Study Protocol

NECESSITY OF STRUCTURED EXERCISE TRAINING PROGRAM AND ITS FEASABILITY ON PHYSICAL CAPACITY AND HEALTH STATUS WITH POST COVID-19 SYNDROME PATIENTS

- **ABSTRACT :-** Coronavirus Disease 2019 (COVID-19) has spread worldwide and has become a global public health emergency. The World Health Organization recently declared the outbreak a pandemic . Pulmonary Rehabilitation has shown Positive Impact on Quality of life , Functional capacity and health status of patients with Chronic Respiratory Disease Recently there are various guidelines and consensus available for Pulmonary Rehabilitation in Post – COVID patients that has been extrapolated from other respiratory condition. There is paucity of literature that has shown the effect of Exercise training program on Physical capacity and Health status of patient with Post COVID 19 syndrome. So the present study uses the available evidence on COVID 19 patients to prepare the exercise program and implement it on post COVID syndrome patients.Thus, the aim of the Study is to evaluate the effect of supervised Exercise Training Program on Post COVID patients

- **METHODOLOGY:** In this experimental study total 70 patients with Post Covid Syndrome will be included and they will be equally divided into two groups. Group A will receive supervised exercise training while Group B will receive unsupervised exercise training will be assessed ~~at the start of treatment after 6 weeks~~. At the start of treatment and at the end of the treatment (end of 6 weeks).

- Where the study will be conducted.

- **DISCUSSION:** This study is conducted to evaluate effectiveness of structured exercise training program and its feasibility on physical capacity and health status of patients with Post COVID19 syndrome.

- **CONCLUSION:** ~~Conclusion will be drawn based to evaluate effectiveness of structured exercise training program and its feasibility on physical capacity and health status of patients with Post COVID19 syndrome.~~

- **Keywords**: Coronavirus disease, pulmonary Rehabilitation syndrome, Pulmonary Rehabilitation exercise Protocol , Post COVID Symptoms, Exercise Prescription Protocol

Keywords should be COVID-19 Pandemic, ARDS, Post – covid syndrome, Chest Physiotherapy, Pulmonary Rehabilitation, Exercise planning and Exercise Prescription

INTRODUCTION (REFERENCE NO ARE NO WHERE MENTIONED IN INTRO)

Since the end of 2019, COronaVIrus Disease 2019 (COVID19), a novel infectious disease emerging from Wuhan, China, has continued to spread rapidly, causing an ongoing global outbreak. Patients may exhibit dyspnea, hypoxia, remarkable pneumonia, acute respiratory distress syndrome (ARDS), or even multiple organ failure.

In addition to the possible sequelae of pulmonary fibrosis which could impair the survivors' ventilation and oxygenation, many other organs could be affected, especially the cardiovascular system.

Common complications of the cardiovascular system may include arrhythmia, myocarditis, acute coronary syndrome, venous thromboembolism, cardiogenic shock, and heart failure Coronavirus Disease 2019 (COVID-19) has spread worldwide and has become a global public health emergency.
The World Health Organization recently declared the outbreak a pandemic. The World Health Organization (WHO) had categorized clinical syndromes associated with COVID-19 as mild illness, pneumonia, severe pneumonia, ARDS, sepsis and septic shock.

The so-called "Post-COVID Syndrome" includes persistent symptoms that could be related to residual inflammation (convalescent phase), organ damage, non-specific effects from the hospitalization or prolonged ventilation (post-intensive care syndrome), social isolation or impact on pre-existing health conditions.

Pulmonary rehabilitation's definition, as adapted from the American Thoracic Society/European Respiratory Society, is comprehensive intervention based on a thorough patient assessment followed by patient tailored therapies that include, but are not limited to, exercise training, education, and behavior change, designed to improve the physical condition of people with respiratory disease.

The purpose of pulmonary rehabilitation in COVID-19 patients is to improve symptoms of dyspnea, relieve anxiety, reduce complications, minimize disability, preserve function and improve quality of life. Pulmonary rehabilitation should be tailored to each individual patient.

Pulmonary rehabilitation during the acute management of COVID-19 should be considered when possible and safe and may include nutrition, airway, posture, clearance technique, oxygen supplementation, breathing exercises, stretching and physical activity. Given the possibility of long-term disability, outpatient post-hospitalization pulmonary rehabilitation .

A Key component in the rehabilitation to restore physical fitness and Independence in Exercise training . Cardio respiratory fitness training is related to perform large muscle group , dynamic , moderate to high intensity exercise for prolonged periods.

