

LIST OF TABLES

	PAGE
TABLE 1.1 DEATHS DUE TO SMOKING RELATED CAUSES	-2
TABLE 4.1 TRIAL GROUP WORK LOAD ACHIEVED -----	62
TABLE 4.2 CONTROL WORK LOAD ACHIEVED -----	63
TABLE 4.3 CHANGE IN VE TRIAL - CONTROL -----	65
TABLE 4.4 STANDARD BICARBONATE -TRIAL -CONTROL ---	73
TABLE 4.5 CHANGE IN DISTANCE 6MWDT TRIAL - CONTROL	75
TABLE 4.6 DISTANCE COVERED IN 6MWDT -----	76
TABLE 4.7 WALKING ABILITY - TRIAL -----	78
TABLE 4.8 INITIAL CRQ SCORES -----	80
TABLE 4.9 CHANGE IN CRQ SCORES TRIAL CONTROL -----	81
TABLE 4.10 CRQ SCORES TRIAL AND CONTROL -----	85
TABLE 4.11 INITIAL LUNG FUNCTION TEST -----	87
TABLE 4.12 CHANGE IN LUNG FUNCTION TRIAL CONTROL	88
TABLE 4.13 CHANGE IN LUNG FUNCTION WITHIN GROUPS	89
TABLE 4.14 LUNG FUNCTION AFTER 2 YEARS -----	91

Abbreviations:

VE = Minute Ventilation

6MWDT = Six Minute Walking Distance Test

CRQ = Chronic Respiratory Questionnaire

8.APPENDIX -----

8.1.INFORMED CONSENT DECLARATION

8.2.INFORMED CONSENT INFORMATION

8.3.QUALITY OF LIFE QUESTIONNAIRE

8.3.1.First administration

8.3.2.Follow up questionnaire

8.3.4.Letter from G.Gyatt

8.4.RATING OF PERCEIVED EXERTION - BORG SCALE

	PAGE
5.DISCUSSION -----	94
5.1.SAMPLE	94
5.1.1.SAMPLE SIZE	94
5.1.2.SAMPLE SIZE AT EACH TEST	94
5.2.BICYCLE ERGOMETER TEST	96
5.2.1.WORK LOAD ACHIEVED	96
5.2.2.MINUTE VENTILATION (VE)	97
5.2.2.1. VE AND BLOOD GASES	99
5.2.2.2. VE AND LUNG FUNCTIONS	100
5.3.THE SIX MINUTE WALKING DISTANCE TEST(6MWDT)	103
5.4.WALKING ABILITY	104
5.5.CHRONIC RESPIRATORY QUESTIONNAIRE	106
5.5.1.DYSPNOEA	107
5.5.2.EMOTIONAL FUNCTION	108
5.5.3.FATIGUE	109
5.5.4.MASTERY	110
5.5.5.LACK OF SIGNS OF DETERIORATION	110
5.6.LUNG FUNCTIONS	112
5.6.1.HYPERINFLATION	112
5.6.2.MAXIMAL VOLUNTARY VENTILATION (MVV)	113
5.7.COMPLIANCE	114
5.7.1.COMPLIANCE IN TRIAL GROUP	114
5.7.2.COMPLIANCE IN CONTROL GROUP	115
6.CONCLUSION	117
7.REFERENCES	120

	PAGE
2.8.1.CYCLE ERGOMETRY OR TREADMILL TEST	34
2.8.2.SIMPLE WALKING TESTS	36
2.8.2.1.SIX MINUTE WALKING DISTANCE TEST	37
3.METHOD -----	40
3.1.SUBJECTS	40
3.2.ENTRANCE CRITERIA	40
3.3.TESTS PERFORMED	41
3.3.1.BICYCLE ERGOMETER TEST	42
3.3.2.SIX MINUTE WALKING TEST	46
3.3.3 QUALITY OF LIFE QUESTIONNAIRE	48
3.3.4.LUNG FUNCTION TEST	51
3.4.THE REHABILITATION PROGRAMME	54
3.4.1.PROCEDURE	54
3.4.2.TRIAL	56
3.4.3.CONTROL	59
4.RESULTS -----	61
4.1.BICYCLE ERGOMETER TEST	61
4.1.1.WORK LOAD	61
4.1.2.VENTILATION	64
4.1.3.METABOLIC RESPONSES	64
4.1.4.BLOOD GASES	70
4.2.SIX MINUTE WALKING TEST	74
4.3.WALKING ABILITY	77
4.4.PSYCHOMETRIC QUESTIONNAIRE	79
4.5.LUNG FUNCTION TEST	86

TABLE OF CONTENTS

	PAGE
DEDICATION	i
ACKNOWLEDGEMENTS	ii
DECLARATION	iii
ABSTRACT	iv
1. INTRODUCTION -----	1
1.1. EXERCISE & COPD	1
1.2. PATHOPHYSIOLOGY	4
2. LITERATURE SURVEY -----	6
2.1. ROLE OF EXERCISE IN REHABILITATION	7
2.2. CONTROLLED STUDIES	8
2.3. HOME PROGRAMMES	10
2.4. PSYCHOLOGICAL EFFECTS IN REHABILITATION	11
2.5. PSYCHOMETRIC QUESTIONNAIRES	14
2.5.1. TYPE OF QUESTIONNAIRE	14
2.5.2. MEASUREMENT PROPERTIES	17
2.6. PHYSIOLOGICAL CHANGES	18
2.6.1. CAUSES OF ABSENCE OF PHYSIOLOGICAL CHANGES	21
2.7. EXERCISE RETRAINING PROGRAMME	30
2.7.1. INTENSITY OF EXERCISE	31
2.7.2. DURATION OF PROGRAMME	33
2.8. TESTS FOR EVALUATING EXERCISE	34

test and full lung functions were done on all the subjects.

No definite changes were found in any of the physiological parameters measured in either group. Both groups produced evidence of an improvement in their quality of life. This improvement was greater in the trial subjects. Compliance in long term participation in this programme was better than that shown in other studies.

ABSTRACT

A study was undertaken to ascertain whether a low intensity, long term home walking exercise programme could produce physiological changes in patients with chronic obstructive pulmonary disease (COPD). Subjective psychological effects of such a programme were also evaluated.

Twenty subjects (twelve trial and eight controls) with COPD participated in the study. All the subjects attended an ongoing programme which exists at the Johannesburg Hospital where patients are taught to manage their condition. This was done by means of education, group support, breathing retraining and relaxation techniques. They are also taught to manage pulmonary mucus and to manage exacerbations caused by bronchial infections.

The trial subjects participated in the hospital programme as well as a structured low intensity walking programme which they carried out at home. The subjects visited the hospital two to four times a month to attend the above mentioned programme and to have their walking schedule monitored and adjusted.

All subjects were tested at five monthly intervals. They performed a bicycle ergometer exercise test where ventilation, metabolic effects and blood gases were evaluated. They answered a disease specific quality of life questionnaire. A six

Declaration.

I declare that this dissertation is my own unaided work.
It is being submitted for the degree of Master of Science in
Medicine in the University of the Witwatersrand, Johannesburg. It
has not been submitted before for any degree or examination in any
other University.

D. J. J. J.

(Name of candidate)

30th day of June, 1994.

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I would like to thank the following people without whose help this thesis would never have reached this stage.

1. My supervisors, Professors Zwi and Rogers for all the time and advice which I received from them.

2. My family for their support.

3. Shula Werner, Anna Mathias and Muriel Goodman for pushing me into attempting this project.

4. Reggie Cohen and Christine van Staden for their assistance clinically and administratively.

5. My patients who volunteered to be subjects in the trial for a whole fifteen months.

7. The late Mr Goldman for doing the lung functions and doing the ear lobe blood tests of all the subjects.

8. My colleagues at the Johannesburg hospital for all their interest and support.

DEDICATION

I hereby dedicate this thesis to the memory of my
parents who always supported me in all my endeavours
throughout my life.

APPLICATION TO THE COMMITTEE FOR RESEARCH ON HUMAN SUBJECTS FOR CLEARANCE
OF RESEARCH PROTOCOL INVOLVING PROCEDURES ON HUMAN SUBJECTS.

CC

THIS APPLICATION MUST BE TYPED

PROTOCOL NO.
(office use only)

22/5/88

1. NAME : PROF/DR/MR/MRS/MISS Diana COHEN
2. PROFESSIONAL STATUS : Senior Physiotherapist.
3. UNIVERSITY DEPARTMENT : Medicine.
4. HOSPITAL OR INSTITUTION WHERE EMPLOYED : Johannesburg Hospital.
FULL-TIME OR PART-TIME? : Part-time.
5. TELEPHONE NO./EXTENSION : 488-3640.

TITLE OF RESEARCH PROJECTS :

A trial to assess the clinical effects of an exercise retraining programme on patients with chronic obstructive airways disease.

EXPECTED DATE OF COMMENCEMENT : As soon as possible.

WHERE WILL THE WORK ON THE HUMAN SUBJECT BE CARRIED OUT ?
(PLEASE FURNISH NAME OF HOSPITAL/INSTITUTION AND THE PARTICULAR DEPARTMENT)

Department of Medicine (Pulmonology Division) Johannesburg Hospital.

NB : IF THIS PROJECT INVOLVES STUDIES WITH DRUGS, APPROVAL MUST FIRST BE OBTAINED FROM THE PHARMACEUTICS AND THERAPEUTICS COMMITTEE.

IF ANY DOUBT EXISTS, THE SECRETARY OF THE P & T COMMITTEE SHOULD BE APPROACHED :

TELEPHONE : Johannesburg Hospital 643-0111 X 2108/9 (Mrs Parkin)
Baragwanath Hospital 933-1144 X 2146 (Dr G Louw)
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J G Strydom Hospital 726-5128 X 418 (Dr R Dowdeswell)
Coronation Hospital 613-4200 X 157 (Dr O Ransome)

IF THE PROJECT IS CLEARED, A COPY OF THE CLEARANCE FORM SHOULD BE SUBMITTED TOGETHER WITH THIS APPLICATION.

A TRIAL TO ASSESS THE CLINICAL
EFFECTS OF AN EXERCISE
RETRAINING PROGRAMME ON
PATIENTS WITH CHRONIC
OBSTRUCTIVE PULMONARY DISEASE

BY: Diana Cohen

A dissertation submitted to the Faculty of Medicine,
University of the Witwatersrand, Johannesburg for the degree
of Master of Science in Medicine.

improvement in exercise capacity than a control group. Busch and Clements (1988) did a study where two groups of patients were placed on a home programme. Each group was visited by the physiotherapist weekly. The one group was given an exercise programme which was supervised by the physiotherapist on her weekly visit. The other group was not involved in exercise at all but were merely assessed by the physiotherapist at each visit. After 18 weeks the control group deteriorated in their work capacity by 18% while the exercise group improved by 13%.

2.3. Home programmes

Many of the patients who are referred to us with COPD are unable to attend the programme regularly because they do not possess private transport and can not afford public transport. A home programme is thus far more practical. Tyderman et al (1984) carried out a study where they exercised eight patients at home and eight patients in hospital for an average of 36 weeks. They found that both groups improved equally in the distance walked and in their sense of well being. Home programmes carried out by McGavin et al (1977) Busch et al (1988) and Mall et al (1988) also reported on favourable results. Holle and Williams (1988) initially exercised their patients under the supervision of a respiratory

such as: being a volunteer in a therapeutic study, increased contact with health care professionals etc." This reduces the credibility of uncontrolled trials.

Two studies, one done by Vyas et al (1971) and another done by Alpert et al(1974) reported on slight physiological changes after exercise reconditioning in COPD but neither trial had a control group.

Jones et al(1988) compared three different groups of patients with COPD. One group was given an exercise programme. The second group exercised their inspiratory muscles by breathing against a device that resisted inspiration. The third group breathed through a placebo device. They found that all three groups improved in the 12 minute walking distance test as well as in the work load exercised on a bicycle ergometer.

There are other controlled studies, however, that have shown differences between the groups. Cockcroft and Berry (1982), when comparing a group who participated in an exercise programme with a group who did not, found that both groups improved psychologically. The exercise group only, however, exhibited an improvement in work capacity. Chester and Belman(1977) also reported on the fact that their exercise group was able to show a greater

can exercise submaximally only. Submaximal testing can only give a crude indication of physical fitness. Patients benefitted socially by the fact that they were able to reduce their " exertion phobia". They felt that even patients who became hypoxic on exercising could participate in exercise under careful supervision.

Two reviews by Lee and Smythe (1985) and Gimenez (1989) agreed that exercise was valuable for patients with COPD, but studies on the subject lacked standardization in respect of patient samples, testing procedures, types of exercise programmes and the final outcomes examined. They also felt that no differentiation was made between the results produced by learning effects and actual psychological and physical causes. These factors could affect the acceptability of some of the reported results.

Bundgaard et al (1984) and Braun et al (1982) in their reviews both reported that exercise for chronic lung sufferers was worthwhile and safe provided it was monitored carefully.

2.2. Controlled studies.

Many of the studies reviewed in the literature were not controlled. Levine et al (1986) stated that "Other factors may contribute to the improvement.

is known to increase the incidence of cor pulmonale and death amongst patients with COPD (Sahn et al 1980). Hospital admissions were low for the Petty group of patients and a large percentage of them were able to return to or regain employment. Staffing for the programme was provided by existing hospital personnel. They thus felt that a rehabilitation programme as described was beneficial for patients with COPD. They also found that their programme was cost effective. A later publication on the subject by Toevs et al (1984) confirmed the cost effectiveness of these programmes. This group analyzed the expenses of behavioral rehabilitation programmes for these patients taking all factors into account and found a financial gain for both the individual and the hospital concerned.

2.1. The role of exercise in rehabilitation programmes.

In 1976 Morley et al reviewed the constituents of a rehabilitation programme and recommended the inclusion of exercise in the programme. Hudson and Pierson in 1981 and Higgs in 1983 agreed with this view.

Cox et al in their review on exercise and COPD (1988) believed that under certain circumstances, exercise produces cardiovascular improvement. Unfortunately many of these patients

CHAPTER 2. LITERATURE SURVEY

Rehabilitation programmes for patients with chronic obstructive pulmonary disease have been well represented in the literature. In most of the programmes described, exercise plays a pivotal role. In spite of this, there is very little information available indicating that exercise produces any physiological changes which could alter the course of the disease. This, together with the fact that exercise can cause hypoxia with adverse physiological effects in some of these patients, has led some people to believe that exercise in patients with COPD should not be recommended.

Sahn, Nett and Petty (1980) reported on a programme that has existed in Denver, Colorado since 1968. This programme for patients with COPD includes education, bronchial hygiene, breathing retraining, physical reconditioning and individualized pharmacology and oxygen therapy. They found that patient survival after five years was 41% and after ten years it was 17%. This was similar to survival rates for patients with COPD not exercising but living at sea level. This was however, considerably better than survival figures at altitude. Denver is situated at a high altitude which

between these three conditions. Clinically, it is difficult to differentiate categorically between them as a great deal of overlap exists in the three conditions. Wanner(1990), said that " it is difficult to determine the degree to which luminal secretions narrow the airway lumen and contribute to airway obstruction in patients with COPD in whom other mechanisms of airflow limitation are also operative". This problem has also been pointed out by others in the literature (Lee et al 1985, Gimer 1989) To eliminate misunderstanding, reduced airflow and resultant hyperinflation are used as the main selection criteria in choosing the subjects. The reduction in airflow is calculated as a percentage of that predicted for age, sex and height.

Some of the subjects have shown a certain amount of reversibility in airflow obstruction on treatment with a bronchodilator. In order to eliminate those subjects who have asthma and who show variable responses to treatment which could interfere with the interpretation of the results, subjects who show a reversibility of greater than 20% were excluded from the study.

1.2. PATHOPHYSIOLOGY OF COPD

In order to clarify the criteria which I used in order to select the sample in my study I will give a brief summary of the relevant pathophysiology.

The definition which was given by the American Thoracic Society in their official statement of 1986 was used as a guideline. The statement defined COPD as "a disorder characterised by abnormal tests of expiratory flow that do not change markedly over periods of several months observation". The definition further states that: "The abnormal airflow may be structural or functional. Specific causes of airflow obstruction such as localized disease of the upper airway, bronchiectasis and cystic fibrosis are excluded. Bronchial hyperreactivity may be present as measured by an improvement in airflow following the inhalation of a beta - adrenergic agent or worsening after inhalation of methacholine or histamine.

Three disorders are incorporated into COPD: emphysema, peripheral airways disease and chronic bronchitis."

In this study no distinction has been made

INTRODUCTION

from medical treatment is limited, exercise is definitely an alternative that should be considered.

Due to the nature of their disease, patients with COPD almost always complain of dyspnoea and diminished exercise capacity. Generally these patients are older and physical prowess and achievement play a less important role than they do in younger people. High intensity aerobic exercises and daily attendances at a gym do not appeal to these patients on the whole.

In this group of patients compliance in an exercise programme is a problem. Atkins et al (1984) reported that compliance was a major problem when organizing exercise programmes for these patients. They stated that most studies found that less than half of those who initiate an exercise programme were still participating after three to six months.

In this study, I have attempted to assess whether a long term exercise programme of low intensity exercise carried out at home by patients with COPD can produce objective physiological benefits. This type of exercise is more acceptable for this patient population. It could also prove to facilitate compliance in such programmes.

Table 1.1* Proportion of all deaths due to smoking-related causes in South Africa, 1988, by race and gender

	African		White		Coloured		Asian	
	Men	Women	Men	Women	Men	Women	Men	Women
Total death	70726	46403	21792	18156	15006	10930	3202	2162
% DUE TO:								
Ischaemic heart disease	0.9	0.8	23.1	17.2	6.4	6.8	19.5	14.5
Lung cancer	1.3	0.5	4.8	2.7	4.1	1.8	1.6	0.7
Pulmonary circulatory disease	0.8	1.0	2.2	2.6	1.0	1.2	0.8	1.1
Chronic obstructive airways disease	2.7	2.3	6.5	5.6	6.4	4.6	7.3	4.3
Aortic aneurysm	0.1	0.1	1.3	0.6	0.2	0.2	0.1	0.1
TOTAL	5.8	4.7	37.9	28.7	18.1	14.6	29.3	20.7

* From "Smoking in S. Africa: Health & Economic Impact" by Yach D, Saloojee Y & McIntyre D. With permission of Yach D.

Table 1.1* **Proportion of all deaths due to smoking-related causes in South Africa, 1988,
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Pulmonary circulatory disease	0.8	1.0	2.2	2.6	1.0	1.2	0.8	1.1
Chronic obstructive airways disease	2.7	2.3	6.5	5.6	6.4	4.6	7.3	4.3
Aortic aneurysm	0.1	0.1	1.3	0.6	0.2	0.2	0.1	0.1
TOTAL	5.8	4.7	37.9	28.7	18.1	14.6	29.3	20.7

* From "Smoking in S. Africa: Health & Economic Impact" by Yach D, Saloojee Y & McIntyre D.
With permission of Yach D.

INTRODUCTION

CHAPTER 1. INTRODUCTION

1.1. EXERCISE AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE

A study was done in 1991 by Yach et al on the impact of smoking on health in South Africa. They looked into the proportion of deaths due to smoking related caused and found the following: (see table 1.1)

With the exception of ischaemic heart disease, chronic obstructive airway / pulmonary (COPD) disease was the greatest tobacco related cause of death in South Africa in 1988. When converting these figures to actual numbers 1,909 men and 1,626 women died of the disease in that year. This does not, however reflect the morbidity caused by this condition, which, no doubt would represent much greater numbers. Any medical intervention that has an effect on chronic COPD is thus relevant to a large number of people in this country.

