STUDY PROTOCOL

A Protocol Paper On Nurse-Led Pulmonary Interventional Package on Pulmonary Function and Quality of Life Among Workers of Coal Mines with Respiratory Diseases in Jharkhand, India: A Randomized Controlled Trial

Athira B[1*], Sushma Saini[2], G Jahnavi[3], C Vasantha Kalyani[4]

[1,4]College of Nursing, All India Institute of Medical Sciences Deoghar, Deoghar, India
[2]National Institute of Nursing Education, Post Graduate Institute of Medical education and Research, Chandigarh, India
[3]Department of Community and Family Medicine, All India Institute of Medical Sciences Deoghar, Deoghar, India

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ABSTRACT

Coal mine dust lung disease (CMDLD) includes a spectrum of occupational lung diseases affecting coal miners. There is conclusive evidence that comprehensive intervention can reduce dyspnoea, improve exercise performance, and enhance health-related quality of life. Nurse-led interventions have shown great changes in disease burden on the healthcare system. So, a nurse-led pulmonary interventional package on respiratory disorders of coal mine workers can change the health status of coal miners. Therefore, this study aims to evaluate the effectiveness of a nurse-led pulmonary intervention package on pulmonary function and quality of life of coal miners with respiratory disorders.

A randomized controlled trial will be conducted. Occupational health units will be cluster-randomized into intervention and control arms. Coal miners who meet the inclusion criteria will be recruited. The estimated sample size is 80(40 in each arm). The Nurse-led pulmonary intervention package comprises of an education session of 10 minutes and exercise training of 20 minutes. to be followed along with regular treatment for 3 months. Primary outcomes include pulmonary function and quality of life. Participants will be assessed at baseline and after the 12th week of post-intervention. The primary outcomes will be analysed using t test. The significance level will be set at two-sided $p < 0.05$ and all statistical tests will be two-tailed. The study results will provide valuable evidence to inform future identification and evaluation of best approaches to implement nurse-led interventions for coal miners with occupational lung diseases.

Keywords: Nurse-led pulmonary interventional package, Coal miners, Respiratory disorders, Pulmonary function, Quality of life

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***Correspondence:** Athira B (Email: athira.nur@aiimsdeoghar.edu.in)

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INTRODUCTION

Coal miners are still vulnerable to respiratory illnesses brought on by coal mine dust and the morbidity and mortality that go along with them, even with advancements in exposure assessment, ventilation controls, and protective government legislation. A collection of occupational lung conditions known as coal mine dust lung disease (CMDLD) are brought on by the repeated inhalation of respirable coal mine dust particles, such as silicates, carbon, and quartz. These illnesses include silicosis, dust-related diffuse fibrosis, mixed dust pneumoconiosis, coal workers' pneumoconiosis (CWP, often known as black lung disease), and chronic obstructive pulmonary disease (COPD). The most severe type of CWP, progressive massive fibrosis (PMF), is also included in the spectrum of CMDLD.[1-3]

The Global Burden of Disease Study reports that the number of pneumoconiosis-related deaths increased from 21,209 in 1990 to 21,488 in 2016, and the incidence of the disease climbed from 36,186 in 1990 to 60,055 in 2017.[4] A total of 915,000 cases of occupational pneumoconiosis have been reported in China by the end of 2021.[5] According to an analysis of the causes of death for coal miners in the United States from 1979 to 2017, coal workers are far more likely than the general population to die from lung cancer, COPD, and CWP.[6]

Multiple studies have linked exposure to coal dust to the development of emphysema, obstructive lung disease, and chronic bronchitis.[7-9] A more recent study further supports the claim that exposure to coal dust causes emphysema independently of smoking.[10] Thus the data, indicates that coal miners are more susceptible to lung diseases caused by coal mine dust, such as COPD, a respiratory risk associated with coal mining.