Thus the purpose of this study is to investigate into the effect of a 6 week physical rehabilitation program on the Post COVID syndrome patients in improving their physical capacity (cardiovascular and musculoskeletal fitness) and health related quality of life of post COVID 19 patients

METHODOLOGY

STUDY SETTING:

After the Ethical approval from the Institutional Ethical Committee of Datta Meghe Institute of Medical Science. Study will be conducted in Pulmonary Rehabilitation OPD. WHERE??

STUDY DESIGN AND SAMPLE SIZE

It is an experimental study. A total of 70patients will be included in the study, out of which 35 patients will be recruited in Group A and 35 in Group B. The sample size was calculated (G power analysis) on the basis of prevalence of Covid-19 patients in Wardha district, Maharashtra Where ,$2^{\alpha}/2$ in the level of significance at 5% i.e. 95% confidence interval = 1.96

PARTICIPANTS

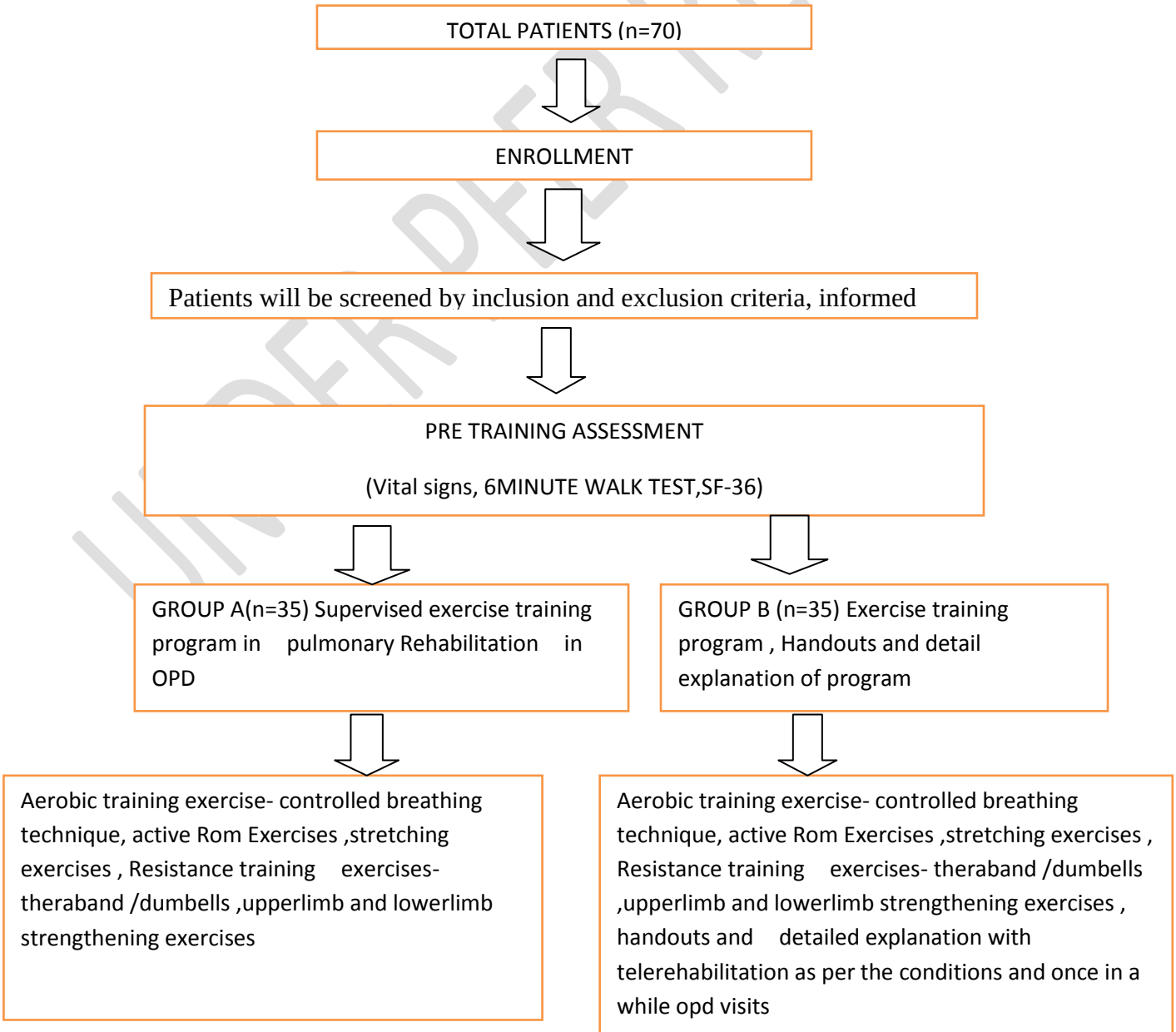
INCLUSION CRITERIA: - more specific inclusion criteria, like dyspnea score, recovery percentage, ct scan score, patients with same severity should be included

- Post COVID syndrome patients
- Both males and females were included

- Patients diagnosed with COVID-19, and meets the discharge criteria
- Patients who are willing to participate
- Patients tested negative for RT-PCR
- Discharged post Covid-19 patients willing to participate.