In the South African Continuing Medical Education Journal of February 1993, Nowitz asked if "exercise can be considered an appropriate medical intervention?" She felt that in COPD where the amount of actual improvement that can be obtained

LIST OF FIGURES

FIG.2.1 IMPAIRMENT DISABILITY HANDICAP -----	13
FIG 4.1 INITIAL EXERCISE TEST TRIAL GROUP -----	66
FIG.4.2 INITIAL EXERCISE TEST CONTROL GROUP -----	66
FIG.4.3 EXERCISE TEST 5 MONTHS TRIAL GROUP -----	67
FIG.4.4 EXERCISE TEST 5 MONTHS CONTROL GROUP -----	67
FIG.4.5 EXERCISE TEST 10 MONTHS TRIAL GROUP -----	68
FIG.4.6 EXERCISE TEST 10 MONTHS CONTROL GROUP -----	68
FIG.4.7 EXERCISE TEST 15 MONTHS TRIAL GROUP -----	69
FIG.4.8 EXERCISE TEST 15 MONTHS CONTROL GROUP -----	69
FIG.4.9 OXYGEN SATURATION CONTROL GROUP -----	71
FIG.4.10 OXYGEN SATURATION TRIAL GROUP -----	72

They categorised the limitations as follows:

- i. Pulmonary mechanics and ventilatory muscles
- ii. Gas exchange.
- iii. Dyspnoea and breathing control.
- iv. Cor pulmonale.

2.6.1.1. PULMONARY MECHANICS AND VENTILATORY MUSCLES

As early as 1976 Butler, in a study where he looked at the effects of diaphragmatic changes in emphysema, reported that the flattening of the diaphragm which occurs due to hyperinflation in emphysema led to shortening of its fibres. He stated that this shortening did not produce atrophy as much as it produced "contracture" of the diaphragm. At a conference held in 1983, Roussos found that in emphysematous hamsters, this "contracture" was due to a reduction in the number of sarcomeres in the diaphragmatic muscle. This same effect was found in the autopsies of humans who had emphysema.

Similowski et al (1991) were of the opinion that this reduction in the number of sarcomeres was an adaptation of the diaphragm to the abnormal mechanics. They did not find that the contractile properties of the diaphragm in patients with emphysema were any worse than that in normal subjects when stimulated electrically.

lactate accumulation in their plasma after training.

The general consensus of opinion in the literature thus seems to be that exercise retraining does improve work capacity and quality of life in people with COPD. There is not sufficient evidence however, to indicate any concrete physiological changes resulting from these programmes.

An outcome criterion which is very difficult to measure but nonetheless important is that exercise reduces the risk of cardiac disease. Blair et al (1989) in an eight year follow up study, found that, even with a moderate amount of exercise, the chance of dying of cardiac disease was considerably reduced.

2.6.1 .WHY DO THE PROGRAMMES NOT PRODUCE PHYSIOLOGICAL CHANGES

The preceding literature indicated the lack of physiological signs of improvement could be attributed to the fact that patients with COPD are unable to exercise enough to produce these physiological changes.

At a symposium in 1984, Loke Mahler et al summed up the limitations that chronic lung pathology inflicts on the work ability of sufferers. Using their guidelines, I would like to examine these limitations.

results in a rise in ventilatory rate. The athletes with lower concentration of lactate can thus exercise for longer without experiencing uncomfortable dyspnoea. Should patients with COPD react in the same way after being trained, it would be a distinct advantage .

Wasserman et al (1989), found that patients who could not exercise sufficiently to produce a lactic acidosis did not benefit physiologically from an exercise programme.

In 1991 Casaburi et al showed that patients with COPD who exercised at loads that produced a greater metabolic acidosis were able to show a larger reduction in blood lactate and a lower minute ventilation after training. They divided their subjects into two groups. The one group exercised at a high work rate (90% of maximum capacity) while the other group worked at a low work load (60% of maximum capacity). Both groups exercised for forty five minutes per day, either in one session or, if they were unable to exercise for so long, it was divided into up to five sessions. The group who exercised at the higher work load were able reduce their lactate and ventilation to a greater extent after training than those who exercised at a lower work load. Both groups, however exhibited a lower

Moser et al(1980) did extensive tests on their patients. They classified the patients into definite functional categories and found that those who had participated in an exercise programme were able to improve their functional abilities. This improvement extended into their activities of daily living, but they too could not show definite physiological changes.

Mungall and Hainsworth(1980) found that their patients showed a small improvement in lung functions but no improvement in cardiorespiratory indices of physical fitness. They felt that this was due to the fact their subjects were too severely disabled and were unable to exercise at a high enough load to produce these changes.

According to Jones and Ehrsam (1983), a fall in the bicarbonate concentration of plasma occurs during exercise which is equimolar to the rise in plasma lactate concentration in normal subjects.

$\text{LaH} + \text{NaHCO}_3 \rightarrow \text{NaLa} + \text{CO}_2 + \text{H}_2\text{O}$. where LaH = Lactic acid, NaHCO_3 = Sodium Bicarbonate, NaLa = Sodium lactate .

It has been shown that the increase in concentration of lactate occurs at a higher oxygen consumption (VO_2) in trained athletes than in untrained subjects (Jones et al 1983). Accumulation of lactate gives rise to metabolic acidosis which

2.6. Physiological changes resulting from exercise programmes

Reports on definite physiological changes produced by pulmonary rehabilitation programmes are few. Many studies reported on improvement in work capacity after participation in exercise retraining in patients with COPD. Changes such as increased oxygen consumption, increased muscle enzymes, improved muscle oxygen extraction and increased capillary circulation (Jones 1989), are not always obvious in patients with respiratory limitation. Chester et al (1977) and Alpert et al (1974) could not prove any physiological training effects after exercise retraining. McGavin et al (1977) also could only report on an increased ability to perform exercise in their subjects after a three month home exercise programme. Belman (1985) reported that when measurements were made in patients with COPD at a similar submaximal oxygen consumption ($\dot{V}O_2$) after an exercise programme, no definite difference could be shown in heart rate, stroke volume, cardiac output, arteriovenous difference and blood lactate levels. Another study which Belman did with Kendregan in 1981, could not show improvement in skeletal muscle enzymes after training COPD patients.

For a questionnaire to be suitable for use in a scientific study, Fitzpatrick et al (1992) and Beyo and Centor (1986), have identified it must possess the following properties : - Validity, reliability and responsiveness.

Gyatt published several articles describing the tests that he and his coworkers did to ascertain whether the Chronic Respiratory Questionnaire (CRQ) fulfilled the necessary criteria to be acceptable for use in studies on the quality of life of respiratory patients (Gyatt et al 1985, Gyatt et al 1987a, 1987d, Kirschner and Gyatt 1985, Gyatt 1988, Gyatt et al 1989). They found that their questionnaire fulfilled all three properties mentioned above.

P.W.Jones (1991a) and Morgan (1991), in two separate articles, questioned the usefulness of the CRQ. The CRQ individualizes the subject's problems by allowing the subject to state actual activities that result in dyspnoea. They felt that this made the questionnaire unsuitable to be used when comparing different populations in comparative studies. Morgan found that the CRQ was not suitable for testing children or those patients who exhibited minimal symptoms. As these objections were not applicable to my trial, I have found the CRQ questionnaire valuable.

COPD. Factors such as symptoms, activity and impacts on the patient are evaluated. The usefulness of this questionnaire was discussed in the Respiratory Medicine Journal in 1991b. This questionnaire has not as yet been fully investigated.

2.5.1.3. Dimension or item specific questionnaires are questionnaires in which only specific dimensions such as dyspnoea are investigated. An example of this type is the Dyspnoea Index Questionnaire designed by Mahler et al in 1984. Mahler et al (1988), when comparing their questionnaire with two other questionnaires, found that it correlated better with lung function scores than the others did. Unfortunately physiologic indices do not always give a good indication of the individual's personal quality of life perception. For the measurement of quality of life, this type of questionnaire is too limiting and may fail to give an overall picture of the patient's perception of his/her quality of life. In a pilot study we used this questionnaire with limited success.

Another questionnaire which looks at respiratory patients' perception of their own breathlessness is the Oxygen Cost Diagram reported on by McGavin et al (1978)

2.5.2. MEASUREMENT PROPERTIES OF THE QUESTIONNAIRE.

in a single questionnaire. Examples of these kind of questionnaires are the Minnesota Multiphasic Personality Inventory (MMPI) and the sickness impact profile. These questionnaires are long and time consuming to administer. These questionnaires were used by Lustic et al (1972), Cockcroft et al (1982) and Agle et al (1973) (see 2.4.)

2.5.1.2. Disease specific questionnaires

- This includes the chronic Respiratory Disease Questionnaire (CRQ), which was designed by Gyatt in 1987a and in 1987c. This is the questionnaire that was used in this study (see Method).

Busch and Clements, when evaluating their home exercise programme for patients with COPD, made use of part of the Chronic Respiratory Disease questionnaire (CRQ) (see 2.2. section of this thesis). They evaluated only the patients' response to dyspnoea after participating in their trial. The quality of life in patients with COPD involves much more than just their perception of dyspnoea. For this reason, even though their results were favourable, I do not believe that they can categorically state the quality of life of their patients improved.

The St Georges' respiratory questionnaire designed at St Georges' hospital in London and reported on by Jones (1991a) also looks at specific factors that affect patients with asthma and

thus improve patient's perception of their functional worth.

2.5. Psychometric Questionnaires

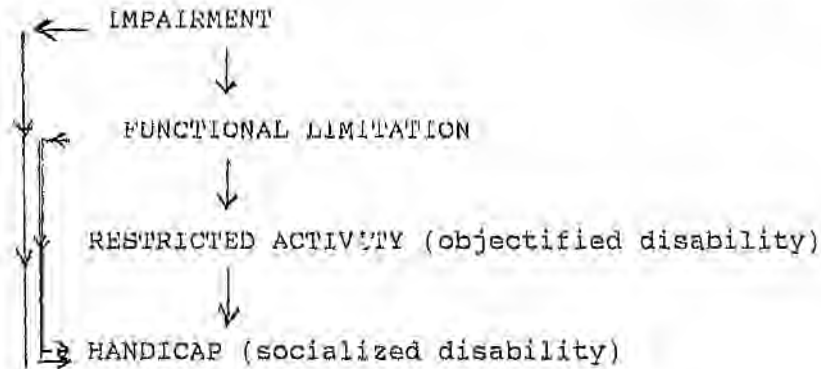
The necessity of evaluating the effects of treatment on the quality of life of chronically ill patients is a well accepted fact. How to measure this quality of life, however, is disputed. Quality of life is a very subjective perception. In order to have a scientifically acceptable tool to measure this, the tool must adhere to definite standards. In a series of articles published in the October and November issues of the British Medical Journal in 1992, quality of life questionnaires were analyzed. Fitzpatrick et al discussed the need for using quality of life questionnaires and their value in clinical trials. Fletcher examined the design of these questionnaires, their application and their interpretation.

Using the B.M.J. articles as guidelines, I examined the use of questionnaires in the literature as follows:

2.5.1. TYPE OF QUESTIONNAIRE.

Quality of life questionnaires can be divided into three types.

2.5.1.1. Generic questionnaires which cover a broad range of general quality of life dimensions



(from Williams 1989 pg 798)

Quality of life is dependant on the individual's perception of his/her own worth. Decreased functional ability leads to the feeling of being handicapped. All the psychological support one can give the patient with COPD is not good enough if it is not accompanied by improvement in function.

Henderson and Cole (1993) did a study using the self efficacy theory, and tested COPD patients before and after an exercise programme. The self efficacy questionnaire assesses the individual's judgement of their capabilities to achieve designated performances. They found that these patients showed a significant improvement in their physical efficacy (how much physical work they were able to achieve) as also an improvement in their emotional efficacy which was not, however as significant as the physical. Exercise programmes can

not. The exercise group improved slightly more than the non exercise group.

Cockcroft et al (1982), in a similar study did not find a correlation between exercise ability and psychological scoring between two groups of patients with COPD, one of which participated in an exercise retraining programme and the other not. The tests used in this study were the Lorr McNair test and the Eysenck Personality test. Both these tests were generalised psychological tests for quality of life.

Agle et al found in a study done in 1973 in which they examined the psychological scores of patients who had been involved in a comprehensive rehabilitation programme for one year, that those who exhibited the greatest functional improvement also showed the greatest psychological improvement. They assessed the psychological improvement by means of psychiatric interviews.

A flow diagram (fig.2.1.) which appeared in a review on the psychosocial nature by Williams in 1989 illustrates the importance of functional ability on the quality of life in respiratory disease:

Fig 2.1 RELATIONSHIP BETWEEN IMPAIRMENT, DISABILITY AND HANDICAP.

therapist three times a week for six weeks, and then they were given a home exercise programme. Twelve months later 24 of the subjects had improved their exercise capacity by 129%. They calculated the total cost of the programme to be between 600 and 800 dollars. This reinforces the opinion that home programmes are could be cost effective and show positive changes for these patients.

2.4. Psychological effects in rehabilitation

Dudley et al in a revue on the psychosocial concomitants in COPD (1980) stated that the role of psychosocial and psychological techniques could not be overemphasized in rehabilitation programmes. Sandhu in a review (1986) also insisted that psychosocial support was of the utmost importance.

Lustig et al (1972) tested patients with COPD extensively using three well known psychological tests i.e. the Minnesota Multiphase Personality Inventory (M.M.P.I.), Medical Orientation Scale and the Work Attitude Scale. They then divided the patients into three groups. One group received exercise and relaxation therapy. The other received psychotherapy and the third group were simply observed over the trial period (six to seven weeks). They found that the first two groups improved on the psychological tests while the third group did

most of them were unable to produce conclusive evidence of physiological improvement.

Mall and Madeiros (1988) followed up 101 patients who had participated in an outpatient community hospital rehabilitation programme over a period of one to five years. They reported on changes in the anaerobic threshold in these patients. Unfortunately it is not clear how many patients were followed up for one year and how many were followed up for more.

Booker (1984) did her study over 12 months and found some changes in lung function in a group of patients who received breathing retraining as well as exercise retraining. She did not report on any other changes in physiological parameters. In my study the patients were followed up for a period of fifteen months.

2.8. Tests for evaluating the effects of exercise in exercise rehabilitation programmes

2.8.1. INCREASING LOAD CYCLE ERGOMETRY OR TREADMILL TEST.

An exercise test is the best way of obtaining objective assessment of exercise tolerance. Spiro (1977) reviewed exercise testing in clinical medicine and felt that increasing work load exercise tests formed the bases of clinical testing. In such a

heart rate. Patients with COPD should exercise for a longer time daily, even if the programme is broken up into several smaller periods.

A study by Gobel in 1991 showed that, even in cardiac patients, exercise of lower intensities can produce favourable results. He found that a group of cardiac patients who participated in a programme of light exercise training showed the same amount of improvement in their performance on a treadmill as a group who had done carefully monitored aerobic exercise training over 1 year. Patients with COPD may show the same effects.

2.7.2. DURATION OF PROGRAMME

The American Sports medicine statement on physical fitness, found that people who are sedentary have to train for longer periods in order to produce physiological changes associated with improved physical conditioning. Patients with COPD, due to the fact that activity results in dyspnoea, usually take up a sedentary life style. In many of the studies reviewed the programmes have been carried out over short periods of time. Examples of these are Busch et al (1988) - 18 weeks, Cockcroft et al (1982) - 8 weeks, Alpert et al (1974) - 18 weeks, Casaburi et al (1989) 8 wee's. This may explain why

When comparing patients who managed to exercise to their aerobic threshold (AT) with those who did not, they found that there were no significant differences in the benefits derived from exercise training between the two groups. They determined AT noninvasively by examining the pattern of the ventilatory equivalent of O₂ ($\dot{V}_E/\dot{V}O_2$) and CO₂ ($\dot{V}_E/\dot{V}CO_2$) as well as the respiratory quotient (R) at increasing loads. This differs from the results of the study done by Casaburi et al (1991) (see 2.6.)

Carter et al (1992) also attempted to establish guidelines for training patients with COPD. They exercised their patients to their ventilatory limits. They also exercised them for longer periods per day (ie 64 to 80 minutes) than other studies have done (Casaburi 1991). This was done by allowing the subjects to exercise at least twice a day. The programme was done in hospital for 12 days and then at home for 3 months after that. Their results showed an improvement in the exercise tolerance and a reduction in dyspnoea in these patients. They reported on an increase in $\dot{V}_E$, most of which was accounted for by an increased tidal volume at peak exercise. After 3 months of training, O₂ consumption and CO₂ production at rest decreased.

They concluded that training intensity in COPD should depend on ventilatory limitation and not on

max. (maximal oxygen consumption) or 50% - 90% of age predicted maximal heart rate ($220 - \text{age}$) carried out for 15 to 60 minutes (continuous or discontinuous) is required to produce an improvement in fitness. These guidelines apply to normal subjects. I am not sure if they are relevant in patients with COPD who possess abnormal respiratory mechanics and are thus unable to achieve the same maximal oxygen consumption as their normal peers.

2.7.1. INTENSITY OF EXERCISE

Punzal et al (1991) questioned using heart rate as a means of determining intensity for exercise training in COPD. They believed that exercise training based on principals derived from those for normal subjects and cardiac patients are misapplied when used for patients with COPD who are limited by other factors than their heart and skeletal muscle function. In their study where 57 patients with COPD participated in a walking retraining programme for 8 weeks, their subjects showed a reduced exercise tolerance in relation to ventilatory limitation (ie high VE/MVV ratio). They trained their patients at higher percentages of their maximal heart rate than was previously recommended. They used ventilatory indication to prescribe exercise ie they used dyspnoea as an indication for termination of exercise.

2.6.1.4. COR PULMONALE

A fact which can not be ignored is -" what will the eventual toll be on the patients cardiovascular system as a result of exercise?" Bahler et al (1977) found that pulmonary arterial wedge pressures were raised on exercise in patients with COPD. These effects were aggravated more by excessive ventilatory effort than by hypoxia.

In a study on the limitation of exercise in COPD, Hughes and Davison (1983), reported that several studies had found that COPD produced adverse effects on cardiac function. Exercise stresses cardiac function and may thus accentuate these effects.

Stewart et al (1985) showed that in patients with COPD cardiac output did not increase sufficiently during exercise. He found that this was caused by the hyperinflated thorax. Biernacki et al (1988) found that the pulmonary hypertension exhibited by these patients did not affect ventricular contractility. It is nevertheless probable that exercise in COPD can result in considerable strain to the heart.

2.7. Intensity and duration of the programme

According to the 1990 American College of Sports Medicine statement on physical fitness, physical activity corresponding to 40% - 80% of $\dot{V}O_2$

stabilization does not always occur in chronic lung disease.

Kepron and Cherniak (1973) when studying the response to the inhalation of carbon dioxide of chronic respiratory patients and normal subjects found that the patients presented with blunted responses to CO₂. Those who suffered from chronic hypoxia showed a slower response to CO₂ than those who were not hypoxic. Although this reduced response may serve to protect the respiratory muscles, it also reinforces the abnormal blood gas picture.

Fahey and Hyde (1983) attempted to differentiate between patients whose exercise capacity was limited by their respiratory musculature and those who did not have the neurological ability to respond to the demand (can't breathe against won't breathe). They discovered that by looking at the ventilatory response of their subjects to CO₂ and comparing it to their measured MVV against the predicted MVV, a prediction could be made as to which subjects were limited from exercising at adequate intensities by their ventilatory muscles, and which were limited by their neurogenic drive to breathe. Although a little complicated, this equation may be a useful when assessing the ventilatory limitation in a patient with COPD.

be caused by deterioration in blood gases and fatigue of respiratory muscles.

This theory is reinforced in a study done by Light and Muro (1989) where patients with COPD were given morphine, a drug which alleviates the unpleasant sensation of breathlessness. These patients were able to improve their exercise capacity considerably. They, however, exhibited a marked deterioration in their blood gases while exercising.

