Anxiety was measured by STAI in two aspects: state and trait anxiety [25]. For each of them there are 20 items which have to be answered

TABLE I.—BASE-LINE CLINICAL DATA

Variable	Treatment A	Treatment B	p
No of cases	76	80	
Age (yr)	55.4 (8.2)	55.7 (8.1)	ns
Males	71 (93)	76 (95)	ns
Working	50 (66)	51 (64)	ns
Married/partner	69 (91)	74 (93)	ns
Infarction size			
Unknown	4 (5)	4 (5)	
Small	20 (26)	27 (34)	ns
Medium	27 (36)	22 (27)	
Large	25 (33)	27 (34)	
Anterior infarction	29 (38)	24 (30)	ns
Mild heart failure	14 (18)	13 (16)	ns
Post-infarction angina	28 (37)	25 (31)	ns
Medication on discharge:			
Beta blockers	20 (26)	25 (31)	ns
Diuretics	27 (36)	20 (25)	ns
Anti-anginal	13 (17)	18 (23)	ns
Start of physical training (weeks after hospital discharge)	4.8 (2.8)	5.2 (2.1)	ns
Maximum work load (Watt)	136 (24)	132 (21)	ns

Data are reported as events and percentage of cases or as means (SD).

on a four-point scale (score range 20–80). (3) Sleeping habits, consisting of questions about hours of sleep and day-time rest and about sleep quality, measured with a 10-item questionnaire [26]; answers are given as yes/no (score range 0–10), e.g. 'I often wake up during the night'. (4) Functional complaints, a 25-item questionnaire constructed to measure complaints, often mentioned by cardiac patients but not typical of angina pectoris; the frequency is indicated on a three point scale: often/sometimes/never (score range 25–75). Examples are: 'Inability to breathe in fully', 'Pain in the chest, especially when I sit quietly'.

Exercise testing. A graded exercise test was performed on a bicycle ergometer (Monark). The test started with a 1-min period of cycling at 60 cycles a minute with zero load, then for 2 min at 60 Watt. The test was continued by increasing the workload with 30 Watt every 2 min until symptoms limited the patient to continue or until the physician terminated the test. The occurrence of angina pectoris, ST-abnormalities and severe dysrhythmias were noted. ST-abnormalities were mostly ST depressions greater than 2 mm, horizontal or downsloping. A bipolar ECG was recorded during the last half-minute before the work load was increased. Blood pressure was measured by cuff sphygmomanometry before the test and directly after maximum work load. The cardiologist was blind to the treatment condition of the patient.

Treatment programmes

Rehabilitation consisted of a programme of exercise training plus relaxation training (Treatment A) or of exercise training only (Treatment B). Thus, all patients followed the same physical conditioning programme. This consisted of five weeks interval training, once a day for half an hour, on a bicycle ergometer. Training was done in groups of four patients supervised by two physical therapists. Each patient was exercised up to 70% of the peak heart rate attained at pre-training exercise testing (Karvonen method).

Relaxation training was given once a week in six individual sessions of 1 hr each, by five specially trained therapists. Three of them were psychologists, one a medical doctor and one a physical therapist. They did not participate in the exercise programme.

Several procedures for active and passive relaxation were employed, centering around a respiratory technique. This is described in detail elsewhere [27, 28]. In short, EMG Feedback of the frontalis muscle is used for muscle relaxation and for monitoring unnecessary inspiratory effort. The patient learned to observe and elicit a 'shift' in the respiratory pattern, such that inspiration expanded both the lower abdomen and the costal margin, expiration was moderated and slow. Manual technique was applied to elicit breathing movements which involve the trunk as a whole and require less effort. This was practised first in the supine, relaxed position, but later also sitting and standing ('active relaxation'). The patient was asked to practice at home, as a daily routine, and when experiencing chest discomfort. Care was taken to introduce relaxation as a normal part of the routine rehabilitation procedure, rather than special psychological help. The treatment itself was presented in a neutral fashion: emphasizing the technical and physical aspects of relaxation, its utility in dealing with daily stress, and providing a rationale in the form of the biofeedback instrumentation and breathing 'exercises'. The therapists were aware, however, that this was a strategy to facilitate possible psychotherapeutic implications of the treatment. Each session the patient was asked to express his experiences with relaxation.

Data analyses

Statistical tests were performed on the measurements separately, using nonparametric tests. Wilcoxon's rank sum test was applied to repeated measurements of ordinal level, and Mann–Whitney U test for independent samples of ordinal level (Treatments A and B). Repeated measurements of a nominal nature were tested with McNemar's test for change, whereas comparison between independent samples was done with chi square analysis. If the data consisted of more than two categories, chi square analysis for trends was done.

Training benefit. In order to get a single measure indicating the efficacy of physical training, the measurements obtained at exercise testing pre and post training were integrated into a composite criterion. Using this criterion, patients were trichomotized as follows: (a) patients with little or no change, (b) patients who improved ('training success') or (c) patients who deteriorated ('training failure'). The procedure is described elsewhere [29]. In short, the measurements were ranked into four levels according to their clinical relevance, (1) signs of cardiac dysfunction (ST-abnormalities, angina pectoris, serious dysrhythmias), (2) exercise tolerance (change $\geq$ 30 Watt), (3) heart rate at highest common work load (change $\geq$ 10% of initial value), (4) systolic blood pressure response (change $\geq$ 12 mm Hg). At each level a patient could be assigned to success or failure when a positive or negative change in the particular measurement had occurred. For cardiac signs a negative change had priority over a positive one. Levels two to four represented physical fitness. Dropouts were included and classified as far as possible on the basis of the reason for not completing the programme. Patients who stopped the training because they resumed their normal daily activities were considered successful; patients who stopped the training for cardiac reasons were considered a failure; patients who stopped for other reasons were assigned to 'no change'. Thus, all randomized subjects could be classified.

Psychic and somatic function. In order to obtain a clear-cut picture of the relation between physical and psychological benefit the psychological questionnaires were grouped into two sets, labeled 'PSY' and 'SOM'. PSY represented psychic aspects and consisted of anxiety-state, anxiety-trait and depression, SOM represented somatic aspects, consisting of subjective invalidity, sleep quality and functional complaints. The scores on the questionnaires were standardized as follows: the pre-post changes were expressed as a percentage of their possible change, which is the difference between the initial score and the minimum score in the case of decrease and the maximum score in the case of an increase. PSY and SOM were each computed as the summed percentage change on three questionnaires. Pre-post change on the scale 'well-being' of the HPPQ was treated as a separate indicator of psychic outcome (WELL).

As a kind of exploration and for reasons of simplicity the scores of PSY, SOM and WELL were dichotomized as positive or negative change on the basis of which patients could be classified as PSY = + or PSY = −, SOM = + or SOM = − and WELL+ or WELL−. Combining with the dichotomized training outcome resulted in four outcome categories, indicating the concurrence of physical and psychological outcome, for PSY, SOM and WELL. The purpose was to investigate the distribution of the individual patients among these categories.

RESULTS

A total of 156 myocardial infarction patients were admitted to the study (Treatment A: 76, Treatment B: 80). There were no differences between the two treatment groups in base-line clinical data (see Table I). Three patients had previous coronary artery grafting, 16 patients had experienced recurrent infarction and 26 patients had a history of angina pectoris. Classification of infarction size was according to the peak serum enzyme levels. In most hospitals, an infarction is classified as small when the serum glutamic–oxaloacetic transaminase (SGOT) level is elevated, but remains below 60 U/l, whereas the infarction is classified as large when SGOT levels rise above 120 U/l. In 47 patients the infarction was classified as small, in 49 patients as medium and in 52 as large. In eight patients the enzyme levels were not available. In-hospital signs of heart failure (hypotension, cardiothoracic ratio >50%, pulmonary congestion) were present in 27 patients (17%). Assessment of ventricular function was not performed routinely in the participating hospitals. About two-thirds of the patients worked. The treatment programme started on the average in the fifth week after hospital discharge.

Training outcome

A total of 139 patients completed the exercise programme (Treatment A: $n = 67$; Treatment B: $n = 72$). There were no significant differences in exercise parameters between the treatments before rehabilitation. Maximum work load increase after training was small but statistically significant for both treatments (Treatment A: 5%, Treatment B: 6.4%). An increase of at least 30 Watt was present in 39 (28%) patients and a similar decrease in seven patients (5%). Heart rate reduction after training was more pronounced for Treatment A at all levels of effort. The difference between treatments did not reach significance. For 20 patients (14%) heart rate at highest common work load was reduced more than 10% of the initial value, whereas it was increased for eight patients (6%). The average changes in blood pressure were negligible and did not differ between treatments. However, 31 patients (22%) had a reduced systolic blood pressure at highest common work load (more than 12 mm Hg lower) and 23 patients (17%) had an increased pressure. Thus, there was a moderate effect on physical fitness (higher work load, lower heart rate and blood pressure response at a given work load). Some patients clearly improved, whereas a minority deteriorated.

ST-abnormalities were present in 44 patients at the initial stress test (Treatment A: 24; Treatment B: 20). After training, they disappeared in half the cases in Treatment A and in only four patients for Treatment B, whereas they appeared anew in only one patient in Treatment A and in five patients in Treatment B. The difference between treatments was significant ($p < 0.02$). Angina pectoris at stress testing was present in 18 patients (nine in both treatments). It disappeared in four patients in treatment A and in six in Treatment B, but appeared in one patient in Treatment A and in three in Treatment B. Serious arrhythmias were present in 14 patients and remained stable, except for one patient in Treatment B, who developed complex ventricular arrhythmia during training.

Following the composite criterion, the signs of cardiac dysfunction had priority over measurements of physical fitness. In addition, patients who dropped out of the study were classified on the basis of the reason for not completing the programme. Two patients felt good enough to resume full activity; they were considered a successful outcome (both in Treatment A). Nine patients had to stop for cardiac reasons (Treatment A: $n = 3$, Treatment B: $n = 6$) and they were considered a negative outcome: three patients had coronary artery bypass operations, two developed arrhythmias, three were readmitted to hospital for unstable angina pectoris and one patient died. Six patients stopped for non-cardiac reasons (Treatment A: $n = 4$, Treatment B: $n = 2$); they were considered neutral with regard to physical outcome. Thus, according to the 'intention to treat principle', all randomized patients could be classified. A successful outcome was present in 42 patients in Treatment A (55%) and in 37 patients in Treatment B (46%). A negative outcome was present in 15 patients in Treatment A (20%) and in 27 patients in Treatment B (33%), whereas 19 patients did not change in Treatment A (25%) and 16 in Treatment B (21%). Thus, in Treatment A the overall outcome is shifted more to the positive side. The difference between treatments is almost significant ($p = 0.09$). A substantial number of patients has a training 'failure'. The odds for a negative outcome, however, are higher for Treatment B (odds ratio: 2.07; 95% confidence interval: 1.002–4.28; $p < 0.05$).

Psychic outcome

Out of 139 patients who completed the programme, two did not complete the questionnaires. Thus, measurements were available from 137 patients (Treatment A: 66, Treatment B: 71). Table II shows that anxiety-trait did not change after rehabilitation; a reduction in anxiety-state appeared in Treatment A ($p < 0.05$), but not in Treatment B. The difference between treatments was not significant.

TABLE II.—PRE-TEST VALUES AND CHANGES (PRE-POST DIFFERENCES) IN ANXIETY FOR TREATMENTS A ($n = 66$) AND B ($n = 71$)

	Pre-test $\bar{x}$(SD)	Change $\bar{x}$(SD)	Within treatment significance
Anxiety state			
Treatment A	37.6 (9.2)	−2.4 (9.0)	$p < 0.05$*
Treatment B	34.7 (10.2)	−0.6 (7.2)	ns
Anxiety trait			
Treatment A	37.4 (8.9)	−0.7 (8.0)	ns
Treatment B	35.3 (10.0)	−0.2 (5.9)	ns

*Between treatment significance: ns.

TABLE III.—PRE-TEST VALUES AND CHANGES (PRE-POST DIFFERENCES) IN SOMATIC FUNCTIONS FOR TREATMENTS A ($n = 66$) AND B ($n = 71$)

	Pre-test $\bar{x}$(SD)	Change $\bar{x}$(SD)	Within treatment significance
Sleep quality			
Treatment A	7.3 (2.5)	0.03 (1.9)	ns
Treatment B	7.5 (2.5)	0.14 (2.0)	ns
Sleeping hours			
Treatment A	7.2 (1.3)	0.06 (1.0)	ns
Treatment B	7.3 (1.2)	0.09 (1.0)	ns
Daytime naps (quarter hours)			
Treatment A	2.5 (2.1)	0.1 (1.6)	ns
Treatment B	2.8 (2.3)	−0.8 (2.3)	$p < 0.01$*
Functional complaints			
Treatment A	35.0 (5.9)	0.5 (4.9)	ns
Treatment B	35.0 (8.4)	0.4 (3.5)	ns

*Between treatment significance: $p < 0.05$, two-tailed.

Table III shows the outcome on somatic aspects. On the average, sleeping quality and sleeping hours were fairly good before and after rehabilitation. Treatments did not differ in this respect. Prior to rehabilitation most patients took a nap at noon (Treatment A: 73%, Treatment B: 66%). Daytime naps decreased considerably for Treatment B ($p < 0.005$), whereas they remained the same in Treatment A. The difference between the treatments was significant ($p < 0.05$). Functional complaints slightly increased after training in both treatment groups.

The HPPQ (Table IV) showed a clear improvement in well-being for Treatment A ($p < 0.0001$), whereas patients in Treatment B did not feel better. The difference between treatments was significant ($p < 0.005$). Feelings of invalidity were reduced for Treatment A ($p < 0.01$), but not for Treatment B. The difference between treatments was not significant. With regard to displeasure and social inhibition, changes were negligible.

Thus, three out of eight measurements of psychological function showed an improvement for Treatment A, whereas for patients in Treatment B no change was demonstrable in this respect.

TABLE IV.—PRE-TEST VALUES AND CHANGES (PRE-POST DIFFERENCES) IN HPPQ FOR TREATMENTS A ($n = 66$) AND B ($n = 71$)

	Pre-test $\bar{x}$(SD)	Change $\bar{x}$(SD)	Within treatment significance
Well-being			
Treatment A	25.7 (7.2)	4.5 (6.7)	$p < 0.001$*
Treatment B	27.5 (7.1)	1.1 (7.2)	ns
Subjective invalidity			
Treatment A	25.5 (6.1)	−1.8 (5.3)	$p < 0.01$**
Treatment B	24.6 (6.1)	−0.8 (4.3)	ns
Displeasure			
Treatment A	15.7 (4.1)	−0.6 (3.8)	ns
Treatment B	16.0 (4.1)	−0.3 (4.8)	ns
Social inhibition			
Treatment A	10.9 (3.1)	−0.1 (1.8)	ns
Treatment B	11.3 (2.8)	−0.1 (2.3)	ns

Between treatment significance: *$p < 0.005$, two-tailed; **ns.

Association of psychic change with training benefit

Since some patients did not complete all questionnaires, the compound scores on PSY and SOM were available for a smaller number of patients (Treatment A: $n = 62$; Treatment B: $n = 67$). Classifying patients into four categories, on the basis of presence or absence of training success on the one hand, and positive or negative psychic change on the other, the concurrence of psychic and physical outcome was investigated. Table V shows multiple comparisons of positive vs negative psychic effect for the two treatments separately. In all instances, more patients improved than deteriorated: the odds for psychic improvement vs deterioration were >1. In most instances, twice as many patients improved: the odds were $\geqslant 2$.

However, the odds for psychic benefit were not higher for patients with training success, compared to those without success. In only two comparisons the odds ratio was >1, but not significantly. In the other comparisons the odds for psychic benefit were actually smaller for patients with training benefit. Two odds ratio's approached significance ($p < 0.10$): fewer patients with training benefit experienced improved somatic function in Treatment A or improved well-being in Treatment B, than patients without training benefit. it can be concluded therefore, that a successful training outcome does not imply psychic benefit.

Next, the odds for psychic benefit were compared between Treatments A and B. Two significant differences were found. In Treatment A patients without training benefit improved more in somatic function ($p < 0.05$) and patients with training success more often had an increased sense of well-being ($p < 0.002$), than patients in Treatment B. Therefore, when relaxation was added to exercise training, the physical outcome had a different psychic implication.

DISCUSSION

Physical outcome

Most cardiac rehabilitation programmes use physical exercise, mainly in the form of aerobic conditioning. Although the primary goal of exercise is increasing physical fitness, it is expected to boost morale and contribute to recovery of the acute cardiac illness. Nevertheless, it is worthwhile to investigate whether intensive training actually

TABLE V.—CHANGES ON PSY, SOM AND WELL ACCORDING TO PHYSICAL OUTCOME FOR TREATMENTS A AND B

	Training successful			Training unsuccessful			
	PSY = +	PSY = −	Odds	PSY = +	PSY = −	Odds	Odds Ratio (95% CI)
Treatment A	25	13	1.9	18	6	3.0	0.64 (0.18–2.29)
Treatment B	22	11	2.0	24	10	2.4	0.83 (0.26–2.65)
	SOM = +	SOM = −	Odds	SOM = +	SOM = −	Odds	Odds Ratio (95% CI)
Treatment A	20	15	1.3	21	5	4.2	0.32 (0.08–1.18)†
Treatment B	22	10	2.2	17	16	1.06*	2.07 (0.67–6.48)
	WELL = +	WELL = −	Odds	WELL = +	WELL = −	Odds	Odds Ratio (95% CI)
Treatment A	34	4	8.5	23	5	4.6	1.85 (0.37–9.40)†
Treatment B	19	16	1.2**	28	8	3.5	0.34 (0.11–1.06)

†$p < 0.1$, two-tailed. *Odds Ratio A vs B: 3.9 (1.06–15.6), $p < 0.05$, two-tailed.
**Odds Ratio A vs B: 7.2 (1.9–30.0), $p < 0.002$, two-tailed.

meets its goal. In this study, only half of the patients showed improved physical condition, and a substantial minority deteriorated. In the absence of a control group who did not follow exercise training, it is uncertain to what extent the outcome can be attributed to training. Yet, it is clear that a daily exercise programme was not effective for all patients [30, 31]. It is intriguing that relaxation improved effectiveness of training [17]. In our opinion, therefore, exercise should be applied selectively and rehabilitation should include more treatment modalities than only exercise training.

Psychic effect of exercise

There was no evidence of psychological benefit of exercise. On the average, patients who performed exercise training solely did not show change on any of the psychological measurements after rehabilitation. Moreover, patients who showed a positive training outcome did not have more psychic benefit than those without training success. On the contrary, there was a tendency to a negative association: more patients without training success improved psychically. It is concluded therefore, that a psychic effect of exercise training for coronary patients could not be demonstrated. Physical benefit does not imply psychic effect.

The lack of psychic effect of exercise training conflicts with clinical impression but is in concordance with other studies [2, 8, 15]. Several factors have been mentioned as an explanation. For instance, patients who are motivated to join a rehabilitation programme may already feel well enough and have little possibility for improvement. The 'over-cautious' and anxious patient may not be inclined to participate. Mayou therefore 'recommended to direct rehabilitation efforts towards selection of subgroups of patients who would benefit most' [2]. Another possible explanation is that standard questionnaires are not sensitive or specific enough to reflect the recovery process of the coronary patient [3, 8, 32]. The questionnaire 'HPPQ', designed specifically to measure well-being of cardiac patients, did show somewhat greater changes than a standard questionnaire for anxiety (STAI). Still, it may be necessary to use questions in which the patient recognizes his concerns more directly, as for instance in 'morale' [9], or in 'self-efficacy' [32].

In our opinion, the main conclusion should be that rehabilitation is effective for some cardiac patients, but not for others [2, 30, 31]. The rehabilitation programme should be tailored to the psychic and physical condition of the individual. Group averages mask the fact that some patients benefit considerably, while others are less suitable for a particular programme. Moreover, both physical and psychological criteria should be applied to evaluate rehabilitation. This results in at least four categories of outcome. The distribution of patients among these categories in this study is shown in Table VI. About half of all patients experienced physical benefit, but only one-third improved both physically and psychically. This means that although training was physically effective, it was not always a sufficient treatment in psychological respect. On the other hand, many patients (26%–36%) without physical benefit still felt better. For them, intensive training was therefore inappropriate. Yet, they could benefit psychically from rehabilitation. Possibly, less strenuous exercises, relaxation therapy, group education sessions, a more psychological treatment or a combination of these would have been more indicated. Alternative rehabilitation forms seem particularly indicated for patients who have a negative outcome in both respects. Their percentage is lower (8–10%) when

TABLE VI.—COMBINED PSYCHIC AND PHYSICAL OUTCOME OF REHABILITATION (PERCENTAGE OF PATIENTS) FOR TREATMENTS A AND B.

	Treatment A (n = 62)	Treatment B (n = 67)
TB = + and PSY = +/SOM = +	40%/32%	33%/34%
TB = + and PSY = −/SOM = −	21%/25%	16%/15%
TB = − and PSY = +/SOM = +	29%/34%	36%/26%
TB = − and PSY = −/SOM = −	10%/8%	15%/25%

TB: Training successful (= +) or unsuccessful (= −).
PSY: change on psychic aspects positive (= +), or negative (= −).
SOM: change on somatic aspects positive (= −), or negative (= −).

relaxation is added than it is when exercise is the only treatment (15–25%). Thus, relaxation reduced the occurrence of training failures as well as the percentage of subjects without training success and without psychic benefit. It would be interesting to investigate the effect of exercise forms, where skills in psychophysiological self-regulation are the purpose [33–35], rather than aerobic conditioning.

It is remarkable that the association between psychic and physical outcome differed for the two treatments. It signifies that relaxation somehow influences the psychological impact of exercise, possibly providing a more favourable context [17], promoting self-efficacy [32] or a sense of personal control [12].

Psychic effect of relaxation therapy

When individual breathing and relaxation therapy was combined with exercise training, improvement was shown in three out of eight measures: anxiety and feelings of invalidity decreased, well-being increased. The patients had been randomly assigned to either of the two treatments. The results cannot be explained by differences in clinical base-line characteristics. It can be concluded therefore that relaxation therapy enhances the psychic effect of rehabilitation. Nevertheless, the changes were modest and the effect of relaxation therapy was smaller than expected. In addition to the above-mentioned explanations, another reason is that patients who needed individual treatment were excluded from the study. The percentage of these patients was small in the beginning, but increased in the latter phase of the study, when more patients were being referred for relaxation therapy after intake interview. The differences between the treatments became less outspoken than at an earlier analysis [28]. Other reasons could be that six sessions were not sufficient for all patients to master relaxation or that the relationship of the patient with the relaxation therapist did not always acquire the necessary quality. In fact, almost half of the patients (44%) achieved good relaxation ability within six sessions and these patients showed unmistakable improvement on all psychological measurements [36]. Finally, the exercise training may have counteracted the effect of relaxation for some patients because the emphasis on effort and force is antagonistic to the nature of relaxation.

In future research these issues should be taken into account; for instance, taking mastery of the relaxation technique as a criterion to terminate the therapy rather than a fixed number of sessions.

No improvement of sleeping quality was found, which was expected as a result of relaxation [23]. Most patients seemed to sleep rather well and without the extended duration of nocturnal sleep (up to 9 hr) which has been reported [37] among patients soon after myocardial infarction. About three-quarters of the patients took a daytime nap, confirming the finding of Van der Sluijs [37]. Patients who learned to relax continued doing so, whereas patients who did exercise training only took fewer daytime naps after rehabilitation. The reason for this difference is not obvious. It seems improbable that relaxation induces fatigue, but patients may learn to take more heed of the need to rest and not interpret that as weakness or invalidity. Or, they may have become used to a daytime rest to practice relaxation.

There was not any indication that relaxation had negative effects [38]. The emphasis on body awareness may sensitize patients to inner body events, including symptoms. Effort and control issues are among the most frequently hypothesized causes of relaxation induced anxiety: the need to remain in control and the belief in effortful strategies as a means to that end. Both apply to cardiac patients. Exercise training confirms these strategies, whereas relaxation challenges them and asserts that control may be achieved relatively effortless or even elude those who make effortful attempts to attain this [38]. Although the idea of 'effortless control' may be expected to evoked resistance [39], the actual treatment appeared to be agreeable and to appeal to most patients [22]. A similar experience is described by Sime, who added relaxation to an exercise training programme. He met at first resistance, but soon relaxation became the 'highlight' of the rehabilitation programme [39].

CONCLUSION

This study indicates that breathing and relaxation therapy is useful to enhance psychic benefit of rehabilitation and to modify physical exercise. The focus on aerobic power, or as Nixon puts it, 'the dogged repetition of mindless exercise' is not the only option available [34]. Body awareness, resulting from the emphasis on coordination, relaxation, flexibility and breathing, is just as important for cardiac patients. Relaxation is a psychophysiological procedure, and particularly suitable to bridge the gap between soma and psyche in a rehabilitation programme. It is a treatment modality in its own, but it can be integrated in an exercise programme as well as in psychological ways of treatment. It will enhance the value of the former and probably lower the threshold for accepting the latter to the patient.

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Chapter 6

Cardiac Events after Myocardial Infarction: Possible Effect of Relaxation Therapy

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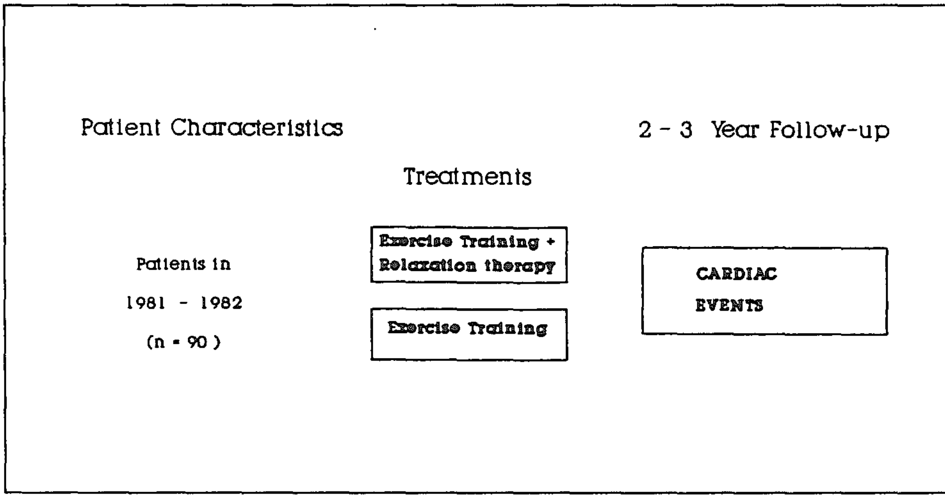

Figure 6.1.
Comparing outcome between treatments: Cardiac Events

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Cardiac events after myocardial infarction: Possible effect of relaxation therapy

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KEY WORDS: Secondary prevention, myocardial infarction, relaxation and breathing therapy, trial.

