Title: Results on health-related quality of life and functionality of a patient-centered self-management program in hospitalized COPD: a randomized control trial

Short title/running head: Self-management in hospitalized COPD patients

Article category: Randomized controlled trial.

Authors: Laura Lopez-Lopez[1], Marie C Valenza[1], Janet Rodriguez-Torres[1], Irene Torres-Sanchez[1], Maria Granados-Santiago[1], Gerald Valenza-Demet[1].

Affiliation:

1. Department of Physiotherapy, University of Granada, Granada, Spain.

Corresponding author:

Marie Carmen Valenza. ORCID: https://orcid.org/0000-0003-2368-1307

Departament of Physioterapy, Av. De la Ilustración, 60, Granada, 18016, Spain, e-mail: cvalenza@ugr.es.

Declaration of interest

The authors report no declarations is interest.

Trial registration

-The name of the registry:

Physiotherapy in Acute Exacerbation of Chronic Obstructive Pulmonary Disease

-The date the trial was registered:

August 4, 2015

-The date the first participant was enrolled:

September 2015

-The URL of the registry and the trial registration number:

NCT02515318 https://clinicaltrials.gov/ct2/show/NCT02515318

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Abstract

OBJECTIVE: The main objective of this study was to evaluate the results of an in-hospital Self-Management program in addition to physiotherapy in patients with Chronic Obstructive Pulmonary Disease (COPD) compared to a physiotherapy program.

METHODS: In this randomized clinical trial, 66 acute exacerbation COPD patients were included and were randomly divided into three groups. The Control group received a standard medical treatment. The Physical therapy group received Control Group intervention plus a Physical Therapy intervention, consisting of neuromuscular stimulation therapy on the quadriceps muscle accompanied by lower limb exercises. The Self-management group received Physical Therapy group intervention plus a Self-Management program, which included educational information complemented with a problem-based session, breathing exercises and relaxation exercises. The main outcomes measured were health-related quality of life and functionality.

RESULTS: All treated groups show improvements in all outcomes, being significant in the case of all total scores of health-related quality of life and functionality($p<0.05$) between Physical Therapy group and Self-Management group. At 3 months, health-related quality of life shows reductions in all subscores in Control Group and

Physical Therapy groups, while Self-Management group shows minimal maintenance of the values.

CONCLUSION: An individualized Self-Management program administered once a day improves health-related quality of life and functionality compared to a Physical Therapy and to a Control Group in hospitalized severe COPD patients.

Keywords: Pulmonary Disease, Chronic Obstructive, Self-Management, Physical Therapy Modalities, Hospital Medicine, Physical Therapy Specialty.

INTRODUCTION

Chronic diseases affect more than 90 million American adults and are responsible for approximately 70% of health care expenditures [1]. These values are expected to increase over the next decades, with pulmonary diseases (38%) and cancer (17%) being the most expensive ones [2].

Within respiratory pathologies, chronic obstructive pulmonary disease (COPD) is the leading one in hospital care cost, physician services and prescription drugs [3]. Although reasons for hospital admission are complex, acute exacerbation is the major cause of hospitalization in patients with COPD [4]. Additionally to the disease progression with the reduction in lung function, patients with COPD experiment a progressive decline in functional capacity and health-related quality of life (HRQoL) [5] with a significant burden in terms of disability [6] that increased with the number of exacerbation[7].

The main treatment for COPD is pharmacological (short-acting bronchodilators, systemic corticosteroids, and antibiotics[8]) and pulmonary rehabilitation [9]. Currently, the use of electrostimulation in patients with COPD has been proposed as the ideal method of retraining exercise without inducing dyspnea [10,11]. showing varying results on symptoms, exercise capacity and quality of life.

The global rise in population ageing and the burden of chronic conditions has led to the apparition of systems-oriented in chronic care on the basis of self-management principles with a patient centered model which leads to reduce hospitalizations, emergency department use, and overall managed care costs [12,13].

Self-management programs aim to teach patients the skills needed to carry out medical regimens specific to long-term diseases and to guide behaviour changes to help them control their own condition and improve their well-being [14]. This way, different chronic pathologies have shown that Self-Management (self-monitoring coupled with medical review and a written action plan) produce greater reductions in nocturnal symptoms, hospitalizations, and emergency department use than usual care [15,16]. Self-Management is the least implemented and most challenging area of chronic disease management due to the relative cost and difficulties in implementing the programs in the community [17].

