CHAPTER III

METHODOLOGY

3.1 RESEARCH APPROACH

An evaluative approach was employed to find out the effectiveness of multidimensional pulmonary rehabilitation, specifically exercises and psychosocial support on pulmonary functional measures, exercise capacity and health related quality of life of patients with chronic obstructive pulmonary disease.

3.2 RESEARCH DESIGN

A single blind randomized controlled trail of repeated measures design was selected for the present study. Blinding was incorporated in outcome measurements. The services of trained personnel who had no information on the grouping of the study were utilised for obtaining unbiased outcome measures.

3.3 SETTING

This research study was conducted at Sri Ramachandra Hospital, Porur, Chennai - 600116 and Government Hospital of Thoracic Medicine, Tambaram, Chennai - 600047 that offer treatment to patients with COPD who normally reside within the urban and suburban limits of Chennai. Sri Ramachandra Hospital, Porur (Figure 3.1), is a 1675 - bedded multi specialty
hospital where every day about 1500 patients are being treated as outpatients. On an average 300 COPD patients are admitted every year for treatment.

Govt. Hospital of Thoracic Medicine, Tambaram, Chennai-47 (Figure 3.2), was formerly known as Tuberculosis Sanatorium established in the year 1928 and is situated in the south at about 25 kilometers from the city of Chennai. It is spread over nearly 200 acres close of the hillock Pachamalai. This hospital has 896 beds, which are distributed in 33 wards. About 25 medical officers and 110 staff nurses render health care to the patients with respiratory disorder. Almost 1800 – 2000 COPD patients are admitted every year for treatment at Government Hospital of Thoracic Medicine.

3.4 POPULATION

The study population comprises of patients with COPD who have underwent treatment at Sri Ramachandra Hospital, Porur, Chennai – 600 116 and Government Hospital of Thoracic Medicine, Tambaram, Chennai – 600 047, Tamil Nadu, India.

3.5 SAMPLE SIZE

Sample size estimation for this study was made, based on an assumption of medium effect for the interventions. A Cohen’s conventional Eta-squared value of 0.06 for medium effect, a value of 0.05 for alpha (level of significance) and a value of 0.80 for the power were used to estimate the size of population for three parallel groups (Polit & Hungler, 1999). The estimated total sample size was 165 patients with COPD. Each group consists of 55 patients in control, exercise and exercise with psychosocial support group respectively.
Figure 3.1 Sri Ramachandra Hospital, Porur, Chennai – 116

Figure 3.2 Govt. Hospital of Thoracic Medicine, Tambaram, Chennai - 47
3.6 SAMPLING TECHNIQUE

Sampling is the process of selecting a portion of population to represent the entire population. Hence a suitable probability (random) sampling technique should be used to avoid bias. In this study a single stage cluster sampling technique was used. A cluster of 3 wards each per gender, out of the available 12 male wards and 6 female wards were randomly selected by lottery method. All the patients with COPD who were admitted to these 6 wards were considered as sample.

3.7 RANDOMIZATION, CONTROL AND MANIPULATION

Randomization involves the placement of subjects in groups on random basis. In consideration of avoiding any possible contamination among the subjects of various groups, a cluster randomization method was employed. If in a same ward the patients allotted to the various groups are admitted then the possibility of interaction between them might result contamination. Hence it was decided to have patients of each group at one selective ward. Accordingly, out of the randomly selected three wards each for the male and female, one ward each per group and per gender was assigned by lottery selection. The selected wards are at a distance of about 50 to 100 meters from one another and hence the possibility of subjects mix up was very low. All the patients who were admitted to the selected wards and signed the patient consent form (APPENDIX - A) were enrolled as subjects for the study.

The term control group, in other words, refers to a group of subjects whose performances are used as a basis for evaluating the performances of other experimental groups. Manipulation involves doing some planned intervention to specific groups (experimental groups).
The main objective of this study is to determine the effectiveness of administering a structured exercise programme to COPD patients with and without psychosocial support. Hence, one control and two experimental groups were selected and they are named as follows (Table 3.0)

i) Control group  
ii) Exercise group (Breathing and physical exercise training)  
iii) Exercise with psychosocial support group (Breathing and physical exercise training with psychosocial support)

3.8 CRITERIA FOR SAMPLE SELECTION

The following are the inclusion and exclusion criteria for the selection of samples.