Comprehensive cardiac rehabilitation aims primarily at improving quality of life, but an effect on morbidity and mortality may also be expected, especially when changes in behaviour and life-style are induced. The value of relaxation therapy and exercise training in post myocardial infarction (MI) patients was investigated. A group of 90 post MI patients were randomly assigned to either exercise training plus individual relaxation and breathing therapy (treatment A), or exercise training only (treatment B). The occurrence of cardiac events, consisting of cardiac death and of readmission to hospital for unstable angina pectoris, coronary artery bypass grafting (CABG) or recurrent infarction, differed significantly for the two treatment groups in the 2–3 years after infarction. Seven out of 42 patients in treatment group A (17%) experienced a cardiac event, in contrast to 17 out of 46 (37%) patients in treatment group B, ($P=0{\cdot}05$*, two-tailed). The results suggest that a combination of a behavioural treatment such as relaxation therapy with exercise training is more favourable for the long-term outcome after myocardial infarction than is exercise training alone.*

Introduction

A variety of measures may be taken to improve the prognosis of patients surviving myocardial infarction (MI). Treatment or modification of risk factors (smoking, hypercholesterolaemia, hypertension, diabetes, overweight) is considered crucial[1,2]. Also treatment with beta blocking agents improves prognosis[3]. The role of cardiac rehabilitation is controversial in this respect as the evidence of its effect on morbidity and mortality is not conclusive[4–6]. Rehabilitation is often equated with exercise training, and most studies of its secondary preventive value investigated that treatment modality. Its main purpose however, is not physical training, but to improve quality of life and to reduce the effects of psychological as well as physical and social impairment. It may be expected that a multifactorial rehabilitation programme, that improves function and well being, will also influence prognosis in those who adhere to the programme[7,8]. A number of studies have shown a positive effect of behavioural treatment modalities, without exercise, on morbidity and mortality[9–14].

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The question arises therefore whether a combined, multi-factorial approach would be more effective than a single treatment. To our knowledge the additional value of a combined rehabilitation programme in comparison to a single treatment programme has not been studied. In this study the effect of relaxation therapy, additional to a physical exercise training, is investigated. The aim of physical training is basically improved adaptation to increasing levels of physical stress. Relaxation training may be useful to prevent inappropriate effort, counteract its negative effects and promote return to a resting state. Patients who learn to relax may also better adapt to their situation, handle excess effort better and thereby reduce their risk for coronary episodes. The question to be studied is whether MI patients who are taught relaxation technique in the rehabilitation period experience fewer cardiac events over the two years following MI than patients who receive exercise training only and not this therapy.

Materials and methods

PATIENTS

After hospital discharge, MI patients were referred to the rehabilitation regional centre at St Joannes de Deo Hospital, Haarlem, The Netherlands, from several neighbouring hospitals.

Table 1 *Base-line clinical data*

Variable	Treatment A	Treatment B	Significance
No. of cases	43	47	—
Age (years)	55·5 (8·4)	54·8 (7·5)	NS
Males	40 (93%)	44 (94%)	NS
History of angina of more than 4 weeks	5 (12%)	9 (19%)	NS
Size of MI:			
unknown	3 (7%)	2 (4%)	
small	10 (23%)	16 (34%)	
medium	18 (42%)	11 (24%)	
large	12 (28%)	18 (38%)	NS
Location of MI:			
anterior	19 (44%)	12 (26%)	
non-anterior	24 (56%)	35 (74%)	NS
Complications of hospital stay			
pump failure	8 (17%)	7 (15%)	NS
cardiac arrhythmias	13 (30%)	17 (36%)	NS
ventricular fibrillation	3 (7%)	5 (11%)	NS
Length of hospital stay (days)	18·3 (4·3)	20·2 (6·0)	NS
Post-infarction angina	14 (33%)	15 (33%)	NS
Medication on discharge:			
beta blockers	10 (23%)	11 (23%)	NS
diuretics	20 (47%)	13 (28%)	NS
anti-anginal	8 (17%)	9 (19%)	NS

Data are reported as events and percentage of cases or as means (SD). Statistical comparison: NS, difference not significant at the 0·05 level. MI, myocardial infarction.

Patients, referred on the basis of a diagnosis other than myocardial infarction, were excluded, as well as those for whom more than 3 weeks time had elapsed after hospital discharge. From March–June 1981 and January–July 1982 a total of 90 patients were eligible for the study. The clinical data at entry to the trial are summarized for the two groups in Table 1. Only six women were referred for rehabilitation. Fourteen patients had a history of angina pectoris. Infarction size was classified on the basis of the peak serum enzyme levels, according to the standards of the participating hospitals. In most hospitals an infarction is classified as small when SGOT level is elevated but remains below 60 $u\,l^{-1}$ whereas the infarction is classified as large when SGOT levels rise above 120 $u\,l^{-1}$. In 26 patients the infarction was classified as small, in 29 patients as medium and in 30 as large infarction. For five patients the enzyme levels were not available. Complications of hospital stay, consisting of signs of pump failure (hypotension, cardio-thoracic ratio >50%, pulmonary congestion), occurred in 15 patients (17%). Assessment of ventricular function was not performed routinely in the participating hospitals. Cardiac arrhythmias occurred in 30 patients (33%), eight of whom (9%) had suffered ventricular fibrillation. On average, the patients stayed almost 3 weeks in hospital. Post-infarction angina was present in one-third of the patients.

MEASUREMENTS

At 30 months after infarction, all patients were invited for a follow-up interview at the rehabilitation centre. Information was also obtained from the patient's cardiologist about the occurrence of cardiac events. They were not aware which treatment group their patients belonged to. An event was defined as any cardiovascular re-admission to hospital (unstable angina pectoris, CABG, recurrent infarction) as well as cardiac death. All events reported by the patient were documented with hospital records.

PROCEDURE

After the initial interview for the rehabilitation programme, patients were randomly assigned to either of the two treatment protocols (treatment A: 43, treatment B: 47). Treatment A consisted of a programme of exercise training plus relaxation training. Treatment B consisted of exercise training only.

The exercise training consisted of 5 weeks interval training, once a day for half an hour, on a bicycle ergometer. Training was done in groups of 4 patients supervized by 2 physical therapists. Each patient was exercised up to 70 to 80% of the maximal heart rate attained at pre-training exercise testing.

Relaxation training was given once a week in six individual sessions of one hour and employed mainly a respiratory technique. This is described in detail elsewhere[15,16]. In short, EMG feedback of the frontalis muscle is used for muscle relaxation and combined with instructions for diaphragmatic breathing. The patient learns to achieve a shift in the respiratory pattern, such that inspiration expands both the lower abdomen and the costal margin, without movement in the shoulder region; exhalation is moderated and slow. Consequently, tidal volume increases and respiration rate slows down; respiration becomes more full, involving the trunk as a whole, and requiring less effort. The patient usually feels quieter and calmer. Hyperventilation, if present, decreases. This is practised first in the supine, relaxed position, but also sitting and standing. The patient is asked to practise at home, as a daily routine, and when experiencing chest discomfort.

METHODS OF ANALYSIS

To study the differential effect of exercise training, versus the combined treatment of exercise and individual relaxation and breathing therapy on secondary prevention, the occurrence of cardiac events in the two groups was compared. The outcomes of all randomized patients were analysed, according to the 'intention to treat' principle. The number of patients in whom an event occurred was counted. As some patients experienced more than one event, statistical testing was conducted on those experiencing subsequent events, using Fisher's exact probability test.

Results

As is shown in Table 1, no significant differences between the two groups in base-line clinical characteristics were seen, nor are there trends which consistently favour one treatment group. Thus, it may be assumed that the randomization procedure was successful. In the follow-up period two patients died, one from sudden cardiac death, the other from heart failure, both in the treatment B group. Another nine patients had a recurrent MI, four in treatment A group and five in treatment B group. Coronary bypass surgery was performed on six patients because of severe or unstable angina pectoris, of whom one was in treatment A group and five in B. In treatment B group, one patient was operated shortly after the second infarction. Three patients of treatment A group were readmitted to hospital once, and seven patients of treatment B group were readmitted 12 times to hospital, many because of angina pectoris. Two patients, one in each group, had moved and were lost to follow-up.

Cardiac events occurred in a total of 7 patients in treatment A group and 17 for treatment B (17% and 37%, respectively; see Table 2). The difference is statistically significant (Fisher exact test, $P=0{\cdot}05$,

Table 2 Cardiac events 2–3 years after myocardial infarction

	Treatment A, exercise + relaxation		Treatment B, exercise only		Significance
Subjects without events (%)	35	(83%)	29	(63%)	
Subjects with events (%)	7	(17%)	17	(37%)	$P=0{\cdot}05$*
Lost to follow-up	1		1		
Total	43		47		

*Fisher exact probability test, two-tailed.

Table 3 Total number of cardiac events after myocardial infarction

	Treatment A, exercise + relaxation ($N=43$)	Treatment B, exercise only ($N=47$)
Readmission to hospital		
Unstable angina pectoris	3	12
Bypass operation	1	5
Recurrent infarction	4	5
Death	0	2
Total Events	8	24

two-tailed). Some individuals experienced more than one event; the total number of events (see Table 3) is, therefore, higher than the number of subjects with events. The difference between treatment groups A and B exists for all events, but not to the same degree. The occurrence of unstable angina pectoris and CABG, in particular, is more frequent in group B. Mortality is very low, 0% in group A and 4·3% in group B. However, the number of patients is too small to test the difference for the classes of events separately.

Discussion

These data suggest that the inclusion of individual relaxation and breathing therapy in an exercise rehabilitation programme reduces the occurrence of cardiac events and decreases hospital readmissions. Although the results must be interpreted with great caution, they are intriguing. The following considerations are important:

(1) The study involved a selected group of MI patients, referred for cardiac rehabilitation. Mortality is quite low, as in other studies[10,11], probably because the seriously ill are already excluded. Cardiac events occurred less frequently than was expected[10,17]. It is therefore quite remarkable that a significant difference in cardiac events between treatments was seen in this study where the control group also received rehabilitation.

(2) The treatment groups do not differ significantly in base-line characteristics. Anterior infarction, which would affect prognosis unfavourably, has occupied more often in treatment group A (44% *vs* 26%). However, this would only strengthen the result. On the other hand, a large infarction was more frequent in treatment group B (38% *vs* 28%). The use of beta-blocking agents, which improve prognosis, is the same for both treatments (both 23%), as well as the presence of post-infarction angina pectoris (both 33%). It seems therefore that the randomization procedure has been successful and that the results cannot be explained by biased allocation of patients of the treatments.

However, the natural course of ischaemic heart disease is dependent on many risk factors; uneven distribution of these among the two treatment groups cannot be excluded, especially with the small number of patients involved. Firm conclusions cannot therefore be drawn from this study. Also, it is not known whether relaxation would be effective as an independent factor, or through reduction of risk factors[18].

(3) The end-points in the study were not predefined. The indications for hospital readmission or CABG may differ among the clinicians involved. There is little change of a treatment bias in this respect, however, as the cardiologists were not aware of the forms of rehabilitation treatment. Nonetheless, the difference between the treatments is greatest for angina pectoris, both as a cause for hospital admission and for CABG. One possibility is that patients who learned to relax were better able to cope with anginal pain. If that idea is correct, the results show a reduction in symptoms, but not necessarily an effect on the natural course of the disease. In a future study, the end-points will have to be considered separately as well.

To summarize the results of this study: it suggests that relaxation and breathing therapy influence cardiac events after myocardial infarction. This result is remarkable in view of the fact that (1) the control group also underwent rehabilitation, (2) the study group already had a fairly good prognosis and (3) the intervention was limited to a two-months rehabilitation period. The stability of this result should be investigated in a replication study, specifically designed for long term outcome on morbidity and mortality. If the effect holds, the implication will be that relaxation therapy has secondary preventive value for MI patients.

For future research, three points should be emphasized. Secondary preventive measures should not be limited to the convalescence phase, but extend beyond the first year after MI[8]. If the influence of relaxation therapy on the natural history of ischaemic heart disease is to be studied, the therapy ought to be continued, and its application assessed, in the same way as compliance with medication or the presence of risk factors are monitored. An example is the recurrent coronary prevention project, which aims at reduction of 'coronary prone' (type A) behaviour in post-MI patients. In that study the intervention group meetings continued monthly for $4\frac{1}{2}$ years, after an initial higher frequency, and its efficacy in changing behaviour was assessed[19]. Patients with reduced type A behaviour had a far lower recurrence rate than those whose behaviour remained unchanged[13]. It is important therefore to apply criteria for relaxation success and ability.

Secondly, the beneficial effect of relaxation therapy may not apply to all patients equally. It is to be expected that patients who experience benefit in the short term are more motivated to continue the practice of relaxation[15]. Possibly, some categories of patient are more apt to find benefit, as for instance, those who approach the exercise programme in an over-zealous manner[14], or who are unable to undergo physical training. The selection criteria for referral to an exercise training programme may not be the same as the criteria for relaxation therapy. Also, patients with a risk of the development of angina, or with a possible indication for CABG may be especially selected for this therapy.

Finally, the integration of relaxation therapy in rehabilitation can take several forms. As a psychophysiological technique, it can be included in a behavioural treatment[11,13,14], but also be part of the exercise training, for instance during the warm up and/or cool down phases. To study the value of relaxation technique as a treatment modality, we chose individual lessons. Breathing technique is especially difficult to teach in groups. On the other hand, motivation will be enhanced when relaxation is also integrated in the other rehabilitation procedures.

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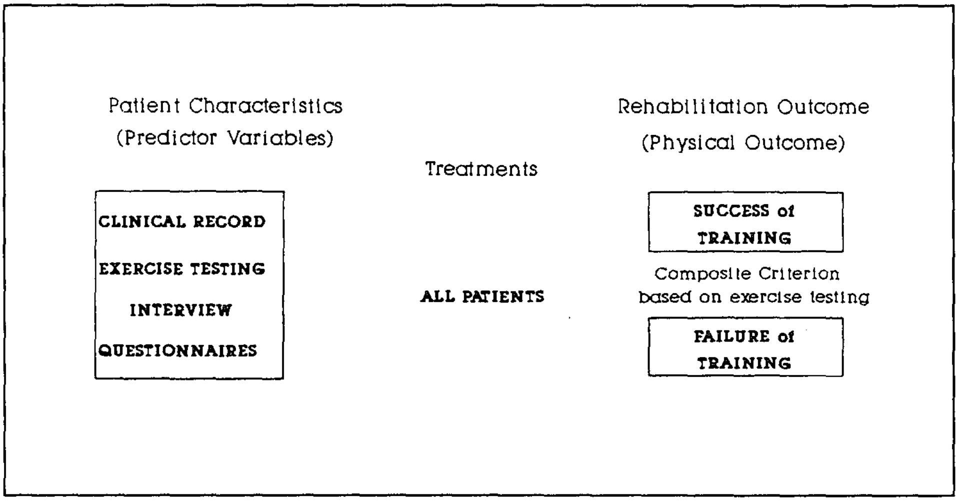

Figure 7.1.
Predicting Success and Failure of Training

Chapter 7

Success and Failure of Exercise Training after Myocardial Infarction: is the Outcome Predictable?

Jan van Dixhoorn, Hugo J Duivenvoorden, Jan Pool

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Success and Failure of Exercise Training After Myocardial Infarction: Is the Outcome Predictable?

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One hundred fifty-six patients underwent a 5 week daily exercise training program after recovery from acute myocardial infarction. Outcome was assessed on the basis of exercise testing, integrating the measurements into a single outcome measure consisting of three categories (positive, n = 79; negative, n = 42; no change, n = 35). This composite criterion served as the end point for determining the predictability of a positive (training success) and negative (training failure) outcome.

With use of logistic regression analysis, the baseline variables of clinical information, exercise data and psychosocial variables were able to identify patients with training success, as well as patients with failure (correct classification rates 81% and 85%, respectively). The characteristics of patients for whom training was beneficial differed from those of patients with a negative outcome. Work status before infarction was the single most important predictor of success, but it did not determine failure. Psychologic variables (type A behavior, well-being, depression) were important for predicting failure, but not for predicting success. Cardiac state and physical fitness largely determined training success.

It is concluded that the physical benefit of exercise training in patients after myocardial infarction is highly predictable. Validation will make it possible to optimally apply exercise training as a therapeutic modality in these patients.

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Cardiac rehabilitation programs can be expensive and carry a risk (1), and intensive physical training does not always result in improved fitness for all patients (2). Much effort could be saved if a patient's likelihood of obtaining a positive training response could be predicted on the basis of initial data (1). Previous studies (1,3–6) obtained moderate success in such prediction.

In this study, a composite criterion is constructed on the basis of several measurements to differentiate patients who will have a successful response to an exercise program from those who will be unsuccessful (7). In addition, this study uses psychosocial data as predictor variables; these have been successfully used to predict psychosocial outcome (8–11), but have rarely been used to predict a physical training effect (5,12).

The main objective of the study was to predict success or failure of exercise training on the basis of clinical information, psychosocial data and initial exercise testing data.

Methods

Study patients. After discharge following acute myocardial infarction, patients were referred from several hospitals to the regional rehabilitation center at St. Joannes de Deo Hospital. A total of 156 such patients (147 men and 9 women) were eligible for the study. Patients who were referred with a diagnosis other than myocardial infarction and patients who needed individual (psychosocial) help in addition to exercise training were excluded from the study. The median age was 56 years (range 36 to 76). In Tables 1 and 2, the clinical data at entry are separately summarized for the three categories of training outcome.

Procedure. Clinical baseline data and medical history were obtained from the referring cardiologist. At entry, patients were interviewed by a psychologist or social worker, who asked about the patient's appraisal of his or her situation (Table 2). The patients were asked to participate in a study designed to assess the effect of the rehabilitation program. After they consented, they completed additional self-administered questionnaires. In addition, half of the patients were assigned at random to relaxation therapy.

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Table 1. Predictive Variables for Training Outcome: Clinical Information and Exercise Data in 156 Patients With Recent Myocardial Infarction

	Success (n = 79)	No Change (n = 35)	Failure (n = 42)	p*	p†
Age (yr)	55 ± 8	56 ± 11	56 ± 7	NS	NS
No. of men	77 (98)	33 (94)	37 (88)	0.07	0.05
Clinical data					
Preinfarction					
Angina pectoris	10 (13)	4 (11)	12 (29)	NS	0.05
Smoking (cigarettes/day)	15 ± 14	19 ± 16	12 ± 11	NS	0.02
Previous infarction	7 (9)	3 (9)	6 (14)	NS	NS
Previous CABG	—	—	3 (7)	0.10	0.01
Beta-blockers	9 (11)	1 (3)	6 (14)	NS	NS
Diuretics	7 (9)	1 (3)	1 (2)	0.08	NS
Anginal med	4 (5)	1 (3)	8 (19)	0.10	0.01
Infarction					
Large	22 (28)	18 (51)	14 (38)	0.06	NS
Anterior	22 (28)	13 (37)	18 (43)	0.10	0.09
Complications	9 (11)	9 (26)	9 (21)	0.07	0.10
Postinfarction					
Angina	19 (24)	6 (17)	15 (36)	NS	0.07
Heart glycosides	8 (10)	6 (17)	9 (21)	0.07	0.09
Anginal med	19 (24)	5 (14)	7 (17)	NS	NS
Exercise testing					
Start of training (weeks after hospital discharge)	5.0 ± 1.4	4.7 ± 1.5	5.8 ± 2.9	NS	0.05
Work capacity‡	86 ± 16	91 ± 18	92 ± 22	0.06	NS
Maximal work load (W)	132 ± 21	137 ± 23	133 ± 25	NS	NS
Heart rate (beats/min)					
Rest	76 ± 14	79 ± 16	86 ± 20	0.03	0.02
60 W	99 ± 16	103 ± 17	109 ± 19	0.008	0.009
Maximal	133 ± 22	137 ± 24	138 ± 25	NS	NS
Blood pressure (mm Hg)					
Systolic rest	131 ± 17	129 ± 19	128 ± 16	NS	NS
Systolic maximal	159 ± 25	155 ± 22	155 ± 18	NS	NS
Chest pain	11 (14)	1 (3)	8 (19)	NS	NS
ST abnormalities	30 (38)	6 (17)	12 (29)	0.07	NS
Arrhythmias	4 (5)	6 (17)	7 (17)	0.02	NS

*Training success versus failure or no change; †training failure versus success or no change. ‡Maximal work load as percent of normal. Data are reported as number of cases or mean values ± SD. Percentages are shown in parentheses. CABG = coronary artery bypass graft surgery; med = medication.

Graded exercise testing was performed on a bicycle ergometer before and after the physical training.

Psychologic questionnaires. These included the following: *1) Heart patients psychologic questionnaire* for measurement of the well-being of patients with cardiac disease (13), consisting of four scales: well-being, subjective invalidity, despondency and social inhibition; *2) anxiety measured by the state trait anxiety inventory (STAI) in two modes:* state and trait anxiety (14); *3) sleeping habits*, consisting of questions about hours of sleep, daytime naps and quality of sleep (15); and *4) functional symptoms*, consisting of complaints not typical of angina pectoris. In addition, the following questionnaires referred to the preinfarction period: *5) Jenkins activity scale* for type A behavior (16); and 6) *Maastricht questionnaire* to evaluate vital exhaustion and depression (17).

Exercise testing. After an adaptation period on the bicycle ergometer, the test began with a 1 min period of cycling at 60 cycles/min without load and then for 2 min at 60 W. The test continued by increasing the work load by 30 W every 2 min until symptoms limited further exercise or the physician terminated the test. The occurrence of angina pectoris, ST segment abnormalities and severe arrhythmias were noted. ST abnormalities were mostly ST depressions ≥2 mm, horizontal or downsloping, occurring during or immediately after the test. Electrocardiographic lead CM_5 was recorded during the last 30 s before the work load was increased. Blood pressure was measured by cuff sphygmomanometry before the test and at maximal work load.

Rehabilitation. All patients underwent a physical conditioning program, consisting of 5 weeks of interval exercise training on a bicycle ergometer, once a day for 30 min.

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Table 2. Predictive Variables for Training Outcome: Psychosocial Information in 156 Patients With Recent Myocardial Infarction

	Success (n = 79)	No Change (n = 35)	Failure (n = 42)	p*	p†
Interview					
Work before infarction	60 (76)	18 (51)	23 (55)	0.005	0.10
Infarction experience					
Doubt of diagnosis‡	8 (13)	2 (7)	2 (8)	NS	NS
Seriously ill‡	29 (45)	13 (45)	19 (70)	NS	0.04
Infarction cause clear	48 (61)	23 (70)	20 (48)	NS	0.10
Optimistic for future‡	49 (78)	21 (72)	17 (63)	NS	NS
Expects full recovery of activities‡	42 (67)	22 (85)	21 (75)	NS	NS
Questionnaires					
Vital exhaustion	90 ± 22	86 ± 19	92 ± 26	NS	NS
JAS (type A)	121 ± 13	121 ± 13	116 ± 14	NS	0.06
Sleep quality	7.2 ± 2.3	7.9 ± 2.4	7.5 ± 2.7	NS	NS
Siesta (quarter of hours)	3.5 ± 1.7	3.9 ± 1.5	4.3 ± 1.5	0.04	0.03
Functional complaints	35 ± 7	33 ± 7	37 ± 9	NS	0.10
Anxiety state	38 ± 10	34 ± 8	37 ± 12	NS	NS
Anxiety trait	37 ± 9	34 ± 9	37 ± 10	NS	NS
Well-being	25 ± 7	28 ± 6	27 ± 8	0.09	NS
Invalidity feelings	25 ± 6	25 ± 6	26 ± 6	NS	NS
Despondency	16 ± 4	14 ± 3	17 ± 5	NS	0.08

*Training success versus failure or no change; †training failure versus success or no change; ‡n = 117. Data are reported as number of cases or mean values ± SD. Percentages are shown in parentheses. JAS = Jenkins activity scale.

Training was done in groups of four patients supervised by two physical therapists. Each patient exercised up to 70% to 80% of the maximal heart rate (Karvonen method) attained at pretraining exercise testing. Half of the patients also underwent individual relaxation therapy. Relaxation training was given once a week in six individual sessions of 1 h duration. Several procedures for active and passive relaxation were employed, with a respiratory technique (18) as a core.

Outcome criterion: training benefit. To obtain a single measure indicating the efficacy of physical training, the measurements obtained at exercise testing both before and after training were integrated into a composite criterion. With this criterion, patients were classified as follows: 1) patients with little or no change, 2) patients whose condition improved (success), or 3) patients whose condition deteriorated (failure) (7). In the flow chart in Fig. 1, four levels are shown according to their clinical relevance: signs of cardiac dysfunction (ST abnormalities, angina pectoris, serious arrhythmias), maximal work load, heart rate and systolic blood pressure response. At each of these levels, a patient could be assigned to "success" or "failure" when a significant change in the particular measurement had occurred. For cardiac signs, a negative change had priority over a positive one. Levels 2 to 4 represented physical fitness. Dropouts were included and classified as far as possible on the basis of the reason for not completing the training program. Patients who stopped the training because they resumed their normal daily activities were classified in the success group. Patients who stopped the training for cardiac problems were classified in the failure group. Patients who stopped for other reasons were assigned to "no change." Thus, all subjects were classified.

Statistical analyses. The association of training outcome with data at entry was analyzed in two ways. Univariate association, with the baseline characteristics as predictor variables, was tested with 1) chi-square analysis for contingencies in case of variables of nominal or ordinal level; and 2) Student's t test in case of variables of interval level.