Different studies have implemented an in-hospital Self-Management program in acute exacerbation COPD patients [18]. The majority of the studies carried out interventions that used to be implemented by nurses and that used to focus on the patient´s education. Few studies have implemented a Self-Management combining education plus exercise, but they compare Self-Management to a control group. Thus, the main objective of this study was to evaluate the results of an in-hospital Self-Management program in addition to physiotherapy in patients with COPD compared to a physiotherapy program.

MATERIAL AND METHODS

Study design

In this randomized controlled trial, participants who met the inclusion criteria were first contacted by visiting them in their room on the first day of their hospitalstay. Those who agreed to participate were provided with an explanation of the research protocol and invited to give written informed consent. All the patients who agreed to participate and provided informed consent were free to withdraw from the study at any time with no

negative consequences. The ethic approval for this study was obtained from the Biomedical Research Ethics Committee of Granada. The study was registered in ClinicalTrials.gov Identifier: NCT02515318. This study was conducted in accordance with the amended Declaration of Helsinki. The CONSORT guideline [19] was followed during the course of the research.

Randomization

The participants were randomly assigned to the following: (1) control group, (2) physiotherapy GROUP, or (3) self-management GROUP in a ratio 1:1:1. The randomization sequence was drawn up and kept off-site by a statistician who was not aware of the study aims, using a random number generator in blocks of eight with no stratification. The sequence of subjects included in the groups was mailed from the statistician to the recruiter.

Participants

All the patients were recruited at the respiratory service of the San Cecilio and Virgen de las Nieves Hospitals, in Granada, Spain from September 2017 to June 2018. Patients of both sexes were included as long as they were older than 40 years of age, were diagnosed with COPD according to the criteria of the Global initiative for chronic Obstructive Lung Disease [5], were hospitalized due to acute exacerbation of COPD and agreed to participate. Exclusion criteria included severe comorbidities, such as unstable cardiovascular disease, orthopedic diseases in the upper and lower limbs, motor sequelae from neurological or visual disorders that interfere with the ability to perform physical exercise, cognitive impairment that could interfere with the evaluation and the treatment, and those who did not agree to participate in the study.

Outcome measures

Data on the history and the current status of the disease, current medications, smoking history, and general physical examination were collected. Main outcomes were measured in hospital at baseline, at discharge and following 3 months after the discharge in the patient´s house by the same assessor, who was blinded to participant group assignment. Secondary outcomes were measured only at baseline.

Main outcomes

Main outcomes were health-related quality of life measured by EuroQol and functionality measured by London Chest Activity of Daily Living Scale (LCADL) and Functional independence measure (FIM).

The EQ-5D is a self-administered, health-related quality-of-life questionnaire that contains two sections, a descriptive section and a valuation section. The descriptive section is a health status classification instrument with the following five dimensions: mobility; self-care; usual activities; pain/discomfort; and anxiety/depression. Each dimension is categorized in three levels of functioning for each of the five dimensions. In the second section, respondents are asked to value their overall health status on a visual analog scale ranging from 0 (defined as the worst imaginable health state) to 100 (defined as the best imaginable health state) [20].

Dyspnea-related functional impairment was measured with the London Chest Activity of Daily Living Scale [21]. This scale evaluates dyspnea limitation during exercises and activities of daily living in patients with COPD. It includes 15 items (personal care, domestic activities, physical activity and leisure) with a score ranging from 0 to 5. Higher values indicate a higher level of functional impairment related to dyspnea.

General Functionality was measured with the Functional Independence Measure [22]. It measures physical and cognitive functionality with 18 items, 13 motor and 5 cognitive scored from 7 to 1. A higher score indicates a higher level of functionality.

Secondary outcomes

Pulmonary function severity was assessed by spirometry (CareFusion, Micro Spirometer, Basingstoke, UK) according to the criteria of the American Thoracic Society and with the Modified Borg Scale [23].