3.8.1 Inclusion Criteria

Patients who were  
i) Suffering from COPD (i.e. FEV$_1$/FVC less than 70% of actual measured values and the FEV$_1$ less than 80% of predicted value) for a period of less than 5 years.  
ii) The age group of 35 years and above.  
iii) Able to speak and/ or read Tamil or English.  
iv) Living within a distance of 100 Kms. from Chennai.

3.8.2 Exclusion Criteria

Patients who have/had  
i) Tuberculosis and/or AIDS  
ii) Cardiac and other systemic diseases  
iii) Neuromuscular disorders  
iv) Any chest or physical deformity.
### Table 3.0  Design of Experimental Study

<table>
<thead>
<tr>
<th>Group</th>
<th>Pre test measurement</th>
<th>Interventions</th>
<th>Post test measurement After a study period of</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>1 month</td>
</tr>
<tr>
<td>Control</td>
<td>O₁</td>
<td>_</td>
<td>O₂</td>
</tr>
<tr>
<td>Experimental-1</td>
<td>O₁</td>
<td>Breathing &amp; Physical Exercises</td>
<td>O₂</td>
</tr>
<tr>
<td>Experimental-2</td>
<td>O₁</td>
<td>Breathing &amp; Physical Exercise and Psycho social support</td>
<td>O₂</td>
</tr>
</tbody>
</table>

O₁ - Demographic profile, Pulmonary functional measures (PFM), Health Related Quality of Life (HRQOL), Six minutes walking distance (6 MWD)

O₂ - HRQOL and 6 MWD

O₃ - PFM, HRQOL and 6 MWD
3.9 HANDBOOK ON PULMONARY REHABILITATION

In order to ensure the baseline knowledge on COPD of all the subjects similar, it was decided to provide a general education on COPD to all the subjects. The investigator prepared a Handbook on COPD and Pulmonary Rehabilitation based on the following literature. The American Thoracic Society statement on Pulmonary Rehabilitation (ATS Statement, 1999), British Thoracic Society statement on Pulmonary Rehabilitation (BTS Statement, 2001), the workshop summary of the National Heart, Lung and Blood Institute (NHLBI) and the World Health Organisation (WHO) entitled Global Initiative for Chronic Obstructive Lung Disease (GOLD) (Pauwels et al., 2001), National clinical guideline for management of COPD (BTS COPD consortium, 2004) and handbooks on Pulmonary Rehabilitation published by reputed hospitals were considered as guidelines for the preparation of Handbook on Pulmonary Rehabilitation in English and translation into local language Tamil.

The Handbook on Pulmonary Rehabilitation describes the disease pathology, signs and symptoms, risk factors and their avoidance with the specific emphasise on smoking cessation, coping strategies, balanced diet, necessary life style modifications and adherence to the health practices (APPENDIX - B).

3.10 EXERCISE PROGRAM

Exercise limitation is a common and disturbing manifestation of COPD. The exercise intolerance is often caused by multiple interrelated anatomic and physiologic disturbances. Importantly, exercise tolerance can be improved despite the presence of fixed structural abnormalities in the lung. Exercise training, undertaken alone or in the context of comprehensive PR,
improves exercise endurance and, to a lesser degree, the maximal tolerated workload of patients with COPD. PR also improves dyspnoea and HRQOL. Exercise tolerance may improve following the exercise training because of gains in aerobic fitness or peripheral muscle strength. The various other benefits of exercise training are enhanced mechanical skill, improvements in respiratory muscle function, breathing pattern, lung hyperinflation as well as reduction in anxiety, fear, and dyspnoea associated with exercise. Gains made in exercise tolerance can last up to two years following a limited duration (6-12 weeks) rehabilitation programme (Bourjeily & Rochester, 2000).

A structured exercise program for PR preferably consists of both breathing exercises for at least 15 minutes a day and physical exercises (upper or lower extremities) for 15 to 30 minutes a day for a period of 8 weeks so as to provide a long term benefits of improving the lung function and HRQOL.

### 3.11 BREATHING EXERCISES

Breathing exercises are helpful in regulating the respiratory rate and pattern. It also attempts to decrease the work of breathing and promote the function of the respiratory muscles. The preferable breathing exercises and respiratory muscle training are

1. Pursed lip breathing
2. Diaphragmatic breathing
3. Ventilatory muscle training

#### 3.11.1 Pursed Lip Breathing

Pursed lip manoeuver is the easiest one and frequently adopted by patients when they became dyspnoeic. Mechanically the manoeuver is
believed to provide internal stability to the airways during expiration, stimulating positive end expiratory pressure by mildly exhaling against pursed lips. The expiratory time is prolonged, the airways are stabilized and premature collapse is prevented. Thus PLB lowers the respiratory rate and increases the tidal volume.