Altose (1985) believed that the sensation of breathlessness is due to two factors. Firstly it is due to the quantity of ventilation required for the activity relative to the maximal voluntary ventilation of which the patient is capable. Secondly this sensation is effected by the neurological response to the demand for ventilation. At rest, this response or drive to breathe is dependent on the changes produced in the blood gases which act on the chemoreceptors in the medulla and in the carotid bodies. In normal subjects blood gases do not change during exercise. In patients with COPD, however, exercise often causes an increase in PCO_2 and a decrease in PO_2 . (D'Urzo et al 1989, Kepron 1973) These changes should make the patient hyperventilate in order to stabilize the blood gases. It appears that this

Dyspnoea or the unpleasant awareness of breathing during activity, is the single most common symptom complained of by patients with COPD. The American Thoracic society in an official statement on the evaluation of impairment and disability secondary to respiratory disease in 1982 stated that dyspnoea could not be used as the "sole criterion for evaluating impairment because the causes of dyspnoea are multiple and complex." This is indeed true as shown by Campbell (1963) in an early investigation. He attributed dyspnoea to a disturbance in the relationship of length and tension of the respiratory muscles. He also stated, however that this sensation was affected by neurological and psychological factors.

While looking at breathlessness associated with exercise, Jones (1984) found that this breathlessness was due to an increased metabolic demand which gives rise to an increased ventilatory response. In patients with chronic respiratory lung disease, the ventilatory musculature is compromised and thus cannot produce the increased ventilatory response required for exercise leading to further exacerbation of dyspnoea.

Killian and Jones (1984) believe that this breathlessness should be viewed as a protective mechanism to prevent respiratory failure which could

patients were affected by the increased work of breathing which resulted in increased usage of substrate. Many of these patients are malnourished which further effects the ability of the muscles to function optimally.

2.6.1.2. GAS EXCHANGE

All the above factors lead to an impaired gas exchange in patients with COPD. They exhibit a decreased oxygen partial pressure (P_{aO_2}) and an increased carbon dioxide tension (P_{aCO_2}) in the circulating arterial blood. Many studies have shown that this lowered P_{aO_2} is accentuated when exercising (Fletcher et al(1989), Danztker et al(1986), Ries et al(1983)). This is one of the greatest limitations to exercise. Hughes and Davison (1983) reported on dangerous arrhythmias that can result from hypoxia. Van Meerhaeghe and Sergysels (1983) found that patients who developed hypercapnia were unable to exercise at as high a load as those who did not. Belman in 1985 stated that patients with COPD breathed with a greater dead space tidal volume ratio due to the inefficiency of their gas exchange.

2.6.1.3. BREATHLESSNESS AND CONTROL OF BREATHING.

Pardy and Roussos(1983) made their subjects hyperventilate until the end partial pressure of carbon dioxide in their arterial blood (P_{aCO_2}) dropped by 10 mm Hg. When comparing 6 normals with 6 patients who had chronic airway limitation, they found that the respiratory muscles of the patients fatigued whereas those of the normal subjects did not. The latter study however, could be criticised since the average age of the normals was thirty two whereas that of the patients was sixty one.

Sharp, in 1985, when considering the therapeutic implications of respiratory muscle function in patients with COPD, summed it up by stating that inspiratory muscles under these circumstances were compromised in several ways:

a. hyperinflation led to shortening of the diaphragmatic fibres and absorption of sarcomeres. This decreased the ability of the diaphragm to generate optimal tension.

b. increased airway resistance added to the load on these muscles which were already strained.

c. hypercapnia led to tachypnoea which decreases the time available for the respiratory muscles to rest within the breathing cycle. This accelerated the fatiguability of these muscles.

Gray Donald et al (1989) and Schols et al (1989) felt that respiratory muscles in these

the alveolar capillary surface which limits diffusion and hypoxia results. This may explain how Dillard et al (1989) found that reduced diffusion in patients with COPD was one of the factors which affected exercise capacity in these patients.

Morrison and Richardson (1989) did a study where they compared ventilatory muscle strength in elderly subjects and patients with emphysema. They found that elderly subjects were able to build up a greater mouth pressure on inspiration than those who had emphysema. This reinforces a statement made by Rochester that the diaphragm in COPD is "better than expected but not good enough".

Dodd et al (1984) examined the action of the chest wall and the abdominal muscles during exercise in COPD patients. They found that very complex adaptations occurred to cope with the stress produced by exercise which could lead to fatigue of these muscles.

Faulkner at the Pulmonology Conference (Braun et al 1983) stated that fatigue results when muscles are required to perform unaccustomed tasks. This would be the case when unfit patients with COPD participate in exercise. Grassino et al (1989) confirmed that the respiratory muscles of these patients fatigued during exercise as shown in electromyogram studies.

Rochester(1983), at the same conference as Roussos above, felt that, although this adaptation does occur, in practice the shortened diaphragm interferes with the movement of gas volumes in the lung which leads to limitation of tidal volume. During exercise this limitation is an impediment.

Dempsey, in the J.B.Wolf memorial lecture in 1986 described how, in order to cope with the increased metabolic demand of exercise, ventilation is boosted by the increase of tidal volume. This is done by encroachment into the inspiratory and expiratory reserve volume. If the tethering action which tends to hold the airways open at low volumes, is removed (as happens with COPD where elastic tissue is lost) these reserves are limited and the increase in tidal volume is restricted. The patient compensates by increasing the frequency of breathing. This increase together with airtrapping produces greater dead space breathing, which limits the amount of oxygen made available for exercise.

Dempsey also found that during exercise the red blood cell transit time through the lung capillaries is reduced because of the increased perfusion resulting from exercise. In normal subjects, expansion of alveolar capillary surface occurs allowing diffusion and blood gases to remain within normal limits. Emphysema causes a reduction in

1.3.2. THE SIX MINUTE WALKING DISTANCE TEST (6MWT)

Exercise tolerance was tested using the six minute walking distance test.

1.3.2.1. THE TEST PROCEDURE

The test was carried out in a hospital corridor 15 meters long. Each subject rested for five minutes sitting on a chair before carrying out the test. He / she was then instructed to walk up and down the corridor. Each was required to cover as much ground as possible in six minutes. The subjects were told to keep going if possible but not to be concerned if they had to slow down or stop to rest. The aim was to feel at the end of the test , that they could not have covered more ground in that time. The distance covered is considered an indication of exercise tolerance.

The measurements taken during the 6MWT included:

- i. distance covered in 6 minutes
- ii. heart rate at rest and immediately at the end of the 6 minutes. This was done using a heart rate monitor (Unilife Sport Tester 300 Hamhurg West Germany). The transmitter was attached to the subjects' chest while the monitor was worn on the wrist.
- iii. the time taken when subjects who were unable to walk without stopping, were forced to pause (due to dyspnoea or leg pain).

METHOD

In the bicycle ergometer test minute ventilation (VE) ,metabolic responses and blood gas results were recorded and analysed at each work load in all four tests.

The results of the trial group was compared with those of the control group at each work load for the initial test and each subsequent test.

Percentage change in Ve was compared between the two groups.

As the sample size was small and the results did not exhibit a normal distribution, the data was analysed using non parametric analyses.I used the Wilcoxon sum of ranks test.

A P - value of less than 0.05 was considered significant.

3.3.1.3. MEASUREMENTS TAKEN

i. Ventilation and oxygen consumption were measured using a one way non rebreathing Hans Rudolph valve connected to an on line analysis system (Oxycon 4 Mijnhardt Bunnik, Netherlands) The instrument was calibrated using a gas of known concentration (Gas chromatograph)

ii. Blood gasses were measured by analyzing blood taken from a warmed ear lobe. This was done by an experienced technologist. This method of obtaining arterial blood gases has been found to correlate well with results of tests done on blood from arterial puncture. (Godfrey et al 1971, Goldman et al 1967, Spiro et al 1976) Blood taken during the last 30 seconds of each work load was analyzed using the ABL 300 Acid Base Laboratory Radiometer (Copenhagen, Denmark).

iii. ECG measurements were monitored continuously via three leads on a Hewlett Packard ECG monitor (model 78351A -Boblingen Germany) The heart rate was recorded in the last 30 seconds of each work pad.

iv. Blood pressure was monitored manually at the end of each work load.

3.3.1.4. STATISTICS

- vi. Further increments of 20 watts were repeated until the test was terminated (see 3.3.1.2.)

3.3.1.2.CRITERIA FOR TERMINATION OF TEST

The bicycle ergometer test was terminated when :

- i. the subject felt that he /she was too breathless to continue.
- ii. the heart rate reached 80% of age predicted maximal heart rate ie $0.8(220 - \text{age})$.
- iii. an abnormal ECG response occurred ie
 - a. depressed ST segment
 - b. more than two consecutive ectopic heart beats
 - c. bradycardia
- iv. an abnormal blood pressure response occurred ie:-
 - a. a decrease or lack of increase in systolic B.P.
 - b. an increase in diastolic B.P. of more than 10 mm Hg.
 - c. a systolic B.P. above 220 mm Hg.

(Guidelines laid down by the American Thoracic Society in 1982)

iv. a full lung function assessment.
These four tests were repeated after 5 months, then again after 10 months, and after 15 months.

3.3.1. THE BICYCLE ERGOMETER EXERCISE TEST

The physiological effects of our programme were evaluated by measuring ventilation and oxygen consumption while the subject exercised on a bicycle ergometer.

3.3.1.1. TEST PROCEDURE

- i. Base line measurements were taken for five minutes with the subject comfortably seated on a chair.
- ii. The subject then exercised on an electronically braked consistent work load bicycle ergometer (Medifette Maarn, Netherlands) .
- iii. Each subject exercised on the bicycle three minutes at a work load of 20 watts.
Measurements were read every 30 seconds and recorded in the last 30 seconds of this three minute period.
- iv. While remaining seated, the subject rested for one minute.
- v. The work load was increased by 20 watt increments and the procedure was repeated.

- vii. have a diastolic blood pressure at rest less than 110 mm. Hg.
- viii. be able to participate in a walking exercise programme.
- ix. be able to carry out pre - programme base - line tests.
- x. not show an improvement in airflow greater than 20% after inhalation of a bronchodilator.

Subjects selected for the trial were divided into two groups - the trial group and the control group. They were allotted into the groups in an alternating manner, according to the order that they were admitted into the trial.

A total of 31 patients were selected but 11 dropped out leaving 20 subjects, of these 12 Patients were trial subjects and 8 Patients were control subjects.

3.3. TESTS PERFORMED

On entering the trial each subject underwent the following :

- i. a graded exercise test using a bicycle ergometer.
- ii. a six minute walking distance test.
- iii. a quality of life questionnaire.

CHAPTER 3. METHOD

3.1. SUBJECTS

All patients with COPD who were referred for physiotherapy at the Johannesburg Hospital and who fulfilled the criteria listed below were asked to participate in the trial. Those who consented to do so filled in an informed consent form (see appendix) and then became subjects for my trial.

3.2. ENTRANCE CRITERIA

Before being accepted as a subject for the study each subject must:

- i. be diagnosed as having chronic obstructive pulmonary disease as defined by the American Thoracic Society in 1986
- ii. be between the ages of 45 and 80 years (male or female).
- iii. be smokers or ex smokers.
- iv. complain of dyspnoea which interferes with normal daily activities.
- v. be mentally able to understand the requirements of the programme.
- vi. not exhibit any signs of cardiac failure.

LITERATURE SURVEY

Swinburn(1985)looked at the 12 MWDT,a submaximal bicycle ergometer test and a paced step test. He repeated each of these tests four times and found that the 12MWDT produced the least variation on retesting(the step test showed the greatest variation).He tested O₂ consumption (VO₂) during the 12MWDT and during the step test using a portable device(Oxylog P.K.Morgan). The bicycle ergometer test and the 12MWDT produced similar VO₂ at the highest work load while the step test produced a higher VO₂. He concluded that all three tests produced valid consistent information about the work capacity of patients with COPD He did feel, however,that the chief disadvantage of their use was dependence on the motivation of the patient.

test (6MWDIT) for testing the exercise capability of patients with COPD was thus initiated.

Bernstein (1994) reanalyzed the 12 minute walking distance test as a tool for measuring exercise tolerance in patients with COPD. They found that the 12 minute distance and the 6 minute distance correlated well ($r=.97$) We have used this test in our trial.

Many studies have made use of this test to assess the effect of treatment on exercise capacity in patients with COPD (Cockcroft et al (1982) Niederman et al(1991) Mungall and Hainsworth (1979) McGavin et al (1977) Mahler et al(1984) and others). In spite of this the value of this test has often been questioned.

Belman in an update on exercise testing in 1985 and Muers in a letter to the editor of Respiratory Medicine in 1990 both questioned this test but were prepared to accept the fact that if the six minute walking distance was carried out according to strict standards, its validity fell within acceptable limits.

Morgan (1989) examined simple exercise tests such as walking tests and step tests. He found that if they were carried out correctly, they could provide a useful measure of exercise performance and disability in respiratory disease.

BACKGROUND In 1968 Doctor Kenneth Cooper when training a large number of servicemen in the United States air force, needed a simple test that would give him an indication of their physical fitness. He needed a valid test that could be done on a large group of people simultaneously. He devised a test in which he encouraged the subjects to run as fast as they could for a definite time (12 minutes). The distance covered in that time was used as an indication of the subject's fitness. When comparing these results with the results obtained on a VO₂max test for these subjects, he found that this distance correlated well with the VO₂ MAX and could be used to measure the exercise capacity.

In 1976, McGavin, Gupta and McHardy investigated whether a 12 minute walking test could be used to assess the exercise tolerance or disability of patients with COPD. They found that this test was suitable for this purpose.

In 1982 Butland et al felt that many patients with COPD found walking for 12 minutes too exhausting. They investigated whether walking for a shorter time could still be an indication of exercise capability. They discovered that walking for 6 minutes correlated well with the 12 minute walking distance test. A six minute walking distance

incremental fashion until exhaustion (Reported on by Brown et al 1984).

The value of using a submaximal bicycle test to evaluate the physiological effects of a medical intervention in patients with COPD has been accepted in the literature generally.

Belman(1985), in a review on exercise testing and training in patients with COPD, felt that a bicycle ergometer test was of limited value as the end point of the test was more often the result of motivation rather than true exercise tolerance.

2.8.2.SIMPLE WALKING TESTS

When looking at the effects of an exercise programme on the exercise tolerance of patients with COPD clinically, I was concerned mainly with the effect that this change has on their daily living activities. Mak (1993) expressed it well when discussing bicycle ergometry and treadmill exercise tests. He said " these forms are unfamiliar to most patients and extrapolation of such data to every day activity may not be appropriate. The six minute walking distance test uses a more familiar type of exercise (ie. walking) for these patients and is a more relevant form of exercise in their daily life."

2.8.2.1.SIX MINUTE WALKING DISTANCE TEST.

test, (either on a bicycle ergometer or on a treadmill) abnormal responses to exercise can be detected by comparing changes in oxygen consumption and ventilation at increasing loads with normal responses. Physiological indications of changes in exercise tolerance can be examined by looking at these changes at the different work loads when testing the effects of certain interventions

Mahler and Harver(1988) recognised the fact that it was not possible to obtain a maximal exercise test in patients with COPD because their ventilation limited them from exercising maximally. They were, however, satisfied that a peak $\dot{V}O_2$ test where the patient exercised to the highest load that he/she was capable of, was a suitable indication of exercise capacity in these patients. They found that the peak $\dot{V}O_2$ on a submaximal bicycle ergometer test correlated well with factors such as age, FEV1 and the dyspnoea index. These factors may not necessarily give a conclusive assessment of the $\dot{V}O_2$ MAX.

Brown et al (1985) investigated the reproducibility of peak oxygen consumption tests in patients with chronic airway limitation. They concluded that, with the exception of a few individuals, these tests were reproducible. In their study they tested their patients exercising on an electronically braked bicycle ergometer in an

breathlessness. To start off with, these patients walked until they felt that they had to stop. The time taken for them to reach this state was then used as their base line exercise prescription. They were subsequently encouraged to increase their exercise until they, too, were exercising at the required heart rate.

All subjects were encouraged to exercise for at least 15 minutes every day. Most subjects had to achieve this by walking for shorter durations several times a day in order to reach this amount of exercise.

iii. Frequency

Subjects exercised at home on a daily basis where possible. They were told to walk on a flat surface. Each patient was given a diary in which to record how much they exercised and how many times per day/week they did so.

iv. Rate of progression

Subjects adjusted their exercise only on the advice of the physiotherapist. Progression was dependent on two factors :

a) the subjects pulse rate at the end of exercise. This pulse rate was taken manually. As soon as the pulse dropped at the same work load of exercise, the walking time was adjusted as follows :

* Subjects who exercised for more than 6 minutes

Sports Medicine (1990) for quality and quantity of exercise necessary to maintain cardiorespiratory and muscle fitness in healthy adults .(Unfortunately, it was not always possible to achieve the intensity required in our group due to the fact that they were limited by their respiratory condition. We did, however attempt to reach the requirements whenever possible.)

i. Mode of activity

Subjects were placed on a walking exercise programme. WALKING was a relevant form of exercise for these people and it could be carried out at home. People in the age group from which this sample was taken felt more comfortable performing an exercise that did not require the learning of new skills.

The recommendation for mode of activity (American College of Sports Medicine 1990) is to use any activity which uses large muscle groups that can be maintained for a prolonged period and is rhythmic and aerobic in nature. Walking exercise is thus suitable.

ii. Intensity and duration of exercise

Subjects walked for a length of time which induced a heart rate corresponding to 60% -80% of age predicted maximal heart rate. Initially some patients were unable to reach this intensity due to their

operate three times a week in the Division of Pulmonology at the hospital.

All subjects had to attend the two lectures initially. (They were also encouraged to attend these lectures again at any stage for revision).

They also had to attend the classes at least twice a month throughout the trial.

3.4.2. THE TRIAL PROGRAMME

In addition to the above, the trial group participated in a carefully structured, monitored, exercise retraining programme.

i. Initially, exercise was prescribed for each subject as described below (3.4.2.1.).

ii. Subjects exercised at home daily.

iii. The subjects had to come in to the hospital once a week to have their exercise monitored and progressively adjusted.

(During the course of the trial their exercise sometimes had to be cut down due to the fact that they developed exacerbations of bronchial infections. This is why continuous monitoring is so important. As the exacerbation cleared up, normal progression of the exercise prescription continued.)

3.4.2.1. EXERCISE PRESCRIPTION

Exercise prescription was based primarily on the principals recommended by the American College of

Progressive relaxation techniques as described by Jacobson (1938) are used in these sessions. Relaxation training is included in the classes given by the physiotherapists three times a week.

iii. Bronchial hygiene. Patient are taught to do postural drainage on an individual bases. This is only done when an actual need for removal of secretions has been established (Sutton 1988, Selsby 1989, Leith 1968).

Bronchial hygiene includes the use of bronchodilators when necessary. It has been shown that patients with COPD do exhibit some reversibility to the administration of bronchodilators under certain circumstances (Oliven et al 1986, Ramsdell 1982). These are prescribed to the patients in the form of metered dose inhalers or in the form of home nebulizers. The nurse and the physiotherapists teach the patients to use their bronchodilator equipment optimally (Newman et al 1981, Blaquiére 1989, Jacobson et al 1990, Zainadin et al 1988).

iv. Breathing retraining. In order to relieve their dyspnoea, patients are taught such techniques as pursed lip breathing (Mueller et al 1970) and breathing control (Kaloczowski 1989, Casciari 1981, Sergysels 1979). This is carried out in classes which

3.4. THE PULMONARY REHABILITATION PROGRAMME

After baseline determinations had been made, all subjects (trial and control) participated in the pulmonary rehabilitation programme which exists at the Johannesburg Hospital. This programme is organized by two physiotherapists and one nursing assistant. The author of this thesis is the physiotherapist responsible for the administration of the programme.

The programme was designed according to the guidelines laid down by the American Thoracic Society statement on Pulmonary Rehabilitation (1981).

3.4.1. THE PROCEDURE

The Johannesburg Hospital programme consists of:

- i. Education (2 lectures). Ignorance about their own condition is known to increase anxiety in patients with COPD (Becker et al 1975, Perry 1981). Lectures on the pathology of COPD and its clinical implications are given on a weekly basis by myself or a physiotherapy colleague. The lectures are designed to encourage as much patient participation as possible.
- ii. Relaxation training. Due to their dyspnoea and their loss of function, patients with COPD generally experience an excessive amount of stress and tension (Light et al 1985). Relaxation training allows patients to gain control over their anxiety and tension (Dudley et al 1980, Agle et al 1977).