Physical status was measured by handgrip dynamometry and the five times sit to stand test (5STS).

Handgrip dynamometry (TEC-60; Productos Técnicos, EE.UU) was performed according to a previously validated procedure [24].

5STS is a test of lower limb function that measures the fastest time it takes subjects to stand five times from a chair with their arms folded across their chest. The 5STS has been found to be reliable, responsive and valid in patients with COPD [25].

Interventions

All three interventions were developed in a daily frequency (once a day) during the hospitalization period. The treatments were administered in the same way by the trainer researchers; in order to avoid discrepancies between hospitals. The interventions start the second day of hospital admission by a physiotherapist in a daily format individually.

The Control group received the standard medical treatment prescribed by the doctor (consisting of bronchodilators, inhaled corticosteroids and antibiotics [26]).

The Physical Therapy group received a combined intervention including the Control Group treatment plus neuromuscular stimulation therapy (SEFAR Rehab X2, DJO France S.A.S., France) on quadriceps accompanied with lower limbs exercises. The intervention was performed following the protocol described by Valenza et alas it has been shown that in severe COPD patients neuromuscular stimulation obtains good results with fewer adverse events [27,28].

Hearth rate and oxygen saturation were measured during the treatment with a pulsioximeter. When this happened, the intensity of the intervention was adjusted to ensure the safety of the patients.

The Self-Management group received Control Group and Physical Therapy intervention combined to a Self-Management program.

The Self-Management intervention has the objective to give patients with COPD more responsibility on the management of the disease. In order to obtain an attitudinal change in patients, the Self-Management plan had to fit patients' goals, priorities, and lifestyle [29]. At the beginning of the program we evaluated the patients' beliefs, thoughts, and feelings about COPD that may support or hinder their efforts in a structured interview format. Additionally, we identified long-term goals in which patients will work during the treatment [30].

The program´s contents included educational information on chronic respiratory disease and healthy life style habits, which were complemented by a problem-based session. In addition, during the Physical Therapy sessions, patients were encouraged to reinforce the potential value of exercise and problem-solving skills to manage exercise-linked

symptoms. Another component was breathing exercises and relaxation exercises, in order to improve symptomatic management linked to activity.

All included subjects received 5-7 sessions during their hospital stay. After hospital discharge, subjects were encouraged to follow a healthy life style and medication control without additional intervention. At 3 months a follow-up was performed.

Statistical analysis

Statistical analysis was performed using the statistical software for Social Sciences version 21[a]. Baseline descriptive statistics for each intervention group and differences were assessed using ANOVA for continuous data and chi-square tests for categorical data. Two-way mixed ANOVAs (3x3) were conducted to determine the significance of any group effect (between-subjects), time effect (within subject) and interaction effect (group x time). For any significant between-subjects' effects difference, a one-way ANOVA was performed followed by a post-hoc analysis in each assessment period. To highlight any significant within-subject change, repeated measures ANOVA with further contrast analysis was conducted in each group. The level of significance was set at $p<0.05$. Intention-to-treat analyses were employed.

Sample size calculation

The sample size was calculated using the GPower 3.1 computer program and was guided by estimates of minimal clinical important difference of EQ-5D VAS. Our analysis indicated that a sample size of 57 participants (19 per group) was needed to

detect a minimal clinically important difference of 15 points and considering a standard deviation of 19.9 [28] with 80% power for the VAS health related quality of life outcome in the groups [29]. We anticipated that approximately 5% of the participants might fail the initial screening or drop out; therefore, we needed to enroll 22 participants per group to account for this loss. This sample is similar to other studies that have implemented a self-management treatment in this population [33,34,35].

Results

Of 216 patients, a total of 66 patients were randomized in the three groups and performed the intervention with pre- and post- assessment. At 3 months 4 patients discontinued the study. The distribution of participants is shown in Figure 1.

PLEASE, INSERT FIGURE 1

The characteristics of the sample are shown in Table 1.

PLEASE, INSERT TABLE 1

As shown in Table 1, all the included patients were moderate COPD (FEV1<40% and Borg 5.03±2.70) showing no differences between treatment groups (F=0.730 and F=6.818 p>0.05 respectively).