According to Roa et al. (1991) the exact mechanism by which PLB decreases dyspnoea is unknown. It does not seem to change functional residual capacity or oxygen uptake but it does decrease respiratory frequency and increase the tidal volume.

3.11.2 Diaphragmatic Breathing Exercise

The abdominal or diaphragmatic breathing is designed to increase the use of the diaphragm during inspiration. The diaphragm is the major muscle of respiration. Diaphragmatic breathing (DB) technique initially has to be taught by a skilled person. Diaphragmatic (abdominal) breathing helps to achieve maximum inhalation and to slow the respiratory rate. Similar to PLB, DB improves the respiratory rate, minute ventilation and tidal volume, (Gosselink, 1995).

Pursed lip breathing (PLB) with Diaphragmatic breathing (DB) is designed to increase the use of the diaphragm during inspiration and prolonging the exhalation time. The diaphragm is the major muscle of respiration. Diaphragmatic (abdominal) breathing helps to achieve maximum inhalation, reducing the respiratory rate, controlling and minimising the discomfort associated with breathlessness.

The techniques of PLB and DB are designed to assist the patients with COPD in controlling and lessening the discomfort associated with
breathlessness. Training of respiratory muscles is recommended in patients with ventilatory limitation during exercise (Gosselink et al., 1997). The PLB and DB techniques result in more efficient pattern of ventilation, and improvement in the dynamic airway compression and a lessening in the sensation of dyspnoea (Kesten, 1997).

### 3.11.2 Ventilatory Muscle Training

According to Belman (1994) any PR programme with an objective to improve the strength of the respiratory muscle should incorporate a suitable exercise to offer a tolerable resistance for the breathing activity. Ventilatory muscle training should be considered for patients who continue to experience exercise limitation and breathlessness despite medical therapy and general exercise reconditioning, improvements in respiratory muscle function, breathing pattern, or lung hyperinflation, as well as reduction in anxiety, fear, and dyspnoea associated with exercise (Bourjeily & Rochester, 2000).

Based on the above guidelines a low and medium resistance expiratory exercises such as

a) Blowing out bubbles through water using a straw
b) Blowing a balloon

were recommended to the patients with COPD in the experimental groups (exercise and exercise with psychosocial support group) to improve the respiratory muscle strength and endurance as a long time benefit. Roomi et al. (1996) have administered balloon blowing exercise in their rehabilitation programme.

### 3.12 PHYSICAL EXERCISES
Exercise training has become an essential component of pulmonary rehabilitation. High intensity training is feasible even in patients with more advanced COPD. Improved sub-maximal exercise performance and increased quality of life were found after muscle training (Gosselink et al., 1997). COPD subjects who perform some level of regular physical activity have lower risk of both COPD admissions and mortality. The recommendation that COPD patients be encouraged to maintain or increase their levels of regular physical activity should be considered in future COPD guidelines, since it is likely to result in a relevant public health benefit (Aymerich et al., 2006).

Berry et al. (1999) conducted a study to compare the performance of Stage I and II patients with COPD on undergoing a 12 weeks exercise program. The study findings revealed that irrespective of their stages and severity all patients with COPD were obtained benefit in physical performance and HRQOL from exercise rehabilitation.

Self reported regular physical activity at baseline was classified into 4 categories (very low, low, moderate and high) from a population based sample recruited in Copenhagen in 1981-83 and 1991-94, a total of 2,386 individuals with COPD (according to lung function tests) were identified and followed until 2000. Moderate and high levels of regular physical activity were associated with lower risk of COPD admission during follow up and lower risk of mortality.

Many other findings listed in section 2.3 also indicate the essentiality and benefits of physical exercises in improving the work capacity and HRQOL. The physical exercises recommended in PR should be a combination of upper and lower extremity exercises.
3.12.1 Upper Extremity Exercises

The role of upper extremity exercise trainings in improving upper arm/torso muscle endurance, handgrip strength, 6MWD, activities of daily living (ADL) and HRQOL has been reported by Lebzelter et al. (2001) and Dourado et al. (2006). It is rather unusual to note that though one of the study administered a low intense unsupported arm exercise (UAE) of bilateral anterior arm elevation to shoulder level (Lebzelter et al., 2001) and the other one used intense exercises such as bench press performed on gymnasium equipment (Dourado et al., 2006) both the study reported significant improvements in many physiological and psychological functions.