METHOD

A P - value of less than 0.05 was considered significant.

(FRC), measured and calculated using the closed system Helium dilution method.

iv. diffusing capacity calculated using the modified Krogh single breath Carbon Monoxide diffusion test (Ruppel 1991 page 87).

v. expiratory flow rates ie peak expiratory flow rate (PEF), expired volume in the first second (FEV1) and maximal expiratory flow rate between 50% and 75% of vital capacity (MEF 50-75) were obtained by dynamic spirometry.

The computer linked to the P.K.Morgan (Kent UK) dry rolling seal spirometer calculated all the results as a percentage of the predicted results for age, height mass and sex (Knutson 1976). These values as well as the actual values were recorded.

3.3.4.3. STATISTICS

The difference between the lung function readings in the tests taken at 15 months and the readings taken at the initial test was compared within each group and between the two groups.

The change in lung function which occurred in the subjects who were still exercising two years after the end of the trial was evaluated.

The data were analysed using the Wilcoxon sum of ranks test.

3.4. LUNG FUNCTION TESTS

3.3.4.1. THE PROTOCOL

- i. The lung function tests were carried out in the lung function laboratory at the Johannesburg hospital.
- ii. The tests were carried out by a trained technologist.
- iii. Subjects were seated throughout the tests.
- iv. The "Transfertest" (P.K.Morgan Kent UK) used to obtain these results included a dry rolling spirometer, a Helium analyser, an oxygen analyser, a Carbon Monoxide analyser and moisture absorbers.

3.3.4.2. TESTS DONE:

Assessment of lung function included:

- i. static lung volumes ie forced vital capacity (FVC), tidal volume (VT), inspiratory reserve volume (IRV) and expiratory reserve volume (ERV). These volumes were obtained by using a dry rolling seal spirometer.
- ii. maximal voluntary ventilation (MVV). This was obtained by measuring the volume of air moved by the subject carrying out a maximal ventilatory manoeuvre into the spirometer for 12 seconds which was extrapolated to one minute and expressed in litres per minute.
- iii. lung subdivisions, ie residual volume (RV), total lung capacity (TLC) and functional residual capacity

METHOD

each category and the baseline score was compared at each test within each group.

The difference between the two groups with regards to percentage change in each quality of life category at the end of the trial was evaluated.

The data was analysed using the Wilcoxon sum of ranks test.

As the scores were compared to baseline at each instance, the results were adjusted using the Bonferonni correction. A P - value of less than 0.0167 was considered significant.

iv. four questions look at the subjects' ability to cope with chronic respiratory disease (mastery).

3.3.3.2. ADMINISTRATION OF QUESTIONNAIRE

i. Each subject was interviewed by myself or a colleague (both are trained interviewers). Where possible, I did not question subjects on the follow up to prevent bias.

ii. Questions were asked exactly as described in the questionnaire. All questions addressed the subjects' feelings during the two weeks prior to the current test.

iii. Subjects were given seven possible answers to each question (supplied on coloured cards with the questionnaire package).

iv. The subjects were given no assistance or encouragement when answering the questions.

3.3.3.3. SCORING FOR THE QUESTIONNAIRE

The seven possible answers supplied were numbered according to the quality of life value measures. The higher the number, the more positive the quality of life measure. A combined score was calculated for each quality of life dimension. These scores were compared at each test.

3.3.3.4. STATISTICS

The difference between the quality of life scores in

3.3.3. QUALITY OF LIFE QUESTIONNAIRE

The effects of the programme on the quality of life of the subjects was tested by making use of a questionnaire which has been designed specifically for patients with chronic respiratory disease at the McMaster university in Canada. The questionnaire and the protocol for its administration was supplied to us by the designers of this questionnaire (Guyatt et al 1986) (see Appendix).

3.3.3.1 DESCRIPTION OF QUESTIONNAIRE

The questionnaire consists of twenty questions evaluating four quality of life dimensions:

- i. five questions evaluate the subjects' perception of dyspnoea. In this section each subject has to decide on the activities of daily living which they personally consider important to themselves and which are affected by their breathlessness. The amount of breathlessness caused by this activity is evaluated according to the structured answers supplied with the questionnaire in the form of a likert scale (Guyatt et al 1987b).
- ii. four questions pertain to the subjects sensation of fatigue. They are asked questions which reflect on how energetic they feel.
- iii. seven questions evaluate the subjects emotional function in relation to their social interactions.

3.3.2.3. STEPS TAKEN TO IMPROVE RELIABILITY OF TEST

- i. The test was repeated three times (Knox et al 1988) at weekly intervals (Muers et al 1990). The best of the three readings was used as an indication of the patient's exercise tolerance
- ii. Standardized encouragement was given to each subject while performing the test (Gyatt et al 1984).

3.3.2.4. STATISTICS

The percentage change in distance covered, resting heart rate and exercise heart rate which occurred at the end of the trial was compared between the two groups.

The difference between the distance covered, the resting heart rate and the exercise heart rate at each test and the baseline score was compared within the two groups.

The data was analysed using the Wilcoxon sum of ranks test.

As the results were all compared with the baseline score, (testB - testA, testC - testA, testD - testA) the results were adjusted using the Bonferroni correction. A P-value less than 0.0167 (0.05/3) was considered significant.

FIG 4.5 EXERCISE TEST AT 10 MONTHS
TRIAL GROUP

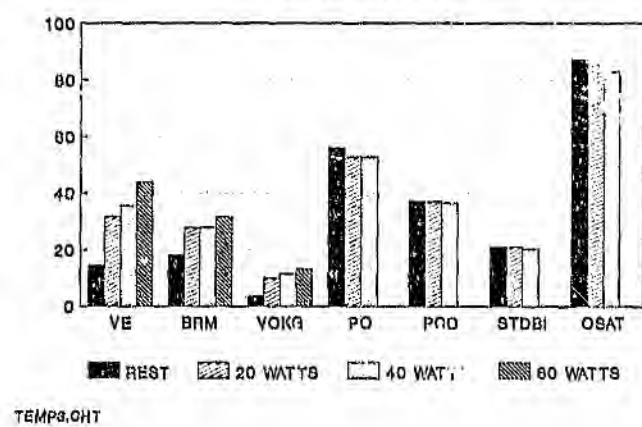


FIG 4.6 EXERCISE TEST AT 10 MONTHS
CONTROL GROUP

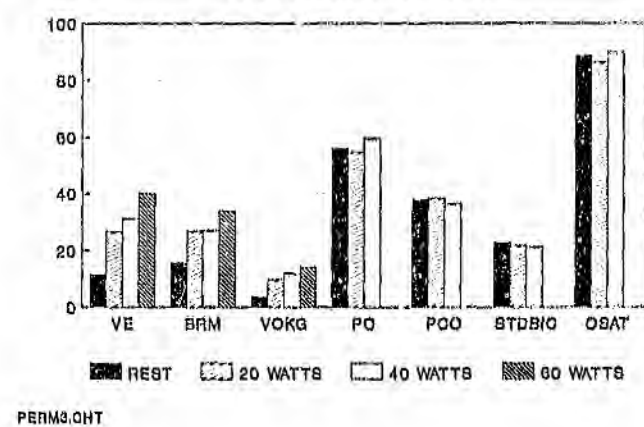


FIGURE 4.5 AND FIGURE 4.6

Ventilation, metabolic responses and blood gases obtained at defined intervals by the trial subjects and the control subjects while performing the bicycle ergometer test at ten months.

Abbreviations: VE Minute - ventilation

BR/M - breaths per minute

VOKG - oxygen consumption per minute

PO - arterial oxygen partial pressure

PCO - arterial carbon dioxide partial pressure

STDBIC - standard bicarbonate

FIG 4.3 EXERCISE TEST AT 5 MONTHS
TRIAL GROUP

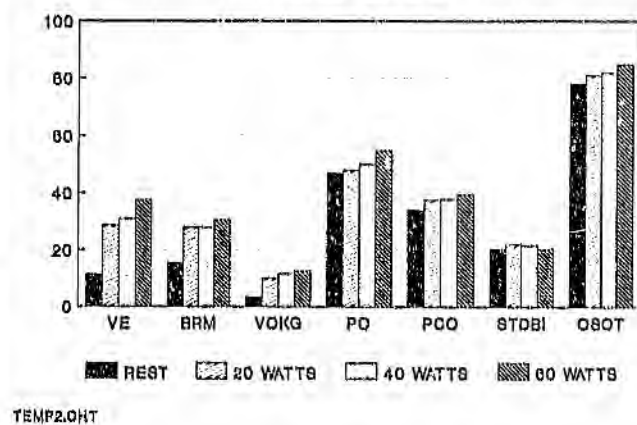


FIG 4.4 EXERCISE TEST AT 5 MONTHS
CONTROL GROUP

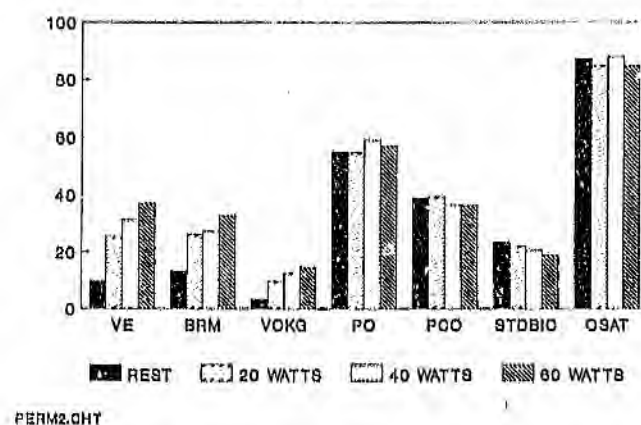


FIGURE 4.3 AND FIGURE 4.4

Ventilation, metabolic responses and blood gases obtained at defined intervals by the trial subjects and the control subjects while performing the bicycle ergometer test at five months.

Abbreviations: VE Minute - ventilation

BR/M - breaths per minute

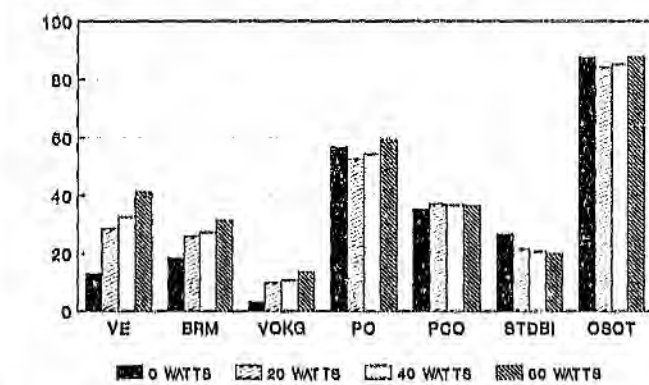
VOKG - oxygen consumption per minute

PO - arterial oxygen partial pressure

PCO - arterial carbon dioxide partial pressure

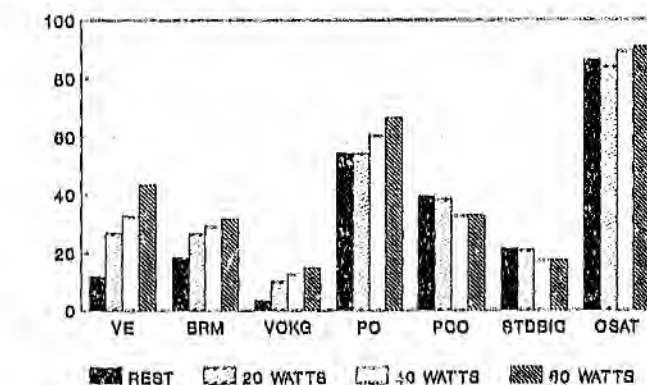
STDBIC - standard bicarbonate

FIG 4.1 INITIAL EXERCISE TEST
TRIAL GROUP



TEMPERATURE

FIG 4.2 INITIAL EXERCISE TEST
CONTROL GROUP



PERMIT

RESULTS

between the two groups at any stage during the trial. There was no significant change within each group either.

TABLE 4.3 COMPARISON BETWEEN TRIAL GROUP AND CONTROL GROUP WITH REGARD TO PERCENTAGE CHANGE IN MINUTE VENTILATION (Ve) WHILE PERFORMING BICYCLE ERGOMETER TEST INITIALLY AND AFTER 15 MONTHS

Work Load	$\frac{VeD - VeA}{VeA} \times 100$				
	Trial		Control		p-value
	Mean	Std Dev	Mean	Std Dev	
Rest	+24.00	46.00	-12.00	14.00	0.0449*
20 watts	+12.00	11.00	-13.00	12.00	0.0007*
40 watts	+10.00	9.00	-5.00	22.00	0.1356
60 watts	+ 7.00	9.00	-6.00	17.00	0.2888

A = Base-line score

D = Score at 15 months

Std Dev = standard deviation

+ = % increase

- = % decrease

4.1.2. VENTILATION

(including minute ventilation (VE), breaths per minute (br\m) and tidal volume (Tv))

When comparing the resting and exercise VE between the two groups at different work loads, the trial group exhibited significantly higher VE than the control group did at 15 months both at rest ($p = .0061$) and when exercising at 20 watts ($p = .0127$).

The percentage change in VE over the 15 month period in the trial group compared to the percentage change in the control group (table 4.3) was significantly different at rest ($p = .0449$) and at 20 watts ($p = .0007$). In the control group this difference was negative while, in the trial group this difference was positive.

Figures 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7 and 4.8 show that the VE in the trial group was consistently higher than the VE in the control group. The difference between the VE in the two groups was only significant at fifteen months at rest ($p = .0061$) and at 20 watts ($p = .0127$).

4.1.3. METABOLIC RESPONSES

(including oxygen consumption (VO_2 and VO_2/KG), carbon dioxide production (VCO_2)).

There was no statistically significant difference in oxygen consumption and carbon dioxide production

TABLE 4.2 CONTROL GROUP: HIGHEST WORK LOAD ACHIEVED BY
INDIVIDUAL SUBJECTS AT TERMINATION OF THE
BICYCLE ERGOMETER TEST AT EACH TEST

Patient No	A	B	C	D
2	20 watts	20 watts	No test	20 watts ±
8	60 watts	80 watts	60 watts	80 watts +
9	80 watts	No test	80 watts	60 watts -
12	20 watts	40 watts	40 watts	60 watts ++
14	20 watts	20 watts	20 watts	20 watts ±
15	60 watts	60 watts	*40 watts	60 watts ±
17	40 watts	60 watts	60 watts	60 watts +
20	60 watts	80 watts	No test	80 watts +
Mean	45 watts	51 watts	50 watts	55 watts

A = initial test

B = test at 5 months

C = test at 10 months

D = test at 15 months

TABLE 4.1 TRIAL GROUP - HIGHEST WORK LOAD ACHIEVED BY
INDIVIDUAL SUBJECTS AT TERMINATION OF THE
BICYCLE ERGOMETER TEST AT EACH TEST

Patient No	A	B	C	D
1	20 watts	40 watts	No test	40 watts $\pm$
3	20 watts	20 watts	No test	20 watts $\pm$
4	20 watts	40 watts	No test	20 watts $\pm$
5	40 watts	40 watts	40 watts	40 watts $\pm$
6	40 watts	40 watts	40 watts	40 watts $\pm$
7	40 watts	No test	40 watts	60 watts +
10	20 watts	40 watts	No test	40 watts +
11	20 watts	20 watts	20 watts	20 watts $\pm$
13	60 watts	80 watts	No test	80 watts +
16	20 watts	20 watts	*40 watts	20 watts $\pm$
18	60 watts	60 watts	*80 watts	60 watts $\pm$
19	60 watts	No test	60 watts	60 watts $\pm$
Mean	35 watts	40 watts	40 watts	41 watts

A = initial test

B = test at 5 months

C = test at 10 months

D = test at 15 months

CHAPTER 4. RESULTS4.1. BICYCLE ERGOMETER TEST4.1.1. WORK LOAD (table 4.1. and 4.2.)

From the tables 4.1 and 4.2. it appears that there is no difference between the work loads achieved at termination of the bicycle ergometer test on all four test days in the trial group and the control group, both in the individual loads and in the mean work load of the two groups ($p > 0.05$).

At 15 months four trial subjects out of twelve (33%) could achieve a work load of 20 watts only in the exercise test, and two out of eight control subjects (25%) could not manage to exercise at a load higher than 20 watts.

In the trial group 25% (3 subjects) improved in their work load at the end of the trial and the rest remained the same. In the control group 50% (4 subjects) improved in the load achieved, 37.5% (3 subjects) remained the same and 12.5% (1 subject) deteriorated.

METHOD

above. They were discouraged from participating in any structured exercise. They were told to continue with whatever activity they were accustomed to do but not to increase this activity in any way.

They were told that exercise has not been proved to have any beneficial effects on COPD patients as yet. If this study proved any benefits, they were promised that they could also join the exercise group after fifteen months.

progressed by 1 minute.

* Subjects who exercised for less than 6 minutes progressed by .5 minute.

b) at the end of the exercise, the patient was presented with a chart to rate their perceived rate of exertion (R.P.E.), according to Borg (1970 and 1982). (See scale in appendix). When the subjects R.P.E. dropped at the same work load, exercise was progressed as described above (provided that the pulse rate was not above 80% of predicted heart rate).

The exercise done by these subjects was of a lower intensity than some of the programmes reported in the literature (Casaburi et al 1991, Holle et al 1988). The reason for this is that there have been several reviews emphasizing the dangers of exercising patients with COPD (Stewart et al 1986, Spiro et al 1975, D Urzo et al 1989 and Phillips et al 1988). In addition, our patients were exercising at home without supervision. Thus, for safety we felt it was advisable to exercise at these lower intensities.

3.4.3. THE CONTROL PROGRAMME

The control group was tested exactly as the trial group was. They participated in the rehabilitation programme at the Johannesburg Hospital as described

TABLE 4.6 A COMPARISON OF THE DISTANCE COVERED IN 6 MINUTES, THE RESTING HEART RATE AND EXERCISE HEART RATE OF THE TRIAL AND THE CONTROL SUBJECTS AT EACH TEST IN RELATION TO THE RESULTS AT THE BASE-LINE TEST

Trial Group						Control Group			
		Mean	St Dev	p value	n	Mean	St Dev	p value	n
Distance Walked (metres)	B	517.55	89.93	0.0743	10	552.99	62.61	0.2500	4
	vs								
	A	490.99	74.85			524.90	71.24		
	C	526.45	41.55	1.0000	6	540.32	70.14	0.7500	4
	vs								
	A	523.99	27.57			533.75	70.73		
	D	532.90	62.57	0.0078	11	551.76	87.36	0.1563	7
	vs								
	A	494.09	71.74			519.93	71.33		
Resting Heart Rate	B	78.22	8.74	0.0202	10	83.20	13.68	0.3125	4
	vs								
	A	86.00	11.66			80.00	12.96		
	C	74.33	8.43	0.0625	6	87.00	12.38	1.0000	4
	vs								
	A	83.67	12.80			86.50	8.23		
Beats per Minute	D	80.73	9.26	0.1074	11	80.00	6.11	0.3125	7
	vs								
	A	86.18	10.45			84.28	6.57		
Exercise Heart Rate	B	109.55	10.94	0.0117	10	104.80**	11.45	0.3750	4
	vs								
	A	121.11	8.49			100.00	16.73		
	C	113.00	9.27	0.8438	6	116.00	7.30	0.1250	4
	vs								
	A	114.33	10.15			109.00	10.52		
Beats per Minute	D	116.73	12.11	0.4405	11	105.71	10.55	1.0000	7
	vs								
	A	118.73	9.43			105.71	9.76		

A = Initial test
 B = Test at 5 months
 C = Test at 10 months
 D = Test at 15 months
 n = Number of subjects

Note: Values for A vary due to change in sample size at each test

TABLE 4.5 COMPARISON BETWEEN THE PERCENTAGE CHANGE IN THE
DISTANCE COVERED, RESTING HEART RATE AND
EXERCISE HEART RATE IN THE 6 MINUTE WALKING
DISTANCE TEST OF THE TRIAL GROUP VERSUS THAT OF
THE CONTROL GROUP

$$\frac{D - A}{A} \times 100$$

	Trial		Control		
	Mean	Std Dev	Mean	Std Dev	p-value
Distance covered	8.00	8.00	6.00	10.00	0.5849
Resting heart rate	-6.00	11.00	-5.00	9.00	0.8919
Exercise heart rate	-1.00	1.00	.50	11.00	0.5559

A = Base-line score

D = Score at 15 months

4.2 SIX MINUTE WALKING DISTANCE TEST (6 MWDT.)

4.2.1. In the 6MWDT, comparing the percentage change which occurred between the final test and the baseline test, there was no statistically significant difference between the trial group and the control group with regard to distance covered, resting heart rate or exercise heart rate (Table 4.5.).