There is currently no documented medical treatment that can reverse CMDLD. Prevention of disease development, routine medical monitoring, and the identification and management of complications are the main goals of patient care for individuals with CMDLD.[10]Comprehensive interventions have been shown to increase exercise performance, lower dyspnea, and improve health-related quality of life. Exercise training, education, and behavior modification are just a few of the patient-tailored therapies that comprise pulmonary rehabilitation (PR), a comprehensive intervention that begins with a complete patient assessment.[11-16]

Many clinical trials have proved pulmonary rehabilitation (with exercise training, health education, and respiratory training) to be effective in improving pulmonary function and health-related quality of life in coal miners with lung diseases.[17-27] Evidence from various studies shows that nurse-led pulmonary interventions are effective in reducing dyspnea and enhancing the quality of life of patients with chronic obstructive pulmonary disease.[28-33]

Occupational health nursing focuses on promotion and restoration of health, prevention of illness and injury, protection from work-related and environmental hazards. In order to strike a compromise between the need for a safe and healthy workplace and a "healthy" bottom line, occupational and environmental health nurses (OHNs) combine their knowledge with healthcare skills.[34-35]

A study conducted in China explored the effect of nurse-led respiratory rehabilitation training on pulmonary function and quality of life among pneumoconiosis patients. 76 patients were randomly allocated to intervention and control group. The control group received the conventional treatment whereas the intervention group received the nurse-led respiratory rehabilitation training combined with conventional treatment. The respiratory rehabilitation training consisted of lip contraction breathing, diaphragmatic breathing training, and vertical and lunge breathing. The pulmonary function and quality of life were assessed after 2 months. The results of this study showed that after 2 months of nursing, the scores of the GQOLI-74 scale and pulmonary ventilation function indexes of patients in the observation group were all higher than those in the control group($p<0.05$), indicating that respiratory rehabilitation training could improve pulmonary ventilation function and improve the quality of life of patients with pneumoconiosis.[36]

The health hazards of coal mining are well known, and miners are frequently afflicted with respiratory conditions such silicosis, chronic obstructive pulmonary disease (COPD), and pneumoconiosis. There is still a dearth of focused treatments and regional health initiatives for coal miners, especially in the setting of Jharkhand, India, despite the substantial body of research on occupational health risks in mining communities worldwide. This area, which is well-known for its abundant coal deposits, has particular difficulties, such as poor access to healthcare, a dearth of specialized pulmonary care, and a high prevalence of occupational respiratory illnesses.

Current research predominantly focuses on epidemiological data and general health interventions, often neglecting culturally and regionally specific solutions that are essential for effective disease management and prevention. Moreover, while there is some evidence on the efficacy of nurse-led interventions in other populations, there is limited exploration of such models within coal mining communities in India.

This randomized controlled trial aims to address this gap by developing and testing a Nurse-Led Pulmonary Intervention Package tailored to the needs of coal miners with respiratory diseases. The intervention focuses on education, self-management strategies, and continuous monitoring, delivered by trained nurses familiar with the local context. By implementing and evaluating this package, the study will not only contribute new knowledge about effec-

tive, scalable healthcare models in underserved mining regions but also provide evidence for the integration of nursing-led initiatives into public health frameworks, fostering a sustainable approach to respiratory disease management in vulnerable populations.

Determining the impact of a nurse-led pulmonary interventional package on coal mine workers' lung function and quality of life would be worthwhile given the possible advantages. Thus, the purpose of this study is to assess how well a nurse-led pulmonary intervention package affects the quality of life and pulmonary function of coal miners who suffer from respiratory conditions.

METHODOLOGY

Study design and setting: A randomized controlled trial will be conducted (Fig1). A list of occupational health units (OHU) of coal mines will be made. Out of the OHUs, two OHUs are cluster-randomized into intervention and control arms. Participants who meet the inclusion criteria will be enrolled by consecutive sampling during the data collection period.