Stepwise logistic regression analysis was used to predict the outcome based on sets of variables. Predictions were first made using variables from four sets of variables: 1) medical history and hospital records, 2) interviews, 3) exercise testing, and 4) psychologic questionnaires, with all sets taking into account age and gender (see Appendix A). Missing values were assigned to a middle category in the case of discrete variables, and to the mean values in the case of interval variables. Next, selected variables from the medical and exercise data were combined to investigate the predictive value of information that is routinely available in a rehabilitation clinic. Ultimately, selected psychosocial data were included, with the exception of incomplete interview variables. The criterion for inclusion of variables was $p < 0.10$; for exclusion, it was $p > 0.15$.

The performance of the resulting logistic function is expressed through its classification rates. This function

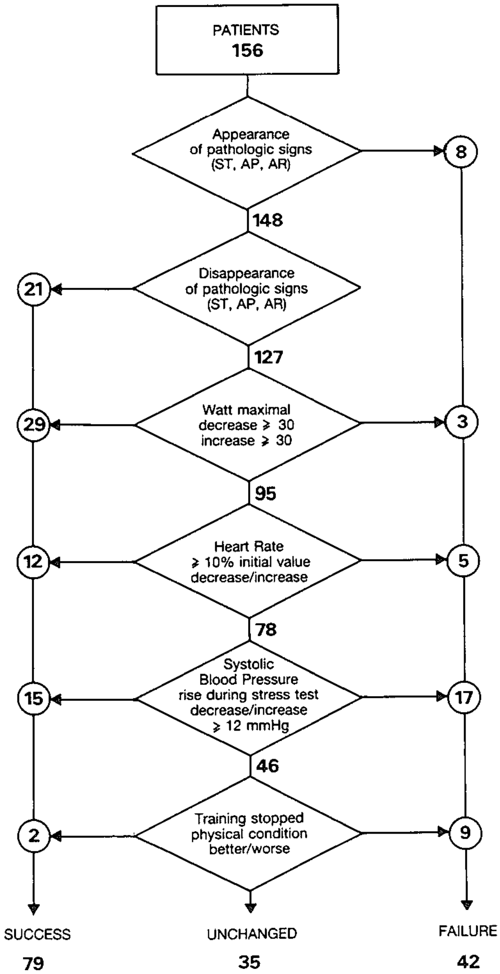

Figure 1. Flow chart for determining success or failure of exercise training in 156 patients with recent myocardial infarction. AP = angina pectoris; AR = arrhythmia; ST = ST segment abnormalities; Watt maximal = maximal work load achieved.

consists of an equation that includes the selected variables with their regression coefficients and a constant. For each patient, the equation yields an estimation of the probability of the particular outcome (either success or failure). Comparing the estimated outcome with the actual outcome at different levels of probability, the power of the logistic function to classify the patient correctly is shown. The rates for the classification with the highest percent of correctly classified patients are given for each function. The variables selected in the final analyses are presented in Appendix B.

Results

Baseline clinical features (Table 1). A total of 156 patients with recent myocardial infarction were admitted to the study. Three patients had previous coronary artery bypass grafting, 16 had experienced recurrent infarction and 26 had a history of angina pectoris. Classification of infarct size was made according to peak serum enzyme levels. In 47 patients, the infarct was considered small, in 49 patients medium and in 52 large. In eight patients, serum enzyme levels were not available, and these patients were included in the medium category. In-hospital signs of heart failure (hypotension, cardiothoracic ratio >50%, pulmonary congestion) were present in 27 patients (17%). On average, patients were hospitalized for almost 3 weeks. Postinfarction angina was present in 26% of the patients.

Training outcome. The exercise program was completed by 139 of the 156 patients. Mean maximal work load increased from 134 to 142 W ($p < 0.0001$) and heart rate at highest equal work load level decreased from 134 to 129 beats/min ($p < 0.0001$). Maximal work load increased by ≥30 W in 39 patients (28%) and decreased in 7 patients (5%). Before exercise testing, 41% of the patients achieved a work load of ≥90% of the normal value. After training, 58% of the patients achieved this work load. On average, blood pressure changes were negligible. ST abnormalities were found in 44 patients before and in 34 patients after training. These abnormalities disappeared in 16 patients and newly appeared in 6 patients. Exercise-induced chest pain was present in 18 patients before and in 12 after training; it disappeared in 10 patients and newly appeared in 4 patients. Serious arrhythmias were present in 14 patients and developed in 1 additional patient after training.

Seventeen patients did not complete the program. Two had fully resumed their activities and were considered to have had a successful outcome. Nine patients had to stop because of cardiac problems and were classified in the failure group. The remaining six patients stopped for noncardiac reasons and were classified as having no change. In the flow chart (Fig. 1), it is shown that training was successful in 79 patients (51%) and unsuccessful in 42 patients (27%). The remaining 35 patients (22%) showed no substantial change. Outcome differed for the two treatment modalities. The addition of relaxation therapy had a positive effect on training benefit (success: 46% in those without such versus 55% in patients with such therapy, failure: 33% versus 20%, respectively).

Univariate Analyses

Training success. About half of the patients benefited from the training program. Compared with those without benefit, in the training group with benefit, there were fewer women, more patients used diuretic drugs and fewer had

Table 3. Performance of Variables Predicting Training Success

	Sets of Predictor Variables					
	A	B	C	D		
Performance Rates	Clinical	Interview	Exercise	Psychologic	A+B+C	All
Correctly classified (%)	60	62	65	60	76	81
Sensitivity (%)	86	76	73	79	75	77
Specificity (%)	33	47	57	42	78	84
True positive (%)	58	63	64	58	78	84
True negative (%)	69	68	67	65	75	78

A = diuretic and antianginal medication preinfarction, heart failure; B = work status; C = gender, maximal work load, heart rate at maximal work load and at 60 W, maximal blood pressure, arrhythmia; D = type A behavior, daytime nap; A+B+C = gender, antianginal medication, angina pectoris pre- and postinfarction, work status, maximal work load, heart rate at 60 W, maximal blood pressure, arrhythmia, ST abnormality; All = variables listed in Appendix B.

anginal medication before infarction; a large or anterior infarction and signs of heart failure were less common and fewer patients used cardiac glucosides after discharge. Likewise, at exercise testing, rest and submaximal heart rates were significantly lower, ST abnormalities were more common and arrhythmias occurred less frequently. More patients with training benefit had worked before their myocardial infarction. They were slightly more optimistic about the future; however, fewer expected to resume their activities fully. They felt less well, but needed less rest during the day.

Training failure. A substantial percent of patients (27%) had a negative outcome. Compared with patients with success or with no change, more patients with training failure had angina pectoris, had used antianginal drugs before myocardial infarction. They smoked less. In all three patients with previous coronary artery bypass graft surgery, exercise training had a negative outcome. Infarct size did not differ, but an anterior location and signs of heart failure occurred more often. After hospital discharge, more of these patients had anginal symptoms and used a glucoside. Antianginal medication was not different. Training started significantly later after infarction and heart rates at rest or at a low work load were substantially higher. They did not differ in work status. In appraisal of their illness, more had felt seriously ill and fewer were optimistic about the future or had a clear idea about the cause of their infarction. They tended to be less active (type A), take longer daytime naps, have more functional symptoms and feel more depressed.

Multivariate Analyses

Training success. The four sets of variables (clinical, exercise, interview, questionnaires) had an approximately identical (range 60% to 65%) ability to predict training success (Table 3). With clinical and exercise data, including work status, a correct classification was attained in 76%. When psychological questionnaires were added, 81% could be correctly classified: 77% of patients with a good training result (sensitivity) and 84% of patients without benefit (specificity) could be properly assigned. Thus, the conclusion that success is predictable to a high degree when all sets of data are combined is justified. The variables selected in the logistic regression analysis are shown in Appendix B. Variables of high predictive value were maximal blood pressure, work status, heart rate, daytime naps, ST abnormality,

Table 4. Performance of Variables Predicting Training Failure

	Sets of Predictor Variables					
	A	B	C	D		
Performance Rates	Clinical	Interview	Exercise	Psychological	A + C	A + C + D
Correctly classified (%)	76	76	79	78	78	85
Sensitivity (%)	26	41	50	26	57	69
Specificity (%)	94	89	90	98	86	90
True positive (%)	61	57	64	85	60	73
True negative (%)	78	80	83	78	78	89

A = gender antianginal medication preinfarction, smoking; B = gender, illness experience, doubt of diagnosis, view of future, expected recovery, attributed cause infarction; C = gender, rest heart rate, chest pain, arrhythmia, start of training; D = type A behavior, daytime nap, well-being, despondency; A + C = gender, antianginal medication preinfarction, rest heart rate, start of training; A + C + D = variables listed in Appendix B.

maximal work load and angina both before and after myocardial infarction.

Training failure (Table 4). The percent of training failures correctly classified did not differ for the four sets of variables (range 76% to 79%). Overall, the performance was better than that for predicting training success, which is attributed mainly to the high specificity. The combination of clinical and exercise data increased the sensitivity, but did not improve overall classification (78%). With the addition of psychological questionnaires, 85% of these patients were correctly classified; 69% of the patients with training failure and 90% without training failure were properly assigned. It can be concluded that training failure is highly predictable when psychologic data are added to clinical and exercise data. Variables used in the final analysis are shown in Appendix B. Despondency, type A behavior, antianginal medication before myocardial infarction and feelings of well being were particularly powerful, followed by physical variables (start of training, arrhythmias during exercise testing and rest heart rate).

Discussion

Experts state (19,20) that cardiac rehabilitation programs should not be applied uniformly or indiscriminately, but should be tailored to the physical and psychologic condition of the individual patient. Intensive exercise training is expensive (1) and although many patients improve physically, others do not and some even experience adverse effects (2,21). The degree of in-hospital deconditioning and the need for subsequent reconditioning vary greatly among patients. Moreover, rehabilitation can be implemented through other treatments such as behavior modification, counseling and patient education (22). To determine which patients will not benefit from exercise training, it is necessary to be able to predict training outcome (1,3–6).

Evaluation of training. In this study, the outcome was assessed by exercise testing variables of cardiac dysfunction and physical fitness. This composite criterion is an application of the primary purpose of exercise training. It is utilized as an indicator for intensive (daily) physical training. Obviously, this criterion does not fully evaluate rehabilitation outcome (for example, psychosocial measurements are not included). This criterion differs from any single measure used in other studies (for example, it does not correlate with the criterion of percent normal maximal work load at the end of rehabilitation used by Fioretti et al. [3,4]). Also, patients with negative changes after rehabilitation (training failures) were distinguished from patients with benefit (training success).

Success implied an improved physical state (training response) that could be attributed to exercise. Thus, for "successful" patients, intensive training seems to have been appropriate (7). However, training success does not necessarily imply psychosocial recovery (23). A "failure" implies that the patient became less tolerant to the stress of effort. Because this is opposite to the purpose of training, intensive exercise seems not to have been indicated. Instead, less intensive exercise or other treatment strategies may have been a more appropriate way of rehabilitation. Failure does not mean that training was unsafe or that cardiac complications occurred during exercise. Indeed, patients with training failure may receive psychosocial benefit of rehabilitation.

Predicting training success. For 79 (59%) of the 156 patients with myocardial infarction, the training was beneficial. On the basis of initial information, 81% of these patients could be identified. Although higher than sensitivity (77%), specificity (84%) was equal to the true positive value: for 84% of the patients who were predicted to have a successful outcome, training was actually beneficial. Training success did not depend on infarct characteristics (size, location), duration of hospital stay or age. Classification was optimal when medical data, initial exercise testing and psychosocial information were combined for prediction. Work status before infarction was the single most important predictor, possibly reflecting the motivation of the patient.

Initial fitness. Fitness and cardiac condition, indicated by lower heart rate, the ability to generate higher blood pressure during exercise and absence of angina, arrhythmia and signs of heart failure in the hospital, were also important for success. This indicates that a good physical state is conducive to training success. The need for less daytime rest or naps for patients with a successful outcome may also be attributed to this. Conversely, a low initial maximal work load (indicating a poor state of fitness) and silent ischemia were also favorable for predicting success. Possibly, initial fitness indicates the ability to sustain progressive effort, on the one hand, and, on the other hand, it offers little room for improvement (1). The positive role of ST abnormalities during exercise is not confirmed by others (1,3,4,24); one explanation is that in our study, ST abnormalities decreased significantly during rehabilitation (mainly among patients who underwent relaxation therapy), which contributed to the outcome criterion (7).

Predicting training failure. Training failure occurred in 42 patients (27%). The overall 85% predictive result in these patients was higher than that in those with training success. Taking this percent as a criterion, sensitivity was low (69%) and specificity high (90%). Thus, not all patients with training failure could be identified. However, 73% of the patients who were predicted to have a training failure had a negative outcome. The performance was optimal when all sets of variables were analyzed jointly. Psychologic variables in particular were able to identify patients with training failure; they enhanced the sensitivity and true positive value discernibly.

The two logistic functions predicting success and predicting failure shared five factors, but in opposite directions:

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gender, antianginal medication before infarction, sleeping habits after infarction and heart rate and arrhythmias during initial exercise testing. The small number of women (6%) signifies that relatively few women had been referred for rehabilitation. Possibly, the reasons for referring these women also determined a negative outcome. This may explain why few women had training success (selection bias). Moreover, when relaxation was added to training, gender had no relation to outcome. It should not be concluded, therefore, that training is particularly indicated for men.

The contribution of clinical information to prediction of patients with training failure was less than the contribution to the prediction of those who benefited. Thus, severity of infarction does not seem to be a contraindication to exercise as a therapeutic modality in rehabilitation. Bivariately, however, a cardiac history, in particular of angina pectoris, is associated more often with training failure than with training success.

Psychologic determinants. It is surprising that psychologic data were among the variables that predicted training outcome. It may be recalled, however, that from the very beginning of cardiac rehabilitation, for instance in the work classification units (25), psychosocial determinants were found to be of importance in the patient's recovery. The positive role of type A behavior supports the findings of Rejeski et al. (5). It seems plausible that an active disposition, as well as work status, and the absence of depression facilitate the motivation for exercise and rehabilitation. That psychosocial components are such determining features suggests that psychosocial interventions could alter the outcome of training. This is an exciting idea, because it would create treatment options for patients who are in need of rehabilitation but who would be likely to experience training failure if exercise was the only treatment. In this study, the addition of relaxation therapy to the exercise program substantially reduced the risk of failure.

Conclusions. It is possible to predict both success and failure of exercise training on the basis of initial data. These data not only were clinical or derived from exercise testing, but also were psychosocial. Furthermore, in predicting training outcome, success and failure must be clearly distinguished. Absence of benefit does not necessarily imply failure. Our study shows that the characteristics of patients for whom training is most appropriate differ from those who should not start training because of an anticipated negative outcome. Before the prediction rules can be justifiably applied, cross-validation in a larger group of patients is needed (26).

Two prediction rules should be looked for: one set of variables estimating the probability of success for a given patient, the other one estimating probability of failure. Validation will make it possible to optimize the application of exercise training as a therapeutic strategy in patients with recent myocardial infarction.

Appendix A

Variables Used as Predictors in the Stepwise Logistic Regression Analysis

Clinical: before infarction	Exercise testing
Hypertension	Weeks after hospital discharge
Physical fitness	Maximal work load
Smoking	Work capacity
Angina pectoris	Maximal heart rate
Coronary bypass surgery	Rest heart rate
Previous infarction	Heart rate at 60 W
Cardiac medication	Rest diastolic blood pressure
Beta-adenergic blockers	Rest systolic blood pressure
Digoxin	Maximal systolic blood pressure
Diuretic drugs	Systolic pressure increase
Antianginal drugs	Chest pain
Antiarrhythmic drugs	ST abnormalities
Clinical hospital	Arrhythmias
Infarction size	Psychologic questionnaires
Infarction location	Sleep quality (before and after MI)
Mild heart failure	Siesta time (before and after MI)
Medication at discharge	Vital exhaustion before MI
Beta-adrenergic blockers	Type A (JAS) before MI
Digoxin	Functional complaints
Diuretic drugs	Sense of well-being
Antianginal drugs	Feelings of invalidity
Antiarrhyhthmic drugs	Despondency
Angina pectoris at discharge	Anxiety state (STAI-S)
Interview	Anxiety trait (STAI-T)
Marital status	
Work status	
Job level	
Infarction appraisal	
Pain experience	
Illness experience	
Doubt of diagnosis	
View of future	
Wishes early start of rehabilitation	
Expectation of activity resumption	
Cause of MI clear	
Attributed cause of MI	
Stress	
External	
Risk factors	
Psychic	

JAS = Jenkins activity scale; MI = myocardial infarction; STAI = state trait anxiety inventory.

Appendix B

Details of the calculation of the logistic function are given below. The formula results in the probability of success or failure, respectively, for a given patient:

$$p = \frac{1}{1 + \exp^{-(a + b_1x_1 + b_2x_2 \cdots + b_nx_n)}}.$$

The probability (p) ranges between 0 and 1. In case of success, the following variables (X), their coefficients (b) and the constant value (a) constitute the equation.

Probability of Success	High
Gender*	1 × −2.21 = −2.21
Work†	1 × −0.65 = −0.65
Anginal complaints before MI‡	0 × −1.32 = 0
Diuretic drugs before MI‡	1 × 1.63 = 1.63
Signs of heart failure in CCU‡	0 × −1.01 = 0
Anginal complaints after MI§	3 × −0.58 = −1.74
Antianginal medication after MI‡	1 × 0.94 = 0.94
Maximal work load	120 × −0.02 = −2.40
Heart rate at 60 W	80 × −0.03 = −2.40
Maximal systolic blood pressure	160 × 0.03 = 4.80
Arrhythmia‡	0 × −1.27 = 0
ST abnormality‡	1 × 1.23 = 1.23
Sleeping quality	6 × −0.25 = −1.50
Constant	8.36
Sum	6.06
Exp (−sum)	0.0023
$p = \frac{1}{1 + \exp(-\text{sum})}$	0.99

*Male = 1, female = 2; †full time = 1, part time = 2, none = 3; ‡present = 1, absent = 0; §absent = 1, possibly present = 2, present = 3; CCU = coronary care unit; MI = myocardial infarction.

Thus, the probability of success is very high (p = 0.99) in the case of a male patient who worked full-time, used diuretic drugs but not anginal medication, did not develop signs of heart failure in the coronary care unit, had no anginal complaints at hospital discharge, used anginal medication, reached a moderate work load during exercise testing, did not have a high heart rate at a low work level, generated a sufficiently high systolic blood pressure during effort, did not have serious arrhythmias, had ST abnormality and slept poorly. In the case of the variables having opposite values, the probability of success is very low (p = 0.0003).

Likewise:

Probability of Failure	High
Gender*	2 × 0.79 = 1.58
Antianginal medication before MI†	1 × 1.75 = 1.75
Rest heart rate	95 × 0.03 = 2.85
Arrhythmia†	1 × 1.16 = 1.16
Start of training‡	6 × 0.24 = 1.44
JAS	110 × −0.04 = −4.40
Daytime nap§	6 × 0.19 = 1.14
Well-being	28 × 0.09 = 2.52
Displeasure	20 × 0.20 = 4.00
Constant	−5.23
Sum	6.81
Exp (−sum)	0.0011
$p = \frac{1}{1 + \exp(-\text{sum})}$	0.99

*Male = 1, female = 2; †present = 1, absent = 0; ‡weeks after hospital discharge; §quarters of hours. MI = myocardial infarction.

The probability of failure is very high (0.99) in the case of a female patient who used anginal medication before infarction, started rehabilitation late, had a high rest heart rate during initial exercise testing as well as arrhythmias during effort, did not show type A behavior, took long daytime naps and reported mood disturbances but still felt well. The probability of failure is very low (p = 0.12) when the same variables have opposite values.

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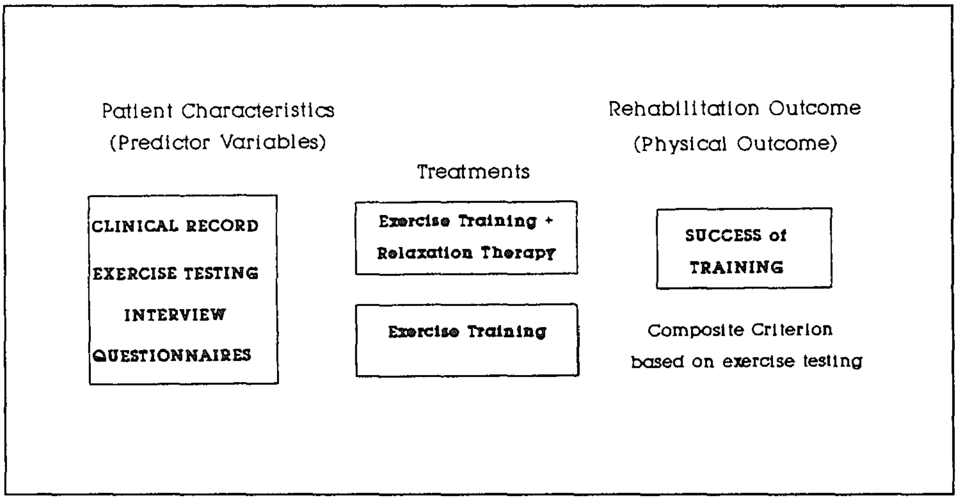

Figure 8.1.
Predicting Success of Training for two treatments

Chapter 8

Outcome of Exercise Training alone and in Combination with Relaxation Therapy after Myocardial Infarction: what Patients benefit from these Treatments?

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The predictability of the outcome of two rehabilitation programmes was studied, aerobic conditioning alone and in combination with individual relaxation therapy. Myocardial infarction patients were randomly assigned to either exercise training (n=80) or a combination of exercise training and relaxation therapy (n=76). The outcome was assessed through a composite criterion, based on exercise testing.

By using logistic regression analysis, the predictive value of baseline variables of clinical information, exercise data and psychosocial variables to identify patients whose training was successful, was investigated. For exercise as single treatment, predictor variables for training success turned out to be predominantly exercise data and clinical information (correct classification: 76%). For the treatments jointly, psychosocial information had incremental value in predicting, beyond clinical and exercise data. With all data sets combined, 91% of the patients were identified correctly. The prediction rules shared only one variable (Type A behaviour), in opposite direction.

This study supports the usefulness of prediction analysis for divergent forms of cardiac rehabilitation. The relaxation therapy modifies the effects of the determinants of training success. Validation is needed to develop a reliable tool to identify patients for whom exercise training is indicated and those for whom additional relaxation therapy is indicated.

Introduction

Predictability of the efficacy of physical exercise training in cardiac rehabilitation has been investigated in a few studies where exercise training constituted the only or main type of treatment (1-4). The aim of this study is to predict the outcome of training for two different types of treatment. Exercise training as a single treatment, is contrasted to a more comprehensive treatment, consisting of exercise and individual relaxation therapy (5). Comparison of the outcome of the two treatments in a previous analysis showed, that relaxation therapy enhanced the effectiveness of rehabilitation (5-7). However, this leaves the question unanswered as to what patients, in particular, will benefit from this comprehensive treatment, which is more expensive and time-consuming than exercise training alone.

The main objective of this study is to investigate the predictability of the training outcome for the two treatments separately, on the basis of initial medical, psychosocial and exercise data.

Patients and Methods

Patients. After discharge, cardiac patients from various hospitals are referred to the regional rehabilitation centre at St. Joannes de Deo Hospital, Haarlem, The Netherlands. A total of 156 myocardial infarction (MI) patients were admitted to the study and were randomly assigned to one out of two treatment protocols. Patients, with a diagnosis other than MI, e.g. coronary artery bypass graft surgery, and patients who needed psychosocial help were excluded from the study. There were 147 men and 9 women. Median age was 56, their age ranging from 36 to 76. Tables 1 and 2 summarize clinical data upon entry for the two treatments, according to the training outcome.

Table 1. Predictor variables for training success: clinical information and exercise testing

	Exercise training success			Exercise + relaxation success		
	no (N=43)	yes (N=37)	p	no (N=34)	yes (N=42)	p
sex (women; %)	4	0	0.08	3	2	ns
	(9)	(0)		(8)	(5)	
Clinical data						
pre infarction						
anginal medication	7	1	0.05	2	3	ns
(%)	(16)	(3)		(6)	(7)	
previous infarction	7	3	ns	2	4	ns
(%)	(16)	(8)		(6)	(10)	
non-cardiac morbidity	16	22	0.08	14	20	ns
(%)	(37)	(60)		(41)	(48)	
infarction						
small	14	13		5	15	
(%)	(33)	(35)		(15)	(36)	
medium	13	13	ns	15	16	0.03
(%)	(30)	(35)		(44)	(38)	
large	16	11		14	11	
(%)	(37)	(30)		(41)	(26)	
heart failure	9	4	ns	9	5	ns
(%)	(21)	(11)		(27)	(12)	
post infarction						
beta blockers (%)	14	12	ns	10	10	ns
	(33)	(30)		(29)	(24)	
diuretics (%)	10	10	ns	16	11	0.09
	(23)	(27)		(47)	(26)	
glucosides (%)	7	3	ns	8	5	ns
	(16)	(8)		(24)	(12)	
Exercise testing						
work capacity (in percent of normal)	90	84	ns	93	87	0.01
	(22.8)	(16.7)		(15.3)	(14.5)	
heart rate resting	82.2	77.1	ns	84.4	76.9	0.06
	(19.4)	(14.6)		(17.8)	(14.3)	
Watt=60	104.5	98.7	ns	108.7	98.5	0.02
	(19.6)	(14.8)		(16.8)	(17.5)	
maximal systolic blood pressure	154.4	156.2	ns	155.2	162.0	ns
	(19.1)	(23.1)		(20.2)	(26.0)	
ST abnormalities	10	11	ns	8	19	0.08
(%)	(23)	(30)		(24)	(45)	
arrhythmias	10	1	0.007	3	3	ns
(%)	(23)	(3)		(9)	(7)	

Data are reported as events and percentages of cases or as means (SD).