The upper extremity exercise trainings are much more important to improve arms function since many activities of daily living involve the use of the arms. A set of easily practicable upper extremity exercises were selected for the present study and are given below

i. Wall hand climbing
ii. Rope turning
iii. Rod lifting
iv. Pulley tugging.
3.12.2 Lower Extremity Exercise

Exercise training, undertaken alone or in the context of comprehensive PR, improves exercise endurance, the maximal tolerated workload, dyspnoea, 6MWD and QOL. Hence Lower extremity training should be included routinely in the exercise prescription. The choice of type and intensity of training are primarily based on the patient's individual baseline functional status, symptoms, needs, and long term goals. When tolerated, high intensity (continuous or interval) training may lead to greater improvements in aerobic fitness than low intensity training but is not absolutely necessary to achieve gains in exercise endurance (Bourjeily & Rochester, 2000).

The benefits gained through exercise programme lasts for a longer period. Troosters (2000) investigated the short and long term effects of a 6 months outpatient rehabilitation program and found significant and clinically relevant changes in 6MWD, maximal exercise performance, peripheral and respiratory muscle strength, and HRQOL. Most of these improvements persisted for 18 months. The types of exercises experimented varied from the low intense walking to the high intense leg push in gymnasium. The other tested and recommended exercises are treadmill and cycling. The most preferable and simple to perform is walking.

Based on the outcomes of the studies listed above and in section 2.3, an incremental walking exercise programme was designed and recommended to the subjects in the experimental groups of the present study.
3.13 INSTRUCTIONAL MANUAL FOR EXERCISE PROGRAMME

In order to implement the exercise programme effectively, an Instructional Manual On Breathing And Physical Exercises was prepared. The Instructional Manual On Breathing And Physical Exercises describes the benefits of breathing and physical exercises, procedure of pursed lip breathing and diaphragmatic breathing, practicing forced breathing by fun exercises such as balloon blowing and bubble blowing in water using straw, upper and lower extremity exercises such as wall hand climbing, rod lifting, rope turning, pulley tugging and walking. All these exercises have been illustrated with suitable schematic sketches. Simple procedures for self assessment of the exertion, the respiration and pulse rate are also included in the manual (APPENDIX - C).

3.14 PSYCHOSOCIAL SUPPORT

Psychosocial support involves provision of a personalized care in terms of assistance, assurance and appreciation. Psychosocial support could be offered by family, friends and caregivers. Though several studies have experimented the effect of psychosocial support either as one of the main component of PR or an adjunct, the significance of psychosocial support is yet to be established.

In this study, the psychosocial support was provided to the subjects of psychosocial support group through telephonic contact every week and home visit at fortnightly.

3.15 INSTRUMENTS

In this study the following forms and instruments were used to assess and record the demographic variables, clinical measurements,
pulmonary functional measures, six minutes walking distance and health related quality of life.

3.15.1 Demographic Assessment

The patients biographic and demographic details such as 1) age, 2) sex, 3) marital status, 4) education, 5) profession 6) monthly income, 7) domicile, 8) duration of exposure to pollutant 9) types of pollutants 10) duration of illness 11) hospitalization were collected by an interview schedule and recorded in Demography form (APPENDIX - D).

3.15.2 Clinical Measurement

Data regarding 1) age, 2) sex, 3) height, 4) weight, 5) pulse rate and 6) respiratory rate of the patients were assessed and recorded in Clinical measurement form (APPENDIX – E1). The data on age, sex, height and weight were used for the prediction of pulmonary functional measures.

3.15.3 Pulmonary Functional Measures

The pulmonary functional measures listed in Table 3.1 were assessed and recorded in a form, which has the provision to record both pre and post values (APPENDIX – E2). The pulmonary functional measures were assessed using a spirometer of model Spirolab –II.
Table 3.1  Pulmonary Functional Measures

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Pulmonary Functional Measures</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>FVC</td>
<td>Forced vital capacity is maximum volume of air that can be exhaled after a maximum inspiration.</td>
</tr>
<tr>
<td>2</td>
<td>FEV₁</td>
<td>Forced expiratory volume in first second of expiration. The amount of air exhaled in first second of forced exhalation. FEV₁ is a vital parameter to measure the severity of airway obstruction.</td>
</tr>
<tr>
<td>3</td>
<td>FEV₁ / FVC</td>
<td>The ratio between FEV₁ and FVC generally expressed in percentage. An useful parameter in differentiating obstructive and restrictive pulmonary dysfunction.</td>
</tr>
<tr>
<td>4</td>
<td>PEFR</td>
<td>Peak expiratory flow rate. Maximum airflow rate during forced expiration, an useful measurement to monitor broncho constriction in asthma.</td>
</tr>
</tbody>
</table>