EXCLUSION CRITERIA:-

- Post Covid patients not willing to participate
- Any severe Cardiovascular, Musculoskeletal and Neurological dysfunction, metabolic , Oncological disorders that can limit physical performance.
- Asymptomatic patients
- CT severity score >10/25 on the day of RT-PCR positive report
- Discharged post Covid-19 patients on ventilator support during the hospitalization period



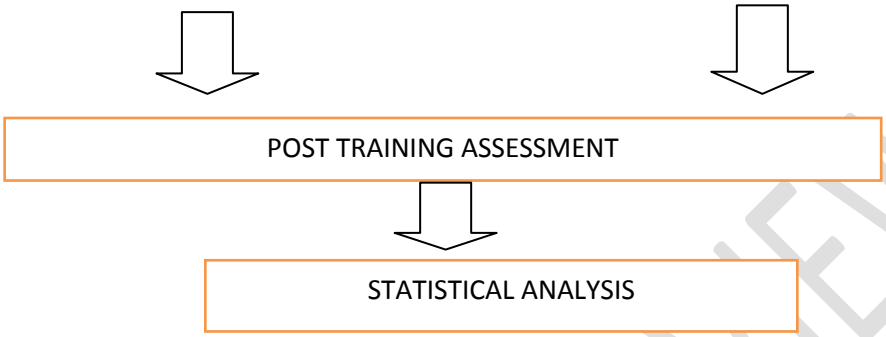


Fig1: Flowchart of the study design

RECRUITMENT PROCEDURE:-

Patients who were admitted in the hospital were consulted on last day of discharge were explained about effects of Pulmonary Rehabilitation and futher willing patients were consulted in Pulmonary Rehabilitation OPD.

PARTICIPANT TIMELINE

Study duration is of 1 year and intervention duration is 6 weeks so participant will be enrolled during first 11 months of study so 6 week intervention will be completed successfully. Assessment will be done on 1st day of visit then in midway (6th week) and end (2nd week) of intervention.

IMPLEMENTATION

Research coordinator and principal investigator will supervise randomization.

BLINDING

Blinding Tester(s) will be blinded to assign the subjects to the group. To ensure binding, subjects will be mandated not to reveal any details of their treatment to the tester.

STUDY PROCEDURE

Initial contact with the patients will be done on a telephonic conversation or direct recruitment from Respiratory OPD. The patients will be screened based on the criteria for inclusion and exclusion. The patients will be instructed to wear comfortable clothing, walking shoes and mask. There are 2groups supervised group and unsupervised group. In supervised group a self made validated Pulmonary Rehabilitation Protocol is explained

- **GROUP A :-** Supervised group consists of Aerobic training Exercises , resistance exercise ,balance training exercise, Respiratory training exercises .The Exercise Training program is prescribed on the basis of FITT (Frequency, Intensity, Type, Time) principle. The exercise training program will be started from day 2 data will be calculated ,statistical analysis will be calculated .The treatment period of Supervised Group _____ how much. (is it in a group or individual based training)
- IF IN BETWEEN THE SESSION SpO2 drops down, dyspnea may be feel by the patients then to avoid these kind of issues what are the pracautions should be taken care by author?
- Should measure Spo2 before and after the exercise.

- **GROUP B:-** In Unsupervised groups same as group A Exercise Training Protocol will be given, Detailed explanation of all exercises and techniques shall be teached and performed by the participants on day 1 ,remaining sessions will be asked to perform at home ,handouts will be given to patients can contact through video calls and telephone I.e tele- rehabilitation in between the treatment period . Treatment will be carried out for 6 weeks in each group.Tailored exercise prescription will be given.Termination indicators to training program will be-Temperature>38.2 degrees , Chest pain, chest tightness, Aggravated cough , Dizziness