Table 2. Predictor variables for training success: psychosocial information

	Exercise training success			Exercise + Relaxation success		
	no (N=43)	yes (N=37)	p	no (N=34)	yes (N=42)	p
Interview						
working (%)	24 (56)	27 (73)	0.10	17 (50)	33 (79)	0.03
infarction experience						
seriously ill (%) 1)	18 (58)	17 (57)	ns	14 (56)	12 (35)	ns
prolonged pain (%)	21 (49)	20 (54)	ns	12 (35)	17 (41)	ns
expects full recovery of activities (%), 1)	22 (73)	22 (71)	ns	21 (88)	20 (63)	0.05
expects to cope differently with work (%)	6 (14)	5 (14)	ns	1 (3)	7 (17)	0.06
attributed cause infarction						
tension (%)	11 (26)	10 (27)	ns	6 (18)	14 (33)	0.10
stressors (%)	15 (35)	11 (30)	ns	8 (24)	20 (48)	0.05
Questionnaires						
JAS (Type A)	102.8 (20.1)	110.8 (20.5)	0.09	109.7 (18.9)	112.9 (19.2)	ns
sleep quality	7.3 (3.0)	7.6 (1.9)	ns	8.2 (2.0)	6.8 (2.5)	0.01
daytime nap (quarter of hours)	4.2 (1.4)	3.8 (1.8)	ns	4.1 (1.7)	3.2 (1.6)	0.06
anxiety-trait	35.3 (10.7)	35.5 (9.3)	ns	35.9 (8.6)	39.1 (9.5)	ns
well-being	27.5 (7.1)	27.0 (7.5)	ns	27.2 (6.9)	24.0 (7.0)	0.05
invalidity feelings	25.1 (6.0)	24.1 (6.4)	ns	25.8 (6.2)	25.8 (6.0)	ns

Data are reported as events and percentages of cases or as means (SD).
1) n=117; JAS: Jenkins Activity Scale.

Procedure. Clinical base-line data and medical history were obtained from the referring cardiologist. Upon entry, patients were interviewed to obtain psychosocial information and they were asked to participate in the study. After informed consent, they completed additional psychological questionnaires. All patients participated in a physical conditioning programme. In addition, half of them were randomly assigned to individual relaxation therapy. Graded exercise testing was performed on a bicycle ergometer before and after physical training, supervised by the cardiologist. He also assessed medication usage.

Exercise testing. After an adaptation period on the bicycle, the test was started with a 1-minute period of cycling at 60 cycles a minute without load, then for two minutes at 60 Watts. The test was continued by increasing the workload with 30 Watts every two minutes until symptoms limited the patient to continue or until the physician terminated the test. The occurrence of angina pectoris, ST-abnormalities and arrhythmias were noted. ST-abnormalities mostly consisted of ST-depressions greater than 2mm, horizontal or downsloping, occurring during or immediately after the test. Arrhythmias were coded as single premature ventricular contractions or as complex (groups or runs or multifocal or frequent premature ventricular complexes, bigeminy or ventricular tachycardia). A bipolar ECG lead (CM5) was taken during the last half-minute before the work load was increased. Blood pressure was taken before the test and at maximum work load.

Psychological questionnaires. (1) Heart Patients Psychological Questionnaire, for measuring the well-being of cardiac patients (8), consisted of four scales: (a) Well-being, (b) Feelings of invalidity, (c) Displeasure, (d) Social Inhibition; (2) Anxiety measured by STAI in two modes: State and Trait anxiety (9); (3) Sleeping habits, consisting of questions about hours of sleep, daytime nap and about quality of sleep (10); (4) Functional symptoms, consisting of complaints, not typical of angina pectoris. In addition, two questionnaires referred to the pre-infarction period: (5) Jenkins Activity Scale (JAS), for Type A behaviour (11); (6) Maastricht Questionnaire, for vital exhaustion and depression (12).

Rehabilitation. Physical exercise training consisted of five weeks of interval training on a bicycle ergometer, once a day, for half an hour. Training was given in groups of four patients, supervised by two physical therapists. Each patient was exercised up to 70 to 80 % of the maximal heart rate (Karvonen method) attained at the pre-training exercise test.

Relaxation training was given once a week in six individual one hourly sessions. The relaxation therapy was provided by five experts. Several proce-dures for active and passive relaxation were applied, with a respiratory tech-nique (13) as a core. The aim was for the patient to become aware of a more relaxed way of breathing so that he would be able to recognize and elicit this. EMG Feedback of the frontalis muscle was used for muscle relaxation and for monitoring unnecessary inspiratory effort. The patient learned to observe and elicit a "shift" in his respiratory pattern, in such a way that inspiration expanded both the lower abdomen and the costal margin, expiration was moderated and slow. Manual techniques and audible lip-breathing were applied to elicit breathing movements involving the trunk as a whole and requiring fewer effort. This was practised first in the supine position, to induce passive relaxation, but later also sitting up and standing ("active relaxation").

The rehabilitation programme did not have a structured form of patient education. At the patients' request information was given and questions were answered by the rehabilitation staff.

Outcome-criterion: training benefit. In order to obtain a single measure indicating the efficacy of physical training, changes in measurements obtained at exercise testing pre and post training, were integrated into a composite criterion for "training benefit". This criterion was used to trichotomize the patients as follows: a. patients with little or no change, b. patients who improved (success) or c. patients who deteriorated (failure). The criterion was an operationalisation of the primary purpose of exercise training to improve physical fitness and lower the threshold for myocardial ischaemia. The predictability of success and failure on this criterion proved satisfactory (14). For the present analysis, patients with success were distinguished from those without. "Success" implied an improved physical condition which could be attributed to exercise. The procedure is discussed in detail elsewhere (5). In short, the measurements were ranked according to their clinical relevance: 1) exercise-induced signs of cardiac dysfunction (ST-abnormalities, angina pectoris, complex ventricular arrhythmias), 2) maximal work load, 3) heart rate and 4) systolic blood pressure response (see figures 8.2 and 8.3). At each level, a patient could be assigned to success or failure when a significant change in a particular measurement had taken place. For cardiac signs, a negative change had priority over a positive one. Levels 2 - 4 represented physical fitness. This procedure allowed for dropouts to be included and classified as far as possible on the basis of the reason for not completing the programme. Thus, following the intention to treat principle, all randomised subjects could be classified.

Statistical analyses were made of the two treatments separately. Since this reduced the number of subjects for each analysis, the outcome categories were collapsed into a dichotomy. Patients with a positive outcome (success) were compared to those with no change or with a negative outcome (no success).

Univariate association with the baseline characteristics as predictor variables was tested with chi square for contingencies, in case of variables of nominal or ordinal level, and with student's t test in case of variables of interval level.

Stepwise logistic regression analysis was used to predict the outcome based on sets of variables. Predictions were first made using four sets: 1) medical history and hospital records, 2) interviews, 3) exercise testing and 4) psychological questionnaires, with all sets taking age and gender into account (see appendix). Missing values were assigned to a middle category in the case of discrete variables and to the means in the case of interval variables. Next, selected variables from the different subsets were combined, with the exception of incomplete interview variables. The criterion for inclusion of variables was $p < 0.10$ and for exclusion $p > 0.15$. The performance of the resulting logistic function is expressed through its classification rates.

In view of the relatively small number of subjects, the variables selected in the final analysis are presented with their regression coefficients and the coefficients/standard error. A value of > 2.0 on this latter measure indicates that the level of statistical significance of the contribution of the variable < 0.05.

Results

A total of 156 patients was admitted to the study, 80 of whom participated in exercise training as a single treatment, and 76 underwent additional individual relaxation therapy. The treatments did not differ in baseline characteristics (tables 1 and 2). Three patients had previous coronary artery bypass grafting, 16 patients had experienced recurrent infarction and 26 patients had a history of angina pectoris. The infarction size was classified according to the patients' peak serum enzyme levels. In

47 patients the infarction was regarded as small, in 49 patients as medium and in 52 as large. Of eight patients, the enzyme levels were not available; they were included in the medium category. In-hospital signs of heart failure (hypotension, cardio-thoracic ratio > 50%, pulmonary congestion) were present in 27 patients (17%). Post-infarction angina was present in one third of the patients. Beta blockers were used by 45 patients.

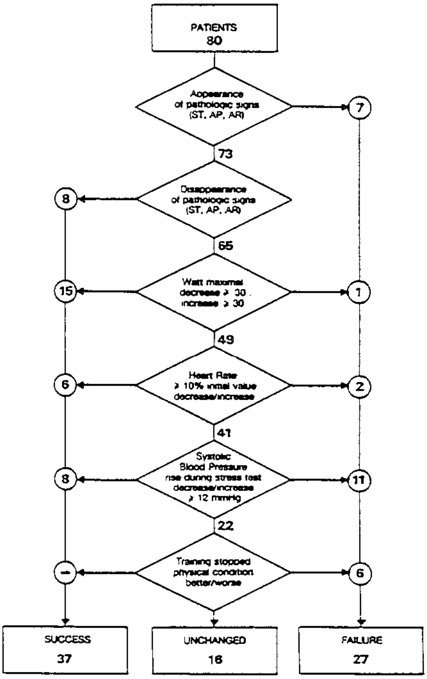

Figure 8.2: Flow chart to decide success or failure of exercise training for **exercise as sole treatment.**

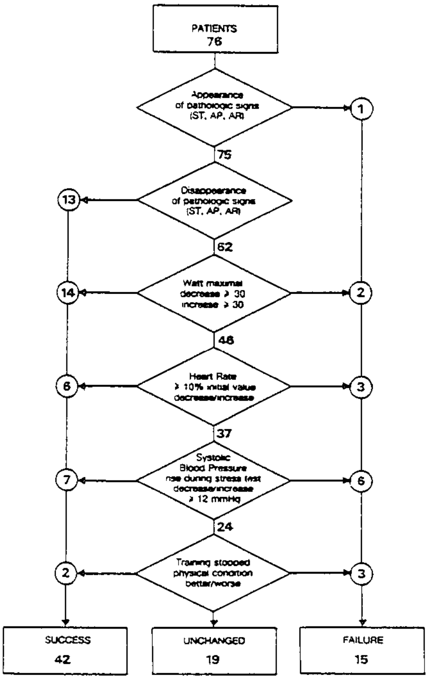

Figure 8.3: Flow chart to decide success or failure of exercise training **for relaxation therapy and exercise training jointly.**

ST: ST-segment depression; AR: complex ventricular arrhythmia;
AP: Angina pectoris; all three induced by exercise (see Methods)

Training outcome. In 139 patients exercise testing results were available before and after training. They have been described in detail elsewhere (5). In short, in both treatments there was a modest training response: maximal work load increased and heart rate at a given work load decreased. Heart rate reduction was more pronounced for patients who participated in relaxation therapy. There was no effect on blood pressure, although there were large individual changes. Exercise-induced signs of cardiac dysfunction remained relatively stable, except for a remarkable decrease in ST-depression in patients who underwent relaxation therapy: it was present in 24 patients and disappeared in half of the cases, whereas it appeared anew in one patient. For exercise training as a single treatment, ST-depression was initially present in 20 patients, it disappeared in four patients and appeared in another five. The difference between treatments was statistically significant. Seventeen patients did not complete their training. Fifteen were classified as unsuccessful because of dropping out: nine had to stop because of cardiac problems and six for non-cardiac reasons. Two patients stopped rehabilitation because they became fully active again: they were classified as successful. There was no significant change in medication during rehabilitation, probably because the programme covered only a short period of time.

Out of 80 patients who participated in exercise as a single treatment, the training outcome was successful for 37 (46%) according to the composite criterion and for 43 it was unsuccessful; for 27 (33%) the outcome was negative and for 16 (21%) there was no change (figure 8.2). Out of 76 patients who underwent relaxation therapy for 42 (55%) the outcome was positive and for 34 patients it was not successful; only for 15 (20%) the outcome was negative and for 19 (25%) there was no change (figure 8.3). Thus, for more patients who underwent relaxation therapy the outcome was positive and for a few the training outcome was negative. The difference in failure was statistically significant: the odds ratio for failure was 2.07 (95% confidence interval: 1.002 - 4.28) for exercise training in comparison to the combined treatment.

Exercise training. Univariately, few base-line characteristics were predictive of the outcome (tables 1 and 2). Female patients, those who used anti-anginal medication before infarction or who showed arrhythmias during exercise testing, were unsuccessful. On the other hand, patients who worked before infarction, those who had a history of one or more non-cardiac diseases and those who scored higher on Type A behaviour, tended more often to have a positive outcome.

Multivariate analysis showed that three of the four sets of variables (clinical, exercise testing and psychological questionnaires) had a limited ability to identify successful patients (table 3). Interview variables, including work status, had no predictive ability. With all data sets combined, 76% of the patients were classified correctly. Type A behaviour, anginal medication before infarction and exercise-induced ventricular arrhythmias, were variables with high differential qualities (table 4). A low initial work capacity was also conducive to success.

Table 3. Performance of predictor variables on training success for exercise training

Performance rates	A Clinical	C Exercise	D Psychological	A+C	All
Classification rates					
correctly (%) classified	54	57	64	63	76
sensitivity (%)	97	97	78	95	84
specificity (%)	16	23	51	35	70
True Pos (%)	50	52	58	56	71
True Neg (%)	88	91	65	88	83

Sets of predictor variables: A, C, D, A+C, All

A: anginal medication pre infarction; C: arrhythmia; D: Type A behaviour; A+C: anginal medication pre infarction, arrhythmia; All: see table 4.

Table 4. Prediction of training success for exercise training: all data.

Variable	regression coefficient	coefficient/s.e.
1) morbidity pre	0.74	1.90
2) anginal medication pre	-2.95	-2.36
3) work capacity (%)	-0.03	-1.81
4) arrhythmia	-2.44	-2.25
5) Type A behaviour	0.05	2.66
constant	-4.15	-1.61

Training success: value 1, no success: value 0.
1) number of major non-cardiac diseases in anamnesis; 2) present=1, absent=0; 4) complex=2, single=1, absent=0 (see under Methods); pre: before myocardial infarction;

Relaxation therapy and exercise training combined. Univariate analyses showed that several medical and exercise variables, as well as psychosocial variables had predictive power for training outcome (tables 1 and 2). For more patients with a small infarction the outcome was positive, as well as for patients with initial ST-depression, a low heart rate or a low work capacity. More patients who worked before infarction, completed the training successfully. Also subjective appraisal was important: most patients, who expected to cope with their work differently in the future, had a positive outcome. More patients who attributed the myocardial infarction to stressors were successful, as well as patients who did not expect to fully resume their activities. The outcome was often more positive for patients with a less optimal sleep quality, those who took shorter daytime naps and those who did not feel very well.

With logistic regression analyses, the four data-sets had a variable predictive ability (see table 5). Medical information had the lowest ability (59%) to classify the outcome correctly. Combining the data sets in the final analysis enhanced the performance substantially, although incomplete interview variables were excluded. Work status and ST-abnormalities had the highest predictive ability, followed by heart rate at 60 Watts and sleeping quality (see table 6). With all data sets, 91% of the patients could be classified correctly.

Table 5. Performance of predictor variables on training success for exercise and relaxation

Performance rates	Sets of predictor variables						
	A Clini-cal	B Inter-view	C Exer-cise	D Psycho-logical	A+C	A+C+D	All
correctly (%) classified	59	78	72	62	78	87	91
sensitivity (%)	74	79	91	69	88	91	91
specificity (%)	41	77	50	53	65	82	91
True Pos (%)	61	80	69	64	76	86	93
True Neg (%)	44	74	81	58	82	88	89

A: infarction size; B: age, work status, infarction pain, illness experience, doubt of diagnosis, expected recovery, cause MI tension; C: work capacity, heart rate 60 Watts, maximal blood pressure, ST-abnormality; D: sleeping quality; A+C: hypertension medication before MI, heart rate 60 Watts, ST-abnormality, beta-blockers, diuretics, systolic blood pressure; A+C+D: hypertension medication pre MI, heart failure, beta-blockers, heart rate 60 Watts, maximal blood pressure, ST-abnormality, sleeping quality, well-being, invalidity feelings; All: see table 6.

Table 6. Prediction of training success for exercise + relaxation: all data

Variable	regression coefficient	coefficient/s.e.
1) infarction size	-1.09	-1.91
2) beta blockers post	-2.17	-1.91
3) glucosides post	-2.55	-2.16
4) hypertension med pre	-1.45	-2.64
5) heart rate W60	-0.09	-2.73
6) ST-abnormality	4.21	3.42
7) Type A behaviour	-0.09	-2.24
8) sleeping quality post	-0.55	-2.65
9) well-being	-0.12	-1.84
10) work status	-1.53	-3.00
constant	34.63	3.81

Training success: value 1, no success: value 0.
1) small=1, medium=2, large=3; 2,3,4,6) present=1, absent=0; 10) full time=1, part time=2, none=3; pre: before myocardial infarction; post: after infarction

Discussion

The results indicate that for patients participating in exercise training as a single treatment, the physical outcome is predictable to a moderate degree, whereas training success is highly predictable for patients who participate in a more comprehensive type of rehabilitation. The limited predictability of the outcome for exercise as a single treatment (76% correctly classified) is in line with other studies (1,3,4). For the combined treatment, more base-line variables were of predictive value, especially psychosocial variables, and the resulting overall predictability was discernibly higher (91% correctly classified).

Few authors evaluated the outcome of exercise training in terms of success and failure instead of average changes in exercise parameters (1,14,15). Hammond et al., as well as Uniken Venema-van Uden, obtained results similar to those in this study: only about half of the patients referred for cardiac rehabilitation, actually benefit from exercise training, in the sense that they improve in exercise testing measurements. It means that, for the other patients, intensive training is not suitable and aerobic conditioning is not a proper therapeutic goal. These patients may nevertheless benefit from rehabilitation, for instance in a psychosocial sense (6), and they may even be in special need of it, but other treatment forms will have to be found, e.g lighter exercises, group sessions for relaxation and stretching exercises, group discussion, patient education, etc (16).

Since this study was primarily designed as a randomised clinical trial of relaxation therapy, the prognostic characteristics of the two treatment groups were basically the same (5). The difference in predictability may therefore be attributed to the nature of the treatment. Thus, when relaxation therapy is added to an exercise training programme, the probability of a training success is slightly higher and the effects of the determinants of training success are modified. In other words, some patients benefit from exercise as a single treatment, whereas others benefit from the more comprehensive approach. Possibly, relaxation improves the context of the exercise training (7), the motivation of the patient, or his arousal level, each of which may facilitate a training effect.

The conclusions seem justified that 1) exercise training is not suitable for all patients, referred to a cardiac rehabilitation programme; 2) it is possible to predict for what patients training will be successful, on the basis of clinical and exercise data and psychosocial information; 3) relaxation therapy modifies the effects of the determinants of training success. These findings have important implications for rehabilitation. They support the idea that rehabilitation should be tailored to the individual, in order to reach a greater number of patients more effectively and to save unnecessary effort (1,17,18).

Prediction analysis appears to be a useful tool in tailor-made rehabilitation. Validation of the results of this study on a larger sample is required in order to apply the prediction rules. The number of predictor variables is relatively high for the number of subjects involved. Nevertheless, all variables selected were statistically significant ($p < 0.10$) and most of them were significant at the 0.05 level (regression coefficient/standard error > 2.0). If predictability remains high in a replication study, application will result in two estimates of the probability of training success. These can be utilised for future patients as a a tool to identify those for whom training will be successful, either with or without relaxation. A substantial difference between the two estimates can be considered an argument in assigning the patient to the treatment with the greatest probability of success, also taking other factors (cost, manpower, patient's motivation) into account.

Acknowledgments

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Appendix A. Variables used as predictors in the stepwise logistic regression analysis.

CLINICAL: before infarction
hypertension
exercise habits
smoking
angina pectoris
coronary bypass surgery
previous infarction
non-cardiac morbidity
cardiac medication:
- beta-blockers
- digoxin
- diuretics
- anti-anginal
- anti-arrhythmic
- anti-hypertensive

CLINICAL: hospital
infarction size
infarction location
mild heart failure
medication at discharge
- beta-blockers
- digoxin
- diuretics
- anti-anginal drugs
- anti-arrhythmic drugs

angina pectoris at discharge

INTERVIEW
marital status
work status
job level
infarction appraisal:
- pain experience
- illness experience
- doubt of diagnosis

view of future
wishes early start of rehabilitation
expectation of activity resumption
cause of MI clear
attributed cause of MI:
- stress
- external
- risk factors
- psychic

EXERCISE TESTING
weeks after hospital discharge
maximal work load
work capacity (%)
maximal heart rate
resting heart rate
heart rate at Watt=60
resting diastolic blood pressure
resting systolic blood pressure
maximal systolic blood pressure
systolic pressure rise
chest pain
ST-abnormalities
arrhythmias

PSYCHOLOGIC QUESTIONNAIRES
sleep quality (pre and post MI)
daytime nap (pre and post MI)
vital exhaustion pre MI
Type A (JAS) pre MI
functional complaints
sense of well-being
feelings of invalidity
displeasure
anxiety state (STAI-S)
anxiety trait (STAI-T)

JAS: Jenkins Activity Scale; MI: Myocardial Infarction; STAI: State Trait Anxiety Inventory.

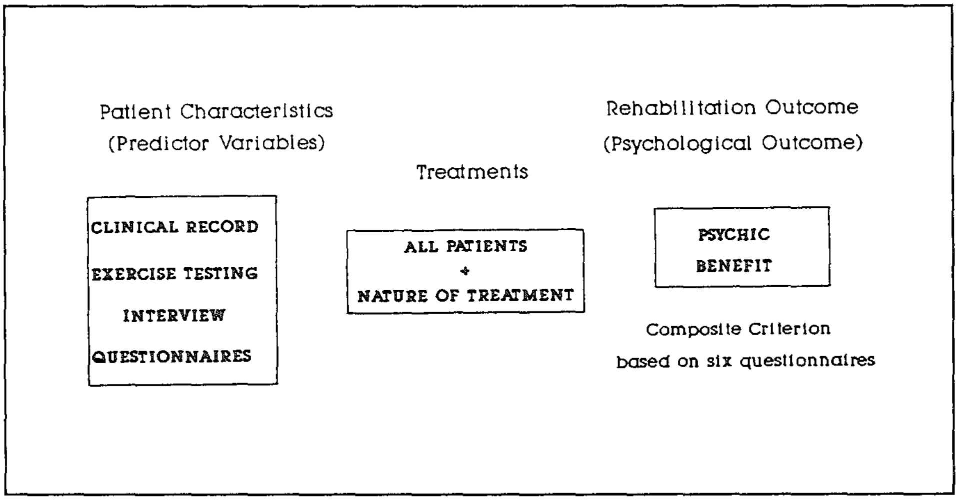

Figure 9.1.
Predicting Psychic Outcome

Chapter 9

Predictability of Psychic Outcome for Exercise Training and Exercise Training including Relaxation Therapy after Myocardial Infarction.

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Predictability of Psychic Outcome for Exercise Training and Exercise Training including Relaxation Therapy after Myocardial Infarction.

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Predictability of the psychic outcome for two cardiac rehabilitation programmes was investigated on 119 myocardial infarction patients. They were randomly assigned to either a five-week daily exercise training or to an identical training in combination with six sessions for relaxation therapy, individually. The psychic outcome was constructed as a composite measure of change on six psychological questionnaires. The aim was to determine the predictive qualities of base-line 1) clinical data, 2) exercise testing, 3) psychosocial information derived from interview and 4) validated psychological questionnaires. The predictive value of these variables was analysed bivariately, set-wise and for the sets jointly.

The psychic outcome turned out to be highly predictable (multiple correlation of 0.72). Predictors of relatively high importance were age, work-status and job-level, followed by mild heart failure, diastolic blood pressure and heart rate, all of them dependent upon the kind of treatment. It implies that the kind of rehabilitation programme modified the effect of the determinants of psychic outcome.

This research strategy is promising and deserves to be stimulated in order to build rehabilitation programmes tailored to the needs and abilities of the individual patient.

Introduction

Several studies have dealt with determinants of outcome of the recovery process after myocardial infarction, with respect to emotional and social endpoints (1-5). The aim of this study is to investigate predictability of psychic outcome after having participated in a cardiac rehabilitation programme. The outcome is composed of changes on six questionnaires, completed before and after rehabilitation. The question is what patients improve after rehabilitation and what patients do not improve or even deteriorate. To date, research studies failed to substantiate the high expectation of the psychological benefit of rehabilitation (6). One explanation is that rehabilitation is effective for a limited percentage of myocardial infarction patients (7). A successful prediction of the outcome will make it possible to assign optimally patients to rehabilitation, in order to avoid possible harmful effects (6,8), save unnecessary time and effort, and raise the efficacy of a programme (9).

In this study the predictability of psychic improvement is investigated for two rehabilitation programmes, consisting of physical reconditioning exercises and of individual relaxation therapy added to physical exercise. Relaxation therapy facilitated psychic improvement (10), although the effect was moderate. Possibly, a combined treatment is beneficial to some patients, whereas simple physical exercises may be sufficient or even preferable to others.

The main questions to be studied are, whether psychic outcome is predictable on the basis of initial medical, psychosocial and exercise data, and whether the kind of rehabilitation programme has any influence on the predictive qualities of the variables.

Patients and Methods

Patients. After discharge from various hospitals, cardiac patients are referred to the regional rehabilitation centre at St. Joannes de Deo Hospital, Haarlem, The Netherlands. A total of 156 myocardial infarction (MI) patients were admitted to the study. They were randomly allocated to one out of two treatment protocols. Patients who were in need of individual (psychosocial) help received relaxation therapy. As a consequence, they could not be randomised and had to be excluded from the study. There were no age limits. Nine women were referred for rehabilitation. For 37 patients information on psychic outcome was either unavailable or incomplete. The data of the remaining 119 patients will be used for analysis. Base-line biographic and medical information is summarised in Table 1.

Table 1. Baseline clinical data

Variable	Exercise training (n=61)	Exercise training + relaxation therapy (n=58)
Age(years)	56.4 (7.8)	55.4 (7.9)
Males	58 (95)	55 (95)
Working	40 (66)	42 (72)
Married/partner	56 (92)	56 (97)
Size of MI:		
small	21 (34)	15 (26)
medium	22 (36)	25 (43)
large	18 (30)	18 (31)
Anterior infarction	17 (28)	22 (38)
Mild heart failure	11 (18)	12 (21)
Post-infarction angina	20 (33)	22 (38)
Medication on discharge:		
beta blockers	21 (34)	14 (24)
diuretics	16 (26)	21 (36)
anti-anginal	13 (21)	11 (19)
Start of physical training (weeks post hospital)	5.3 (1.9)	5.0 (2.2)
Maximum work load (watt)	133 (21)	137 (23)

Data are reported as events and percentage of cases or as means (SD). MI, myocardial infarction.