3.15.4  Six Minutes Walking Distance

Six minutes walking distance (6MWD) is one of the indicators of exercise capacity (ATS Statement, 2002). This measure is widely used in many research studies to predict the effectiveness of intervention on exercise capacity. In this study 6MWD was measured three times viz. on enrolment of patients for the study, in the mid of PR programme (i.e) after 4 weeks and at the end of the study. The form used to record the 6MWD had the provision to enter all the three measurements (APPENDIX – E3).
3.16 DEVELOPMENT OF NEW HRQOL QUESTIONNAIRE

3.16.1 Quality of Life

Quality of life (QOL) generally defined as a multi dimensional concept with many domains including physical, psychological, social, economical, cultural and spiritual. The key three indicators of QOL are the well being, satisfaction with life and functional status. A generic measure of QOL may not be appropriate and sensitive to evaluate the outcomes of a health care research study. Hence domain specific instrument is preferable to sense the changes brought out by interventions.

3.16.2 Health Related Quality of Life

Health related quality of life (HRQOL) specifies the general concepts in the domain of health and the measures include symptoms, physical functioning, mental health, role functioning and overall health perceptions (Corles et al., 2001). In recent days, the need for disease specific instrument for detecting even a small change is felt and accordingly many disease specific HRQOL instruments are being developed.

3.16.3 Varieties of HRQOL Instruments

Recently, Names and Bumbacea (2005) stated that the HRQOL has been an important field of research for the past one decade. Several HRQOL questionnaires have been developed, validated and used. Measuring HRQOL is important in order to evaluate the impact of the disease on patient life, it can also be used to measure the therapeutic effect of pharmacological or non pharmacological therapies (Kaplan & Ries, 2005).
a) **Disease Specific and General HRQOL Instruments**

In many rehabilitation studies disease specific HRQOL instruments such as Chronic Respiratory Questionnaire (CRQ), St. George Respiratory Questionnaire (SGRQ) and General measures such as the Short Form-36 (SF-36) or Quality of Well Being Scale (QWB) have been employed. General measures demonstrate less sensitivity than disease specific questionnaires but have value for cross disease comparisons and health economic analysis.

b) **Few Other Related Instruments**

Pulmonary Functional Status Scale (PFSS), Clinical Chronic obstructive Questionnaire (CCQ), Seattle Obstructive Lung Disease Questionnaire (SOLDQ) and Pulmonary Functional Status and Dyspnoea Questionnaire (PFSDQ) are minimally used disease specific instruments; their sensitivity to measure the change due to rehabilitation has yet to be investigated in detail.

Some argue that information on function is already included in some of the disease specific health status measures therefore additional questionnaires are unnecessary. As domestic independence is an important goal of rehabilitation, this should be reflected by standardized activity of daily living (ADL) scales (BTS Statement, 2001).

### 3.17 THE NEED FOR DEVELOPMENT OF NEW HRQOL INSTRUMENT

Curtis et al. (1994) emphasised that the future researcher needs to design an appropriate instrument to assess the aspects which are directly related to COPD and other general factors such as emotional functioning, social role
functioning, activities of daily living and the ability to enjoy activities. After a detailed review on effect of pulmonary rehabilitation of COPD on HRQOL, Wurtemberger and Hutter, (2001) suggested that the researcher in future, if they need to use HRQOL instrument, should use combined disease specific and generic measure questionnaire. Comprehensive assessment of the effects of COPD requires a battery of instruments that not only tap the disease specific effects, but also the overall burden of the disease on everyday functioning and emotional well being (Engstrom et al., 2001). The issues arising due to variation in culture, religion, education, income and many other socio demographic variables between the countries and nations are to be carefully considered while evolving and validating HRQOL instruments (Corles et al., 2001).

3.17.1 Components of New Instrument

The health related quality of life (HRQOL) questionnaire for the present study was designed to suit the Indian conditions so that the subjective well being of the patients with COPD prior and after the intervention could be measured (Appendix-F). The new HRQOL questionnaire was prepared based on the guidelines of Maille et al. (1997) and Jones et al. (1992). The salient features of the existing standard instruments such as Chronic Respiratory Questionnaire (CRQ), St. George Respiratory Questionnaire (SGRQ), etc. were considered while framing the new instrument.