The mean of hospital stay was 9 days in all the groups and the functionality status mediated by symptoms was in all groups moderate showing no differences across groups (F=1.479 and p>0.05).

Table 2 shows the mean and secondary outcomes values at discharge among groups.

PLEASE, INSERT TABLE 2

From admission to discharge all treatment groups show significant improvements in all clinical variables (FEV_1 and Borg dyspnea scale, $p<0.05$), with better results in the case of Self-Management and Physical Therapy groups. In main outcomes all groups shown improvements in HRQoL total scores, but only Physical Therapy and Self-Management obtained significant betterment in functionality ($p<0.05$).

All Health related Quality of life subscores shows significant differences between Control Group and Self-Management at discharge except on Pain subscore. There are significant differences in VAS subscore between Control Group, Physical Therapy and Self-Management, being higher in Self-Management group.

Functionality presents no significant differences in LCADL Leisure activities subscore and FIM cognitive subscore among groups, while the rest of subscores show significant differences between Control Group, Physical Therapy and Self-Management groups at discharge.

Table 3 shows 3 months follow up main and secondary outcomes among groups.

PLEASE, INSERT TABLE 3

As shown in Table 3, the clinical variables show no significant worsening in all clinical variables in all the groups.

From discharge to follow up, health-related quality of life shows reductions in all subscores in the Control Group and Physical Therapy groups, while the Self-Management group shows minimal maintenance of the values.

At 3 months follow up, results for functionality show significant differences in all outcomes between the Control Group and Physical Therapy groups when compared to the Self-Management group.

DISCUSSION

The aim of this study was to evaluate the effects of a Self- Management intervention developed during hospitalization in severe patients with COPD. Our results revealed that the therapeutic program was more effective than other interventions with significant improvements at discharge and at 3 months follow up in health related quality of life and functionality.

The number of studies that employed Self-Management programs in pulmonary patients is on the rise [36,37]. The results of this study agree with other authors showing that a Self-Management can have beneficial effects on functionality and quality of life [38].

Patient centered programs have been previously used in different pathologies and are recognized to be safe, convenient, inexpensive and effective with results on hospitalization rates, health care cost and general health related variables [39,40].

In this study, all groups obtained significantly improvements in the clinical variables at discharge due to the pharmacological treatment. Nevertheless, these improvements disappear at 3 months follow up.

Our results show improvements between baseline and discharge measures in all groups, with significant better results in the Self-Management group that persist up to 3 months after discharge. These results are similar to those found in a review by Zwerink et colleagues [41] where Self-Management trainings in patients with COPD shows improvements in health-related quality of life, reductions in respiratory-related and all cause hospital admissions, and improvements in dyspnea. In our study, it is important to take into account the short duration of the program compared to other studies developed in the community [42,19].

Patients with COPD commonly report many episodes of worsening respiratory symptoms that resolve spontaneously the majority of the times [43], In our study, the included patients were hospitalized due to an acute symptomatic exacerbation and as a results the medication intake and treatments during hospitalization could have affected our results. In our study, we included three group of treatment, including standard medical treatment to avoid the possible confounder of the natural possible recovery of our included patients.

Self-Management programs are diverse and usually include smoking cessation, self-recognition and self-treatment of exacerbations, advice about diet, and advice about medication or coping with breathlessness [44]. During the last years, Self-Management programs have progressed and now include multicomponent exercise training which show better results in all clinical variables [45]. Those results are in line with ours showing better results in Self-Management with physiotherapy program.

In Monninkhof et cols [46] study, the authors didn`t find positive effects of a Self-Management program among moderately-severe patients with COPD. After a year, there were no significant improvements in Health related quality of life compared to

patients in the Control Group. In our case, the main outcomes show improvements between baseline and discharge and after 3 months in Self-Management group. Physiological and functional impairments in patients with COPD often go together with a reduced health-related quality of life [47]. Ghanem and colleagues [48] mentioned significant improvements in the scales of physical functioning in the Self-Management group compared to a Control Group. Our study has shown that functionality results in the Self-Management group did not worsen at 3 months follow up compared to the Physical Therapy groups and to the Control Group.