Procedure. Clinical base-line data and medical history were obtained from information of the referring cardiologist. At entry, patients were interviewed to obtain psychosocial information and were asked to participate in the study. After informed consent, they completed additional psychological questionnaires. The questionnaires were again administered after the patient completed the programme. All patients participated in a physical reconditioning programme. In addition, half of them were randomly allocated to individual relaxation therapy. Graded exercise testing was performed on a bicycle ergometer before and after physical training.

Clinical data. Information on infarction size, location and complications were derived from hospital records. An infarction was classified as small when serum glutamic-oxaloacetic transaminase (SGOT) was elevated but remained below 60 U/l, whereas SGOT levels above 120 U/l indicated a large infarction.

In-hospital occurrence of hypotension, a cardiothoracic ratio > 50% or pulmonary congestion were taken as signs of (mild) heart failure. Also, data were noted concerning a previous infarction, coronary bypass surgery, and angina pectoris of longer duration than one month before infarction, as well as on the presence of angina at discharge and the use of cardiac drugs before infarction or at discharge. In addition, information on hypertension and smoking habits before infarction was gained.

Psychosocial interview. The patient was interviewed, partly also on the clinical data, particularly regarding the pre-infarction period (smoking, hypertension). Work situation and job level were noted. Job level was ranked as follows: manual unskilled, manual skilled labourers, lower level white collar workers, independent, intermediate and high level white collar workers. The patient was asked about his feelings of pain during the infarction and his attribution of the cause of the infarction. Moreover, the interviewer rated the presence of psychosocial stress in the life situation of the patient.

Psychological questionnaires. They were described in detail elsewhere (10). In short: (1) Heart Patients Psychological Questionnaire (11), to measure the well-being of cardiac patients in three scales: (a) Well-being, (b) Subjective invalidity, (c) Displeasure. (2) Anxiety measured by STAI in two modes: state and trait anxiety (12). (3) Sleeping habits, consisting of questions about hours of sleep, daytime nap and sleep quality (13). (4) Functional symptoms, consisting of physical complaints, not typical of angina pectoris. In addition, two questionnaires referred to the pre-infarction period: (5) Jenkins Activity Scale (JAS), for Type A behaviour (14), and (6) Maastricht Questionnaire, for vital exhaustion and depression (15).

Exercise testing. After an adaptation period on the bicycle, the test was started with a 1-minute period of cycling at 60 cycles a minute without load, and for two minutes at 60 Watts. The test was continued by increasing the workload with 30 Watts every two minutes until symptoms limited the patient to continue or until the physician terminated the test. The occurrence of exercise-induced angina pectoris, ST-abnormalities and arrhythmias were noted. ST-abnormalities were mostly ST-depressions of 2mm or more, horizontal or downsloping. Arrhythmias were coded as single premature ventricular complexes, or as complex (groups or runs or multifocal or frequent premature ventricular complexes, bigeminy or ventricular tachycardia). A bipolar ECG lead (CM5) was taken during the half minute before the workload was increased. Blood pressure was taken before the test and at maximum workload.

Rehabilitation consisted of a programme of either exercise training plus relaxation training or of exercise training alone. Exercise training consisted of five weeks of interval training, once a day for half an hour, on a bicycle ergometer.

Training was given in groups of four patients supervised by two physical therapists. Each patient was exercised up to 70% of the peak heart rate attained at pre-training exercise testing. Relaxation training was given once a week in six individual sessions of one hour each, by five trained therapists. Three of them were psychologists, one a medical doctor and one a physical therapist. They did not participate in the exercise programme. Several procedures for active and passive relaxation were applied, centring around a respiratory technique. This is described in detail elsewhere (16) In short, EMG Feedback of the frontalis muscle is used for muscle relaxation and for monitoring unnecessary inspiratory effort. The patient learned to observe and elicit a 'shift' in the respiratory pattern, such that inspiration expanded both the lower abdomen and the costal margin, expiration was moderated and slow. Manual technique was applied to elicit breathing movements involving the trunk as a whole and requiring less effort. This was practised first in the supine position to induce 'passive relaxation', but later also sitting up and standing ('active relaxation'). The patient was asked to practise at home, as a daily routine, and in case chest discomfort was experienced. Care was taken to introduce relaxation as an ingredient of the routine rehabilitation procedure, rather than psychological help. The treatment itself was presented unbiasedly: emphasizing the technical and physical aspects of relaxation, its utility in dealing with daily stress, and providing a rationale in the form of the biofeedback instrumentation and breathing 'exercises'. The therapists, however, were aware that this was a strategy to facilitate possible psychotherapeutic implications of the treatment.

Outcome criterion. In order to obtain a single measure, indicating the psychic outcome after rehabilitation, six psychological questionnaires were integrated into a composite change score: one set represented psychic aspects and consisted of Anxiety State and Trait and Displeasure, another set represented somatic aspects, consisting of Subjective Invalidity, Sleep quality and Functional Complaints. In order to correct for the influence of the initial value, pre-post changes were expressed as a percentage of their possible change, which is the difference between the initial score and theoretically the minimum score in the case of a decrease and the maximum score in the case of an increase. Each set consisted of the averaged percentage change on three or at least two questionnaires. The overall outcome was construed as the average of the two sets, transformed into a means of 50 and a standard deviation of 10.

Statistical analysis. In order to investigate the predictive qualities of 'baseline' factors the method of multiple regression analysis was applied. To get an insight into the relative importance of variables in predicting the psychic outcome, the standardized regression coefficient (B) is convenient. The P-values indicate the level of significance of the pertinent regression coefficients. They were calculated for all predictor variables individually, as well as for four sets of variables: clinical, interview, exercise data and psychological questionnaires. The multiple correlation coefficient (MR) is just Pearson product-moment correlation coefficient between the set of predictor variables on the one side and the outcome variable on the other; the corresponding F- value indicates whether the MR is statistically significant. MR squared (sometimes called coefficient of determination) indicates the percentage of explained variance, identical to the meaning of Pearson correlation squared. In order to determine the influence of the treatment form, the joint treatment was coded as 1 and exercise training as 2, and interaction terms were constructed, consisting of each predictor variable times treatment form. Thus, the sets consisted of the relevant predictor variables and their respective interaction terms. The procedure was as follows: first, all variables pertaining to one set were entered into the regression equation, after which the variables not meeting the criterion for removal ($P < 0.10$), were eliminated one by one. Next, in order to get an insight into the differential qualities of the four sets jointly, all variables selected in one of the foregoing four sets of regression, were entered into the final regression analysis, meeting the same level of removal.

Results

A total of 156 myocardial infarction patients were admitted to the study, 139 of whom completed the exercise programme. Out of 17 dropouts, two patients resumed full activity, nine patients had to stop for cardiac reasons (one patient died, three were re-admitted to the hospital for unstable angina pectoris, two developed arrhythmias and three underwent coronary artery bypass grafting) and six patients stopped for non-cardiac reasons. Exercise testing measurements after training were not available for them. Moreover, psychological questionnaires were not always completed. 119 Patients fully completed the questionnaires, before and after the programme. Thus, the composite score for psychic improvement could be calculated only for them and the prediction analysis had to be limited to these patients. Their base-line clinical data are summarized in table I. There were no differences between the treatments. A comparison with the base-line of the total study population, reported on earlier (10), did not reveal significant differences.

Exercise testing showed a moderate training response consisting of increased maximal work load from 134 to 142 Watt ($p < 0.001$) and heart rate reduction at the highest common work load from 134 to 129 beats/min ($p < 0.0001$) (8). The treatments did not yield significant differences, although heart rate reduction was higher for the joint treatment at all levels of effort (17). The exercise parameters were integrated into a single measure for the training outcome, indicating a positive outcome in 79 patients (51%), a negative outcome in 42 patients (27%) and no clear change in 35 patients (22%). A negative outcome (training failure) occurred significantly less in the joint treatment (17). Both the positive and the negative outcome were highly predictable on the basis of base-line variables (8). Medical and exercise data were predictive for both, work status was the single most important predictor for training success, but did not determine failure. Psychological variables substantially enhanced predictability of the negative outcome. Age was unrelated to the training outcome. Severity of infarction (size, pump failure) was marginally associated with the training success although not with training failure.

On average, psychological questionnaires did not show a change after exercise training. However, anxiety state and subjective invalidity decreased whereas well-being increased for patients receiving the treatments jointly. The difference between treatments was significant for well-being (10). The average value on the composite score for psychic change was 50.4 (9.6) for the treatments jointly and 50.0 (9.3) for exercise training. Thus, the addition of relaxation therapy to exercise training did not have any effect on this outcome measure.

TABLE 2: Bivariate regression analysis of psychic outcome

predictor variables	B (standardised)	p
Treatment	-.02	.86
Clinical		
Sex 1)	-.03	.79
Age	.11	.21
Hypertension (pre) 2)	-.11	.22
Smoking 3)	.04	.69
Angina pectoris (pre) 4)	.03	.75
Cardiac history 5)	-.18	.06
Beta-blockers (pre) 2)	-.10	.26
Diuretics 2)	-.02	.86
Infarction size 6)	.05	.61
Mild heart failure 2)	.19	.04
Cardiac drugs 7)	.04	.64
Beta-blockers 2)	-.04	.63
Angina pectoris 8)	-.04	.68
Interview		
Work status 9)	.22	.02
Level of job 10)	.00	.97
Infarction pain 11)	-.08	.36
Cause MI: stress 2)	-.08	.40
Cause MI: external 2)	-.10	.28
Cause MI: risk factors 2)	.19	.04
Cause MI: psychic 2)	-.28	.00
Psychosocial stress 12)	-.08	.40

predictor variables	B (standardised)	p
Exercise testing		
Maximum workload	-.14	.14
Work capacity (%)	-.10	.27
Heart rate (maximal)	-.11	.23
Heart rate (resting)	.11	.25
Heart rate (Watt=60)	.07	.44
Diastolic BP (resting)	-.22	.02
Systolic BP (resting)	-.12	.18
Systolic BP (maximum)	-.15	.11
Systolic BP (rise)	-.06	.48
ECG-abnormalities 13)	.05	.56
Psychological questionnaires		
Sleep quality	.17	.06
Daytime nap 14)	.09	.36
Vital exhaustion (pre)	-.24	.01
Type A behaviour (pre)	-.02	.87
Functional complaints	-.30	.00
Wellbeing	.16	.08
Subjective invalidity	-.19	.04
Displeasure	-.02	.80
Anxiety (state)	-.11	.23
Anxiety (trait)	-.14	.12

Treatment: exercise + relaxation =1, exercise only =2; BP: Blood Pressure. 1) male=1, female=2; 2) present=1, absent=0; 3) number of cigarettes; 4) anginal complaints or anti-anginal drugs =1, else=0; 5) previous infarction or coronary bypass surgery =1, else=0; 6) small=1, medium=2, large=3; 7) heart glucosides or diuretics or anti-arrhythmic drugs =1, else=0; 8) anginal complaints at hospital discharge or anti-anginal drugs or exercise-induced chest pain =1, else=0; 9) fulltime=1, parttime=2, none=3; 10) low level=1, high level=6 (see methods section); 11) severe=1, moderate=2, hardly or none=3; 12) much=1, moderate=2, hardly=3; 13) exercise induced ST-abnormalities or arrhythmias =1, else=0; 14) quarters of hours.

Prediction analysis

Differential qualities of the variables individually. Of the clinical variables mild heart failure (B= 0.19) and cardiac history (B= -0.18) turned out to be relevant to psychic change after rehabilitation (see table 2).

From the interview data the attribution of the infarction genesis as perceived by the patient had predictive power. Patients who attributed the MI to emotional factors did not ameliorate in psychic outcome so much (B= -0.28), whereas those who attributed the MI genesis to risk factors did improve (B= 0.19). Also, work status had predictive power (B= 0.22). Unexpectedly, those who had a job improved less than those without work. Of the exercise variables only resting diastolic blood pressure reached statistical significance: patients with high diastolic blood pressure improved relatively less (B= -0.22).

The psychological variables were of material importance. Five variables contributed to estimating psychic outcome. Of paramount importance appeared to be functional complaints (B= -0.30), followed by vital exhaustion before MI (B= -0.24) and subjective invalidity (B= -0.19): the higher the initial score, indicating more complaints, the lower improvement. Sleep quality (B= 0.17) and well-being (B= 0.16) were also associated, although only marginally significant. Patients who slept or felt relatively well initially, improved more after rehabilitation.

Differential qualities of the four sets of variables individually.

The performance of clinical variables jointly is to be considered moderate (MR = 0.35). Treatment condition in interaction with age (B = 1.46) contributed highest, followed by treatment condition (B = -1.18). This indicated that older patients benefit more from exercise training than those who are younger; and, vice versa, relatively young patients benefit from exercise training and relaxation therapy jointly more than the other patients. The contribution of treatment condition to the prediction implied that the effect of exercise training solely was less positive than that of exercise training combined with relaxation therapy (see table 3).

The performance of the interview variables was the highest of all sets (MR = 0.56). Table 3 shows that sex, age and work status were of high relevance, mostly even of higher relevance when combined with treatment. It is worth mentioning that sex (B = 0.61) was positively related with psychic outcome, while sex in interaction with treatment (B = - 1.08) was negatively related. It means that on average women benefit more than men, unless they only participated in exercise training. Similarly, the association of work status with psychic outcome was positive (B= 1.03) and reversed of direction when treatment condition was taken into account (B=0.97). It means that on average patients without jobs improved more, but if treatment form is taken into account, patients with jobs improved more when they received comprehensive rehabilitation. The relationship of age was the same as in the set of clinical variables. It was inversely related to outcome (B = -0.75), whereas in interaction with treatment the association yielded a highly positive value (B = 1.96).

The performance of exercise variables jointly turned out to be of moderate level (MR = 0.49). In complete line with the performance of the previous sets, treatment in interaction with the baseline measurements derived from exercise testing reached a high level of differential qualities, compared to variables without interaction. A relatively high level of importance was treatment in interaction with maximum workload (B = 1.06): patients with a high level of initial fitness had a high level of improvement when exercise training was the sole treatment. The bivariate relationship of resting diastolic blood pressure was strengthened when treatment was taken into account (B= -0.96): high initial blood pressure was particularly unfavourable for psychic outcome when exercise was the sole treatment. On the other hand, a high resting heart rate was relatively favourable for patients who only participated in exercise training (B= 0.86).

TABLE 3: Multiple regression analyses for psychic outcome, four sets separately

predictor variables	B (standardised)	p
Clinical		
Mild heart failure	.86	.00
T * Age	1.46	.05
Age	-.51	.10
T * Mild heart failure	-.72	.02
T * Cardiac history	-.17	.07
Treatment	-1.18	.00
MR =	.35	F(6,112) = 2.64
MR2 =	.12	P < .02
adjusted MR2 =	.08	

predictor variables	B (standardised)	p
Interview		
Level of job	.60	.03
Cause MI: risk factors	.16	.06
Age	-.75	.00
T * Cause MI: stress	-.22	.02
Sex	.61	.01
T * Werkstatus	-.97	.01
Cause MI: psychic	-.36	.00
Work status	1.03	.00
Psychosocial stress	-.27	.00
T * Level of job	-.64	.04
T * Sex	-1.08	.00
T * Age	1.96	.00
MR =	.56	F(6,112) = 4.06
MR2 =	.32	P < .01
adjusted MR2 =	.24	

predictor variables	B (standardised)	p
Exercise		
T * Maximum work load	1.06	.01
Systolic BP (rise)	.53	.08
Maximum work load	-.29	.09
T * Systolic BP (rise)	-.70	.06
T * Age	.56	.01
T * Heart rate (resting)	.86	.00
T * Work capacity (%)	-.42	.10
T * Diastolic BP (resting)	-.96	.00
T * Maximum heart rate	-.82	.00
MR =	.49	F(9,109) = 3.74
MR2 =	.24	P < .001
adjusted MR2 =	.17	

predictor variables	B (standardised)	p
Psychological		
Subjective invalidity	.63	.04
Sleep quality	.52	.08
Functional complaints	-.23	.03
T * Sleep quality	.20	.04
T * Daytime naps	-.69	.10
T * Subjective invalidity	-1.19	.01
Treatment	1.32	.02
MR =	.41	F(7,111) = 3.28
MR2 =	.17	P < .01
adjusted MR2 =	.12	

T= treatment. Variable values: see Table 2.

The performance of the psychological variables jointly was moderate (MR = 0.41). Of this set of variables treatment (B = 1.32) appeared to be of highest weight, closely followed by the interaction of treatment with subjective invalidity (B = -1.19). Also of interest were daytime naps in interaction with treatment (B= -0.69) and sleep quality (B = 0.52).

Differential qualities of the variables jointly. The performance of the four sets of variables jointly turned out to be (MR =) 0.72, which has to be valued as high (see Table 4). From the analysis of the variables selected in any of the foregoing four sets it appeared that ultimately age, work status, and to a lesser degree, level of job, were relatively of high importance in predicting the psychic outcome. These variables contributed significantly to predicting the outcome, individually as well as in interaction with treatment. Although of lesser importance, several clinical and exercise variables had differential power, for the greater part in interaction with treatment. Patients with a high resting diastolic blood pressure, and patients with a high maximal heart rate improved relatively less psychically, when exercise was the sole treatment. For resting heart rate, the nature of the association was reversed: patients with a high resting heart rate improved relatively more, when exercise training was the sole treatment. Interestingly, psychological variables, including the attribution of the genesis of MI by the patient, had the smallest predictive value.

TABLE 4: Multiple regression analyses for psychic outcome, four sets jointly

predictor variables	B (standardised)	p
T * Subjective invalidity	-.23	.06
Psychosocial stress	-.20	.01
Level of job	.77	.00
Mild heart failure	.70	.00
T * Cardiac history	-.26	.00
Cause MI: psychic	-.24	.00
Work status	1.21	.00
T * Cause MI: stress	-.17	.04
T * Daytime naps	.16	.06
Age	-.89	.00
T * Heart rate (resting)	.69	.00
T * Diastolic blood pressure (resting)	-.74	.00
T * Mild heart failure	-.57	.01
T * Maximum heart rate	-.65	.00
T * Level of job	-.81	.00
T * Work status	-1.24	.00
T * Age	2.23	.00

MR =	.72	F(17,101) = 6.27
MR2=	.51	P << .001
adjusted MR2=	.43	

T= treatment. Variable values: see Table 2.

Discussion

The psychological benefit after an early five-week rehabilitation programme was highly predictable on the basis of inital medical, exercise and psychosocial data. This finding is promising. If predictability remains high in case of replication, we are in principle able to construct a tool for assigning patients optimally to rehabilitation. It will be of paramount importance to identify patients who will not benefit from a given treatment, e.g. exercise training, and who are at risk for psychological deterioration (1,3). For them, other kinds of treatments will have to be applied or built, tailored to the abilities and needs of the individual patient.

The aim of this report was to make an in-depth analysis of predictability of outcome on a single criterion rather than on multiple outcome measurements (1,3). A similar approach is required to analyse social and medical outcome, both in the short and long term (2,5). For instance, we found that physical improvement, measured by exercise testing before and after rehabilitation, was also highly predictable (8). Thus, several prediction rules will yield a number of estimations of rehabilitation outcome for different outcome criteria. Taken together, a more complete picture of the determinants of recovery and rehabilitation benefit will be achieved.

Our special interest concerned the effect of the nature of rehabilitation. Two programmes were compared. On average, the two treatments did not yield significant differences in psychic outcome on the composite criterion. Nevertheless, from a multivariate analysis the kind of treatment turned out to be of high differential value. Briefly, we added interaction terms consisting of the predictor variables times the kind of treatment. It appeared that the nature of the treatment influenced the effects of the predictor variables materially. In the final analysis almost all selected variables were interaction terms. Only two variables were selected regardless of the kind of treatment. This result has two important implications: first, it implies that some patients had a more positive outcome with the one treatment (exercise training) and other patients with the comprehensive treatment (exercise training and individual relaxation therapy). Thus, the population of cardiac rehabilitation patients is not homogeneous with respect to suitability for different rehabilitation programmes. The second implication is therefore that group averages are not sufficient to assess the possible value of an intervention for a heterogeneous population. This may explain why research studies often showed only little psychosocial effect of cardiac rehabilitation (6). Thus, the philosophy of "tailor-made rehabilitation" found empirical support in this prediction analysis (18).

The most important predictors for psychic outcome were age, work status and job level. In the literature, age appears to be related to return to work (4,5), but not to psychic outcome (19), often because rehabilitation is limited to younger patients (1). There were no age limits for participation in this study. In some studies work status had a predictive value (19); however, it is often not utilised (20,21) or rehabilitation is limited to employed patients (5). In this study, psychic benefit was greater on average for those who did not work.

However, for all three variables, the direction of the association with outcome reversed when treatment was taken into account (i.e. interaction term). The interpretation of an interaction term is not obvious and can best be illustrated by an example (see figure 9.2). The variable "Treatment * age" was the strongest predictor. Bivariately, age was unrelated to psychic change. In the final analysis, age was negatively associated, but when treatment was taken into account the relationship became positive. Since exercise solely was coded 2, and the treatments jointly coded

1, a positive association of the interaction term implies that older patients benefited relatively more from exercise as sole treatment. For younger patients the comprehensive treatment was more beneficial.

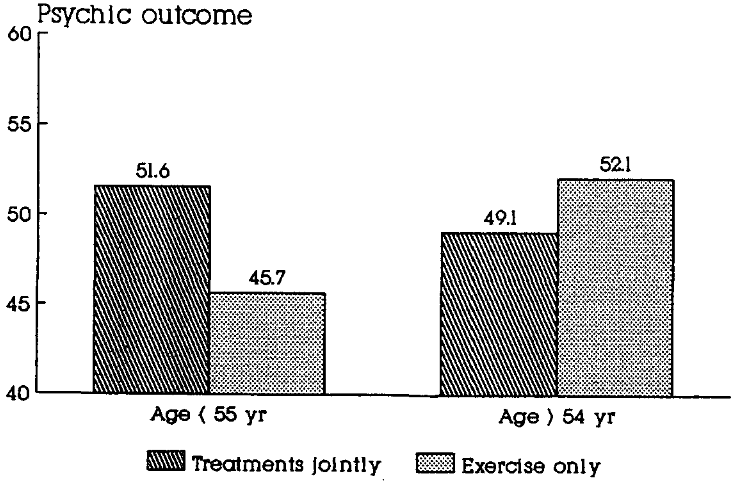

Figure 9.2. The psychic outcome for two treatments and two age groups.

Another example will clarify this point. Multiple regression analysis results in an equation that estimates the outcome measure, in this case psychic change. On average, patients have a value of 50.2 (SD = 10.8) on the outcome criterion. Using the variables selected in the final analysis, examples can be construed of patients with differing outcome estimates for the two treatments. For example: a person, 40 years of age, with a high job level, working full time, with high psychosocial stress according to the interviewer, who feels strongly invalidated, had signs of mild heart failure in the hospital, and a history of previous infarction, coronary surgery or cardiac arrhythmias, attributes the infarction to stress, but not to emotional factors, takes little or no daytime naps, has a resting heart rate of 70 bpm, a diastolic blood pressure of 100 and a maximal heart rate of 160. The estimated benefit of exercise training for this person is 15.6 whereas the estimated benefit of the joint treatments is 53.2. In other words, for such a person exercise as a single treatment falls short to a high degree. What kind of person would benefit more from exercise? A 60-year old manual worker, fully employed, with no feelings of invalidity, high psychosocial stress according to the interviewer, no signs of heart failure, nor a cardiac history, who does not attribute the infarction to emotional factors or stress, who takes daytime naps, has a resting heart rate of 80 bpm, a diastolic blood pressure of 70 and a maximal heart rate of 130: this person has an estimated improvement of 71 with exercise training, and of 47 with the treatments jointly. Thus, simple exercise is much better psychically.

To conclude, a fine-grain analysis, such as illustrated above, is cogently needed. In all probability, a comparison of group effects leaves out invaluable information. Prediction analysis is at least as informative as analysis of treatment effects. Treatment effects can be tested equally well in prediction analysis. The result of this study underlines that the goal of individualized rehabilitation is feasible, rendering rehabilitation more valuable, compared to a standard programme.

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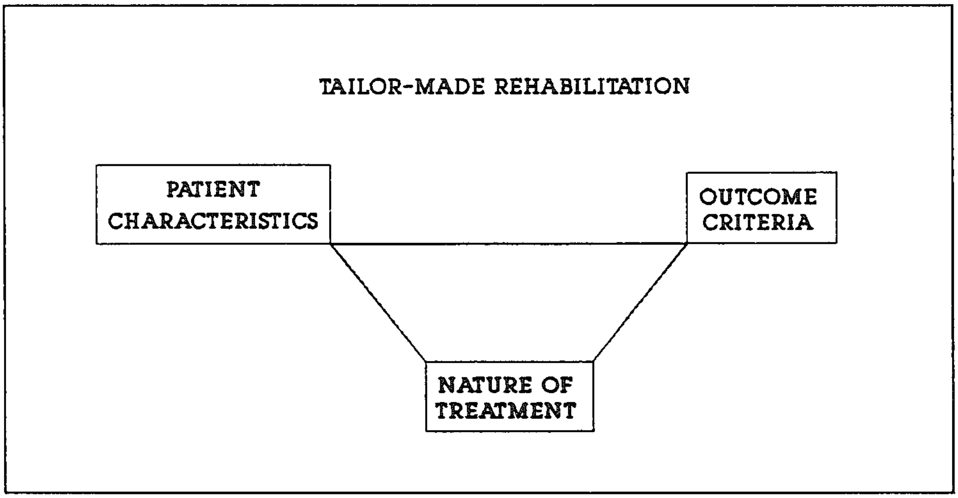
TAILOR-MADE REHABILITATION
PATIENT CHARACTERISTICS
OUTCOME CRITERIA
NATURE OF TREATMENT

Figure 10.1.