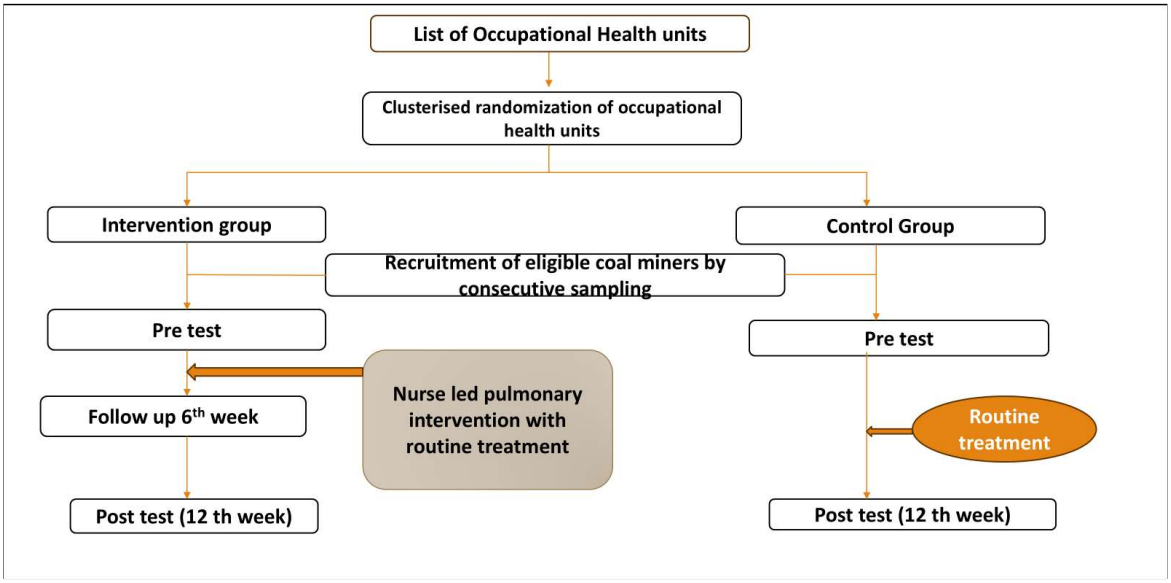

Figure 1: Study Design

Participants: All the workers of coal mine attending or admitted in the General Medicine Department of the two Occupational health units will be recruited if they 1) are aged 18 years and above; 2) have at least one year of tenure or above in the coal mine; 3) willing to participate; 4) diagnosed COPD and occupational asthma; 5) have medical fitness by the treating doctor for nurse-led intervention; Participants will be excluded if they have serious illnesses that compromise exercise training.

Sample size estimation: The sample size is determined using the formula

$n = [(Z_{\alpha/2} + Z_{\beta})^2 \times \{2(ó)^2\}] / (\mu^1 - \mu^2)^2$

Where n is sample size required in each group, μ^1-μ^2 = clinically significant difference, ó = standard deviation; Zα/2: This depends on the level of significance, for 5% this is 1.96; Z_{β}: This is dependent on power and is 0.84 for 80%.

Based on the above formula, the sample size in the protocol will be 36 in each arm, assuming a standard deviation of 8.9812[36] using a two-tailed t-test of difference between means with 80% power and a 5% level of significance. Considering a dropout rate of 10% and after rounding off, the sample size required is 80 (40 per group)

Recruitment: Two Occupational health units are cluster-randomized from the list of occupational health units into experimental and control arms. Randomization of occupational health units will help in preventing contamination. Then, potential study participants will be recruited by the researcher using consecutive sampling methods in the outpatient department or inpatient department. The researcher will explain the aim of the study, undertake a screening to determine eligibility and obtain consent to participate in the study.

Study Outcome

Primary outcomes

a) ***Pulmonary function***: In this study, it refers to the status of respiratory function in coal miners and will be assessed by measuring PEFR with peak flow meter and dyspnea assessment by dyspnea scale.

b) ***Quality of life***: Here it refers to the impact of the respiratory disease and treatment on the worker of a coal mine's ability to live a fulfilling life which will be measured by the St George Respiratory Questionnaire (SGRQ).