4.2.2. Looking at the results within the two groups the following was noted (table 4.6):

4.2.2.1.DISTANCE COVERED IN 6 MINUTES

Initially ten trial patients covered a mean distance of 490.99 metres and seven controls covered a mean distance of 524.9 metres. There was no significant difference between these two groups.

At the second test, there was an improvement in the distance covered by both groups. The trial group covered 517.55 metres and the control group covered 552.99 metres. Statistically the difference in distance between the first and second test was not significant for either group. Ten trial subjects and five controls participated in this test.

At ten months the trial group continued to walk further in six minutes to 526.4 metres while the control group appeared to cover less distance. Neither of these results were statistically significant.

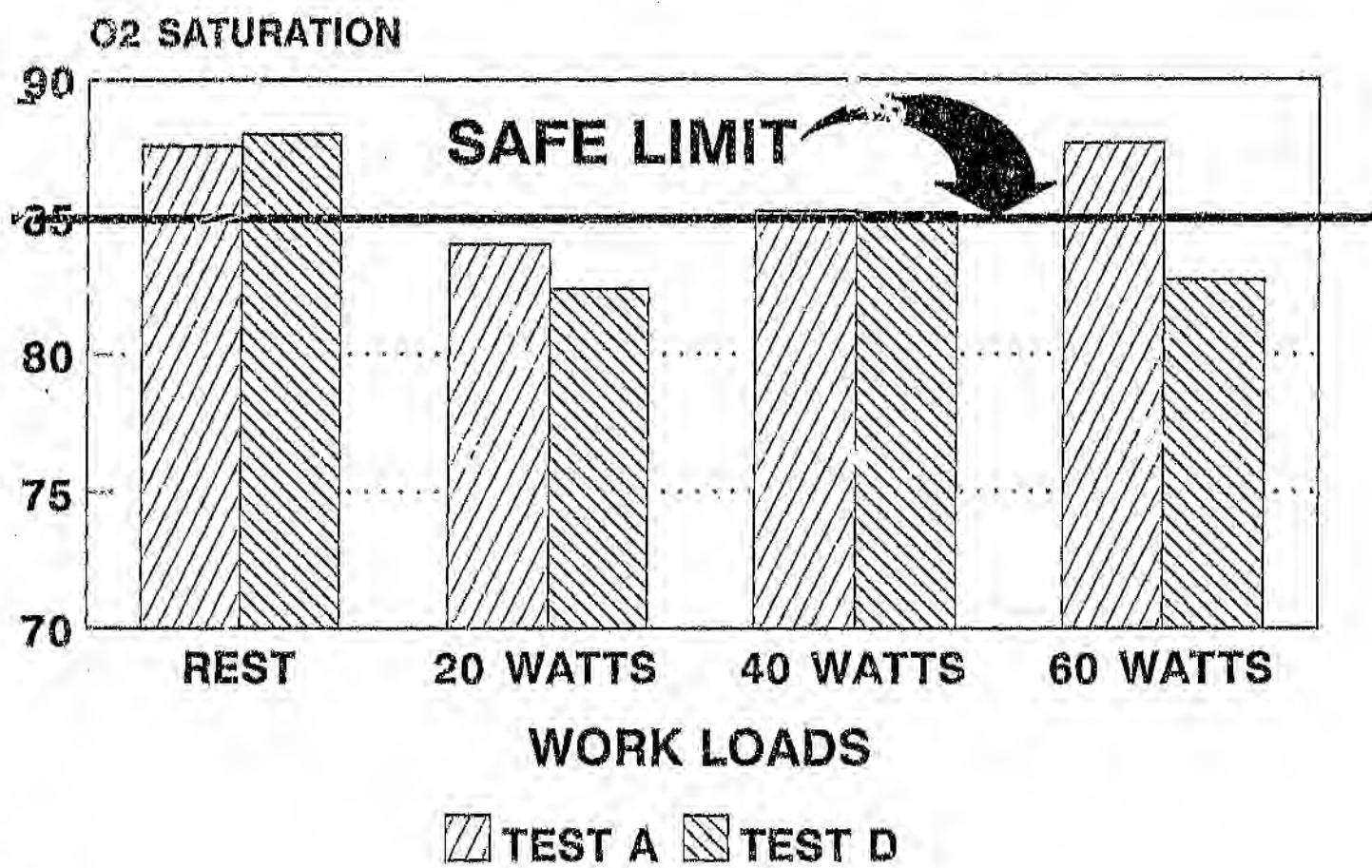
TABLE 4.4 DIFFERENCE BETWEEN STANDARD BICARBONATE IN BLOOD SAMPLES OF INDIVIDUAL SUBJECTS OBTAINED WHILE EXERCISING AT THEIR HIGHEST LOAD INITIALLY AT HIGHEST LOAD AND WHEN TESTED AT 15 MONTHS IN THE TRIAL GROUP AND IN THE CONTROL GROUP

TRIAL			CONTROL		
Patient	Test A	Test D*	Patient	Test A	Test D
1	+ 2.7mEq	- 0.40mEq	2	- 0.4mEq	+ 0.6mEq
3	- 1.2mEq	- 1.9mEq	8	- 2.6mEq	- 2.6mEq
4	+ 0.3mEq	+ 0.3mEq	9	- 2.1mEq	- 0.9mEq
5	+ 1.2mEq	+ 0.3mEq	12	+ 0.6mEq	- 2.0mEq
6	- 0.3mEq	- 1.3mEq	14	- 0.6mEq	- 1.2mEq
7	- 0.7mEq	- 0.1mEq	15	- 0.7mEq	- 1.2mEq
10	+ 0.8mEq	- 2.4mEq	17	- 2.0mEq	- 3.7mEq
11	- 1.3mEq	- 1.7mEq	20	- 2.4mEq	- 0.3mEq
13	- 2.4mEq	- 2.1mEq			
16	+ 0.2mEq	- 1.2mEq			
18	- 2.8mEq	- 2.8mEq			
19	- 1.7mEq	+ 2.0mEq			

A = Base-line test;

D = Final test at 15 months

FIG 4.10
O2 SAT TRIAL GROUP



OXYGEN

FIGURE 4.10

Oxygen saturation obtained at defined intervals by the trial subjects while performing a bicycle ergometer test initially and after participating in a trial for fifteen months.

Code: Test A -initial test

Test D - Test at fifteen months

Safe limit - oxygen saturation above 85%

FIG 4.9

O2 SAT CONTROL GROUP

O2 SATURATION

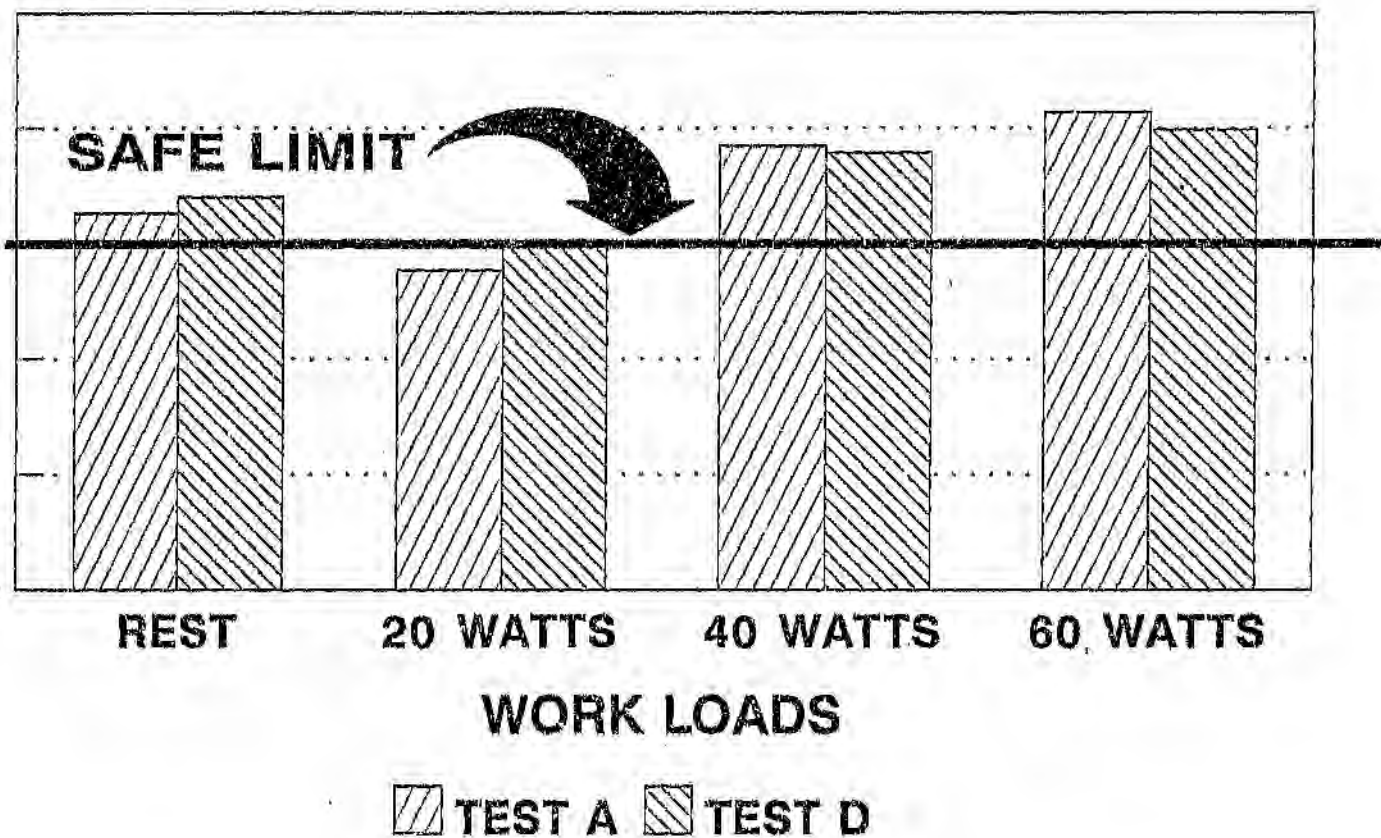


FIGURE 4.9

Oxygen saturation obtained at defined intervals by the control subjects while performing a bicycle ergometer test initially and after participating in a trial for fifteen months.

Code: Test A -initial test

Test D - Test at fifteen months

Safe limit - oxygen saturation above 85%

4.1.5. HEART RATE

There was no significant change in heart rate at rest or at peak exercise during the whole trial. This applied to both groups.

4.1.4. BLOOD GASES

(including arterial oxygen partial pressure (PO_2), arterial carbon dioxide partial pressure (PCO_2), arterial standard bicarbonate (HCO_3), arterial base excess (BE), oxygen saturation in arterial blood (O_2 sat.) and arterial blood pH).

No statistically significant difference was found between the two groups at any stage and at all work loads in all the blood gas parameters mentioned above.

No significant changes occurred within the two groups either.

Should an oxygen saturation of 85% be considered a safe limit (Carter et al 1992, Niederman et al 1991), the trial group appeared to show a greater tendency to drop to these low levels than the control group did. In figs. 4.9 and 4.10, we see that at 20 watts both groups displayed low O_2 sats. After 15 months the control group appeared to improve while the trial group deteriorated even more. The results at 15 months when exercising at 60 watts were influenced by the fact that the sample was small (4 trial and 4 control subjects). One of the trial subjects produced an O_2 sat of 72%.

The standard bicarbonate results were variable in both groups (see table 4.4) with no significant difference being noted.

FIG 4.7 EXERCISE TEST AT 15 MONTHS
TRIAL GROUP

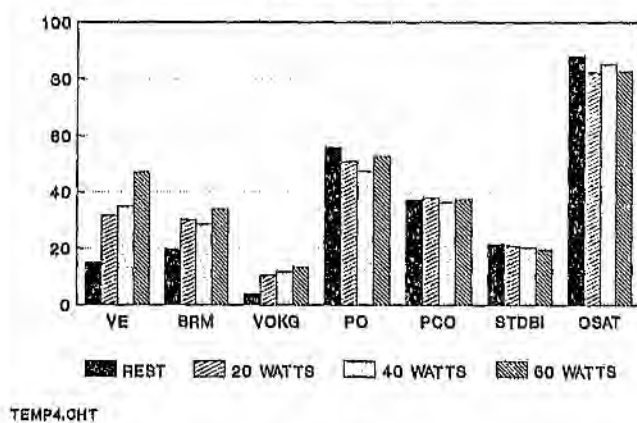


FIG 4.8 EXERCISE TEST AT 15 MONTHS
CONTROL GROUP

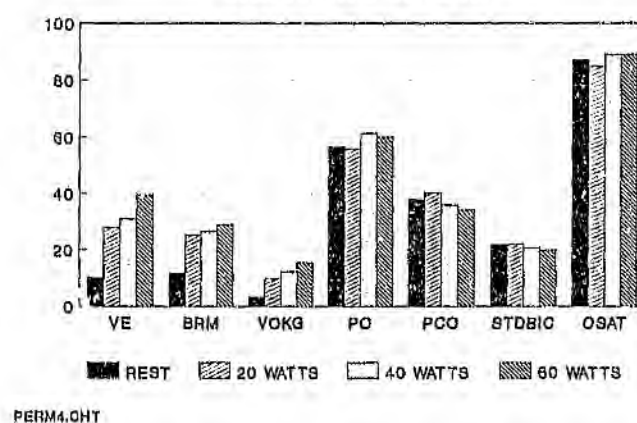


FIGURE 4.7 AND FIGURE 4.8

Ventilation, metabolic responses and blood gases obtained at defined intervals by the trial subjects and the control subjects while performing the bicycle ergometer test at fifteen months.

Abbreviations: VE Minute - ventilation

BR/M - breaths per minute

VOKG - oxygen consumption per minute

PO - arterial oxygen partial pressure

PCO - arterial carbon dioxide partial pressure

STDBIC - standard bicarbonate

TABLE 4.11 INITIAL RESTING PULMONARY FUNCTION TEST RESULTS IN TRIAL AND CONTROL SUBJECTS

	TRIAL	CONTROL	p Value
Age (Years)	65.9 $\pm$ 8	65.7 $\pm$ 7.8	0.8866
Weight (kg)	72.6 $\pm$ 12.8	71.9 $\pm$ 15.7	0.6436
Height (cm)	1.67 $\pm$ 0.7	1.63 $\pm$ 0.9	0.3922
FVC (litres)	2.83 $\pm$ 0.6	2.48 $\pm$ 0.79	0.2702
FEV ₁ (litres)	1.44 $\pm$ 0.56	1.44 $\pm$ 0.63	0.6440
FEV ₁ /FVC	50 $\pm$ 12.4	58.1 $\pm$ 14	0.2267
PF (l/sec)	4.89 $\pm$ 1.99	5.14 $\pm$ 1.8	0.6693
MEF 25-75 (l/sec)	0.71 $\pm$ 0.39	0.84 $\pm$ 0.48	0.4773
MVV (l/min)	58.33 $\pm$ 23.1	51 $\pm$ 1.28	0.8032
FRC (litres)	4.93 $\pm$ 0.89	3.67 $\pm$ 21.6	0.0107
RV (litres)	4.53 $\pm$ 1.6	2.77 $\pm$ 1.19	0.0087
TLC (litres)	6.92 $\pm$ 1.29	5.28 $\pm$ 1.42	0.0135
RV/TLC	56.85 $\pm$ 8.01	49.64 $\pm$ 14.78	0.2569
DLCO (CO/min/mmHg)	18.05 $\pm$ 7.45 (n=8)	13.8 $\pm$ 11.21 (n=3)	0.7589
Va	6.23 $\pm$ 1.32 (n=8)	5.08 $\pm$ 0.71 (n=3)	0.1530
DLCO/Va	3.15 $\pm$ 0.97	2.77 $\pm$ 2.15 (n=3)	0.6831

Abbreviations:

n = subject number; CO = Carbon monoxide; Hg = mercury;
 FVC = Forced vital capacity; FEV₁ = Flow volume in first
 second; PF = peak flow rate; MEF₂₅₋₇₅ = mid expiratory
 flow; FRC = functional residual capacity; RV = residual
 volume; TLC = total lung capacity; DLCO = diffusion; Va =
 alveolar ventilation

4.5. LUNG FUNCTION TEST

4.5.1. INITIAL (table 4.11.)

Initially there was no difference in the lung functions of the trial group and the control group in all the tests except for the tests which give a measure of hyperinflation (FRC, RV AND TLC). This indicates that the trial group were more hyperinflated than the control group.

4.5.2. AFTER 15 MONTHS

4.5.2.1. Examining the difference in the percentage change in lung functions after 15 months between the two groups, there was no significant difference in the change in any of the parameters measured (table 4.12).

4.5.2.2. Examining changes within the groups after 15 months, no difference was found in the lung functions of the control group (table 4.13).

In the trial group, the lung functions showed no statistically significant changes in any of the parameters except: a) RV which decreased from 4.211 to 3.311 (P-value = 0.0391)

b) RV/TLC which decreased from 59.5% to 52% (P-value = 0.0469)

c) FEV1/FVC which decreased from 45.5% to 40.9% (P-value = 0.0117)

d) MVV which decreased from 51.1 to 44.5 (P-value = 0.0078)

TABLE 4.10 COMPARISON BETWEEN THE QUALITY OF LIFE TEST SCORES OBTAINED BY THE TRIAL AND THE CONTROL SUBJECTS AT EACH TEST IN RELATION TO THE BASE-LINE SCORES

Trial Group							Control Group					
		Mean	St Dev	p value	Diff	n	Mean	St Dev	p value	Diff	n	
Dyspnoea	B	23.09	±4.5	0.0010 *	5.73	12	20.2	±5.7	0.2500	5.5	4	
	vs A	17.36	±4.1				14.7	±10.2				
	C	24.8	±5.6	0.0313	7.47	6	25.2	±6.6	0.1250	4.7	4	
	vs A	17.33	±5.0				20.5	±6.1				
	D	24.33	±6.0	0.0047 *	7.08	12	24.6	±6.0	0.0938	4.2	8	
	vs A	17.25	±4.0				20.4	±4.8				
Emotional Function	B	38.2	±5.2	0.0039 *	4.84	12	34.7	±5.9	1.0000	-0.3	4	
	vs A	33.36	±6.6				35.0	±3.6				
	C	42.00	±2.9	0.1563	5.5	6	39.0	±6.0	0.8750	-0.5	4	
	vs A	36.5	±5.7				40.5	±3.0				
	D	41.5	±4.6	0.0020 *	6.5	12	40.00	±5.8	0.5625	2	8	
	vs A	34.0	±6.6				38.00	±4.2				
Fatigue	B	20.09	±2.6	0.0327	3.0	12	18.5	±3.0	0.7500	1	4	
	vs A	17.09	±2.8				17.5	±4.0				
	C	21.7	±5.0	0.2500	3.2	6	22.5	±4.6	1.0000	0.3	4	
	vs A	17.53	±2.8				22.2	±3.3				
	D	21.5	±2.8	0.0579	3.5	12	22.1	±3.7	0.0938	2.3	8	
	vs A	17.0	±2.7				19.8	±4.6				
Mentary	B	24.3	±3.5	0.0313	2.4	12	25.75	±3.3	1.0000	-0.25	4	
	vs A	21.9	±5.2				26.0	±1.8				
	C	26.7	±2.2	0.2500	4.2	6	25.00	±4.1	0.2500	2.8	4	
	vs A	22.5	±6.6				22.20	±4.4				
	D	25.9	±2.9	0.0363	3.6	12	24.6	±3.9	0.4375	1.3	8	
	vs A	22.3	±5.2				23.1	±3.3				

A = Base-line; B = 5 months; C = 10 months; D = 15 months

* = Significant at p-value <0.167

n = Number of subjects

CRO RESPONSE SHEET

1. BEING ANGRY OR UPSET NO
2. HAVING A BATH OR SHOWER
3. BENDING
4. CARRYING, SUCH AS CARRYING GROCERIES
5. DRESSING
6. EATING
7. GOING FOR A WALK NO
8. DOING YOUR HOUSEWORK NO
9. HURRYING NO
10. MAKING A BED NO
11. HOPPING OR SCRUBBING THE FLOOR NO
12. MOVING FURNITURE NO
13. PLAYING WITH CHILDREN OR GRANDCHILDREN NO
14. PLAYING SPORTS NO
15. REACHING OVER YOUR HEAD
16. RUNNING, SUCH AS FOR A BUS NO
17. SHOPPING
18. WHILE TRYING TO SLEEP
19. TALKING
20. VACUUMING NO
21. WALKING AROUND YOUR OWN HOME
22. WALKING UPHILL NO
23. WALKING UPSTAIRS NO
24. WALKING WITH OTHERS ON LEVEL GROUND
25. PREPARING MEALS NO

OTHER ACTIVITIES

Getting in + out the car.