The new HRQOL questionnaire consists of 4 sub sections with number of items in each section ranging between 5 and 10. The items in the sub sections were designed to measure the subjective self- perception on

i) Breathing status (7 items),
ii) Physical activity (10 items),
iii) Social status (5 items) and
iv) Emotional status (8 items).
A total of 30 items are incorporated in the questionnaire. It is an operator led interview type questionnaire (APPENDIX – F). Each item has score value ranging between 0 and 4 in 5 point Likert scale. The maximum and minimum score of the HRQOL questionnaire is 120 and 0 respectively. Approximately it takes 15 to 20 minutes to record the responses of the patient to the questionnaire. The choice of questionnaire as outcome measure may also be influenced by the ease of use. The CRQ is easy to score but currently may take 20 minutes to administer, while the SGRQ is nominally self administered but has more complicated scoring.

3.17.2 Comparison of HRQOL Instruments

A comparison on the various aspects such as number of items, number of domains, scales, type of administration, time duration of assessment, validity and reliability of the 3 questionnaires (CRQ, SGRQ and present study questionnaire) was made and the details are presented in Table 3.2

3.17.3 HRQOL Score Interpretation

The score range of the present study questionnaire is 0 – 120. In order to grade them, the score range is subdivided into six categories as very poor (0-30), poor (31-45), fair (46-60), good (61-75), very good (76-90) and excellent (91-120). The classification is done by allotting the lower and upper quartiles for the tail categories namely very poor and excellent, whereas to have better demarcation in the intermediate quartiles, these are divided into 4 groups namely poor, fair, good and very good with uniform score ranges.
Table 3.2: Comparison of CRQ, SGRQ and Present Study Questionnaire

<table>
<thead>
<tr>
<th>Name of the Questionnaire</th>
<th>CRQ</th>
<th>SGRQ</th>
<th>Present Study Questionnaire</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description</strong></td>
<td>Disease specific instrument for the use of fixed and reversible airway obstruction</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Developer</strong></td>
<td>Guyatt et al. (1987)</td>
<td>Jones et al. (1991)</td>
<td>Investigator of the present study</td>
</tr>
<tr>
<td><strong>No. of items</strong></td>
<td>20</td>
<td>76</td>
<td>30</td>
</tr>
<tr>
<td><strong>No. of Domains</strong></td>
<td>4</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td><strong>Name of Domains / Categories</strong></td>
<td>Dyspnoea - 5, Fatigue - 4, Emotional - 7, Mastery - 4</td>
<td>Symptom Activity Impacts</td>
<td>Dyspnoea - 7, Daily activity - 10, Social activity - 5, Emotional - 8</td>
</tr>
<tr>
<td><strong>Scale</strong></td>
<td>1-7 Likert scale</td>
<td>Dichotomous &amp; 0-4 Likert scale</td>
<td>0-4 Likert scale</td>
</tr>
<tr>
<td><strong>Administration</strong></td>
<td>Interviewer administered (or) Interviewer led Later-Self-report</td>
<td>Self administered questionnaire</td>
<td>Interviewer led</td>
</tr>
<tr>
<td><strong>Time to Complete</strong></td>
<td>First use: 15 - 25 mins. Subsequent use: 10 – 15 mins.</td>
<td>20 min</td>
<td>15 – 20 min</td>
</tr>
<tr>
<td><strong>Validity and Reliability</strong></td>
<td>Well documented in multiple trials</td>
<td>Well documented in multiple trials</td>
<td>Tested for reliability and validity in the present study</td>
</tr>
</tbody>
</table>

Source: Curtis and Patrick (2003); Molken et al. (1999)
3.18 VALIDITY AND RELIABILITY

3.18.1 Validity

The term validity refers to the degree to which an instrument measures what it is supposed to be measuring. The content validity is necessarily based on judgment. It becomes increasingly common to use a panel of experts in the content area to evaluate and document the content validity of new instruments.

The content validity of the newly prepared Health Related Quality of Life Questionnaire was ensured by subjecting it for scrutiny by experts in the field of pulmonology, thoracic medicine and nursing (APPENDIX – G).

3.18.2 Reliability

Reliability of an instrument is the degree of consistency with which it measures the attribute it is supposed to be measuring (Polit & Hangler, 1999). It is always preferable to ensure the reliability of a new instrument prior to using the same for a full fledged study. Even while translating a well proven reliable instrument to another language, a reliability check becomes essential. Guell et al. (1998) translated the CRQ into Spanish and verified the reliability. Barr et al. (2000) assessed the reliability, validity, and sensitivity to change of the modified version of the St. George's Respiratory Questionnaire (SGRQ) when it was translated into American English (SGRQ-A). Damato et al. (2005) validated the Italian version of Clinical Chronic Obstructive Pulmonary Disease (COPD) Questionnaire (CCQ) using test – retest procedure.