Secondary outcomes

Hospital admission rate in last three months, level of practice of occupational hygiene, management practices related to use of nebulization, steam inhalation, and inhalers

Data Collection Tools: The data will be collected by interview schedule (Table1) which comprises of

Section A: Demographic profile, which will be used to collect details of the demographic characteristics like age, type of family, educational status, housing, marital status, type of work in mines, years of tenure in mining, and presence of comorbidity

Section B: Pulmonary Functional status consists of

a) Questions related to hospital admission rate (clinical Profile),
b) Assessment of Peak expiratory flow rate by Mini wright Peak flow meter the normal peak flow is 450-550 L /min in adult males and it is 320-470 L/min in adult females. A disposable mouthpiece will be provided to each subject for the prevention of cross-infection.[37-38]
c) The Medical Research Council Dyspnea Scale will be used to measure the level of dyspnea of the participants in the study.[39-41]

Section C: Checklist for Level of Practice of occupational hygiene: A structured checklist of 15 questions will be used to measure the level of practice of occupational hygiene. These 15 items have responses scored as Yes or No. Each item scores 1, with a total score of 8 and more indicating good practice. The checklist has been validated by experts from nursing and pulmonary and community medicine.

Section D: Checklist to assess Health management practice of Participants: The structured checklists will be used to assess the correct use of inhalers (metered dose with spacer, without a spacer, and dry inhalers), correct use nebulization and steam inhalation. These checklists have been adopted for this study after obtaining permission.[42]

Section E: The St George Respiratory Questionnaire (SGRQ) Quality of life of the participants will be assessed using the St George Respiratory Questionnaire (SGRQ). It is a 50-item survey designed to measure the impact of obstructive airway disease on the daily lives, overall health, and perceived well-being of patients. The frequency and severity of symptoms are covered in Part 1, and activities that cause or are limited by dyspnea, as well as its impact on social functioning and psychological issues due to airway illness, are covered in Part 2. Greater restrictions are indicated by higher ratings; the values range from 0 to 10. The Hindi translated tool is available from the publishers and permission have been obtained for use. The tool has been used in Indian settings as well as among coal mine population.[43-45]

Intervention: Nurse-led pulmonary intervention package: A nurse-led pulmonary intervention package has been developed after the related search of literature in the guidance of experts in the fields of Pulmonary Medicine, Community Medicine, and Nursing. It will be developed in the form of a booklet and flash booklet entitled Pulmonary Intervention Package. Flash book will be used for teaching and the booklet will serve as a ready reference for the participants as well they will also mark the exercise log book present in the booklet for compliance. The booklet includes information on chronic lung conditions from occupational coal dust exposure, preventive measures with emphasis on occupational safety measures, personal hygiene, the importance of periodic checkups, early diagnosis and treatment, nutrition counselling, lifestyle changes; demonstration of the procedure of Use of inhaler (MDI, MDI with spacer and DPI), Use of nebulization, Steam Inhalation and training on exercise regimen. The researcher will encourage compliance by telephonic reminders.

Control: Usual care: Participants in the control group will receive usual care provided to coal miners with respiratory disorders without any additional intervention. Usual care includes some or all of the following services: - hospital checkups, treatment by the consulting doctor including medications, in patient treatment, follow up appointments in an outpatient clinic. The usual care does not include any kind of exercise training.

Data collection procedures: The data will be collected from the two occupational health units randomly selected as intervention and control. The researcher will screen the participants in a face-to-face interview for their eligibility and willingness to participate in the study. Written consent will be obtained from those who are eligible.

The data will be collected in person through face-to-face interview with an interview schedule comprising of demographic profile, clinical profile, and checklist of occupational hygiene, MRC Dyspnoea scale, checklist to assess the correct use of inhalers (with spacer, without spacer, dry), steam inhalation, nebulization and St George Respiratory Questionnaire. In addition, the physical parameters like standing height and peak expiratory flow rate will be also assessed for evaluating pulmonary function.