Activity 3a) Getting in + out the car
 Activity 3b) Dressing
 Activity 3c) Bathing
 Activity 3d) Shopping
 Activity 3e) Carrying

RESULTS

The ability of a patient to cope with their own condition showed the following results; At no stage did either the trial or the control group produce indications of statistically significant changes.

Four questions were asked on mastery.

Clinically the trial group improved at each retest whereas the control group improved at the test done at 10 months only.

See example of individual psychometric response sheet on page 86.

Dyspnoea = questions 4a ~ 4c

Fatigue = questions 7, 10, 14, 16

Emotional Function = questions 5, 8, 11, 13, 15, 17,

19

Mastery = questions 6, 9, 12, 18.

4.4.1.2. Emotional Function

Statistically, within the trial group, emotional function was significantly better after participation in the trial. The control group did not produce significant results.

According to the questionnaire protocol, the clinical significance of these changes was as follows: There were 7 questions. An improvement of 3.5 was considered clinically significant. After 5 months the average improvement in the scores of the trial group was 4.84. After 10 months it was 5.5 and after 15 months it was 6.5. Significant improvement was thus present at each stage in the trial group.

In the controls the changes were -.3 and minus .2 and 2. None of these changes were significant.

4.4.1.3. Fatigue

Statistically, the results within the groups for the fatigue category were all not significant.

The clinical scores however, showed an improvement in the trial group (there were 4 questions in this category). At 5 months the increase was 3. At 10 months, it was 3.2 and at 15 months it was 3.5. The control group showed a clinically significant improvement at 15 months only.

4.4.1.4. Mastery

RESULTS

According to the protocol of the questionnaire, clinically significant improvement is measured by an increase of .5 score points per question. In the dyspnoea category there were 5 questions. An improvement of 2.5 would thus be clinically significant. If this method of evaluating the questionnaire were to be used, the control group also experienced an improvement in their perception of being able to carry out familiar activities with less breathlessness.

At the 5 months, the difference between the groups was not marked. (Trial group 5.73 and control group 5.5). It was, however, clinically significant in both groups.

After 10 months the trial group improved by 7.47 questionnaire score points while the control group only improved by 4.7 points.

At 15 months the trial group continued to improve by another 7.08 points and the control group by 4.2 points.

Sample sizes were as follows:

Initial test, trial : 12 subjects, control = 8 subjects.

5 months trial : 11 subjects control = 4 subjects.

10 months trial = 6 subjects, control = 4 subjects.

Final trial : 12 subjects and control = 8 subjects.

TABLE 4.9 DIFFERENCE BETWEEN PERCENTAGE CHANGE IN QUALITY
OF LIFE QUESTIONNAIRE SCORES IN THE TRIAL GROUP
AND IN THE CONTROL GROUP

	$\frac{D - A}{A} \times 100$				
	Trial		Control		p-value
	Mean	Std Dev	Mean	Std Dev	
Dyspnoea	46.0	46.0	25.0	46.0	0.1630
Emotional Function	28.0	41.0	5.0	14.0	0.1619
Fatigue	30.0	28.0	14.0	16.0	0.0755
Mastery	23.0	41.0	7.0	18.0	0.5809

D = Score at 15 months

A = Scores at base-line test

TABLE 4.8 QUALITY OF LIFE QUESTIONNAIRE SCORES OBTAINED
BY TRIAL AND CONTROL SUBJECTS AT COMMENCEMENT
OF THE STUDY

	Trial		Control		p Value
	mean	SD	mean	SD	
Dyspnoea	17.25 ± 4.0		18.00 ± 7.97		0.3717
Emotional Function	34.00 ± 6.64		38.00 ± 4.41		0.1997
Fatigue	17.00 ± 2.70		19.89 ± 4.25		0.0739
Mastery	22.33 ± 5.17		23.44 ± 3.43		0.6679

4.4. PSYCHOMETRIC QUESTIONNAIRE

4.4.1. There was no statistically significant difference in the psychometric scores produced by the trial group or the control group when answering the CRQ questionnaire in respect of all four quality of life parameters measured at the initial test (table 4.8).

4.4.2. When comparing the percentage change that occurred in the psychometric scores at the final test with the scores at the first test, no statically significant difference was found between the trial group and the control group with regard to dyspnoea, emotional function, fatigue or mastery (Table 4.9).

4.4.3. Examination of the changes that occurred within the groups (table 4.10) with regard to the psychometric scores produced the following:

4.4.1.1. Dyspnoea

(This category indicated the amount of breathlessness experienced by the subjects when carrying out relevant activities in their daily living).

Within the trial group, when comparing the feeling of breathlessness that this group experienced there does appear to be a significant improvement whereas there appears to be a non significant improvement within the control group.

TABLE 4.7 COMPARISON BETWEEN THE DISTANCE AND TIME THAT THE TRIAL SUBJECTS WERE ABLE TO WALK AT DEFINED INTERVALS DURING THE TRIAL AND THE DISTANCE AND TIME THEY WERE ABLE TO WALK INITIALLY

		Mean	St Dev	p value	Range
Training Distance (in meters)	B	588.27	248.33	0.0020	1280-245
	vs A	403.45	133.53		612-201
	C	702.78	404.27	0.0039	1680-227
	vs A	390.55	140.69		612-201
	D	722.18	404.12	0.0010	1820-210
	vs A	403.45	133.53		612-201
Training Time (in minutes)	B	6.62	1.73	0.0010	10.0-3.3
	vs A	4.77	1.17		6.5-2.5
	C	7.16	2.20	0.0078	10.5-3.3
	vs A	4.56	1.21		6.0-2.5
	D	8.18	3.33	0.0010	16.0-3.5
	vs A	4.77	1.17		6.5-2.5

A = Baseline
B = At 5 months
C = At 10 months
D = At 15 months

The sample size was smaller as only 6 trial subjects and 4 controls participated in this test.

At the final test the trial group improved more (532.9 metres while the control group walked slightly less than they had at the second test. Eleven trial subjects and seven controls participated in the last test.

4.2.2.2. HEART RATE

The trial group started with a resting heart beat of 86 beats per minute and the control group with a heart rate of 80 beats per minute (b/m). The difference between the two was not significant.

There was no significant changes in the resting or exercise heart rates in either group at any stage in the trial.

4.3. EFFECT OF TRAINING ON THE WALKING ABILITY OF THE TRIAL SUBJECTS (Table 4.7)

At the end of the trial the trial subjects were able to walk a mean distance of 319.7 metres further than they could initially while their heart rate was 60% of 220 minus their age. This was significant to a P - value of .0010. They were also able to walk for a mean time of 3.31 minutes more than they could originally.

5.2.2.1.VE and blood gases

According to Spiro (1977), minute ventilation (VE) increases during exercise to prevent hypoxemia and hypercapnia. The blood gases of the trial patients taken while performing the exercise test in our trial did not seem to indicate that the increased VE resulted in these effects. The trial group did not show an increase in PaO₂. If anything, the PaO₂ dropped slightly (not statistically significant) at similar work loads, after participation in exercise retraining. Increased ventilation should have produced a decrease in PaCO₂. This did not occur either.

When looking at the O₂ saturation(sat) while exercising at different loads at any stage in the trial we saw that the mean O₂ sat often dropped below 85 percent. Niederman et al (1991) terminated their exercise test when the O₂ sats dropped below 85%. They felt that saturations below this level could compromise their subjects physiologically. We must remember that if a mean value was at this low level some individual scores were considerably lower.

Although analyses of O₂ sats. did not produce any significant changes, clinically I could not ignore persistent deterioration in O₂sats. It does appear that the the trial group, when exercising at

DISCUSSION

VE at comparable loads after participation in an exercise programme. My subjects were more severe and older than those of Casaburi et al. The mean FEV₁ of my subjects was 1.44 litres against 1.69 litres and the mean age of my subjects was 65 years against 49 years in Casaburi's subjects. This reinforces the criticism that Carter et al (1992) made of Casaburi's study that the latter's subjects did not represent the general COPD cohort in medical practise.

When comparing the VE of my trial subjects with that of the controls who were not participating in a structured exercise programme, the difference was significant at rest and at 20 watts at the 15 month test only.

Patients who were more severely affected by the disease were not able to exercise at a higher load than 20 watts. They thus contributed to the statistics at this load only. This group of subjects may thus have been responsible for the significantly higher VE at this load.

A question now arises - is this raised VE a positive effect of exercise retraining in the trial group, or is it a negative effect?

In order to attempt to answer this question, I looked at the following:

DISCUSSION

ethical reasons, I was fully justified in setting these limits to my exercise testing.

Another criterion for terminating the test was the subject's perception of the amount of dyspnoea that he or she was able to tolerate before terminating the test. It is possible that they stopped exercising before they had reached their full potential. The strangeness of the laboratory situation may have been responsible for this premature termination of the test (Mak et al 1992). Although an attempt to familiarise the subjects with the laboratory situation before commencing the tests was made, they still found the environment alien and displayed signs of nervousness when carrying out the relevant tests.

They also found the mouthpiece and headgear uncomfortable. This discomfort may have caused the subjects to stop the test sooner than they would have done otherwise.

5.2.2 MINUTE VENTILATION (VE)

The changes which occurred in the VE of my trial subjects after participating in an exercise retraining programme appeared to contradict the results of Casaburi et al (1991). Their subjects showed a lower VE at comparable loads after training. My subjects appeared to exhibit a higher

5.2. BICYCLE ERGOMETER TEST

5.2.1 WORK LOAD ACHIEVED

When looking at the work loads that both groups were able to attain in the bicycle ergometer test (table 4.1 and 4.2), the results were so erratic that subjectively they did not warrant statistical analyses. There was no obvious difference between the two groups. It was interesting that 50% of the control subjects were able to exercise at a higher work load at the final bicycle test whereas only 25% of the trial subjects were able to exercise at higher load. This was balanced off by the fact that one of the control subjects could exercise at a lesser load only after 15 months while none of the trial subjects deteriorated in this manner.

It is possible that these erratic results could be ascribed to the criteria that I used to terminate the exercise test (see 3.3.1.2.). I terminated the test when the subjects reached a mandatory heart rate of 80% of $220 - \text{age}$. According to Funzal et al. 1991 and Carter et al 1992, heart rate measurement gives a poor indication of exercise ability in patients with COPD.

My subjects exhibited a great deal of oxygen desaturation while exercising (figure 4.9 and 4.10). This desaturation often reached levels that were not considered safe. I thus feel that, for

DISCUSSION

months and at ten months may not have been fully relevant. Different groups of subjects were tested at each interim test.

I did however make sure that the initial and the final test 15 months later were entirely compatible. The individuals that were tested at the first test were also tested at the final test. Any subject who could not fulfil this criterion was eliminated from the trial.

CHAPTER 5. DISCUSSION5.1 SAMPLE5.1.1.SAMPLE SIZE

Subjects were recruited from the patients referred for rehabilitation to the Physiotherapy Department at the Johannesburg Hospital. This trial was completed in 3 years. During this time approximately 300 patients were referred for physiotherapy. Only 32 of these patients were suitable as study subjects. Any attempt to obtain a larger sample size would have extended this study over an impractically long period.

5.1.2.SAMPLE SIZE AT EACH TEST

During the course of the trial difficulty was experienced in retesting the subjects at the exact time intervals that were laid down by the protocol of the study. The reasons for this was either equipment dysfunction or the vagaries of chronic respiratory disease or both.

A feature that is common in COPD patients is periodical exacerbation resulting from infection. Thus some of the subjects became unavailable for retesting on various occasions. This was the reason that the sample size varied at each retest. Although statistical methods were used to compensate for these inconsistencies, the interim tests at five

RESULTS

in 3.4.2.1. as I had promised them originally (see 3.4.3). Two trial subjects died within this period. Both subjects died of malignancies. One of cancer of the lung and the other of cancer of the bladder.

4.6.COMPLIANCE

4.6.1.DIARIES

When examining the diaries of the subjects, the following results were obtained:

4.6.1.1.TRIAL PATIENTS - exercised regularly as required. They seldom walked more than once per day even though they had been requested to do so.They said that they found that they were unable to do so on most days.

Initially, all subjects exercised daily.As the programme advanced,however, they became less enthusiastic and some of the subjects did not exercise every day.All exercised at least 4 times a week throughout the trial unless they were ill.Any trial subjects who exercised for less than this, were eliminated from the trial.

4.6.1.2.CONTROL PATIENTS - were a little more active than they had been initially while they participated in the trial.They did not, however walk regularly or adjust the amount of activity that they participated in.

4.6.2.ADHERENCE TO PROGRAMME

Two years after completion of the trial, 9 subjects were still participating in the exercise programme.Trial subjects and controls were participating in an exercise programme as described

TABLE 4.14 PULMONARY FUNCTION MEASUREMENTS OF TRIAL
AND CONTROL SUBJECTS AND TAKEN AT COMPLETION
OF TRIAL + 2 YEARS LATER

TEST	TEST D SD	TEST E SD	p VALUES
FVC (1)	2.6 ± 5.6	2.17 ± 0.42	0.0313
FEV ₁ (1)	1.25 ± 0.39	0.99 ± 0.35	0.0625
MEF ₂₅₋₇₅ (1/sec)	0.63 ± 0.26	0.42 ± 0.31	0.0938
MVV (1)	46.33 ± 16.95	45 ± 2186	0.4063
RV (1)	2.49 ± 0.96	3.90 ± 0.47	0.0313
TLC (1)	5.29 ± 1.32	6.43 ± 1.59	0.0313
RL/TLC	45.5 ± 7.59	59.5 ± 4.13	0.0313
DLCO (CO/min/mmHg)	16.21 ± 11.17	16.17 ± 5.32	0.8438
DLCO/VA	3.43 ± 2.40	3.99 ± 1.04	0.6875

Test D = test at 15 months; Test E = test 2 years later

Note: Number of subjects = 8

4.5.3. LUNG FUNCTIONS OF SUBJECTS STILL PARTICIPATING IN THE TRIAL 2 YEARS LATER (table 4.14.)

Examining the changes in the lung function of the subjects who were still participating in the programme which included exercise retraining two years after the end of the trial, the following results were obtained (table 4.14):

(It must be noted that at this stage subjects who participated in exercise retraining were from the control group as well as from the trial group)

There was no significant change in any of the lung function parameters measured except:

- a) FVC which decreased (P value = 0.0313)
- b) RV which increased (P-value = 0.0313)
- c) TLC which increased (P-value = 0.0313)

TABLE 4.13 COMPARISON BETWEEN THE CHANGE IN PULMONARY FUNCTION OVER 15 MONTHS IN THE TRIAL GROUP VERSUS THE CHANGE IN THE CONTROL GROUP

TEST	Trial Group D-A	p Value	Control Group D-A	p Value
FRC (l)	-0.76 (4.28-5.04)	0.0663	-0.42 (3.21-3.64)	0.2188
RV (l)	-0.89 (3.31-4.2)	0.0391	-0.46 (2.46-2.93)	0.3125
TLC (l)	-0.58 (6.38-6.97)	0.6406	-0.02 (5.25-5.27)	1.0000
RV/TLC	-7.49 (52.0-59.49)	0.0469	-3.5 (50.75-54.25)	0.6250
FVC (l)	0.38 (3.21-2.83)	0.1731	-0.13 (2.56-2.43)	0.4375
FEV ₁ (l)	-4.67 (40.89-45.55)	0.0117	-1.00 (54.33-55.33)	0.5625
FEV ₁ /FVC	-0.09 (1.21-1.31)	0.0663	-0.00 (1.35-1.35)	0.8438
PF (l/sec)	0.45 (4.65-4.2)	0.1731	-0.08 (4.95-5.02)	1.0000
MEF ₂₅₋₇₅ (l/sec)	-0.10 (0.52-0.62)	0.0504	-0.01 (0.67-0.68)	0.5625
MVV (l/min)	-6.55 (44.55-51.11)	0.0078	1.00 (53.33-52.33)	0.8750

DLCO * Va could not be calculated due to lack of data

D = measurements at 15 months

A = Base-line measurements

TABLE 4.12 DIFFERENCE BETWEEN TRIAL GROUP AND CONTROL GROUP IN RESPECT OF PERCENTAGE CHANGE IN LUNG FUNCTIONS AFTER PARTICIPATING IN THE TRIAL FOR 15 MONTHS

$$\% \text{ Change ie } \frac{D - A}{A} \times 100$$

	Trial		Control		p-value
	Mean	Std Dev	Mean	Std Dev	
RV/TLC	-0.12	0.15	-0.07	0.11	0.4909
RV	-0.18	0.23	-0.10	0.24	0.5186
TLC	-0.07	0.15	-0.02	0.11	0.8973
FVC	0.12	0.2	0.03	0.24	0.6374
FEV ₁	-0.06	0.10	-0.02	0.11	0.5557
MEF ₂₅₋₇₅	-0.14	0.14	-0.03	0.24	0.1573
MVV	-0.11	0.09	-0.07	0.01	0.2625

Sample size in DLCO + DLCO/Va too small for statistical analysis

A = Initial test

D = Test at 15 months

deterioration, is that it is difficult to have an objective measure of how much the subjects would have deteriorated without treatment.

Patients with COPD deteriorate emotionally as the condition progresses. We have already noted that our programme does not affect the natural decrease in lung function of these patients, and yet these patients did not show a reduction in their perception of their quality of life. In fact both groups showed signs of improvement in their quality of life with the trial group exhibiting slightly better results than the controls.

It thus appears that the comprehensive rehabilitation which is provided for patients with COPD at the Johannesburg hospital produces an improvement in the quality of life of these patients in respect of perceptions of dyspnoea, emotional function, fatigue and mastery. Exercise seems to have an additional effect on these improvements.

the support that they receive from the programme may, in fact feel less fatigued.

Four questions were asked on fatigue.

5.5.4. MASTERY

As part of the programme all the subjects were given lectures on how to cope with their condition. Both groups were taught behaviour modification techniques (Dudley et al 1980,2). In this each group received exactly the same information. In spite of this the trial group improved by 3.6 points while the control gained 1.3 points only. As there were four questions in the mastery category, the controls did not exhibit significant changes.