While there are numerous studies that have performed Self-Management interventions on COPD, to our knowledge no one compared this to a physiotherapy group and a control group-. The authors of this study believe that during hospital stay is a good time to approach patients, because it is a clinical moment in which the patients are more susceptible to accept the guidelines that are offered. In future studies, more interventions will be carried out in the hospital environment.

Some limitations of this study need to be taken into account. One limitation is the small sample size (n =66), which inevitably leads to limited statistical power, but given the population is a reasonable number of patients. Although no significant between-groups differences were found at baseline, the fact that in our study patients were treated in different hospitals can limit the generalization of findings. Additionally, we included a long-term 3 months follow-up, while the majority of the studies that focus on Self-Management programs they include longer periods [41].

In conclusion our result have shown that an individualized Self-Management program administered once a day improves health-related quality of life and functionality

compared to a Physical Therapy and to a Control Group in hospitalized severe COPD patients.

AUTHOR'S CONTRIBUTIONS

GVD had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis, especially including any adverse effects. LLL contributed substantially to the study design, data analysis and interpretation, and the writing of the manuscript. MCV had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. JTS contributed substantially to the study design, data analysis and interpretation, and the writing of the manuscript. ITS contributed substantially to the study design, data analysis and interpretation, and the writing of the manuscript. MGS had full access to all of the data in the study and takes responsibility for the integrity of data and the accuracy of the data analysis.

FINANCIAL DISCLOSURES

No potential conflict of interest was reported by the authors

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Conflict of interest: The authors declare that there are no conflicts of interest.

REFERENCES

1.- Carlson SA, Fulton JE, Pratt M, Yang Z, Adams EK. Inadequate physical activity and health care expenditures in the United States. Prog in cardiovasc dis.2015;57(4): 315-323.

2.- Vogeli C, Shields AE, Lee TA, Gibson TB, Marder WD, Weiss KB, Blumenthal D. Multiple chronic conditions: prevalence, health consequences, and implications for quality, care management, and costs. J Gen Intern Med.2007; 22(3): 391-395.

3.- Mapel DW, Hurley JS, Frost FJ, Petersen HV, Picchi MA, Coultas DB. Health care utilization in chronic obstructive pulmonary disease: a case-control study in a health maintenance organization. Arch Intern Med.2000;160(17): 2653-2658.

4.- Collet JP, Shapiro S, Ernst P, Renzi P, Ducruet T, Robinson A. Effects of an immunostimulating agent on acute exacerbations and hospitalizations in patients with chronic obstructive pulmonary disease.Am J Respir Crit Care Med.1997;156(6):1719-24.

5.- Rabe KF, Hurd S, Anzueto A, Barnes PJ, Buist SA, Calverley P, Zielinski J (2007). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: GOLD executive summary. Am J Respir Crit Care Med.2007;176(6):532-555.

6.-Annesi-Maesano I. Epidemiology of chronic obstructive pulmonary disease. In: Siafakas NM, editor. Management of Chronic Obstructive Pulmonary Disease. Wakefield: European Respiratory Society journals Ltd; 2006. p. 41e70.

7.- Roche N, Wedzicha JA, Patalano F, Frent SM, Larbig M, Shen S, et al. COPD exacerbations significantly impact quality of life as measured by SGRQ-C total score: results from the FLAME study.2017

8.- Vestbo J, Hurd SS, Agusti AG, Jones PW, Vogelmeier C, Anzueto A. (2013). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: GOLD executive summary. Am J Respir Crit Care Med. 2013; 187: 347–365.

9.- McCarthy B, Casey D, Devane D, Murphy K, Murphy E, Lacasse Y.Pulmonary rehabilitation for chronic obstructive pulmonary disease. The Cochrane Library.2015

10.-Maddocks M, Nolan CM, Man WD, Polkey MI, Hart N, Gao W.et al. Neuromuscular electrical stimulation to improve exercise capacity in patients with severe COPD: A randomised double-blind, placebo-controlled trial. Lancet Respir Med. 2016;4(1):27-36.

11.- Lopez Lopez L, Granados Santiago M, Donaire Galindo M, Torres Sanchez I, Ortiz Rubio A, Valenza MC. Efficacy of combined electrostimulation in patients with acute exacerbation of COPD: Randomised clinical trial. Medicina Clínica. Med Clin .2018;151(8):323-328.