These questionnaires, checklist and assessment of physical parameters will be administered to both arms at baseline (before the intervention) and after 12th week of post intervention. The Nurse led pulmonary intervention package (Table2) comprises of an education session of 10 minutes and exercise training of 20 minutes. The education session includes health teaching on chronic lung conditions from occupational coal dust exposure, preventive measures with emphasis on occupational safety measures, personal hygiene, importance of periodic checkups, early diagnosis and treatment, correct use of inhalers, steam inhalation and nebulization, nutrition counselling, lifestyle changes.

Table 1: Data Collection Tool

Section	Outcome Measures	Tool	Measurement Tool Description
A		Demographic Profile	Participants' socio-demographic characteristics and other factors
B (a)	Hospital admission rate in last three months	Clinical Profile	5 questions to collect information on hospital admission related to respiratory illness in the last three months
B (b)	Peak Expiratory flow rate	Instrument: Mini Wright Peak flow meter.	Instrument: Mini Wright Peak flow meter. The normal peak flow is 450-550 L /min in adult males and 320-470 L/min in adult females.
B (c)	Level of Dyspnea	Medical Research Council Dyspnea Scale	The MRC dyspnoea scale is a brief, reliable, and valid questionnaire that consists of five statements about perceived breathlessness: grade 1, "I only get breathless with strenuous exercise"; grade 2, "I get short of breath when hurrying on the level or up a slight hill"; grade 3, "I walk slower than people of the same age on the level because of breathlessness or have to stop for breath when walking at my own pace on the level"; grade 4, "I stop for breath after walking 100 yards or after a few minutes on the level"; grade 5, " I am too breathless to leave the house".
C	Level of practice of occupational hygiene	Checklist for practice of occupational hygiene	A checklist with 15 questions to assess the practice of occupational hygiene in coal mines. These 15 items have responses scored as Yes or No. each item scores 1, with a total score of 8 and more indicating good practice. The checklist has been validated by experts.
D	Management practices		
(a)	Use of metered dose inhaler with spacer	Checklist to assess the correct steps of use of metered dose inhaler with spacer	A checklist with 9 questions to assess steps in the use of metered dose inhaler with spacer These 9 items have responses scored as Yes or No. each item scores 1.
(b)	Use of metered dose inhaler without spacer	Checklist to assess the correct steps of use of metered dose inhaler without spacer	A checklist with 8 questions to assess steps in the use of a metered dose inhaler without spacer These 8 items have responses scored as Yes or No. each item scores 1.
(c)	Use of dry powdered inhaler	Checklist to assess the correct steps of use of dry powdered inhaler	A checklist with 8 questions to assess the steps in the use of dry powdered inhaler. These 8 items have responses scored as Yes or No. each item scores 1.
(d)	Use of nebulization	Checklist to assess the correct steps of nebulization	A checklist with 10 questions to determine the steps of performing nebulization at home. These 10 items have responses scored as Yes or No. each item scores 1.
(e)	Use of steam inhalation	Checklist to assess the correct steps of nebulization	A checklist with 10 questions to assess the steps of performing steam inhalation at home. These 10 items have responses scored as Yes or No. each item scores 1.
E	Quality of life	St George Respiratory Questionnaire (SGRQ)	A 50-item questionnaire intended measure the impact of obstructive airway disease on the daily lives, overall health, and perceived well-being of patients. The frequency and severity of symptoms are covered in Part 1, and activities that cause or are limited by dyspnea, as well as its impact on social functioning and psychological issues due to airway illness, are covered in Part 2. Greater restrictions are indicated by higher ratings; the values range from 0 to 10

The exercise training starts with warm up, breathing exercises, aerobic exercises(walking) and end up with cool down exercises. The coal miner will be advised to do exercise 4 to 5 days in a week starting with warm up, breathing exercises (10 minutes) and an aerobic exercise (walking) for 20 minutes. To promote adherence to the intervention, a booklet will be provided for compliance. The intervention package is to be followed along with regular treatment for 3 months. The nurse will ensure the compliance with the intervention through telephonic, video conferencing and follow up visit at 6th week.