An attempt was made to assess the reliability of the present HRQOL questionnaire using both Cornbach’s $\alpha$ analysis and Pearson correlation analysis. Cornbach’s $\alpha$ analysis was performed on the pre scores of the four components namely breathing, physical, social & emotional and total HRQOL scores of the 30 COPD patients enrolled for the pilot study and found to be 0.71. Test and
retest was also carried out among these 30 COPD patients in two consecutive mornings by two different evaluators. The Pearson correlation coefficients (‘r’ values) for the four components and the total HRQOL scores varied between 0.65 and 0.85. For most purposes, reliability coefficients above 0.7 are considered satisfactory (Polit & Hangler, 1999). Hence the new HRQOL questionnaire was considered to be fairly reliable and utilized in this study.

3.19 PILOT STUDY

The pilot study was conducted among 30 patients of COPD who met the inclusion criteria. They were randomly allotted by lottery method either to control, exercise and support group. Once the patients are allotted to the groups, differential rehabilitative interventions were applied to the three groups following the planned procedure, which is detailed in the following section 3.18. On completion of the pilot study the responses of the subjects were recorded and reviewed.

3.19.1 Modifications Based on Pilot Study

Based on the results of the pilot study the following changes were made.

1. In HRQOL questionnaire the two items in the activity components viz. 1. Walking inside the house and 2. Outside level ground walking was merged together into one item.

2. Few other items under activity components such as walking up hills, playing sports, gardening and lifting or carrying heavy loads were removed because majority of the pilot study subjects stated that they do not involve much in the first three (items) activities.
Thus the initially planned 15 items under the activity components were reduced to 10 items.

3.20 REHABILITATIVE INTERVENTION AND DATA COLLECTION METHODS

Based on the holistic concept of probing the effect of various interventions in improving the short and long term health related quality of life and functional capabilities of patients with COPD, three major interventions viz. education, exercise and psychosocial support were manipulated in this study. However finding the differential effects of exercise with and without psychosocial support is the major aim of the study, whereas the general education on COPD is administered to all the three groups to normalize their knowledge level at the start of the study.

3.20.1 Enrolment of Patients

The clinical measurements and the pulmonary functional measures of the patients were assessed as and when they were hospitalized during the study period in the selected wards of the settings of the present study. If the patient satisfies the inclusion and exclusion criteria then his/her consent was sought for the study. Once the consent of the patient was obtained, he/she was enrolled as a subject of the study and assigned to a particular group depending on the ward to which he/she got admitted (The sampling and randomization details are given in Sections 3.6 & 3.7).

3.20.2 Timings of Measurements

The information regarding the demographic profile was collected on selection of patients. The Pulmonary Functional Measures (FVC, FEV₁, FEV₁/FVC ratio & PEFR) were assessed on enrolment and after 8 weeks of pulmonary
rehabilitation. Assessment of HRQOL & 6 MWD was performed on enrolment, after 4 weeks and 8 weeks of the pulmonary rehabilitation. The PFM, HRQOL and 6MWD assessments were made by trained personnel who had no information about the patients grouping (single blind).

3.20.3 Methods of Measurements

a) Pulmonary Functions Measurement

The pulmonary functional measures (FVC, FEV$_1$, FEV$_1$/FVC ratio & PEFR) were assessed utilizing a diagnostic spirometer of Model Spirolab II a make of MIR (Medical International Research). Spirolab II is fitted with a digital turbine whose flow sensor requires no calibration and complies with the standards of American Thoracic Society (ATS). Figure 3.3 shows the performance of spirometry testing on a subject of the present study. Whenever there was a doubt in identifying the disease of a patient as COPD due to the presence of few symptoms related to asthma then a reversibility test was performed after administering a bronchodilator (BTS COPD Consortium, 2004). If the reversibility in FEV$_1$ is $> 400$ ml then such patients were excluded. Figure 3.4 shows the administration of bronchodilator through nebuliser for reversibility checking.

b) Six Minutes Walking Distance Measurement

The six minutes walking distance measurements (6MWD) were made on a specially prepared walking circuit of length of 80 meters which had the marking for every metere on a concreted level ground (Figure 3.5). Initially the subjects of the study were given instruction on the test procedure (Figure 3.6) and then the measurements were made on allowing the individuals to walk on the circuit in their normal pace for a duration of six minutes (Figure 3.7).
Figure 3.3 Spirometry measurement

Figure 3.4 Administration of bronchodilator for reversibility checking
Figure 3.5  The six minutes walking circuit

Figure 3.6  The six minutes walking test demonstration
c) **HRQOL Measurement**

The newly developed HRQOL questionnaire consists of 30 items in 4 sub sections. It is an operator led interview type questionnaire in consideration of the low educational status of majority of the patients. The HRQOL assessment was made at a convenient time of both the interviewer and the subjects in a separate room to avoid any possible interruptions. All the above given three measurements (PFM, 6MWD, HRQOL) were made by trained persons who had no information regarding the patient grouping (Single blind).