12.- Von Korff M, Gruman J, Schaefer J, Curry SJ, Wagner EH. (1997). Collaborative management of chronic illness. Ann Intern Med. 1997;127(12): 1097-1102.

13.- Rich MW, Beckham V, Wittenberg C, Leven CL, Freedland KE, Carney RM. A multidisciplinary intervention to prevent the readmission of elderly patients with congestive heart failure. N Engl J Med.1995;333(18); 1190-1195.

14.- Bourbeau J, Julien M, Maltais F, Rouleau M, Beaupré A, Bégin R, Singh R. Reduction of hospital utilization in patients with chronic obstructive pulmonary disease: a disease-specific self-management intervention. Arch Intern Med. 2003;163(5): 585-591.

15.- Gibson PG, Powell H, Wilson A, Abramson MJ, Haywood P, Bauman A, Roberts J J. Self‐management education and regular practitioner review for adults with asthma. The Cochrane Library.2012.

16.- Gibson PG, Powell H, Coughlan J, Wilson AJ, Abramson M, Haywood P, et al. Self-management education and regular practitioner review for adults with asthma. Cochrane Database Syst Rev. 2004;(4):CD001117.

17.- Glasgow RE, Davis CL, Funnell MM, Beck A. Implementing practical interventions to support chronic illness self-management. Jt Comm J Qual Saf. 2003;29:563–74

18.- Greening N J, Williams JE, Hussain SF, Harvey-Dunstan TC, Bankart MJ, Chaplin,et al. An early rehabilitation intervention to enhance recovery during hospital admission for an exacerbation of chronic respiratory disease: randomised controlled trial. Bmj.2014; 349: 4315

19.- Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. BMC medicine.2010; 8(1): 18.

20.- EuroQoL Group. EuroQol: a new facility for the measurement of health-related quality of life. Health Policy. 1990; 16:199 –208

21.- Garrod R, Bestall JC, Paul EA, Wedzicha JA, Jones PW. Development and validation of a standardized measure of activity of daily loving in patients with severe COPD: the London Chest Activity of Daily Living scale (LCADL). Respir Med 2000;94(6):589-96

22.- Keith RA, Granger CV, Hamilton BB, Sherwin FS. The functional Independence measure: a new tool for rehabilitation. Advances in clinical rehabilitation. Volumen 1. New York: Springer-Verlag;1987;6-18.

23.- Macario CC, Martín IGT, de Torres Tajés JP. La disnea en la EPOC. Archiv bronconeumol.2005;41: 24-32.

24.- Taekema DG, Gussekloo J, Maier AB, Westendorp RG,de Craen AJ. Handgrip strength as a predictor of functional, psychological and social health. A prospective population-based study among the oldest old. Age and ageing.2010; 39(3):331-337.

25.- Jones SE, Kon SS, Canavan JL, Patel MS, Clark AL, Nolan CM, Man WD. The five-repetition sit-to-stand test as a functional outcome measure in COPD. Thorax, thoraxjnl-2013