Analysis of data: Statistical analyses will be performed using the IBM SPSS Statistics version 22 (SPSS Inc., Chicago, IL, USA). To handle missing data due to participant dropout, multiple imputation methods will be employed to preserve statistical power and reduce potential bias. Descriptive statistics will be used to summarise participants' baseline characteristics and outcome variables. All continuous outcomes will be assessed for normality in distribution. Appropriate transformation of skewed data will be performed before analysis. Chi-square tests and independent t-tests will be used to compare the demographic and clinical characteristics, and mean scores of outcomes between the intervention and control groups at baseline. The primary outcomes will be analyzed using t test. Significance level will be set at two-sided $p < 0.05$ and all statistical tests will be two-tailed.

Table 2: Intervention Description

Session	Content
Education Session	• Introduction of session • Information on occupational lung diseases among coal mine workers • Prevention of occupational lung diseases • Practice of Occupational hygiene • Correct use of inhalers (MDI with spacer and without spacer and Dry powdered inhaler • Correct use of steam inhalation and nebulization
Exercise training	• Introduction of session • Benefits of exercise • Instructions on how to initiate exercise safely • Frequency of exercise • Exercise session Warm up: 5minutes Breathing exercises: 10 minutes Walking: 20 minutes Cool down (Stretching exercise) : 5 minutes

Ethics and dissemination: As stated in the Declaration of Helsinki, the international guidelines for scientific research will be considered regarding autonomy, integrity, beneficence, non-maleficence and justice. The Institutional Ethics Committee, AIIMS Deoghar, Jharkhand have approved the study. This trial has been registered in the Clinical Trial Registry of India in the number CTRI/2024/06/069241. Before consent is obtained, the subject will get a participant information sheet. Every participant in the study will provide written and informed consent. Additionally, they will be told that participants are free to withdraw from the study at any moment, with no repercussions or explanation. Every piece of study-related data will be safely kept. The documents like informed consent where participant identification details are present will be kept separate from the pre-test and post data material identified using participant numbers. The password-protected electronic database will be kept safe. The computerized database will not be updated with participant identity information.

Once the study will be completed, the researcher plans to present the findings at national and international conferences, submit report to occupational health settings and publish results in clinical journals.

Discussion and Conclusion

Coal mine dust lung diseases are one of the major occupational health hazards among workers of coal mines. Many studies have revealed that coal miners with respiratory disorders have very poor pulmonary functional status and there hamper their day-to-day activities. Most of the prevalence studies have shown that coal miners with respiratory disorders have issues related to anxiety, depression, and poor quality of life. There is no complete cure for these occupational lung diseases among coal miners. Several studies have recognised that pulmonary rehabilitation to be effective in improving pulmonary function status of patients with occupational lung diseases.

The recent recognition of nurse led interventions in the management of various diseases has been highlighted in studies and have been adopted in various settings.[17-20,24-26,33,36] Many studies have reported that nurse led pulmonary intervention is effective in improving dyspnea level, anxiety, depression and quality of life of patients with occupational lung diseases.[27-32]

This is the first randomized controlled trial that, as far as the authors are aware, looks at how well a nurse-led pulmonary intervention affects pulmonary function and quality of life in Indian coal mine workers who have respiratory illnesses. It is expected that coal miners with respiratory disorders receiving the 12-week structured nurse-led pulmonary interventional package will have improved pulmonary function and quality of life. If the Nurse-Led Pulmonary Intervention Package proves successful, it could significantly influence policy by emphasizing the pivotal role of nurse-led initiatives in addressing occupational respiratory diseases, particularly in underserved populations like coal miners. However, the generalizability of the findings may be limited, as this study is conducted within the socio-cultural and occupational context of Jharkhand, which may not entirely reflect conditions in other regions.

Author Contribution: AB, SS: Conceptualization; **AB, SS, JG, KCV:** Data curation; **AB, SS:** Writing – original draft; **AB, SS, JG, KCV:** Writing – review & editing

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