Chapter 10

General Discussion

1. Tailor-made rehabilitation.

Experts state that cardiac rehabilitation should be "tailored to the individual" (1-3). In actual practice, the main component of rehabilitation is physical exercise (4). It is becoming increasingly clear however, that some patients will benefit from exercise, others will not (5,6). This is one of the reasons why the effectiveness of exercise rehabilitation is limited (7-9) and the development of cardiac rehabilitation is stagnated (10). Tailor-made rehabilitation can solve this situation because it implies a more comprehensive approach, tailored to the individual patient.

In order to individualise rehabilitation, two basic requirements have to be met: first, one has to select patients who are likely to benefit from a given programme, and secondly, one has to construct a programme for a given individual patient. The latter requirement not only means the adjustment of a particular treatment, e.g. individualising exercise prescription (11), but also the composition of a programme out of a variety of treatment components (12). There is a considerable variety in patients' motivation and rehabilitation goals (13). Individualised rehabilitation also implies a context with adequate personal attention.

The main findings of this study provided empirical support for the concept and feasibility of tailor-made rehabilitation.

2. Main findings.

2.1. Exercise training is appropriate for about half of all referred myocardial infarction patients.

Few authors evaluated the outcome of exercise training in terms of success and failure instead of average changes in exercise parameters, although it is known that the training response of coronary patients is less clear-cut than that of healthgy individuals and some patients do not get a positive training effect (5,14-16). We constructed a composite criterion, integrating the main parameters of exercise testing before and after rehabilitation, on the basis of which patients with a clear positive outcome could be distinguished from patients with no clear change or with a negative outcome. A positive outcome can be taken as an indication that exercise training was appropriate. Such a "training success" occurred in 51% of the patients (table 1). By contrast, a negative outcome was found in 27% of the patients, who can be said to have had a "training failure". Similar results were reported by others. Hammond et al. (17) found that the percentage of patients showing at least 5% improvement in a training response, after one year of training, three times a week, was 44% for resting heart rate and thallium ischemia, 58% for heart rate at low work level, 52% for measured maximal oxygen uptake. Uniken Venema-Van Uden et al. (18) used a composite criterion for outcome of training, similar to that used in this study, on 370 cardiac patients who were rehabilitated in three centres with differing lengths (6 - 12 weeks) and intensities (twice - five times a week) of training. On the whole, 54% improved after training and 16% deteriorated. The outcome differed between the centres, with a range of success of between 50% and 61% and of failure of between 11% and 23%. Unlike our criterion, patients who dropped out (13%) were not included in the outcome. That may be the reason why in this study the outcome is less positive. Table 1 shows that 46% of our patients who participated in a similar programme of exercise-rehabilitation as a single treatment, were successful and 33% failed.

Thus, it seems realistic to say that for about half the patients, exercise training is appropriate. This statement questions the very basis of present-day exercise rehabilitation and deserves further qualification:

Table 1. Training outcome (percentages of patients)

	All patients n=156	Exercise only n=80	Exercise + relaxation n=76
Training success (%)	51	46	55
No change (%)	22	21	25
Training failure (%)	27	33	20

* A reference group of patients, not participating in supervised exercise training, is not taken into account in any of the above-mentioned studies. Since some improvement is to be expected as part of the natural recovery process after an acute coronary event (16,19), subtraction of the natural improvement would reduce the percentage of patients with training success even more.

* Training failure may be considered of higher clinical relevance than training success. The percentage of patients with a negative outcome ranges from 10 - 30%. Although a negative outcome is not necessarily caused by training, it may be taken as a sign that training was inappropriate. A possible conclusion may be that training is suitable for all other patients. This would increase the percentage of patients who were rightly referred for training, to 70 - 90%. In any case, early identification of patients with failure deserves serious research efforts, in order to avoid harm to the patient and to save effort. Besides, their exclusion will raise the effectiveness of training considerably. In other words, their identification implies a contra-indication for training.

* The safety of exercise for coronary patients has been an issue of major concern. In our study, no cardiac calamity occurred during training. However, our results also show that the fact that exercise is safe does not imply that it is successful. Nor does it exclude a negative training outcome. Thus, safety is not sufficient as a criterion to determine indications and contra-indications for exercise training in cardiac patients.

* The training outcome is not identical to rehabilitation outcome. Training "success" only indicates the appropriateness of (intensive) exercise training as a treatment modality and of aerobic conditioning as the purpose of exercise. For instance, patients for whom training failed may nevertheless need rehabilitation. Probably, they need moral or social support and they could benefit from relaxing

exercises. Although they get a negative outcome of training, they may benefit from rehabilitation psychosocially.

* The percentage of patients with training success may be expected to rise when training intensity is increased, but this idea is not necessarily valid for coronary patients. Hammond did not find a correlation between training intensity and outcome (17). Blumenthal et al. found an equal (even slightly greater) change in VO2max in cardiac patients with low intensity compared to high intensity aerobic training (20).

* The training outcome also depends on the context of the rehabilitation setting. For instance, in this study, the addition of relaxation therapy reduced training failure. A communicative attitude of the rehabilitation staff favours adherence to exercise (21). In the above-mentioned Dutch study of three rehabilitation centres, the centre that used large patient groups with the least personal attention, had the highest percentage of failure (18). Thus, contextual factors of rehabilitation centres, in relation to their effects, are of importance in future studies.

2.2. *It is possible to predict what patients will benefit from training and what patients will not (see figures 10.2 and 10.3). Psychosocial variables are of value in predicting the physical and psychological rehabilitation outcome.*

Selection of suitable patients is a good way of preventing the occurrence of training failure, saving time and effort and increasing training effectiveness. Thus, a successful prediction of the rehabilitation outcome is obviously useful. In this study, three outcome categories for physical effect of training were used: success, no change, failure. It appeared that base-line variables could identify patients with success and patients with failure to a high degree (correct classification rates: 81% resp. 85%). Moreover, it turned out that variables predicting success were not the same as those predicting failure. Training success was associated with a good medical and physical status: the ability to generate higher blood pressure during exercise, the absence of angina, as well as the absence of arrhythmia during exercise and the absence of signs of heart failure in hospital. Work status was the single most important determinant of success but did not determine failure. Age was not related to success nor to failure. Interestingly, patients with training failure were not those with the worst medical status; that is, their status was not worse than that for patients with no clear change. Only heart rates, resting and at low work load, were related linearly to the three outcome categories: they were lowest for successful patients, highest for patients with failure, and had intermediate values for patients with no clear change. Figures 10.2 and 10.3 show that prediction was highest with all sets of predictor variables combined. Psychological variables were particularly valuable for the prediction of patients for whom training failed.

Several authors used base-line clinical and exercise data to predict physical training effect. Hammond found 'that a patient's success or failure in improving aerobic capacity was poorly predicted from initial clinical, treadmill or radionuclide data' (17). Fioretti obtained similar results from two studies (22,23). They both concluded that patients should not be excluded from rehabilitation based on a poor left ventricular function, or signs of myocardial ischemia. The results of this study are in agreement with their conclusion. They also found that initial low fitness was the best predictor of improvement in the respective measurement, confirming the idea that patients with a relatively high level of physical deconditioning, because of prolonged bedrest, would benefit more from reconditioning (24). In this study, a low initial maximal work load was also predictive of success, although marginally significant. By contrast, a good physical state, indicated by lower heart rates, was associated with success. The explanation of this difference is not clear. It may be partly due to the nature of the outcome criterion, which in this study is a composite criterion, rather than a single measurement of fitness. Or, high heart rates can be taken as a sign of high arousal and exhaustion which would be an unfavourable condition to start physical training (25).

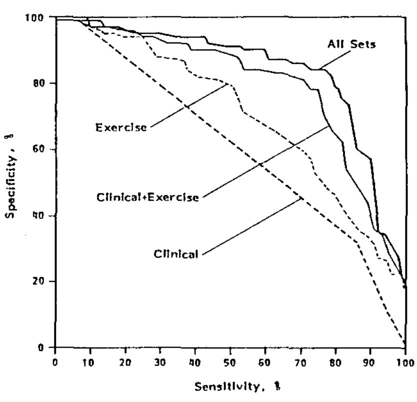

Figure 10.2. Specificity and sensitivity for predicting **training success** of clinical data, exercise testing, the combination of clinical and exercise data and work status, and the combination of these with psychological questionnaires (all sets).

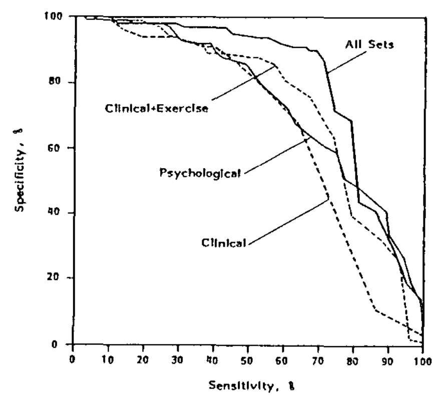

Figure 10.3. Specificity and sensitivity for predicting **training failure** of clinical data, clinical data and exercise testing, psychological questionnaires, and the combination of these three sets (all sets).

In this analysis, psychosocial variables were predictive of outcome, and the combination of physical and psychosocial data was optimal. Myers and Froelicher, in an editorial comment on these findings, consider the idea that psychosocial data predict physical training outcome provocative (24) and in need of further study. To my mind, the result is not very surprising, but it is a strong argument in favour of comprehensive, multidisciplinary rehabilitation. It supports the practice of a psychosocial intake at entry to rehabilitation. For instance, work status substantially raised the predictive power of clinical and exercise data for predicting success.

Sleeping habits, Type A behaviour, well-being and displeasure were also of predictive value, in particular for predicting failure. Work status and Type A behaviour seem to refer to the motivation and active disposition of the patient. By contrast, the presence of the combination of exhaustion and arousal, which Nixon presented as an important issue to solve (25,26), can be seen in the need for long siestas, high displeasure and a tendency to increased functional complaints. Similarly, Uniken Venema-Van Uden found that a combination of medical and psychological variables was important to predict recovery (18). Training failure occurred in particular among patients who were tired and psychologically in an unfavourable condition. Thus, those who seem to need rehabilitation most, least benefited from it, when it was limited to exercise training. This supports the idea of a comprehensive approach, including a more psychological treatment (18,21,27), relaxation therapy, or other measures for arousal reduction.

2.3. A minority of patients benefit psychologically from physical exercise as a single treatment. Aerobic conditioning is not the only or main effective ingredient of exercise.

Postinfarction patients are very enthusiastic about exercise training and the vast majority is convinced that exercise training is extremely helpful in convalescence. The results of this study, however, were negative: we did not find signs of improvement in any of eight psychological questionnaires after having participated in exercise training. Moreover, we found that patients with a positive training response did not improve more, psychologically, than patients without physical benefit. Thus, exercise did not seem to be helpful for psychic convalesence. Hughes reviewed the results of trials of exercise training for all kinds of participants and recently Langosch did the same for coronary patients (12,28). They found that the evidence of a psychological effect, in general, is weak. Langosch concluded that 'exercise training should not be recommended for postinfarction patients mainly for the purpose of improving their psychological and psychosocial functioning, and that especially patients with more severe psychological disturbances will not benefit very much, psychologically, from this treatment'.

This may be disappointing, but it should not come as a surprise, considering that the primary goal of physical exercise training is to increase physical fitness. However, secondary benefits do occur and include for instance alleviation of fear and depression and a higher morale. It should be borne in mind, therefore, that such a negative conclusion is based on average group outcome. Uniken Venema-Van Uden distinguished psychological outcome categories and found that 39% of the patients improved whereas 18% maintained a good psychological state (6). Another 18% deteriorated and 9% remained in bad shape. Taken together, the average result would indeed be only a modest improvement. Nevertheless, some patients do benefit. She did not indicate for how many patients psychological and physical benefit concurred. In this study, one third of the patients benefited both psychologically and physically. It can be concluded therefore, that exercise training can be sufficient, but only for a (substantial) minority of patients.

Langosch recommended the integration of exercise into a treatment package, consisting of information, counselling, relaxation training and stress management (6), because a comprehensive rehabilitation programme would be more effective (29). This idea is confirmed by the results of this study (see 2.4). However, a comprehensive programme will be more time-consuming and more expensive. But, this is not necessarily the case. One possibility is to become more selective: some patients are assigned to exercise training, others to relaxation therapy (individually or in groups) without exercise and only some would get both treatments.

Another interesting possibility is to re-consider the nature of exercise training itself. The lack of association between training success and psychic improvement, in this study as well as elsewhere (6,21), questions the need for increasing fitness as a purpose of exercise. For instance, Moses et al. found psychological benefits in moderate exercise, but not in intense exercise in a normal population (30). Thus, other mechanisms than aerobic conditioning play a role, for instance, perceived self-control, change in life-style, expectation, diversion, social and emotional support (11,12,21). These mechanisms are more of a psychological nature and they also refer to the context of the exercise sessions. Thus, a more comprehensive orientation of the staff, rather than allowing the "dogged repetition of mindless exercise" as Nixon puts it (31), could make the programme an "arena for interchange and education" (11). In this study, relaxation therapy induced increased positive body awareness, which was found to be associated with improved somatic functioning, particularly for patients without training success. This indicates that the psychological impact of exercise may increase when it is integrated with relaxation. As a result, the purpose of exercise may also shift and include "body awareness".

2.4. The effect of relaxation therapy is not limited to teaching of relaxation skills. It enhances the overall effectiveness of rehabilitation.

The primary purpose of relaxation therapy is to teach relaxation skills. Several studies demonstrated the "acute" physiological effect of relaxation, practised by cardiac patients (32-34). In this study, the patients were not examined for their ability to demonstrate their skills, for two reasons. First, the purpose was the integration of relaxation into the habitual behaviour of the patient. Second, testing had to be blind to the treatment condition of the subjects. Nevertheless, we found highly significant changes in respiration and body awareness as a result of relaxation therapy. These two were indicators of success of the relaxation method applied. Usually, only single measurements are taken as criteria of mastery of a technique (35). However, it would be worthwhile to construct a criterion for relaxation success on the basis of multiple indicators, analogous to the criterion for training outcome, which represent the goal of the therapy more fully.

For instance, although relaxation reduced the occurrence of training failure, the changes in respiration and body awareness that we found were not related to training outcome. If the respiration rate and positive body experience were the only possible indicators of relaxation success, this would mean that relaxation success had no specific bearing on training outcome and that aspecific factors were more important, e.g. the relationship with the therapist. Aspecific factors would be expected to play a role particularly for psychological effects. However, the psychological outcome was related to the indicators of relaxation success: patients who improved in the scale of

"Well-being" had a lower respiration rate and patients who improved in the composite score for somatic functioning, were also breathing slower and had more often a positive body experience. Therefore, it seems more likely that other indicators have to be included in the criterion for relaxation success, for example, reflecting autonomic balance (end-tidal carbon dioxide concentration (31), heart rate variability).

The main usefulness of relaxation therapy resides in its wider effects, which include the following:

First, relaxation reduces the stress of a high sympathetic tone. Physiological changes to that effect have been demonstrated and the therapeutic effect of relaxation is usually explained in that way (36,37). In this study, increased heart rate variability was the most direct indicator of such a change, reflecting a shift in autonomic tone from sympathetic towards more parasympathetic tuning. Also, heart rate reduction after training was more pronounced. Possibly, the other physical effects of relaxation therapy, reduction of training failure and of the occurrence of exercise-induced ST-depression, were partly mediated through reduction of sympathetic tone.

Secondly, the stress-reducing effect is perceptible by the individual: one feels quieter, becomes less anxious and reactive to stimuli. Thus, it is not surprising that on the scale "Well-being", a clear relaxation effect was shown, since this scale contains questions on recent feelings of being 'easy', 'quiet', 'relaxed' etc. Relaxation may also induce anxiety (38). However, on average, we did not find any indication of increased anxiety or complaints, as a consequence of relaxation.

Thirdly, relaxation might influence life-style and coping style. Relaxation practice is an ingredient of a healthy way of living, which seems to be uncommon among cardiac patients (39). Besides, it offers another way of dealing with stress, through internal control rather than actively trying to solve the problem in the outside world. Thus, relaxation is the core of what is often called "stress management" or "behaviour modification" programmes (40-42). My approach implies offering the patient new techniques and sensory experiences of himself, and then exploring the utility and meaning for him, rather than giving structured and directive guidance. This seems to have been successful, in that stable effects over a long period of time were induced, indicating a change in behavioral pattern. For instance, three months and even two years later, patients who had learned to relax took more daytime rest and their respiration rate was still lower.

Since stress management programmes are meant to promote a healthier life-style, they may also contribute to secondary prevention. In one major study such a programme reduced mortality after myocardial infarction(43). We conducted a two-year follow-up of the patients, admitted to the study in 1981-1982. It turned out that fewer cardiac events (cardiac death, reinfarction, coronary bypass surgery, readmission to hospital for unstable angina pectoris) occurred among patients who underwent relaxation therapy. Although the number of patients (n=90) is too small to draw any firm conclusions, this finding is of paramount importance. There were no differences in base-line prognostic characteristics between the two randomised groups which could explain the difference in long-term outcome. Besides, it should be realised that relaxation therapy had an effect in addition to the influence of exercise-rehabilitation, on a population of relatively low-risk patients. It seems therefore that the potential value of relaxation therapy and stress management beyond the scope of rehabilitation deserves further investigation, particularly on a population of cardiac patients including all levels of risk and illness severity.

In conclusion, physiological, psychological and behavioral changes can be the result of relaxation. To be specific, we found a decrease in training failure, a decrease in ST-depression, an increase in heart rate variability, an increase in well-being and a reduction in cardiac events, as a result of relaxation therapy. A diverse range of effects was also found by Krampen and Ohm who studied a mixed programme of muscle relaxation and self-suggestion, in addition to a regular exercise programme, in 105 myocardial infarction patients (44). Ohm replicated the study on 420 patients (45). Relaxation had many effects, e.g. the physician's rating of health improved more, patients felt more optimistic and had a higher sense of self-control. Interestingly, the treatment environment of the rehabilitation unit was perceived more positively by patients who attended relaxation classes. We fully agree with their conclusion that the effects of relaxation training go beyond the teaching of relaxation skills: it enhances the general effectiveness of rehabilitation.

2.5. *Relaxation therapy modifies the effects of the determinants of the rehabilitation outcome.*

An intriguing finding is that prediction of rehabilitation outcome differed between the two treatment groups. For both physical and psychic outcome, the nature of the treatment influenced the effect of the predictor variables on outcome. It implies that for some patients the outcome was positive with one kind of treatment and other patients benefited from the other. Thus, the core concept of tailor-made rehabilitation found empirical support in prediction analysis.

For instance, the influence on training success of anti-anginal medication before infarction or a history of non-cardiac disease or exercise-induced arrhythmia, disappeared when relaxation was added to exercise. Conversely, other factors were predictive especially for the combined treatments, e.g. infarction size, work status, exercise-induced ST-abnormalities, sleep quality, well-being. With respect to the psychic outcome, the three most important predictors were age, job status and job level. In all three, the direction of the association with the outcome reversed when treatment was taken into account in the form of an interaction term. The interpretation of an interaction term is not obvious and can best be illustrated by an example. Treatment * age was the strongest predictor. Bivariately, age was unrelated to psychic change. In the multivariate final analysis (Chapter 9), age was negatively associated, but when treatment was taken into account, the relationship became positive. The positive association of the interaction term (age * treatment) implies that older people benefited relatively more when exercise is the single treatment. Younger patients would benefit more from comprehensive rehabilitation (figure 3). In the literature, age appears to be related to return to work (46,47), but not to the psychic outcome (18), often because rehabilitation is limited to younger patients (48). In this study, age bore no relation with training success, whereas in other studies the effects of training in younger patients are sometimes greater (17), sometimes smaller (22,23).

A differential effect of an intervention was also found by Diederiks (8). Over a two-year follow-up period, patients who participtaed in exercise-rehabilitation improved slightly in fitness when they resumed work, whereas patients who did not return to work improved more when they had not participated in rehabilitation. He suggested that rehabilitation had possibly created expectations of work resumption which became a negative factor when it was not fulfilled. In this study, work status also had a highly differential effect as well. Having a job was the single most important predictor of training success, particularly for combined treatment. On the other hand, psychic benefit was greater on average for those who did not work; but when treatment was taken into account, psychic benefit was relatively greater for those who worked and had participated in the combined treatments. In some studies, work status is found to have a predictive value in some studies (18), but it is often not utilised (22,23) nor is it applicable when rehabilitation is limited to patients with employment (47). Unemployment was one of three variables which successfully predicted anginal pain relief (49).

These results are both intriguing and promising. Since all patients participated in the same exercise training and since they had been randomly assigned to additional relaxation therapy, the conclusion seems justified that relaxation therapy modifies the effects of the determinants of the rehabilitation outcome. Future studies are necessary to replicate these findings. Validation will make it possible to optimally apply exercise training and relaxation therapy as therapeutic modalities in recovery after myocardial infarction.

There are two implications with regard to the utility and interpretation of the results of a clinical trial. When the effect of an intervention (e.g. relaxation therapy) is demonstrated in comparison to a reference treatment (e.g. exercise training), the question remains whether to adopt the new intervention in the future, and if so, for what patients in particular. Second, a negative outcome of a trial does not mean that there is no use for the intervention under investigation. The above-mentioned analyses showed that two interventions may have opposite effects for different patient categories. It is of high clinical relevance to realise this. It is challenging to detect the determinants of both a positive and a negative outcome of a particular treatment.

2.6. Conclusion.

In our opinion, the main findings of this study support a more comprehensive and individual approach to cardiac rehabilitation. First, it was shown that exercise training was effective for a limited percentage of patients and data were provided on specific indications for training. Besides, it was suggested that the context of training and the attitudē of the staff was as important an ingredient as aerobic conditioning. Secondly, the value of relaxation therapy was demonstrated. It has physical, psychological and behavioral effects, enhancing the general effectiveness of rehabilitation. It can be employed as an alternative treatment option, but also as a means to modify the nature and context of exercise training. Thirdly, indicators were found determining what patients would benefit (physically and psychically) from exercise training, and what patients would particularly benefit from a combined treatment. Thus, prediction analysis offers a tool for assigning patients to the treatment which is most beneficial to them.

3. Rehabilitaton policy: How to tailor.

3.1. Prediction analysis

In this study altogether five prediction rules have been formulated, three of them estimating the probability of training success (one for the total study population, and one for each treatment), one of them estimating the probability of training failure, and one of them estimating the psychic outcome. Since the last rule took treatment form into account, it will produce two estimations, one for each treatment form. Supposing that these analyses have been validated in a large-scale replication study, how can they be applied as a tool for tailor-made rehabilitation?

The prediction rules are based on information available at entry into the rehabilitation programme. Data from medical records, as well as information from a psychosocial interview, and measurements obtained by exercise testing and psychological questionnaires are required. These data constitute base-line measurements which are available when a multidisciplinary intake procedure is applied. For each patient the prediction rules can be calculated as soon as the intake procedure is completed. As a result, six estimations are present which may used as a tool to decide if and how rehabilitation should be implemented.

The first option concerns exercise training. A programme of exercise sessions, aimed at gradually increasing the patient's work load, is indicated when exercise testing can be expected to show an improvement after training. In terms of our composite criterion: when the probability of success is high and the probability of failure is low. Conversely, when the probability of failure is high and the probability of succes is low, exercise training is not indicated.

The decision to start exercise training can be further qualified, by considering the predicted psychic outcome as well, and by distinguishing between success for exercise as a single treatment and success for a combined treatment. Is exercise training sufficient to improve psychically? In other words, what is the co-occurrence of training success and the predicted psychic benefit of training. In case the predicted psychic outcome is positive, exercise seems to be sufficient as a single treatment. In case the predicted psychic outcome is not positive enough, additional treatment(s) may be required.

The second option concerns additional relaxation therapy. "Additional" implies that there is already sufficient reason to start exercise. Relaxation therapy is indicated, when there is a substantial difference in the outcome, predicted for the combined and the single treatment (see figure 10.4). The probability of success may be higher or the predicted psychic benefit may be greater for the combined treatment. Conversely, relaxation therapy is contra-indicated, when the predicted outcome of the combined treatment is lower than for the single treatment. A large difference in probability of training success, in favour of the combined treatment, makes relaxation therapy a prerequisite for training: exercise sessions should be started, only in combination with relaxation therapy.

A third option concerns the situation when training is not indicated, because the probability of success is too low or the probability of failure is too high. This study does not provide data on that situation. In particular, it is not known what the probability of improvement would be without any rehabilitation. In practice, there are several rehabilitation options. One is to start exercise sessions anyway, but they may be of low intensity and the staff will have special attention to the patient's response. This seems indicated when the predicted psychic benefit of the patient is good. Another option is to start with relaxation therapy, individually or in groups, and possibly add light exercise sessions. This seems indicated when there is a difference in predicted benefit in favour of relaxation therapy. Finally, it may be best not to rehabilitate the patient or to resort to yet another method of treatment. It should be remembered however that monitoring possible negative responses during supervised exercise sessions is a way of obtaining valuable information on the patient's cardiac condition.

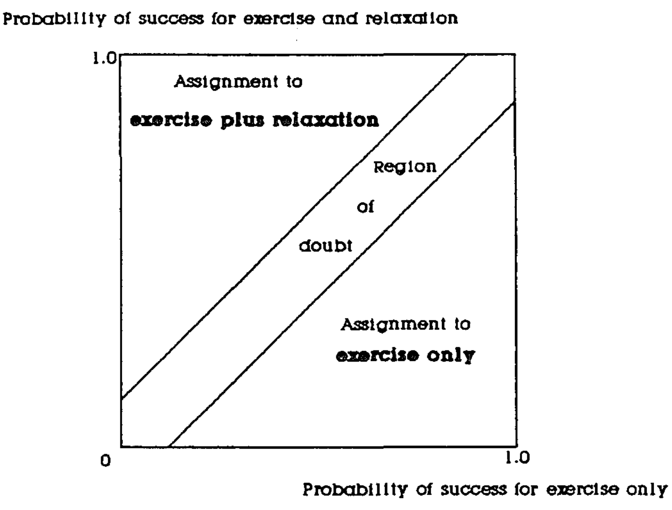

Figure 10.4. Assignment to exercise as a single treatment or combined with relaxation therapy, based on the predicted success for each of the treatments.