Table 1: POST COVID 19 SYNDROME EXERCISE PROTOCOL

TECHNIQUES	TYPES OF EXERCISES	DURATION	
AEROBIC EXERCISES	Walking, jogging, upper limb ergometer training etc. (IN WHICH SEQUENCE, TIME OF EACH??)	Warm up- 10min Conditional training-20min Cool down-10minutes	
POWER TRAINING	Advanced resistance training, therabands, dumbells. (WHICH THERABAND, WEIGHT OF DUMBELL, REPITITIONS, WHICH EXS??)	Training time for each group 2-4 times / week	
BALANCE TRAINING	Balancing balance includes unbalanced training and a balance training tool (WHICH TOOL)	2 minutes each	
RESPIRATORY EXERCISES	Deep breathing exercises, pursed lip breathing exercises	10 repitations	

BE MORE PRECISE IN EXERCISE PRESCRIPTION

Table 2: EXERCISE PRESCRIPTION FOR POST COVID 19 SYNDROME

TECHNIQUES	TYPES OF EXERCISES	DURATION
AEROBIC EXERCISES	Walking, jogging, upper limb ergometer training etc.	Warm up- 10min Conditional training-20min Cool down-10minutes
STRENGTH TRAINING	Progressive resistance training, therabands,dumbells	The training interval of each group is 2-4 times/week.10 repitations each.
BALANCE TRAINING	Balance training including unarmed balance training and balance training instrument	2 minutes each
RESPIRATORY EXERCISES	Deep breathing exercises, pursed lip breathing exercises	10 repitations

AEROBIC TRAINING EXERCISE	4-5 times a week FOR 6 Weeks	Maintaining a HR reserve of 40-59% during exercise , while while the HR refers to the difference between the predicted maximum heart rate and the resting heart rate	10 min
RESISTANCE TRAINING	2-3 days per week	Strength training involves using a weight eqvivalent of 60-70% of one of the repitation maximum,using	2-4 sets with at least 48nhr interval 10 reps each
			20 MIN

Should attach handouts with proper diagram which should be given to group 2 samples.

Outcome measures:

Primary outcome measure:

- 6 MINUTE WALK TEST
- QUALITY OF LIFE QUESTIONNARIE – SF-36

- **6 MIMUTE WALK TEST :-**

The six-minute walk test (6MWT) is a commonly used sub-maximal exercise test for measuring physical functional capacity. The 6MWT is a simple test that measures the distance walked during a 6 minutes. The distance travelled by women is calculated using Enright and Sherill equation,6MWT distance = (2.11 × height (cm)) − (2.29 × weight (kg)) − (5.78 × age) + 667 m for women33, Accuracy of 6MWT = 80%Sensitivity and Specificity = >90% intraclass correlation coefficient = 0.85 35,36

- **QUALITY OF LIFE QUESTIONNARIE – SF 36 :-**

The Medical Outcomes Study Short-Form Health Survey (SF-36) is a widely used generic health-related quality of life (QoL) instrument consisting of 36 questions and measuring health in eight dimensions: physical functioning (PF), role limitations due to physical health problems (RP), bodily pain (BP), social functioning (SF), general mental health covering psychological distress and well-being (MH), role limitations due to emotional problems (RE), vitality, energy and fatigue (VT) and general health perceptions (GH). SF-36 has been adapted and translated into several languages, and its validity and reliability established in several countries.

SF-36 has been used in India to assess health outcomes in several diseased populations. However, no studies regarding the validity and reliability of SF-36 in the general Indian population have been cited in electronic scientific databases. The primary objectives of this study were to adapt and translate SF-36 for use in India and to study its validity and reliability. Additionally, the study aimed to explore the higher order factor structure of the eight SF-36 scales.

Should include thoracic expansion, Dyspnea rating scale, Spo2 measurement

STATISTICAL ANALYSIS:

Data collected will be noted down and then will be placed in a tabular format. It will be analyzed with the help of SPSS latest version. Both statistical analyzes should be conducted with a 95% confidence interval (p-value < 0.05) to assess effect of two measures. Homogeneity of the two

study classes will be tested for individual studies using the Student's t test. Mann-Whitney U will be used for comparing Groups at baseline

ETHICAL APPROVAL AND DISSEMINATION:

The participant individuals of the study and DMIMSU who will fund it will be able to retrieve findings of study. After completion of study and publication of results data will be stored in the DMIMSU data repository

Patient Consent – ATTACH CONSENT FORM HERE IN ENGLISH AND MARATHI LANGUAGE

Principal Investigators will obtain the written informed consent from the participant on a printed form (local language) with signatures and give the proof of confidentiality.

Confidentiality

The study program will be explained to the participant, the principal investigator will take subjective information. The consent form will include the confidentiality statement and signatures of the principal investigator, patient and a witnesses . If required to disclose some information for the study, consent will be taken from the patient with complete assurance of his confidentiality

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(PLS SELECT QUALITATIVE ARTICLE FOR EXERCISE PRESCRIPTION)