### 3.20.4 Patient Education

Education on COPD and pulmonary rehabilitation with the aid of wall charts and a specially prepared Hand book (APPENDIX - B) was performed to all three groups. Figures 3.8 and 3.9 show the displayed education charts and the educator.
Figure 3.8  Education Charts on COPD and Pulmonary Rehabilitation

Figure 3.9  Educator and Education Charts on COPD and Pulmonary Rehabilitation
The education programme covered the various aspects such as disease pathology, signs and symptoms, risk factors and their avoidance with the specific emphasise on smoking cessation, coping strategies, balanced diet, necessary lifestyle modifications and adherence to the health practices. Education sessions were conducted in batches of about 5 patients of same group for a duration of about 10 to 15 minutes.

3.20.5 Exercise Training

The demonstration of breathing and physical (Upper & Lower Extremities) exercises was performed to the exercise group and exercise with psychosocial support group. Generally this demonstration was given after the education programme.

a) Breathing Exercises

The breathing exercises advised are pursed lip breathing, diaphragmatic breathing, practicing ventilatory muscle training by fun exercises such as balloon blowing and bubble blowing in water using straw. Figures 3.10 and 3.11 show the demonstration and practice of diaphragmatic breathing exercise. Figures 3.12 and 3.13 show the demonstration and practice of balloon blowing exercise.

b) Physical Exercises

The upper extremities exercises are wall hand climbing, rod lifting, rope turning and pulley tugging (5 minutes each/ day). The lower extremities exercise is (walking, 15-30 minutes/day) for a period of 8 weeks. Figures 3.12 and 3.13 show the demonstration and practice of upper extremities exercises. The COPD patients were advised to begin the lower extremities exercise (Walking) with the minimum of 15 minutes brisk walking for the first 2 weeks, 20 minutes for the third and fourth weeks, 25 minutes for fifth and sixth weeks and to aim for the maximum duration of 30 minutes at the beginning of seventh week to till the end of eighth week.
Figure 3.10 Demonstration of diaphragmatic breathing exercise

Figure 3.11 Practice of diaphragmatic breathing exercise
Figure 3.12 Demonstration of Balloon blowing exercise

Figure 3.13 Practice of Balloon blowing exercise
Figure 3.14  Demonstration of upper extremity exercise

Figure 3.15  Practice of upper extremity exercise
The experimental group samples were advised to perform the suggested rehabilitative measures at their respective homes. Weekly telephonic call and fortnightly home visit was carried out for the psychosocial support group.

### 3.2.1 DATA ANALYSIS

The gathered data was suitably organized and analyzed using descriptive and inferential techniques with the assistance of computer based statistical tool SPSS Version 10. Descriptive method was used to analyze the demographic data and to estimate the mean and standard deviation of the various measures of clinical, pulmonary functional measures (PFM), six minute walking distance (6MWD), and health related quality of life (HRQOL). Inferential technique was adopted to analyze the significance in differences between the groups and within the subjects. Paired t test was performed to find any significant changes occur in PFM and clinical measures such as respiratory rate and pulse rate after 8 weeks of practicing multidimensional pulmonary rehabilitation. A simple random design analysis of variance (ANOVA - SRD) was used to test the differences between three group means each of PFM, 6MWD and HRQOL. A Tukey’s honestly significant difference (HSD) post hoc test was performed following ANOVA for the significantly different groups (Crichton, 1999). This multiple comparison was performed for the aspects that significantly differed in intermediate and post values of 6MWD and HRQOL of all three groups. Repeated measures analysis of variance (ANOVA – RMD) was used to find out the significant differences in the pre, intermediate and post measures of each group. The aspects which indicated significance difference were analysed further using a post hoc pair wise comparison with Bonferroni correction (Bland and Altman, 1995) to find out in which phase the differences occurred and the trends. Pearson correlation between HRQOL and \( \text{FEV}_1 \), HRQOL and 6MWD were also found out.