Thus, the estimations from the prediction rules serve as additional information to help the decision on how to proceed. A couple of other factors also have to be taken into account:

- Cost of treatment. Exercise training is done in groups and is about as expensive as individual relaxation therapy. Obviously, the combined treatment is most expensive.
- Manpower. In case there are not enough qualified therapists available for individual treatment, or when there is insufficient place in the exercise therapy, the treatment of choice has to be postponed.
- Risk of treatment. Training "failure" is to be avoided, as well as a negative psychic outcome. However, a high risk for a negative outcome does not necessarily imply that the treatment should not take place; it may tell the staff to be alert and attentive and may play a role in the medical care and in advising the patient on the resumption of his activities.
- Difference between treatments. A substantial difference is one argument to assign the patient to the treatment with the highest probability of benefit. However, when the difference is rather small other factors may determine the decision.
- Nature of determinants. Many determinants are of a fixed nature (sex, age, history etc), but others are open to change, e.g. heart rate, psychological state. Thus, it may be possible to change the patient's characteristics, in such a way that he becomes more suitable for treatment.

3.2. Further considerations.

The validity of the prediction analysis is limited to the treatment that was investigated. For instance, the effect and indications of relaxation therapy as a single treatment, without exercise, either individually or in groups, have not been investigated. Also, the integration of relaxation in the exercise sessions is possibly different from the combination investigated. Thus, it is to be recommended that prediction analysis will be continued for other rehabilitation settings and programmes.

The prediction analysis only makes sense if the outcome criteria are valid. Do they represent the goals of rehabilitation adequately and do they measure them accurately ? Obviously, other criteria than we used can be taken as endpoints as well. For instance, return to work or resumption of daily activities; risk factors; cardiac events. Also, other time intervals can be used. Long-term criteria reflect other goals than recovery, e.g. secondary prevention.

In fact, rehabilitation goals may not be the same for all patients. For one patient, return to work can be the main goal, and an adequate physical condition is a necessary step to that end. For another, the decision not to resume work may be the best solution. Thus, uniform criteria are, to some extent, artificial, and do not reflect rehabilitation success adequately (13).

In this study, effects of two kinds of treatment were investigated. Of course, we do not pretend that they fully cover rehabilitation. On the contrary, rehabilitation is composed of various treatments. Psychotherapy, risk factor reduction, group counseling, patient education are utilised. It will be of interest to estimate their usefullness more accurately. Besides, relaxation and exercise can be varied also. We showed that aerobic conditioning is not the only ingredient of exercise. The (social) context of the sessions is equally important. Also, relaxation offers another point of view on exercise, i.e. a way to increase body awareness. Thus, there is a challenge for future research, which will enable a truly individualised rehabilitation.

3.3. Conclusion

To tailor rehabilitation to the individual patient, multi-disciplinary assessment is a conditio sine qua non. Prediction analysis can be useful in identifying patients for whom a certain treatment is indicated or contra-indicated. Moreover, alternatives to exercise training have to be developed. Exercise training seems cheap, because it follows a standard group format, but it is often ineffective or even unnecessary and insufficient. Comprehensive rehabilitation, however, has more value because it can be selective and is in principle able to match the programme to the needs and possibilities of the individual.

4. Practical implementation of relaxation therapy.

4.1 Relaxation method

The beneficial effects of the relaxation method, that we studied, probably depend on several ingredients: a general "relaxation response", aided by biofeedback, the (specific) technique of breathing and sensory awareness, the therapist and the rehabilitation context. Since we do not know which of these are most important, all of them have to be taken into account, when implementing relaxation therapy into rehabilitation. If relaxation is limited to a simplified and standard procedure, like Benson's relaxation response (34,36), or if it is taught in groups or using casette tapes (50), the effect is not necessarily the same as what was found in this study.

Group relaxation, particularly, tends to be more superficial than individual instruction, with less learning effect and less mastery of technique. However, if the number of sessions is extended (51,52), if the dynamics of the group interaction is utilised well (44,45), or if it is added to individual instruction (53), the group situation can enhance the therapeutic effect and the motivation, too. This depends on the qualiteis of the group leader. Individual biofeedback may also be integrated into group practice (54).

Integration of relaxation into exercise sessions is therefore ambiguous. Since exercise appeals to the patient, is wide-spread and consists of many sessions, it is, on the one hand, an opportunity to offer cardiac patients the experience of relaxation (55,56). Besides, incorporating relaxation in the cool-down phase can further enhance the quality of the exercise session, and help to slow down the hectic pace of some patients (56). On the other hand, the effort- and goal-directed atmosphere of exercise sessions and the attitude of theexercise therapist may impede the patients' relaxation experience or limit its depth. Therefore, it requires a high level of motivation and expertise on the part of the therapist, to retain a minimum of quality.

In our experience, practical implementation of relaxation requires a comprehensive rehabilitation setting, which facilitates the patient's motivation and an adequate relationship with the relaxation therapist. Conversely, practising relaxation may induce a more comprehensive attitude of the staff. The nature of the exercise sessions could be changed, too, with more emphasis on quality and differentiation of movement, on coordination and mobility, rather than on aerobic power. It may also be incorporated into discussion or counseling groups, or into patient education programmes, thereby enlarging the scope and appeal of these psychosocial interventions.

However, we would recommend to have at least a few classes of purely relaxation technique and breathing awareness, as well as individual relaxation therapy, for two reasons. First, this may be the treatment of choice for some patients. Second, this allows therapists to maintain, and preferably increase their proficiency and interest in teaching relaxation. It will be interesting to assess the role of relaxation therapy outside the the cardiac rehabilitation setting (54).

4.2 Therapist qualifications.

The major prerequisite for applying relaxation therapy is extensive, personal experience. This is indispensable (57). The therapist has to be thoroughly acquainted with several methods of relaxation and body awareness, to have felt the effects on him or herself, recognized the factors which may promote or hinder a positive response, to accept possible side-effects and to be motivated to practise himself. He has to be convincing and clear to the patient, elicit a sufficient sense of safety and confidence and be a "model" (58,59).

Because there is no formal training to become "relaxation therapist", it is necessary to have a background in a health-care or teaching profession. If one is already working clinically, for instance in cardiac rehabilitation, relaxation therapy may be added to one's repertoire. The disadvantage of this arrangement is that relaxation tends to have low priority. Each profession has its specific assets. Interestingly, Patel found that general practitioners did better in teaching relaxation than psychologists or a yoga teacher (60).

To date, there are no courses, that cover the theoretical aspects adequately. Pathophysiological knowledge, in general and concerning the relevant patient categories, is obviously desirable. Specific knowledge is required of the autonomic nervous system, the various stress models, the theoretical models of the relaxation procedures and their possible (side-)effects. Even if biofeedback equipment is not used, understanding its (psycho-physiological) principles is very useful. The problem is, that too much knowledge may distract one from the experiential basis. Relaxation and body awareness are beyond the distinction between the subjective (psychotherapeutic) and objective ((para)-medical) approaches (61). "Body awareness" implies a meeting of these two approaches, in the self-experience of the patient. Therefore, integration of theoretical knowledge into the personal experience of the therapist is essential.

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Chapter 11

Summary

Cardiac rehabilitation is very often equated with physical exercise training, thereby neglecting its multidisciplinary, comprehensive character. In this study, the value of individual relaxation therapy, in addition to a regular exercise training programme, was investigated. A relaxation method was developed by the author, and used in the Cardiac Rehabilitation Unit at St. Joannes de Deo hospital, Haarlem. It was taught individually and a breathing technique was used as a core element (see **appendix**). Also included were biofeedback, manual handling to promote relaxed breathing and body awareness, and application of relaxation in a passive state (supine) as well as actively (sitting, standing). Its contribution to the rehabilitation of cardiac patients was assessed in a randomised controlled clinical trial.

Myocardial infarction patients, referred for rehabilitation, were randomly assigned to either exercise training alone or to a combination of exercise training and relaxation therapy. The first question to be studied was whether the combined treatment had any incremental value. The second was whether the rehabilitation outcome was predictable on the basis of information available at entry into the programme.

In three intake periods, in 1981-1983, a total of 156 myocardial infarction patients were admitted to the study; 147 men and 9 women, their average age was 55. All of them participated in a 5 week daily exercise training, and 76 patients received also six one-hourly sessions of individual relaxation therapy.

The combined and single treatments were compared on the basis of three sets of measurements, before and after rehabilitation: exercise testing, psychological questionnaires and respiratory variables (chapters 3 to 5). Cardiac events after rehabilitation are described in chapter 6. Out of these measurements, two main criteria evolved, indicating physical and psychic benefit of rehabilitation. Predictability of the outcome, for the two criteria, is described in chapters 7 to 9.

Outcome.

The relaxation method under investigation aims primarily at awareness of a more relaxed way of breathing. Therefore, a positive body experience and respiratory variables were used as indicators of the efficacy of the method (**chapter 3**). The experience of the body during rest of patients who received the combined treatment was more often positive and they were breathing slower after rehabilitation, whereas there were no changes in patients who participated in exercise training alone. The differences between the two treatments were highly significant and remained stable after a three month follow-up. They indicate a more relaxed state in patients who underwent relaxation therapy.

A fine-grain analysis in patients studied in 1982, revealed that lower respiration rate also implied a more efficient ventilation since tidal volume increased whereas minute volume remained practically unchanged. Hyperventilation decreased. In addition, heart rate variability, a measure of parasympathetic tone, increased as a result of relaxation therapy.

These changes in body awareness and respiration rate were unrelated to improvements in exercise testing after rehabilitation, but there was a relation with psychological measurements. In the combined treatment, patients who showed improvement in the scale "well-being" were breathing slower and patients whose "somatic functioning" improved were breathing slower and their body experience during rest was more often positive. Thus, relaxation success was, to some degree, associated with positive rehabilitation outcome. On the other hand, patients for whom exercise was the only treatment and who improved in "psychic functioning", turned out to breathe faster after rehabilitation.

Exercise testing (**chapter 4**) before and after the training programme showed a modest training response in both treatments: maximum workload increased and heart rate at a given work level decreased. The decrease in heart rate was more pronounced in the combined treatment at all levels of effort. Exercise-induced signs of cardiac dysfunction were: ST-segment depression, ventricular arrhythmias and angina pectoris. These remained stable during rehabilitation, except for a statistically significant decrease in ST-abnormalities in patients who underwent relaxation therapy.

A model was developed to integrate the major exercise testing parameters (signs of cardiac dysfunction, maximal workload, heart rate and blood pressure) into a single outcome criterion, as indicator of the efficacy of training. The model used clear changes in either of these measurements to classify patients into three categories: clear positive change, negative change and no clear change. Since the model operationalised the primary purpose of training to improve physical fitness, a positive change was regarded as a "training success" and a negative change as a "training failure". Patients who had dropped out of the study were also classified, on the basis of the reason for not completing the programme. The result was that the outcome was successful for only about half of the patients: 42 patients (55%) in the combined treatment and 37 patients (46%) in the single treatment. On the other hand, the training failed in a number of patients: 15 patients (20%) in the combined and 27 patients (33%) in the single treatment. The odds for failure were twice as high for the single treatment (odds ratio: 2.07; 95% confidence interval: 1.002-4.28). This means that training was not appropriate for all referred patients and that relaxation therapy reduced the risk of a negative training outcome.

The psychological impact of exercise training and relaxation therapy was measured by using questionnaires (**chapter 5**). They consisted of scales for well-being, subjective invalidity, displeasure, social inhibition, anxiety (state and trait), sleeping quality and functional complaints. Patients in the combined treatment improved in well-being, state anxiety and subjective invalidity, whereas no change was visible in the single treatment. The difference between treatments was highly significant for well-being.

The contribution of aerobic conditioning, as the primary purpose of exercise training, to rehabilitation outcome was further investigated by comparing psychic change in patients with and without training success. Three scales (subjective invalidity, sleeping quality and functional complaints) were integrated into a score for "somatic functioning" and three other scales (displeasure, anxiety state and anxiety trait) were integrated into a score for "psychic functioning". It turned out that training outcome was not associated with psychic outcome. Patients whose training was successful did not benefit more psychologically, compared to patients whose training was not successful.

The implication is twofold: first, patients whose training is unlikely to be successful may yet benefit from rehabilitation in a psychological respect. Secondly, aerobic conditioning should not be the only purpose of exercise. The context of exercise and the attitude of the staff are probably equally important; improved coordination, relaxation and body awareness may also be a purpose of exercise. Interestingly, the association between training benefit and psychic benefit differed for the two treatments: more patients in the combined treatment whose training was unsuccessful improved psychologically compared to successful patients or to unsuccessful patients in the single treatment.

A combination of the two outcome measures showed that both training success and psychic improvement occurred in 32% to 40% of the patients. Absence of training success and psychic deterioration occurred in a minority: 8% to 10% of the patients in the combined treatment and 15% to 20% of the patients in the single treatment.

Follow-up data were available for virtually all of the patients (n=88) who joined the study in 1981-1982. The results are described in **chapter 6**. Over a two to three year period (average of 30 months) cardiac events were documented. They consisted of cardiac death, reinfarction, coronary artery bypass grafting and readmission to hospital for unstable angina pectoris. In the combined treatment 8 events occurred in 7 out of 42 patients (17%), and 24 events occurred in 17 out of 46 patients in the single treatment (37%). The difference between treatments reached significance ($p=0.05$). The study was not designed to measure longterm effects, but the outcome supported the potential value of stress management for secondary prevention.

Predictability.

The composite criterion for physical outcome indicated that only about half of the patients (51%) actually responded positively to training, whereas in 27% training failed. Using a logistic regression analysis (**chapter 7**), base-line variables, consisting of clinical information, exercise data and psychosocial variables, could to a high degree identify patients whose training was successful as well as those whose training failed (correct classification rates: 81% and 85% resp.). The characteristics of patients for whom training was beneficial differed from those with a negative outcome. Work status before infarction was the single most important predictor for success, but it did not determine failure. Psychological variables (Type A behaviour, well-being, displeasure) were important for the prediction of failure, but not for predicting success. Clinical and exercise data largely determined training success.

Predictability of training success was also investigated for each treatment, because it is important to find out what patients, in particular, will benefit from the comprehensive treatment.

The results of the analyses showed that predictability differed between the treatments (**chapter 8**). Work status determined success in the combined treatment but not in the single treatment. Gender, anti-anginal medication and arrhythmia determined lack of success in the single treatment, but bore no relationship with the outcome in the combined treatment. On the other hand, ST-abnormalities and a small infarction were associated with success only in the combined treatment. With the exception of Type A behaviour, psychosocial variables had predictive qualities only for the combined treatment. The performance of the prediction rules was also different. The correct classification rates were 91% in the combined treatment and 76% in the single treatment. Thus, even though patients participated in the same exercise programme, the addition of relaxation therapy modified the effect of the determinants of a positive training outcome.

Predictability of the psychic outcome was also investigated (**chapter 9**), using a composite score of the scales, constituting psychic and somatic functioning, as the endpoint of prediction. Complete data on the psychic outcome were available for 119 patients. Multiple regression analyses were used to predict the outcome in a stepwise procedure, based on interview variables, clinical information, exercise testing and psychological questionnaires. The nature of the treatment was included in the analysis in the form of interaction terms with each predictor variable. The psychic outcome turned out to be highly predictable (multiple correlation of 0.72). Predictors of relatively high importance were age, work status and job-level, followed by mild heart failure, diastolic blood pressure and heart rate. Interestingly, all of them depended on the nature of the treatment. Thus, relaxation also modified the effect of the determinants of psychic outcome.

These results imply that it is possible to predict what patients will benefit from a single treatment, and what patients will benefit from a combined treatment, using a number of variables, available at entry into a rehabilitation programme. Validation will make it possible to optimally apply exercise and relaxation as therapeutic modalities and to tailor rehabilitation to the individual patient.

Conclusion.

The results are discussed in **chapter 10**. They confirm the conclusion from the one major study of relaxation therapy in cardiac rehabilitation by Ohm, that the aim and function of relaxation in cardiac rehabilitation go well beyond the optimisation of relaxation skills: they concern the general effectiveness of a rehabilitation programme. However, just as important was the finding that exercise is only effective for a limited percentage of patients. Moreover, exercise was not instrumental in bringing about psychological improvement. It is crucial therefore to differentiate rehabilitation programmes and tailor the programme to the individual. Prediction analysis can be a useful tool for that purpose.

Samenvatting

Hartrevalidatie wordt zeer vaak gelijkgesteld aan inspannings-training, waardoor het echter geen volledige, multidisciplinaire revalidatie meer is. In deze studie werd de waarde onderzocht van individuele ontspanningstherapie, toegevoegd aan een standaard trainingsprogramma. De schrijver ontwikkelde een ontspanningsmethode, ten behoeve van de hartrevalidatie in ziekenhuis St. Joannes de Deo te Haarlem. De therapie werd op individuele basis uitgevoerd en richtte zich vooral op de ademhaling (zie **Appendix**). Er werd ook gebruik gemaakt van biofeedback, van handgrepen om een ontspannen adembeweging en lichaamsbewustwording te bevorderen en ontspanning werd passief beoefend (liggend) alsook aktief (zittend en staand). De bijdrage van ontspanning aan de revalidatie van hartpatienten werd onderzocht middels een (gerandomiseerd en gecontroleerd) therapeutisch experiment.

Hartinfarctpatienten die verwezen werden voor revalidatie werden at random toegewezen aan hetzij inspanningstraining alleen, hetzij een combinatie van inspanningsoefeningen en ontspanningstherapie. De eerste onderzoeksvraag luidde of de gecombineerde behandeling enige meerwaarde opleverde boven de enkelvoudige. De tweede vraag was of de uitkomst van de revalidatie voorspelbaar was op grond van gegevens die beschikbaar waren bij aanvang van het programma.

Gedurende drie intake periodes, tussen 1981 en 1983, werden 156 patienten tot het onderzoek toegelaten; 147 mannen en 9 vrouwen, gemiddeld 55 jaar oud. Allen namen deel aan een 5 weken durend programma van dagelijkse inspanningsoefeningen en 76 patienten kregen daarnaast zes individuele behandelingen van een uur met ontspanningstherapie.

De gecombineerde en enkelvoudige behandelingen werden vergeleken op grond van drie soorten metingen voor en na revalidatie: veranderingen op de inspanningsproef, in psychologische vragenlijsten en in ademhalingsvariabelen (hoofdstukken 3 t/m 5). In hoofdstuk 6 wordt het optreden van cardiale incidenten na revalidatie beschreven. Van deze metingen werden twee hoofdcriteria afgeleid, die de mate van fysiek en psychisch baat van revalidatie aangaven. De voorspelbaarheid van de uitkomst op deze twee criteria is beschreven in hoofdstukken 7 t/m 9.

Uitkomsten.

Het doel van de te onderzoeken ontspanningsmethode is in eerste instantie bewust te worden van een meer ontspannen wijze van ademen. Als indicatoren voor het welslagen van de methode werden lichaamsgevoel en ademhalingsvariabelen gebruikt (**hoofdstuk 3**). Patienten die de gecombineerde behandeling ontvingen, hadden na de revalidatie vaker een positieve ervaring tijdens rustig liggen en zij ademden langzamer, terwijl patienten die alleen aan de inspanningsoefeningen deelnamen hierin geen verandering toonden. De verschillen tussen beide behandelingen waren hoog significant en na drie maanden nog aanwezig. Zij duidden op een meer ontspannen toestand van de patienten die ontspanningstherapie hadden gekregen.

Een meer gedetailleerde analyse van patienten die in 1982 in de studie waren opgenomen liet zien dat een lagere ademfrekwentie ook een meer efficiente ademhaling inhield, aangezien het ademvolume was toegenomen terwijl het ademminuutvolume gelijk was gebleven. Hyperventilatie nam af. Bovendien was de variabiliteit van de hartfrequentie, een maat voor de parasympathische tonus, toegenomen onder invloed van de ontspanning.

Deze veranderingen in lichaamservaring en ademfrekwentie hielden geen verband met verandering in de uitkomst van de inspanningsproef na de revalidatie, maar wel met veranderingen in de beantwoording van de psychologische vragenlijsten. In de gekombineerde behandeling ademden patienten die waren verbeterd op de schaal "welbevinden" langzamer. De patienten die in "lichamelijk functioneren" waren verbeterd ademden langzamer en hadden vaker een positieve lichaamservaring tijdens rust. Het welslagen van de ontspannings-methode ging dus in zekere mate samen met een positieve revalidatie uitkomst. Daarentegen bleken patienten die alleen aan inspanningsoefeningen deelnamen en die in "psychisch functioneren" waren verbeterd juist sneller te ademen na revalidatie.

De inspanningsproef (**hoofdstuk 4**) voor en na het trainings programma liet een matig trainings effect zien, na beide behandelingen: de maximale belasting nam toe en de hartslag tijdens een gelijke belasting nam af. De hartslagdaling na training was op alle nivo's van belasting duidelijker na de gecombineerde behandeling. Daarnaast werd gekeken naar cardiale afwijkingen tijdens inspanning: ST-segment daling, ventriculaire aritmiëen en angina pectoris. Deze waren nauwelijks veranderd na de revalidatie, afgezien van een opvallende vermindering van ST-afwijkingen bij patienten die ontspanningstherapie kregen. Het verschil tussen de behandelingen in dat opzicht was statistisch significant.

De voornaamste metingen bij de inspanningsproef (cardiale afwijkingen, maximale belasting, hartfrequentie en bloeddruk) werden volgens een bepaald model geintegreerd in èèn enkel criterium, als indicator voor het welslagen van de training. Met behulp van dit model werden duidelijke veranderingen in deze metingen gebruikt om patienten in te delen in een van drie mogelijke categoriëen: positieve verandering, negatieve verandering en weinig of geen verandering. Het model was een operationalisering van het primaire doel van inspanningstraining, de fysieke belastbaarheid te verhogen, en daarom kon een positieve verandering opgevat worden als een training succes en een negatieve verandering als het mislukken van de training. Patienten die het programma voortijdig staakten werden ook ingedeeld, en wel op grond van de reden voor het beeindigen van de training. Het resultaat was dat ongeveer de helft van alle patienten de training met succes beeindigde: 42 patienten (55%) met de gecombineerde behandeling en 37 patienten (46%) met de enkelvoudige behandeling. Daarentegen mislukte de training bij een aantal patienten: 15 patienten (20%) met de gecombineerde en 27 (33%) met de enkelvoudige behandeling. De "odds" voor mislukken was tweemaal zo groot bij de enkelvoudige behandeling dan bij de gecombineerde behandeling (odds ratio 2.007; 95% betrouwbaarheidsinterval: 1.002 - 4.28). Dit betekent dat training niet geschikt was voor alle verwezen patienten en dat ontspanningstherapie het risico voor mislukken verlaagde.

De psychische invloed van inspanningstraining en ontspanningstherapie werd gemeten met behulp van vragenlijsten (**hoofdstuk 5**). Deze bestonden uit schalen voor welbevinden, subjectieve invaliditeit, ontstemming, sociale geremdheid, (toestand en dispositie) angst, slaapkwaliteit en functionele klachten. Patienten die de gecombineerde behandeling ontvingen, verbeterden in welbevinden, toestands-angst en subjectieve invaliditeit, terwijl bij patienten in de enkelvoudige behandeling geen verandering optrad. Het verschil tussen de behandelingen was hoog significant voor welbevinden.

De bijdrage van het trainingseffect (het primaire doel van training) aan de uitkomst van de revalidatie werd nader onderzocht door psychische verandering te vergelijken tussen patienten die de training wel en patienten die de training niet succesvol beeindigden. Drie schalen (subjectieve invaliditeit, slaapkwaliteit en functionele klachten) werden samengevoegd tot een enkele score voor "lichamelijk functioneren" en drie andere schalen (toestand- en dispositie-angst en ontstemming) werden samengevoegd tot een score voor "psychisch functioneren". Het bleek dat het optreden van training succes niet samenhing met psychische verbetering. Patienten die de training met succes beeindigden hadden niet meer psychische verbetering, dan patienten voor wie de training geen succes was.

Deze bevinding heeft twee implicaties: ten eerste, patienten voor wie training waarschijnlijk geen succes heeft, kunnen desalniettemin voordeel van revalidatie hebben in psychologisch opzicht. Ten tweede, het bereiken van een trainingseffect moet niet het enige doel van lichaamsoefeningen zijn. De context van de oefensessies en de houding van de begeleiders zijn waarschijnlijk net zo belangrijk als het trainen zelf; coordinatie, ontspanning en lichaamsbewustwording kunnen ook een doel van lichaamsoefening zijn. Het is interessant dat de samenhang tussen fysieke en psychische verbetering verschillend was voor de twee behandelingen: patienten met gecombineerde behandeling die geen succes hadden met training verbeterden meer in psychisch opzicht dan patienten met een succesvolle training, of dan patienten met enkelvoudige behandeling zonder training succes.

Een combinatie van de twee hoofdcriteria liet zien dat zowel fysieke als psychische verbetering optrad bij 32% tot 40% van de patienten. Uitblijven van fysieke verbetering en gelijktijdige psychische achteruitgang trad op bij een minderheid: 8% tot 10% van de patienten met gekombineerde behandeling en 15% tot 20% van de patienten met enkelvoudige behandeling.

Gegevens over de lange termijn waren beschikbaar van vrijwel alle patienten (n=88) die in 1981-82 in het onderzoek waren opgenomen. De resultaten staan in **hoofdstuk 6**. Over een periode van twee tot drie jaar (gemiddeld 30 maanden) werd het optreden van cardiale incidenten vastgelegd. Deze bestonden uit overlijden door een cardiale oorzaak, re-infarct, open hart operatie en heropname wegens instabiele angina pectoris. In de groep met gecombineerde behandeling waren 8 incidenten bij 7 van de 42 patïenten (17%) en in de enkelvoudige behandeling waren 24 incidenten bij 17 van de 46 patienten (37%). Het verschil tussen de behandelingen was significant (p=0.05). Hoewel het onderzoek niet was opgezet om dergelijke lange termijn effecten te meten, steunt de uitkomst toch de waarde van "stress management" voor de secundaire preventie.