Quantitatively, I was unable to show any difference between the two groups functionally. Qualitatively, however, the subjects who participated in an exercise retraining programme showed a greater improvement than those who did not.

5.5.5. LACK OF SIGNS OF DETERIORATION

It is interesting to note that the control group deteriorated slightly in emotional function after 5 months and after 10 months. They were also less energetic after 5 months.

One of the shortcomings of a study on patients with a condition like COPD which naturally produces

According to questionnaire scores as calculated by the authors of the questionnaire, emotional function deteriorated slightly in the control group initially and then showed a slight improvement at the final test. The score was 6.5 points higher than it had been originally in the trial group while it was only 2 points higher in the controls.

There were seven questions on emotional function. It is thus clear that the trial group improved whereas the controls did not.

5.5.3. FATIGUE

In this category of the questionnaire, feelings of energy and vitality are evaluated.

The average age of my subjects was 65 years. At this age, people generally are not as energetic as they were when they were younger. Dudley et al (1980) stated that COPD is "a disease that interferes with breathing and reduces energy and vitality." Any improvement in this category could thus be considered unusual in this group of people. Although no statistical improvement was found in this category, both groups did show relevant clinical improvement. The difference between the change of score for the controls and the trial group was small (3.5 for the trial group and 2.3 for the controls). Patients who feel less helpless due to

index and in the 6MWD the controls showed improvement initially. Psychological support which the subjects received from the programme may have resulted in the patients feeling better initially. The gains resulting from this type of treatment appears to be limited and not ongoing.

There were five questions on dyspnoea and as an increase of .5 point per question is considered clinically significant, both groups improved with regard to dyspnoea. The trial group improved to a greater extent.

5.5.2. EMOTIONAL FUNCTION

Within the groups, the trial group showed significant improvement in their perception of their emotional function while the control group did not. As the trial group participated in an exercise retraining programme which resulted in an increased walking ability (see 5.4.), increased walking ability in patients who are usually restricted in all physical activities, will lead to improved functional ability. In a review by Williams (1989), he stated that "Impairment and functional limitation results in a perception of being handicapped," a perception which must affect emotional function. Reduction in this functional limitation should lead to improved emotional function and thus may explain this improved questionnaire scores in the trial group.

DISCUSSION

Schmoll in a book on research in Physical Therapy by Bork (1993). She says that "quantification of qualitative data places the researcher at risk of presenting data out of the "real life" context and thus undermining the very strength and significance of qualitative research."

When looking at the results of the questionnaire, I took this into consideration and examined clinical significance as described by the authors of the questionnaire as well as the quantitative statistical data.

The clinical analyses within the two groups produced the following results:

5.5.1. DYSPNOEA

The author of the questionnaire calculated the significance of improvements differently to the calculations of the statisticians (see Results). If we examine the results in this light, it appears that initially the both groups showed a decreased perception of breathlessness. This decrease in the sensation of dyspnoea did not continue in the controls while it did in the trial group.

In COPD, dyspnoea on activity is the major cause of discomfort and reduction in quality of life (Sandhu, 1986). Breathlessness is also known to be affected by psychological issues (Campbell, 1956). It is interesting to note that both in the dyspnoea

5.5. CHRONIC RESPIRATORY QUESTIONNAIRE (CRQ)

Rehabilitation programmes for patients with COPD have frequently reported an improvement in quality of life. (Lustic et al 1972, Angle et al 1973, Henderson et al 1993). "Is this improvement the result of the psychological support given to the subjects, or can it be attributed to improved functional ability (Williams 1989)". In my study, the control group received the same psychological support and attention that the trial group did (See method). The control group did not however participate in a structured, supervised monitored exercise programme.

When evaluating quality of life in patients with COPD, I made use of a questionnaire which examined subjective perceptions of dyspnoea, fatigue, emotional function and mastery. These perceptions were evaluated by the responses of the subjects on a likert scale which provided relevant options to the subjects. It must be noted that the higher the number on the scale, the more positive the response. When analyzing the results statistically, there was no difference between the two groups in any of the four categories in terms of change produced over fifteen months.

This type of research is qualitative rather than quantitative. This is described by Beverley

DISCUSSION

the trial and the control group. I can thus say that, according to the 6MWDT, the exercise programme which the trial patients took part in did not improve their walking ability. We cannot ignore the fact, however that these patients were able to walk further at the end of the trial while their heart rate was the same as it was when walking the smaller distances at the beginning of the trial.

It is interesting to note that even after 15 months of exercise training, the trial subjects were still able to walk for an average time of 8.18 minutes only. According to the statement on physical fitness by the American College of Sports Medicine (1990), in normal subjects, the duration of exercise should be 15 to 60 minutes of continuous or discontinuous aerobic activity for a training effect to occur. My trial subjects were not able to reach this level of exercise. It is possible that the difference between the exercise done by each group may not have been large enough to show changes in the 6MWDT is the difference between the structured programme and the amount that the controls did in their every day living activities

DISCUSSION

deteriorated. In my study, unfortunately, due to no statistical significant verification, no definite scientific conclusion can be drawn from these observations. It does, however leave the way open to possible effects which could have been illustrated with greater sample sizes.

I looked at resting and exercise heart rate in the 6MWDt., a factor that was not investigated by other researchers. Here also, no significant differences were found between the groups as regards percentage change. Within the groups, significant changes were found in the trial group but not in the control group.

5.4. WALKING ABILITY

The exercise retraining programme which the trial subjects participated in showed that the distance and the time that they were able to walk for after 15 months improved significantly ($p = 0.001$). They walked significantly further while their heart rate did not change from 60% of 220 minus age (see 3.4.2.1.).

The six minute walking distance test (6MWDt) which is a well documented test of walking ability in patients with COPD (Bernstein et al 1994) showed no significant difference in the results obtained in this test after participation in the trial between

5.3. THE SIX MINUTE WALKING DISTANCE TEST

The distance covered in the 6MWDT is considered an indication of the exercise capacity of patients with COPD. (McGavin et al 1976; Butland et al 1982; Bernstein et al 1994).

The fact that when comparing the difference between the trial and the control groups with regard to the percentage change in the distance walked in six minutes after fifteen months was not significant indicates that exercise retraining was not responsible for any change in the 6MWDT.

Within the group, however, it was interesting to note that the control group covered a greater distance in six minutes at the second test; they did not manage to cover a greater distance at 10 months or at 15 months whereas the trial group walked a greater distance at each test. These changes were not significant and the interim samples were very small but other investigators have reported on similar results. Nosworthy et al (1992), when comparing a group of patients, after participating in a large muscle group exercise training programme for six weeks, with patients who receive postural drainage only, found that both groups showed an increase in the 6MWDT initially. After three months however the exercise group continued to show an improvement, while the postural drainage group actually

DISCUSSION

low work loads where patients with severe disease contributed to the results whereas at higher loads where this group played no part in the result, these differences were not significant.

DISCUSSION

status of the respiratory muscles. Should the increase in VE in the trial group have been as a result of improvement in respiratory muscle function, MVV should have shown signs of an increase. In fact, the MVV decreased significantly within the trial group whereas it increased in the control group (not significant).

The relevance of this decrease is questionable as there is no statistically significant difference between the two groups when looking at percentage change over the 15 months. Furthermore this deterioration did not continue with subjects who were exercising 2 years after completion of the trial.

What can be said is that exercise retraining in the trial group did not produce an improvement (increase) in MVV and the increased VE is unlikely to be due to improved respiratory status.

In conclusion, when looking at the results of the bicycle ergometer test, we can only say that there occurred a significant increase in VE at low work loads after participation in exercise retraining. This increase was not accompanied by any difference in blood gases or in lung functions which could indicate advantages to exercise retraining. One must be aware of the fact, however that these effects were only statistically significant at the

DISCUSSION

low work loads, showed even greater desaturation after 15 months than they had initially. This did not appear to occur in the controls. As described earlier, subjects with severe COPD could often not exercise to a higher work load than 20 watts. It may thus have been this group that was responsible for the results at 20 watts. At 40 watts, there did not appear to be a great difference between the two groups in respect of desaturation when looking at the final compared to the initial result.

Unfortunately, the results at 60 watts may have been affected by the fact that, in a small sample (4 trials and 4 controls) one subject desaturated to 72%. This may have been a chance result because this particular subject did not exhibit such low O₂ sats. at any other stage during the trial.

Spiro also said that the increased VE may be due to raised plasma lactate levels. Had this been so, the standard bicarbonate should have shown a significant decrease (Jones and Ehrsam 1982). This did not happen either (see table 4.4.).

Examination of the blood gas results can thus not confirm the possibility that the increase in VE produced positive changes on exercising blood gases.

5.2.2.2. VE and lung functions

According to Ruppel (1991 page 58), maximal voluntary ventilation (MVV) is an indication of the

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6. CONCLUSION

6.1. I have shown that a comprehensive rehabilitation programme produces an improvement in the quality of life in patients with COPD. This improvement is greater when exercise retraining is included in the programme

6.2. Definite beneficial physiological indications of training effects at this low intensity exercise were not found.

6.3. Even at low intensities of exercise signs of potential harmful blood gas effects were present in some patients.

6.4. Patients found this programme easy to adhere to over an extended period.

6.5. Exercise retraining did not halt the deterioration in the lung functions of these patients.

DISCUSSION

more than I would have liked to. Practically, it is almost impossible to ban a group of subjects from activity for 15 months.

Atkins et al (1984) reports on a 50% dropout in patients participating in a rehabilitation programme for 3 to 6 months. In the present study 20 patients participated in the programme for 15 months with a dropout of 50% (11 subjects dropped out see 3.2). Two years after completion of the trial 9 (45%) subjects were still exercising. It does thus appear that, in my group of patients, this programme does result in better compliance than that reported on by Atkins et al.

DISCUSSION

acceptable form of exercise for the patients with COPD who were referred to the physiotherapy department at the Johannesburg Hospital.

In spite of a slight deterioration in compliance as the programme advanced, the subjects did exercise enough to fulfil the requirements of the programme for the full 15 months.

Unfortunately the actual amount of exercise done by each subject on a daily bases was dependant on the credibility of the reports in the dairies of the patients. At no stage did I have any reason to question the reliability of these dairies and I feel that they are a valid indication of the compliance of my subjects.

5.7.2.COMPLIANCE IN THE CONTROL GROUP

Although I had asked these subjects not to initiate any changes in their normal activity levels while they were participating in this trial, they did do a little more exercise than they had done before because they felt less dyspnoeic. Not one of these subjects, however, exercised as often or in as structured a manner as the trial group had. As I was investigating a clinical situation, this is, unfortunately one of the difficulties that one encounters. I was looking at low intensity exercise, and even small amounts of exercise in the control group may have resulted in equating these two groups

(a factor which was eliminated in our entrance criteria to the study) c) should not have been affected by exercise. Ruppel does state that normal MVV can vary up to 30% from the mean. The manoeuvre required to elicit this result often exaggerates air trapping. Even with this clarification I do not believe it can explain the fact that the trial group deteriorated significantly in their MVV and the control group did not.

Analyses of the percentage change in MVV in the two groups after fifteen months, did not show any significant difference between the trial and control groups. This could have meant that had my sample been different, the control group may also have shown a deterioration.

Retesting of the group of subjects who were still exercising two years after termination of the trial did not produce significant signs of deterioration in MVV.

These facts, nevertheless do not explain the significant deterioration in MVV in the trial group which occurred.

5.7.COMPLIANCE

5.7.1.COMPLIANCE IN TRIAL GROUP

An aim of our study was to ascertain whether a long term low intensity exercise programme would be an

trial, they exhibited signs of an increase in hyperinflation. This change may, be an indication of the normal progression of the disease. The decrease in hyperinflation shown in the study may have been of a transitory nature.

This seems to confirm the official statement on pulmonary rehabilitation given out by the American Thoracic Society in 1981 which stated that the majority of published studies had not shown any extension of life span or slowing of pulmonary function deterioration as a result of comprehensive respiratory care programmes. Later investigators reported the same results (Carter et al 1992 and Niederman et al 1991).

5.6.2. MAXIMAL VOLUNTARY VENTILATION (MVV)

A finding which is rather puzzling and which has not been reported by other investigators, is the significant deterioration of $\dot{V}_E$ within the trial subjects. This is contrary to what would have expected. According to page 58 (1991), MVV measurement depends on:

- a) status of respiratory muscles
- b) compliance of the lung and thorax system
- c) resistance offered by airway and lung tissue

One would expect exercise to improve a) and b) above and, unless a patient has exercised induced asthma

5.6 LUNG FUNCTIONS

5.6.1. HYPERINFLATION

Initially, the trial group were more hyperinflated than the control group (see 4.5.1). It is interesting to note that had I not used a controlled study, and had only looked at the results within the trial group, I would have been lead to believe that exercise results in a reduction in hyperinflation due to the significant decrease in residual volume in the trial group after exercise retraining. Mungall et al (1980) also reported on such findings in their study, where their subjects participated in an exercise retraining programme for twelve weeks. They did find, however that these changes in lung function returned to their previous levels when exercise was discontinued.

This apparent reduction in hyperinflation cannot be categorically attributed to the effects of exercise retraining due to two reasons. Firstly, when comparing the percentage change in RV, RV/TLC and TLC which occurred during the trial in the exercising group and that change in the control group who did not exercise, no significant difference was noted. Secondly, when retesting the lung functions of a group of patients who were still exercising two years after they had completed the

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9. In the last 2 weeks, how much of the time did you feel very confident and sure that you could deal with your illness? Please indicate how much of the time you felt very confident and sure that you could deal with your illness by choosing one of the following options from the card in front of you: [YELLOW CARD]

- 1 NONE OF THE TIME
- 2 A LITTLE OF THE TIME
- 3 SOME OF THE TIME
- 4 A GOOD BIT OF THE TIME
- 5 MOST OF THE TIME
- 6 ALMOST ALL OF THE TIME
- 7 ALL OF THE TIME

10. How much energy have you had in the last 2 weeks? Please indicate how much energy you have had by choosing one of the following options from the card in front of you: [PINK CARD]

- 1 NO ENERGY AT ALL
- 2 A LITTLE ENERGY
- 3 SOME ENERGY
- 4 MODERATELY ENERGETIC
- 5 QUITE A BIT OF ENERGY
- 6 VERY ENERGETIC
- 7 FULL OF ENERGY

11. In general, how much of the time did you feel upset, worried, or depressed during the last 2 weeks? Please indicate how much of the time you felt upset, worried, or depressed during the past 2 weeks by choosing one of the following options from the card in front of you. [BLUE CARD]

- 1 ALL OF THE TIME
- 2 MOST OF THE TIME
- 3 A GOOD BIT OF THE TIME
- 4 SOME OF THE TIME
- 5 A LITTLE OF THE TIME
- 6 HARDLY ANY OF THE TIME
- 7 NONE OF THE TIME

6. How often during the past 2 weeks did you have a feeling of fear or panic when you had difficulty getting your breath? Please indicate how often you had a feeling of fear or panic when you had difficulty getting your breath by choosing one of the following options from the card in front of you: [BLUE CARD]

- 1 ALL OF THE TIME
- 2 MOST OF THE TIME
- 3 A GOOD BIT OF THE TIME
- 4 SOME OF THE TIME
- 5 A LITTLE OF THE TIME
- 6 HARDLY ANY OF THE TIME
- 7 NONE OF THE TIME

7. What about fatigue? How tired have you felt over the last 2 weeks? Please indicate how tired you have felt over the last 2 weeks by choosing one of the following options from the card in front of you: [ORANGE CARD]

- 1 EXTREMELY TIRED
- 2 VERY TIRED
- 3 QUITE A BIT OF TIREDNESS
- 4 MODERATELY TIRED
- 5 SOMEWHAT TIRED
- 6 A LITTLE TIRED
- 7 NOT AT ALL TIRED

8. How often during the last 2 weeks have you felt embarrassed by your coughing or heavy breathing? Please indicate how much of the time you felt embarrassed by your coughing or heavy breathing by choosing one of the following options from the card in front of you: [BLUE CARD]

- 1 ALL OF THE TIME
- 2 MOST OF THE TIME
- 3 A GOOD BIT OF THE TIME
- 4 SOME OF THE TIME
- 5 A LITTLE OF THE TIME
- 6 HARDLY ANY OF THE TIME
- 7 NONE OF THE TIME

- c) Please indicate how much shortness of breath you have had during the last 2 weeks while [INTERVIEWER: INSERT ACTIVITY LIST IN 3c] by choosing one of the following options from the card in front of you: [GREEN CARD]

- 1 EXTREMELY SHORT OF BREATH
- 2 VERY SHORT OF BREATH
- 3 QUITE A BIT SHORT OF BREATH
- 4 MODERATE SHORTNESS OF BREATH
- 5 SOME SHORTNESS OF BREATH
- 6 A LITTLE SHORTNESS OF BREATH
- 7 NOT AT ALL SHORT OF BREATH

- d) Please indicate how much shortness of breath you have had during the last 2 weeks while [INTERVIEWER: INSERT ACTIVITY LISTED IN 3d] by choosing one of the following options from the card in front of you: [GREEN CARD]

- 1 EXTREMELY SHORT OF BREATH
- 2 VERY SHORT OF BREATH
- 3 QUITE A BIT SHORT OF BREATH
- 4 MODERATE SHORTNESS OF BREATH
- 5 SOME SHORTNESS OF BREATH
- 6 A LITTLE SHORTNESS OF BREATH
- 7 NOT AT ALL SHORT OF BREATH

- e) Please indicate how much shortness of breath you have had during the last 2 weeks while [INTERVIEWER: INSERT ACTIVITY LISTED IN 3e] by choosing one of the following options from the card in front of you: [GREEN CARD]

- 1 EXTREMELY SHORT OF BREATH
- 2 VERY SHORT OF BREATH
- 3 QUITE A BIT SHORT OF BREATH
- 4 MODERATE SHORTNESS OF BREATH
- 5 SOME SHORTNESS OF BREATH
- 6 A LITTLE SHORTNESS OF BREATH
- 7 NOT AT ALL SHORT OF BREATH

5. In general, how much of the time during the last 2 weeks have you felt frustrated or impatient? Please indicate how often during the last 2 weeks you have felt frustrated or impatient by choosing one of the following options from the card in front of you: [BLUE CARD]

- 1 ALL OF THE TIME
- 2 MOST OF THE TIME
- 3 A GOOD BIT OF THE TIME
- 4 SOME OF THE TIME
- 5 A LITTLE OF THE TIME
- 6 HARDLY ANY OF THE TIME
- 7 NONE OF THE TIME

- c) Of the remaining items, which is most important to you in your day-to-day life?

[LIST ITEM ON RESPONSE SHEET]

- d) Of the remaining items, which is the most important to you in your day-to-day life?

[LIST ITEM ON RESPONSE SHEET]

- e) Of the remaining items, which is the most important to you in your day-to-day life?

[LIST ITEM ON RESPONSE SHEET]

[FOR ALL SUBSEQUENT QUESTIONS, ENSURE RESPONDENT HAS APPROPRIATE RESPONSE CARD IN FRONT OF THEM BEFORE STARTING QUESTION]

4. I would now like you to describe how much shortness of breath you have experienced during the last 2 weeks while doing the five most important activities you have selected.