Voorspelbaarheid.

Volgens het samengesteld criterium voor fysieke verbetering blijkt dat slechts ongeveer de helft van de patienten (51%) met succes trainde, terwijl training bij 27% mislukte. Met behulp van logistische regressie analyse (**hoofdstuk 7**) konden patienten met succes alsook patienten voor wie de training een negatieve uitkomst opleverde in hoge mate herkend worden op grond van gegevens die bij aanvang beschikbaar waren, afkomstig van klinisch onderzoek, inspanningsproef en psychosociaal onderzoek (correct ingedeeld werden 81% resp. 86%). De kenmerken van de patienten met een trainingssucces verschilden van degenen voor wie training mislukte. Een werkkring voor het infarct was de belangrijkste voorspeller variabele van een gunstige uitkomst, maar had geen relatie met mislukken van training. Psychologische variabelen (Type A gedrag, welbevinden, ontstemming) waren van belang voor het voorspellen van mislukken, maar niet voor het voorspellen van succes. Klinische en inspanningstest gegevens bevatten de voornaamste bepalende factoren van trainingssucces.

De voorspelbaarheid van succes van training werd ook voor de behandelingen apart onderzocht, omdat het belangrijk is te achterhalen welke patienten in het bijzonder voordeel hebben van een gecombineerde behandeling.

De voorspelbaarheid verschilde tussen de behandelingen (**hoofdstuk 8**). De werksituatie hing samen met de training uitkomst van de gecombineerde behandeling, maar niet van de enkelvoudige behandeling. Sexe, anti-angineuse medicatie en aritmiëen hingen samen met succes van de enkelvoudige behandeling, maar vertoonden geen samenhang met de uitkomst van de gecombineerde behandeling. Daarentegen waren ST-afwijkingen en een klein infarct alleen bij de gecombineerde behandeling aan succes gebonden. Psychosociale variabelen, met uitzondering van Type A gedrag, voorspelden alleen bij de gecombineerde behandeling voorspellende de uitkomst. Ook het voorspellend vermogen van de predictie formules verschilde tussen de behandelingen. Bij de gecombineerde behandeling werd 91% van de patienten juist ingedeeld en bij de enkelvoudige behandeling 76%. Ondanks het feit dat de patienten aan eenzelfde trainings-programma hadden deelgenomen, blijkt dus dat het effect van de determinanten van de uitkomst van training wordt beinvloed door de toevoeging van ontspanningstherapie.

De voorspelbaarheid van psychische verbetering werd ook onderzocht (**hoofdstuk 9**), waarbij als uitkomstmaat voor de predictie een samengestelde score van de zes vragenlijsten die psychisch en lichamelijk functioneren weergaven gebruikt werd. Volledig ingevulde vragenlijsten waren slechts beschikbaar van 119 patienten. Met multipele regressie analyse werd in een stapsgewijze procedure de psychische uitkomst voorspeld, op grond van interview variabelen, klinische gegevens, belastingproef en psychologische vragenlijsten. De aard van de behandeling werd in de analyse opgenomen door middel van een interactieterm met elke voorspeller-variabele.

Psychische verbetering bleek in hoge mate voorspelbaar te zijn (multipele correlatie van 0.72). Leeftijd, werksituatie en arbeidsnivo waren van relatief groot belang als voorspeller, gevolgd door hartfalen tijdens opname, diastolische bloeddruk en hartfrekwentie. Het is opmerkelijk dat al deze voorspeller-variabelen vooral in de vorm van een interactieterm van belang waren. Ontspanningstherapie beinvloedt derhalve ook het effect van de determinanten van de psychische uitkomst.

Deze resultaten tonen aan dat het binnen zekere grenzen mogelijk is, met gebruik van gegevens die bij aanvang van revalidatie bekend zijn, te voorspellen welke patienten voordeel zullen hebben van een enkelvoudige behandeling, en welke patienten voordeel zullen hebben van een gecombineerde behandeling. Validatie van deze bevindingen maakt het mogelijk optimaal gebruik te maken van inspanning en ontspanning als therapeutische middelen en de revalidatie toe te snijden op de individuele patient.

Conclusie.

De resultaten zijn besproken in **hoofdstuk 10**. Zij bevestigen de conclusie van het enige grote onderzoek naar het effect van ontspanningstherapie in de hartrevalidatie, door Ohm, dat het doel en de rol van ontspanning in de hartrevalidatie verder gaat dan het aanleren van ontspanning: het verhoogt de effectiviteit van het revalidatie programma. Even belangrijk echter was de bevinding dat inspanningstraining slechts effectief is voor een deel van de patienten. Bovendien bleek een fysiek trainingseffect niet bepalend te zijn voor het bereiken van psychische verbetering. Het is daarom essentieel dat revalidatie programma's gedifferentieerd worden toegepast en toegesneden worden op het individu ("maatwerk"). Voorspellings analyse kan daarbij een nuttig hulpmiddel zijn.

Appendix

Body Awareness: the proper Application of Relaxation and breathing Technique

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Body Awareness: the proper Application of Relaxation and breathing Technique

Jan van Dixhoorn, MD

Relaxation techniques are widely used, but often applied in a partial fashion. Proper application of relaxation may well be a treatment in its own right, if the concept of relaxation is not limited to "physical rest". Techniques for a multiple relaxation training are described, which show on the one hand an emphasis on physical rest and immobility (passive relaxation, EMG-feedback, and ESR-monitoring) and on the other hand on physical movement and mobility (active relaxation, manual handling, and breathing).

These elements form a meaningful whole, through (1) the role of respiration, and (2) the concept of "body awareness". When breathing and body awareness are recognized and used as integrating factors, the application of relaxation techniques will gain in quality and will be less often partial and limited. This is of special importance for the health care, where standardised application to the manifold problems of patients is hardly allowed. A multiple relaxation program on this basis has proven to function well in a cardiac rehabilitation program. As to therapeutic use in general, there is need of further training of therapists and research into treatment indications.

Introduction

Relaxation techniques are widely used in medical, para-medical and psychological professions. They are commonly applied as an additional element to a treatment in an abbreviated form. Although this favoured popularization of relaxation training, it led also to misunderstanding of its nature. Bruce Paul (1980) mentions six points where relaxation is often misunderstood and misapplied: (1) it is regarded as an extra that may be of some help when added to an existing programme, (2) it is used routinely without regard for the time and manner of its introduction, (3) there is failure to give the client an understanding of its nature and how it works, (4) there is failure to motivate and assist the client to practise regularly, (5) there is failure to employ methods to facilitate transfer to life situations, (6) there is failure to recognize its many applications.

Indeed, most relaxation methods were originally developed as rather complete systems, both for psychophysical re-education and for treatment of complaints. The work of Jacobson has been re-examined recently in this light and found to be much more effective than the actual use of progressive relaxation (Lehrer, 1982). Proper application can therefore be a treatment in its own right.

This type of application has been experimented with since 1974 in the Cardiac Rehabilitation Unit of St. Joannes de Deo Hospital in Haarlem, The Netherlands (Van Dixhoorn, 1975). Many different techniques have been tried for active and passive relaxation, including biofeedback, respiratory regulation, massage and manual technique, in individual angroup sessions. It was found that a multiple relaxation training, not limited to a single standardized technique can be an important element of cardiac rehabilitation, especially if the team approach is truly comprehensive.

In this paper I would like to elaborate on the question how the concept of body awareness helps to apply properly different relaxation techniques. I will do this through a detailed description of techniques that shows the underlying principles. I will refer especially to myocardial infarction (M.I.) patients and to (1) passive relaxation, (2) active relaxation and (3) regulation of respiration.

Techniques for Body Awareness

This description is based on experience gained in the department of Biofeedback as a member of the Cardiac Rehabilitation Team in St. Joannes de Deo Hospital. From 1977 - 1983 several hundred patients were treated, usually about 20 % of the total number of patients attending the rehabilitation programme. Treatment consists of four to eleven individual session, seven on average. Each session lasts almost one hour.

Group sessions have also been held regularly, usually for 4 - 8 participants. It was found, however, that the relaxation proper became secondary in this situation and that the group discussion took most of the time. Many individuals could not really be taught to practise correctly. Individual sessions are therefore chosen as the model for description. Its effectiveness is currently being assessed in a randomised controlled trial (Van Dixhoorn, De Loos & Duivenvoorden, 1983).

Passive Relaxation

One begins with a period of rest in the supine position on the bed. The patient is asked to do the same at home, when he wants to take a break and can lie down on a carpet, couch, bed or in a reclining chair. The purpose is to learn what actually happens when one rests. In order to quiet down, it suffices to recline in a well-supported position, not to move, to direct attention to the body and to simply continue this for 8 - 10 minutes. In this period a "relaxation response" may occur (Benson, Beary and Carol, 1974): muscle tension, heart and respiration frequency diminish, thoughts slow down, body sensations become more apparent, time perception changes and electrical skin resistance increases. Subjectively, this period may seem quite long. To not to do anything at all, not even think about things, and still remain attentive is a real task for both the patient and the therapist. Relaxation "techniques" often have no other purpose that to fill this emptiness; the art of the technique is to make the relative emptiness bearable, without filling it completely with things to do (Ikemi, Ishikawa, Gogeche, Sasaki, 1978).

The first way to do this, is to inquire about the experience. Two or three times during the rest period the therapist starts talking, asking questions in a normal tone of voice: how the patient is doing and what he feels. In this way, silence does not create an overpowering atmosphere and the patient learns to understand better what is asked of him: just lie down and feel the body lying down. Also, he can mention things that bother him, which sometimes results in a remarkable drop of tension level.

Another way to make this rest period more acceptable and compre-hensible is electromyographic (EMG) feedback. Usually electrodes are attached to the Frontalis muscle, sometimes to leg, arm, shoulder or neck muscles. Knowing that one is connected to a technical device may help him to lie still. The auditory feedback signals provide a point of attention that facilitates concentration and which may help, together with awareness of the electrodes, to perpetuate rest. Next, the feedback signals transmit information about tension changes in the recorded mucles. The meaning of the signals is explained without giving any explicit assignment towards slowing down the signals and decreasing the tension. Too much attention on the signals or the wish to master a task may increase the arousal of the patient and disturb his rest (Lo, Johnston, 1984). Therefore, the instrument is adjusted to provide a non-irritating, background signal.

A third way is to give verbal instructions aimed at focussing attention, for instance: on the backside of the body, where support is felt, or the soles of the feet, on breathing movement, tension in the jaw, tongue, eyes, etc. Sometimes the patient is asked to slightly contract and relax muscles, for instance through endorotation of the legs, stretching the achilles tendons, rolling the head or frowning. This facilitates contact with the body, it can illustrate the meaning of the feedback and it prevents stiffening of the muscles.

It is essential to perpetuate the immobility and to continuously notice bodily changes. This is the "royal" road to understand relaxation and the passivity, mentally and physically, it involves. It can all be applied at home, but it may be difficult to perpetuate silence and immobility, especially at home. The therapist should therefore watch for signs of bodily tension increases during rest. This paradoxical reaction is not uncommon: muscle tension may increase, or skin resistance decreases, respiration becomes irregular or quickens, and sometimes the patient is visibly relieved to get up again. It is of importance to discuss unexpected "negative" reactions: awareness of bodily discomfort, unrest, itches, pains, tightness as well as feelings of irritation, wasting one's time, etc.. Relaxing implies to become aware of tension, so the signs of experienced tension cannot be avoided. One of the reasons that people do not apply relaxation at home routinely is that they do not accept this fact.

The relationship between patient and therapist is of importance as well. The therapist should be alert and attentive, but in a neutral way: not watching the patient fixedly, not being too intent on the patient's success or failure in achieving relaxation, not interfering too quickly or too much. On the one hand, the therapist is not imposing his presence, but on the other hand he behaves as a model to the patient, exemplifying the purpose of the training and showing unconditional acceptance of the patient and his experiences (Bram Amar, 1978).

Regulation of respiration.

Respiration is intimately connected to relaxation and body awareness. During physical rest, i.e. successful immobility, ventilation decreases. Consequently, respiration rate and tidal volume decrease, and the pause after exhalation becomes longer. Sometimes, respiratory suspension periods may occur, especially when mental calmness is deep, as for instance during meditation (Badawi, Wallace, Orme-Johnson, 1984). If, however, the concentration to achieve immobility is too much of an effort, respiration does not decrease or may even become faster. On the other hand, when the rest period is accompanied by pleasurable body sensation, the pattern of breathing movement may change into a more diaphragmal type (Grossman, 1983). As a result, tidal volume will increase, respiration rate diminishes even more, the post-exhalation pause disappears and is replaced by a continous, smooth and slow breathing rhythm. When a person can feel, for instance, the lower back, shoulder blades, hips, jaws, neck, etc., and these parts relax well, the trunk will allow an easier respiratory movement. The person may notice breathing movement along the whole length of the spine and in the whole of the trunk. This pattern of full, slow breathing is associated with active relaxation, and remains more or less the same in different postures. The slow, small breathing movement of passive relaxation on the other hand, disappears with body movement to sitting or standing or other physical sitmulation. Therefore, *these respiratory changes are suitable indicators of passive and active relaxation.*

Also, techniques have been developed to modify breathing in order to stimulate these changes. Some of them will be outlined below.

1) Information about the respiratory movements is augmented when the patient or therapist lies his hands on the back, abdomen, chest or sides. In this way, respiration becomes a suitable focus for attention. Usually, fast and difficult breathing becomes slower and easier; shallow, high-thoracic breathing becomes deeper and more diaphragmal. If this does not occur, one can guide the movement manually or verbally.

2) Making the air passage audible. Pursing the lips a little will increase the resistance on the air passage. Consequently, the breathing becomes audible (which provides another feedback). Also diaphragmal inspiratory contraction is stimulated. The tidal volume increases and the pattern of movement shifts to a more costo-abdominal pattern in which the lower ribs expand sideways, more than being lifted up vertically. Lateral expansion occurs especially when the lumbar and abdominal muscles relax during inspiration. After some audible breathing cycles, one shifts to normal nose-breathing and compares the respiration that follows with the pattern previously (Van Dixhoorn, 1981). This comparison needs some repetition: it is necessary to let the breathing changes occur spontaneously. It is crucial that breathing regulation does not become an exercise, being performed mechanically.

Most cardiac patients experience a sense of relief and lessening of the pressure in the chest, which indicates the existence of tension in that area. Often these techniques suffice to significantly diminish anginal pain, shortness of breath and hyperventilation.

3) A more indirect approach: the therapist introduces pressure, massage or small movements into the respiratory rhythm. Or he asks the patient to, for instance, push away the heels during exhalation and relax the legs at inhalation. Usually inhalation is coupled with effort and exhalation with relaxation. Here, this connection is reversed and effort is made during exhalation, on purpose, to increase awareness and stop the effort at inhalation. This approach fits in with active relaxation, to be described below. It may also serve as an aid, to facilitate relaxation in persons who experience no change with the first two techniques.

Active relaxation

Active relaxation consists of learning to apply relaxation in different postures and activities. This is important for the final phase of passive relaxation, where one should integrate relaxation in the daily life.

Systems for active relaxation *begin* with body movement itself (Brieghel - Muller, 1979; Feldenkrais, 1972; Gelb, 1981). They resemble exercise training, physiotherapy and gymnastics but differ basically in approach and purpose: active relaxation centers around the subjective perception of the body, the senses and the process of a movement, whereas the performance of an exercise is of minor significance.

As there is a countless number of body movements, and a large number of basic patterns and individual variation of them, it is not feasible to learn active relaxation in a few sessions or to standardise the sessions. However, a few examples to incorporate in relaxation training are necessary. Instructions are given in movement or posture, the concentration of attention, and breathing. Description of the "exercises" used, can be found in publications by Balfooort & Van Dixhoorn (1979), Van Dixhoorn (1981, 1983b).

A few exercises are usually sufficient for the patient to understand the basic difference to his habitual pattern of action. He is recommended to regularly practise the exercises done, and also to notice breathing in relation to his normal activites. The purpose is, that when a movement or posture is relaxed, breathing will shift spontaneously to a costo-abdominal pattern.

Manual technique

As additional elements for body awareness two manual techiques will be described.

1) Touching parts of the body provides strong feedback to the patient about muscle tensions in his body and helps him make mental contact with these parts. Therefore, touching with a knowing hand is a sure way for the therapist to guide the patient in his inner exploring of bodily tension. For instance, putting one hand on the small of the back prevents the patient from pushing out his abdomen, trying to "perform" diaphragmal breathing: he may then notice the ease of inhalation while relaxing the abdomen. Also, the small of the back relaxes, thus making the pull of gravity more obvious. The patient will start discovering, consciously and unconsciously, the alignment of body parts, best adjusted to gravity. The contact with the floor and the weight of the body become more apparent. Also the blood circulation to and from the legs increases, making them warm and tingling.

The therapist may add pressure or passive movement to mobilize or stretch muscles, but the primary purpose of increasing awareness is retained. In that way it is the patient who will change himself.

2) Some physical treatment may be very helpful and even necessary for achieving relaxation. There is a variety of treatments, ranging from massage, muscle facilitating techniques, treatment of reflex areas to manipulation of joints. Most of these constitute a specialty on their own, but some elements

should be available in multiple relaxation training. First, it is important to observe the musculoskeletal structure in order to see which posture or movement allows relaxation, and which does not. Tensions mostly block the range of some motions in some respects. Second, the therapist should be able to alleviate these limitations somewhat by arranging the posture or applying treatment. One possibility is the treatment of "pressure points" as for instance, "myofascial trigger points" (Travell & Simons, 1983). A trigger point is considered to be a highly irritable focus within a muscle, that is sensitive to pressure and can be palpated as a small, hard nodule. The existence of such a trigger point prevents the muscle from lengthening. Its continued contraction may then result in radiating pain and discomfort, not infrequently mimicking organic pain patterns. Treatment of these muscles sometimes gives complete relief and restores the full range of motion.

ESR monitoring

As an adjunct to the EMG-feedback and an aid to the therapist, a small inexpensive instrument is used to measure the electrical skin resistance (ESR) during passive relaxation (Blundell & Maxwell Cade; Maxwell Cade, 1972). Commonly, a decrease of sympathetic arousal, resulting in higher levels of skin resistance and fewer electrodermal reponses, is taken as a sign of relaxation and is used as a feedback signal (Patel, 1977).

Simultaneous measurement of ESR and EMG shows that the two indicators of physiological relaxation often don't match; it means that a person may successfully relax a muscle, but at the same time become aroused by the effort to do this. As some persons have low EMG levels from the beginning, the ESR then gives useful information about relaxation response. Therefore, the combined use of multiple indicators, including observation of motor and respiratory behaviour is desired for a reliable profile.

A pitfall in ESR measurement is that some patients have very high levels to begin with. This is not uncommon among cardiac patients (Van der Valk, 1958). If such a patient reaches a lower level during the rest period, it may also be taken as a positive sign, especially when he reports feeling refreshed. Therefore, the ESR is used as a monitoring aid and not as a feedback device.

Topics for discussion with the patient

Relaxation is primarily a non-verbal affair. However, some points merit explicit discussion.

1) The purpose of the relaxation sessions is introduced as a learning and training procedure to acquire a habit which is new but also natural and healthy. The practice of relaxation will become normal and automatic in the long run, if the patient becomes motivated. Cooperation is only asked for to try it out, now that the time and opportunity is provided in the post M.I. recovery period. The (psycho) therapeutic value is not put to the fore, as cardiac patients often resist to admit having problems.

2) Experiences during the session commonly are the main topic of conversation. The focus is on concrete, physical observations. The patient is helped to verbalize his experience and to distinquish between sense perceptions and thoughts about a relaxed state. Often "relaxation" is understood to be "feeling nothing", i.e. without discomfort or complaints. The point is made that sense impressions are always there, if one takes time to notice, and are valuable feedback for self-control.

3) The opinions and emotional reactions of the patient cannot be neglected, as far as they block or enhance the trust in the therapist and the practice of relaxation. However, psychosocial counseling is not meant for, nor is psychotherapy, although the motivation to that may grow and referral for joint treatment regularly occurs.

Understanding of tension phenomena and of relaxation and body awareness as an active coping strategy is central to the discussion during the sessions (Goldfried & Trier, 1974). It is hoped that continued practice becomes motivated by positive experience and finds a reward in itself. Although this may contribute to the secondary prevention after myocardial infarction, the fear for recidive should not remain the only motive to continue practice.

Conclusion

Summarising the techniques described we find on the one hand an emphasis on physical rest and immobility (passive relaxation, EMG-feedback and ESR-monitoring) and on the other hand physical movement and mobility (active relaxation and manual handling).

The elements that connect passive and active relaxation and differentiate these from exercise training are (1) regulation of respiration, and (2) body awareness. For that reason they play a key role in the multiple relaxation training, described above.

Awareness training is not designed for treatment but for teaching. Its use in therapy, and health care is a small but specialized part of its applications. It will have to be adapted to the setting of the health care institution and to the patient group one is dealing with. Also, new combinations with existing treatments will develop. Therefore, one should not equate (group) lessons in relaxation, breathing and awareness with therapy, on the only ground that one works as a health care professional or that patients join the lessons.

Our training procedure is fitted to the psychosocial condition of the MI patient and to the rehabilitation setting. Individual sessions are necessary, but parts of the training may also be incorporated in the physical exercise programme and/or in group meetings. The MI patient is in need of individual guidance and counseling because of the many problems and changes that face him or her after hospital discharge. However, this need is usually not dealt with directly because the patient often does not like to admit having problems and also because the aftercare is usally provided on a somatic level. Cardiac rehabilitation centers around exercise training, although most team members acknowledge that psychosocial effect is the main purpose. Relaxation training offers a solution to this paradoxical situation because it approaches the patient on a physical level, providing a skills training, whereas it equally deals with the subjective and emotional aspects. This dual approach is implied in the concept of "body awareness".

As to its general applicability, three main problems deserve to be mentioned: (1) the methodological coherence, (2) the qualification of the therapist, (3) the indications for application.

ad 1) A multiple relaxation system allows for ample variation in techniques and procedures by the therapist. Obviously, standardisation is only partially possible. The training system, however, should not be a random collection of techniques, or a so-called "eclectic"system, but show some degree of internal consistency. It should be possible to formulate a training criterion. In our approach this is given on a technical level by the role of respiration, which is used as an indicator and regulator of relaxation, during passive relaxation as well as in varying postures. Body awareness provides for a methodical consistency in the training. It determines the selection and sequence of techniques, as well as the topics for discussion. Therefore, the training criterion to rate success and relaxation ability consists of the ability to quieten the respiratory pattern and to adequately perceive this. Our results show that about 40% of MI patients fulfill the criterion, 45% do so incompletely, and about 15% cannot learn it at all (Van Dixhoorn, 1984).

ad 2) In a multiple relaxation training much depends on the skills of the therapist, whose task it is to match the tension pattern of the patient with the available techniques. The therapist should not only have adequate under-standing of psychosomatic processes, as well as of the musculoskeletal system, and have sufficient knowledge about the illness of the patient, but also be well-trained himself. Failure to use expert therapists is one reason that efficacy studies of relaxation often show doubtful results (Steiner & Dince, 1981). As a treatment, body awareness shares elements with medical treatment, physical therapy and psychotherapy, without being identical to any of these. Practitioners may come from any of these fields, but for further special training, there is hardly any institutional facility available, yet.

ad 3) Indications for relaxation training are usually listed in terms of medical diagnosis. This is of little value, considering that (1) relaxation is often understood as a simple technique for passive rest, and (2) medical condition will hardly predict extent of effect. Medical diagnosis may provide some indication as to treatment elements. In rehabilitation of hemiplegic patients for example, manual handling will play a large part because it effectively increases sensory input to the paralysed patient (Feldenkrais, 1977). In the case of chronic lung disorders, passive relaxation is important but repiratory control should be the first objective, either directly or indirectly (Konuk & Peper, 1984). However, the choice of specific techniques largely depends on the expertise of the therapist.

The extent of effect would probably depend on psychosocial characteristics of the patient. Relaxation as a body awareness technique affects the patient on a physical-emotional level. It affects the body, as it is experienced. Therefore, results on physical disorders may be complicated by emotional reactions and vice versa. Overall effect then, would depend on the patient's ability to change in both respects. Also, relaxation effect depends on generalisation to daily life. The life situation as well as the motivation of the patient would determine effect.

Until the issue of selection of suitable patients is clarified by further research, it is recommended to critically evaluate the treatment after 4 - 6 times and judge the progress in learning body awareness, next to improvement in specific complaints of the patient's disorder.

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Curriculum Vitae

De schrijver van dit proefschrift werd geboren op de avond van de dag (2 april 1948) dat zijn ouders naar Delft verhuisden. Hij behaalde het eindexamen Gymnasium-beta in 1966 te Velsen, het kandidaatsexamen geneeskunde aan de Medische Faculteit Rotterdam in 1969 en het artsexamen aan de Universiteit van Amsterdam in 1977. Vanaf 1973 was hij betrokken bij een onderzoeksproject van het Instituut Sociale Geneeskunde naar de toepassing van Biofeedback in de revalidatie van hartinfarct-patienten. Per 17 oktober 1977 volgde een part-time aanstelling bij het ziekenhuis St Joannes de Deo te Haarlem voor de functie "Biofeedback". Het onderzoek, waarop dit proefschrift is gebaseerd, vond in dit ziekenhuis plaats tussen 1981 en 1984 met subsidie van de Nederlandse Hartstichting.

In 1978 schreef hij, samen met de stempedagoog en ademtherapeut Bram Balfoort, het boek "Ademen wij vanzelf?". In 1979 trouwde hij met Tamiko Maeda te Osaka, en vestigde met haar de "Praktijk voor Ademtherapie" te Amersfoort. In 1984-1986 had hij een part-time dienstverband aan de afd. Medische Zaken van de Nederlandse Hartstichting. Hij is lid van de inter-universitaire werkgroepen 'Respiratoire Psychofysiologie' en 'Psychosociale Determinanten van het hartinfarct' en van de International Stress Management Association. Hij volgde daarnaast opleidingen in Acupunctuur, de Feldenkrais methode en Craniosacrale Therapie.