- a) Please indicate how much shortness of breath you have had during the last 2 weeks while [INTERVIEWER: INSERT ACTIVITY LIST IN 3a] by choosing one of the following options from the card in front of you: [GREEN CARD]

- 1 EXTREMELY SHORT OF BREATH
- 2 VERY SHORT OF BREATH
- 3 QUITE A BIT SHORT OF BREATH
- 4 MODERATE SHORTNESS OF BREATH
- 5 SOME SHORTNESS OF BREATH
- 6 A LITTLE SHORTNESS OF BREATH
- 7 NOT AT ALL SHORT OF BREATH

- b) Please indicate how much shortness of breath you have had during the last 2 weeks while [INTERVIEWER: INSERT ACTIVITY LISTED IN 3b] by choosing one of the following options from the card in front of you: [GREEN CARD]

- 1 EXTREMELY SHORT OF BREATH
- 2 VERY SHORT OF BREATH
- 3 QUITE A BIT SHORT OF BREATH
- 4 MODERATE SHORTNESS OF BREATH
- 5 SOME SHORTNESS OF BREATH
- 6 A LITTLE SHORTNESS OF BREATH
- 7 NOT AT ALL SHORT OF BREATH

1. BEING ANGRY OR UPSET
2. HAVING A BATH OR SHOWER
3. BENDING
4. CARRYING, SUCH AS CARRYING GROCERIES
5. DRESSING
6. EATING
7. GOING FOR A WALK
8. DOING YOUR HOUSEWORK
9. HURRYING
10. MAKING A BED
11. MOPPING OR SCRUBBING THE FLOOR
12. MOVING FURNITURE
13. PLAYING WITH CHILDREN OR GRANDCHILDREN
14. PLAYING SPORTS
15. REACHING OVER YOUR HEAD
16. RUNNING, SUCH AS FOR A BUS
17. SHOPPING
18. WHILE TRYING TO SLEEP
19. TALKING
20. VACUUMING
21. WALKING AROUND YOUR OWN HOME
22. WALKING UPHILL
23. WALKING UPSTAIRS
24. WALKING WITH OTHERS ON LEVEL GROUND
25. PREPARING MEALS

- 3.a) Of the items which you have listed, which is the most important to you in your day-to-day life? I will read through the items, and when I am finished, I would like you to tell me which is the most important.

[READ THROUGH ALL ITEMS SPONTANEOUSLY VOLUNTEERED AND THOSE FROM THE LIST WHICH PATIENT MENTIONED]

Which of these items is most important to you in your day-to-day life?

[LIST ITEM ON RESPONSE SHEET]

- b) Of the remaining items, which is the most important to you in your day-to-day life? I will read through the items, and when I am finished, I would like you to tell me which is the most important.

[READ THROUGH REMAINING ITEMS]

Which of these items is most important to you in your day-to-day life?

[LIST ITEM ON RESPONSE SHEET]

CHRONIC RESPIRATORY INDEX QUESTIONNAIRE

First Administration, 7 Point Scale

INTERVIEWER FORM

This questionnaire is designed to find out how you have been feeling during the last 2 weeks. You will be asked about how short of breath you have been, how tired you have been feeling and how your mood has been.

1. I would like you to think of the activities that you have done during the last 2 weeks that have made you feel short of breath. These should be activities which you do frequently and which are important in your day-to-day life. Please list as many activities as you can that you have done during the last 2 weeks that have made you feel short of breath.

[CIRCLE THE NUMBER ON THE ANSWER SHEET LIST ADJACENT TO EACH ACTIVITY MENTIONED. IF AN ACTIVITY MENTIONED IS NOT ON THE LIST, WRITE IT IN, IN THE RESPONDENT'S OWN WORDS, IN THE SPACE PROVIDED]

Can you think of any other activities you have done during the last 2 weeks that have made you feel short of breath?

[RECORD ADDITIONAL ITEMS]

2. I will now read a list of activities which make some people with lung problems feel short of breath. I will pause after each item long enough for you to tell me if you have felt short of breath doing that activity during the last 2 weeks. If you haven't done the activity during the last 2 weeks, just answer 'NO'. The activities are:

[READ ITEMS, OMITTING THOSE WHICH RESPONDENT HAS VOLUNTEERED SPONTANEOUSLY. PAUSE AFTER EACH ITEM TO GIVE RESPONDENT A CHANCE TO INDICATE WHETHER HE/SHE HAS BEEN SHORT OF BREATH WHILE PERFORMING THAT ACTIVITY DURING THE LAST WEEK. CIRCLE THE NUMBER ADJACENT TO APPROPRIATE ITEMS ON ANSWER SHEET]

PULMONOLOGY DIVISION
DEPARTMENT OF MEDICINE, JOHANNESBURG HOSPITAL.

Thank you for agreeing to take part in my trial. The results of this trial will greatly benefit many people suffering from chronic lung problems.

This letter is just to confirm what I have already told you about what is expected of you while participating in this trial.

1. This trial will last one year. During this period, whenever possible, I would like you to attend our clinic once a week. During this visit you will join the exercise and relaxation classes and I will check on your progress and plan your further treatment accordingly. Please inform me should you have to miss visits.
2. The following tests will be carried out on you every 4 to 5 months.
 - a) An exercise test on the stationary bicycle;
 - b) A walking test;
 - c) To answer a questionnaire;
 - d) Lung function tests.
3. You will attend two lectures on this subject in order to understand and cope with your condition. Should you, at any stage feel that you have forgotten a few details of this information, you will have to attend the relevant lectures again.
4. It is essential at all times that you be completely honest with me as to the amount of exercise that you do at home. It is advisable to follow our instructions explicitly, but if you are unable to do so at any stage and do either less or more than we have prescribed, please let me know. Record all the exercise done accurately in your log book.
4. Any change in your medication or oxygen use (even if you are doing it without your doctor's instructions) must be reported to me.

I have to have all this information, for my results to be of any value, in order to prove what my treatment can do for patients with lung conditions.

Let me remind you that you are at liberty to discontinue this trial as long as you let me know of your intentions.

1. You will certainly gain a lot from taking part in this trial and will also be helping many future patients.

Thanking you once again,



DINKY COHEN

I N F O R M E D C O N S E N T

JOHANNESBURG HOSPITAL

I Paul Joseph Myer, consent to take part in a trial to assess the effect of physiotherapy on my condition.

I am fully aware that the following tests are going to be carried out on me.

1. Certain breathing tests will be carried out which may cause me some tiredness.
2. I will take part in an exercise test on a stationary bicycle to test my ability to do exercise. This may also make me tired. While this test is being done, my heart rate, my blood pressure and my breathing will be monitored. Blood will be taken from an ear prick while I am exercising to check the effect of exercise on my blood.
3. A questionnaire will be filled in by me to find out how I feel about my condition.

At any stage during this trial, I have the right to withdraw.


(SIGNATURE OF SUBJECT)

WITNESSES

1. Reata
2. Ju. Stander

DC/hj

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THE 15 GRADE SCALE FOR RATINGS OF
PERCEIVED EXERTION (BORG SCALE)

- 1-----
- 2 VERY VERY LIGHT -----
- 3 -----
- 4 VERY LIGHT -----
- 5 -----
- 6 FAIRLY LIGHT -----
- 7 -----
- 8 SOMEWHAT HARD -----
- 9 -----
- 10 HARD -----
- 11 -----
- 12 VERY HARD -----
- 13 -----
- 14 VERY VERY HARD -----
- 15 -----

(Taken from Med. and Sci. in Sport and Ex. 1982, 14:378)

McMaster University
Health Sciences Centre - Rm. 1H7
1100 Main St. West
Hamilton, Ontario,
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May 17, 1988

J. Cohen
P O Box 390673
Lyndhurst
2106
Johannesburg
Republic of South Africa

RE: The Chronic Respiratory Disease Index Questionnaire

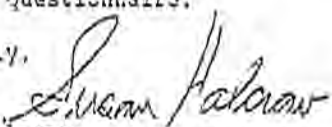
Enclosed is material which we have found useful in teaching interviewers to administer the CRQ.

1. Training Manual
(background information and tips for interviewing and scoring)
2. Training Cassette Tape
(a simulated interview and illustrations of problem situations)
3. The CRQ and Answer Sheet
(1st Administration and Followups)
4. Coloured Response Cards

I trust this material will be of value to you. Should you have any further questions, please feel free to contact Dr. Gord Guyatt or a member of his research staff (Sue Halcrow, Jana Keller or Sharon Nogradil). The best way to reach us is by calling Dr. Guyatt's Secretary at McMaster (416) 525-9140, Ext. 2160. If one of us is available, Dr. Guyatt's Secretary will put the call through. If we are not available, please leave a message and we will return your call as soon as possible.

Thank you for your interest in the Questionnaire.

Sincerely,


Susan Halcrow,
Research Assistant
for Dr. G. Guyatt

Encl.

14. How often during the last two weeks have you felt low in energy? Please indicate how often during the last two weeks you have felt low in energy by choosing one of the following options from the card in front of you, keeping in mind that last time you answered the questionnaire you chose [INSERT PATIENT'S ANSWER FROM PREVIOUS ADMINISTRATION]. [BLUE CARD]
15. In general, how often during the last two weeks have you felt discouraged or down in the dumps? Please indicate how often during the last two weeks you have felt discouraged or down in the dumps by choosing one of the following options from the card in front of you, keeping in mind that last time you answered the questionnaire you chose [INSERT PATIENT'S ANSWER FROM PREVIOUS ADMINISTRATION]. [BLUE CARD]
16. How often during the last two weeks have you felt worn out or sluggish? Please indicate how much of the time you felt worn out or sluggish by choosing one of the following options from the card in front of you, keeping in mind that last time you answered the questionnaire you chose [INSERT PATIENT'S ANSWER FROM PREVIOUS ADMINISTRATION]. [BLUE CARD]
17. How happy, satisfied, or pleased have you been with your personal life during the last two weeks? Please indicate how happy, satisfied or pleased you have been by choosing one of the following options from the card in front of you, keeping in mind that last time you answered the questionnaire you chose [INSERT PATIENT'S ANSWER FROM PREVIOUS ADMINISTRATION]. [GRAY CARD]
18. How often during the last two weeks did you feel upset or scared when you had difficulty getting your breath? Please indicate how often during the last two weeks you felt upset or scared when you had difficulty getting your breath by choosing one of the following options from the card in front of you, keeping in mind that last time you answered the questionnaire you chose [INSERT PATIENT'S ANSWER FROM PREVIOUS ADMINISTRATION]. [BLUE CARD]
19. In general, how often during the last two weeks have you felt restless, tense, or uptight? Please indicate how often you have felt restless, tense, or uptight by choosing one of the following options from the card in front of you, keeping in mind that last time you answered the questionnaire you chose [INSERT PATIENT'S ANSWER FROM PREVIOUS ADMINISTRATION]. [BLUE CARD]

8. How often during the last two weeks have you felt embarrassed by your coughing or heavy breathing? Please indicate how much of the time you felt embarrassed by your coughing or heavy breathing by choosing one of the following options from the card in front of you, keeping in mind that last time you answered the questionnaire you chose [INSERT PATIENT'S ANSWER FROM PREVIOUS ADMINISTRATION]. [BLUE CARD]
9. In the last two weeks, how much of the time did you feel very confident and sure that you could deal with your illness? Please indicate how much of the time you felt very confident and sure that you could deal with your illness by choosing one of the following options from the card in front of you, keeping in mind that last time you answered the questionnaire you chose [INSERT PATIENT'S ANSWER FROM PREVIOUS ADMINISTRATION]. [YELLOW CARD]
10. How much energy have you had in the last two weeks? Please indicate how much by choosing one of the following options from the card in front of you, keeping in mind that last time you answered the questionnaire you chose [INSERT PATIENT'S ANSWER FROM PREVIOUS ADMINISTRATION]. [PINK CARD]
11. In general, how much of the time did you feel upset, worried or depressed during the last two weeks? Please indicate how much of the time you felt upset, worried, or depressed during the last two weeks by choosing one of the following options from the card in front of you, keeping in mind that last time you answered the questionnaire you chose [INSERT PATIENT'S ANSWER FROM PREVIOUS ADMINISTRATION]. [BLUE CARD]
12. How often during the last two weeks did you feel you had complete control of your breathing problems? Please indicate how often you felt you had complete control of your breathing problems by choosing one of the following options from the card in front of you, keeping in mind that last time you answered the questionnaire you chose [INSERT PATIENT'S ANSWER FROM PREVIOUS ADMINISTRATION]. [YELLOW CARD]
13. How much of the time during the past two weeks did you feel relaxed and free of tension? Please indicate how much of the time you felt relaxed and free of tension by choosing one of the following options from the card in front of you, keeping in mind that last time you answered the questionnaire you chose [INSERT PATIENT'S ANSWER FROM PREVIOUS ADMINISTRATION]. [YELLOW CARD]

- c) Please indicate how much shortness of breath you have had during the last two weeks while [INTERVIEWER: INSERT ACTIVITY LISTED IN 3c] by choosing one of the following options from the card in front of you, keeping in mind that last time you answered the questionnaire you chose [INSERT PATIENT'S ANSWER FROM PREVIOUS ADMINISTRATION]. [GREEN CARD]
- d) Please indicate how much shortness of breath you have had during the last two weeks while [INTERVIEWER: INSERT ACTIVITY LISTED IN 3d] by choosing one of the following options from the card in front of you, keeping in mind that last time you answered the questionnaire you chose [INSERT PATIENT'S ANSWER FROM PREVIOUS ADMINISTRATION]. [GREEN CARD]
- e) Please indicate how much shortness of breath you had during the last two weeks while [INTERVIEWER: INSERT ACTIVITY LISTED IN 3e] by choosing one of the following options from the card in front of you, keeping in mind that last time you answered the questionnaire you chose [INSERT PATIENT'S ANSWER FROM PREVIOUS ADMINISTRATION]. [GREEN CARD]
5. In general, how much of the time during the last two weeks have you felt frustrated or impatient? Please indicate how often during the last two weeks you have felt frustrated or impatient by choosing one of the following from the card in front of you, keeping in mind that last time you answered the questionnaire you chose [INSERT PATIENT'S ANSWER FROM PREVIOUS ADMINISTRATION]. [BLUE CARD]
6. How often during the past two weeks did you have a feeling of fear or panic when you had difficulty getting your breath? Please indicate how often you had a feeling of fear or panic when you had difficulty getting your breath by choosing one of the following options from the card in front of you keeping in mind that last time you answered the questionnaire you chose [INSERT PATIENT'S ANSWER FROM PREVIOUS ADMINISTRATION]. [BLUE CARD]
7. What about fatigue? How tired have you felt over the last two weeks? Please indicate how tired you have felt over the last two weeks by choosing one of the following options from the card in front of you, keeping in mind that last time you answered the questionnaire you chose [INSERT PATIENT'S ANSWER FROM PREVIOUS ADMINISTRATION]. [ORANGE CARD]

CHRONIC RESPIRATORY DISEASE INDEX QUESTIONNAIRE

Follow-up, 7 Point Scale, Informed

You have previously completed a questionnaire(s) telling us about how you were feeling and how your lung disease was affecting your life. This is a follow-up questionnaire designed to find out how you have been getting along the last [insert length of time since last seen].

When you are answering the questions this time I will tell you the answer you gave us the last time. I would like you to give your answer today keeping in mind what you said the last time. For example, let's say that last time I asked you how short of breath you were while beating carpets [GIVE RESPONDENT GREEN CARD] and you said "4 Moderate shortness of breath". If you were exactly the same today, you would answer 4 once again. If you were more short of breath you would choose 1, 2, or 3 and if you were less short of breath you would choose 5, 6, or 7.

[FOR QUESTIONS 4a) to 4e) INSERT ACTIVITIES 3a) to 3e) FROM FIRST ADMINISTRATION ANSWER SHEET]

4. I would now like you to describe how much shortness of breath you have experienced during the last two weeks while doing each of the five most important activities you have selected.

- a) Please indicate how much shortness of breath you have had during the last two weeks while [INTERVIEWER: INSERT ACTIVITY LISTED IN 3a] by choosing one of the following options from the card in front of you, keeping in mind that last time you answered the questionnaire you chose [INSERT PATIENT'S ANSWER FROM PREVIOUS ADMINISTRATION]. [GREEN CARD]
- b) Please indicate how much shortness of breath you have had during the last two weeks while [INTERVIEWER: INSERT ACTIVITY LISTED IN 3b] by choosing one of the following options from the card in front of you, keeping in mind that last time you answered the questionnaire you chose [INSERT PATIENT'S ANSWER FROM PREVIOUS ADMINISTRATION]. [GREEN CARD]

18. How often during the last 2 weeks did you feel upset or scared when you had difficulty getting your breath? Please indicate how often during the past 2 weeks you felt upset or scared when you had difficulty getting your breath by choosing one of the following options from the card in front of you: [BLUE CARD]

- 1 ALL OF THE TIME
- 2 MOST OF THE TIME
- 3 A GOOD BIT OF THE TIME
- 4 SOME OF THE TIME
- 5 A LITTLE OF THE TIME
- 6 HARDLY ANY OF THE TIME
- 7 NONE OF THE TIME

19. In general, how often during the last 2 weeks have you felt, restless, tense, or uptight? Please indicate how often you have felt restless, tense, or uptight by choosing one of the following options from the card in front of you: [BLUE CARD]

- 1 ALL OF THE TIME
- 2 MOST OF THE TIME
- 3 A GOOD BIT OF THE TIME
- 4 SOME OF THE TIME
- 5 A LITTLE OF THE TIME
- 6 HARDLY ANY OF THE TIME
- 7 NONE OF THE TIME

15. In general, how often during the last 2 weeks have you felt discouraged or down in the dumps? Please indicate how often during the last 2 weeks you felt discouraged or down in the dumps by choosing one of the following options from the card in front of you: [BLUE CARD]

- 1 ALL OF THE TIME
- 2 MOST OF THE TIME
- 3 A GOOD BIT OF THE TIME
- 4 SOME OF THE TIME
- 5 A LITTLE OF THE TIME
- 6 HARDLY ANY OF THE TIME
- 7 NONE OF THE TIME

16. How often during the last 2 weeks have you felt worn out or sluggish? Please indicate how much of the time you felt worn out or sluggish by choosing one of the following options from the card in front of you: [BLUE CARD]

- 1 ALL OF THE TIME
- 2 MOST OF THE TIME
- 3 A GOOD BIT OF THE TIME
- 4 SOME OF THE TIME
- 5 A LITTLE OF THE TIME
- 6 HARDLY ANY OF THE TIME
- 7 NONE OF THE TIME

17. How happy, satisfied, or pleased have you been with your personal life during the last 2 weeks? Please indicate how happy, satisfied or pleased you have been by choosing one of the following options from the card in front of you: [GRAY CARD]

- 1 VERY DISSATISFIED, UNHAPPY MOST OF THE TIME
- 2 GENERALLY DISSATISFIED, UNHAPPY
- 3 SOMEWHAT DISSATISFIED, UNHAPPY
- 4 GENERALLY SATISFIED, PLEASED
- 5 HAPPY MOST OF THE TIME
- 6 VERY HAPPY MOST OF THE TIME
- 7 EXTREMELY HAPPY, COULD NOT HAVE BEEN MORE SATISFIED OR PLEASED

12. How often during the last 2 weeks did you feel you had complete control of your breathing problems? Please indicate how often you felt you had complete control of your breathing problems by choosing one of the following options from the card in front of you: [YELLOW CARD]

- 1 NONE OF THE TIME
- 2 A LITTLE OF THE TIME
- 3 SOME OF THE TIME
- 4 A GOOD BIT OF THE TIME
- 5 MOST OF THE TIME
- 6 ALMOST ALL OF THE TIME
- 7 ALL OF THE TIME

13. How much of the time during the last 2 weeks did you feel relaxed and free of tension? Please indicate how much of the time you felt relaxed and free of tension by choosing one of the following options from the card in front of you: [YELLOW CARD]

- 1 NONE OF THE TIME
- 2 A LITTLE OF THE TIME
- 3 SOME OF THE TIME
- 4 A GOOD BIT OF THE TIME
- 5 MOST OF THE TIME
- 6 ALMOST ALL OF THE TIME
- 7 ALL OF THE TIME

14. How often during the last 2 weeks have you felt low in energy? Please indicate how often during the last 2 weeks you have felt low in energy by choosing one of the following options from the card in front of you: [BLUE CARD]

- 1 ALL OF THE TIME
- 2 MOST OF THE TIME
- 3 A GOOD BIT OF THE TIME
- 4 SOME OF THE TIME
- 5 A LITTLE OF THE TIME
- 6 HARDLY ANY OF THE TIME
- 7 NONE OF THE TIME

Author: Cohen,D.

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