26.- Hurst JR, Vestbo J, Anzueto A, Locantore N, Müllerova H, Tal-Singer R, et al. Susceptibility to exacerbation in chronic obstructive pulmonary disease. N Engl J Med. 2010;363:1128–38
27.- Valenza MC, Torres Sánchez I, López López L, Cabrera Martos I, Ortiz Rubio A, Valenza Demet G. Effects of home-based superimposed neuromuscular electrical stimulation in severe chronic obstructive pulmonary disease patients: a randomized controlled clinical trial. Eur J Phys Rehabil Med 2017.
28.- Abdellaoui A, Préfaut C, Gouzi F, Couillard A, Coisy Quivy M, Hugon G, Hayot M. Skeletal muscle effects of electrostimulation after COPD exacerbation: a pilot study. Eur Respir J.2011; 38(4): 781-788.
29.- Rubin RR, Anderson RM, Funnell MM: Collaborative diabetes care. Pract Diabetol 21:29–32, 2002
30.- Bandura A. Social foundations of thought and action: a social cognitive theory. NJ, USA: Prentice-Hall, 1986
31.- Kühl K, Schürmann W, Rief W. Mental disorders and quality of life in COPD patients and their spouses. Int J Chron Obstruct Pulmon Dis.2008;3(4): 727.
32.- Badia X, Diaz-Prieto A, Gorriz MT, Herdman M, Torrado H, Farrero E et al. Using the EuroQol-5D to measure changes in quality of life 12 months after discharge from an intensive care unit. Intensive care med. 2001; 27(12):1901-1907.
33.- Boxall A, Barclay L, Sayers A, Caplan GA. Managing chronic obstructive pulmonary disease in the community. A randomized controlled trial of home‐based pulmonary rehabilitation for elderly housebound patients. J Cardiopulm Rehabil. 2005;25(6):378‐85.
34.- Emery CF, Schein RL, Hauck ER, MacIntyre NR. Psychological and cognitive outcomes of a randomized trial of exercise among patients with chronic obstructive pulmonary disease. Health Psychol.1998;17(3):232‐240.
35.- Gallefoss F, Bakke PS. How does patient education and self‐management among asthmatics and patients with chronic obstructive pulmonary disease affect medication?. Am J Respir Crit Care Med. 1999;160(6):2000‐5.
36.- Bucknall CE, Miller G, Lloyd SM, Cleland J, McCluskey S, Cotton M, et al. Glasgow supported self-management trial (GSuST) for patients with moderate to severe COPD: randomised controlled trial. Bmj. 2012; 6;344:e1060.
37.- Simpson E, Jones MC. An exploration of self-efficacy and self-management in COPD patients. Br J Nurs. 2013;22(19):1105-9.
38.- Monninkhof EM, Van Der Valk PD, Van Der Palen J, Van Herwaarden CL, Partidge MR, Walters EH, et. Self-management education for chronic obstructive pulmonary disease. Cochrane Database Syst Rev. 2003;1. CD002990.
39.- Mallinger JB, Griggs JJ, Shields CG. Patient-centered care and breast cancer survivors' satisfaction with information. Patient Educ Couns. 2005;(3):342-9.
40.- Shippee ND, Shah ND, May CR, Mair FS, Montori VM. Cumulative complexity: a functional, patient-centered model of patient complexity can improve research and practice. J Clin epidemiol.2012; 65(10): 1041-1051
41.- Zwerink M, Brusse‐Keizer M, van der Valk PD, Zielhuis GA, Monninkhof EM, van der Palen,et al. Self management for patients with chronic obstructive pulmonary disease. The Cochrane Library.2014.

42.- Parsi K, Chambers CJ, Armstrong AW. Cost-effectiveness analysis of a patient-centered care model for management of psoriasis. J Am Acad Dermatol. 2012;(4):563-70.
43.- Aaron SD, Donaldson GC, Whitmore GA, Hurst JR, Ramsay T, Wedzicha JA. Time course and pattern of COPD exacerbation onset. Thorax.2012; 67(3): 238-243.
44.- Coventry PA, Bower P, Keyworth C, et al. The effect of complex interventions on depression and anxiety in chronic obstructive pulmonary disease: systematic review and meta-analysis. PLoS One. 2013;8:e60532.
45.- Ortiz, OH, Aristizabal MC, Stathatos M, Wolkove N, Sounan C, Boucher JP,et al .Combined Resistance And Aerobic Training Program On Functional Physical Performance In COPD Patients. Med Science Sports Exer.2015; 47(5S): 683.
46.- Monninkhof E, van der Valk VDP, Van der Palen J, Van Herwaarden C, Zielhuis, G. Effects of a comprehensive self-management programme in patients with chronic obstructive pulmonary disease. EurResp J.2003; 22(5): 815-820.
47.- Heyworth ITM, Hazell ML, Linehan ML, Frank TL. How do common chronic conditions affect health-related quality of life?.British Journal of General Practice 2009;59(568):833–8.
48.- Ghanem M, Abd ELaal E, Mehany M, Tolba K. Homebased pulmonary rehabilitation program: effect on exercise tolerance and quality of life in chronic obstructive pulmonary disease patients. Annals of Thoracic Medicine 2010;5(1):18–25.

Figure 1. CONSOT Flow diagram

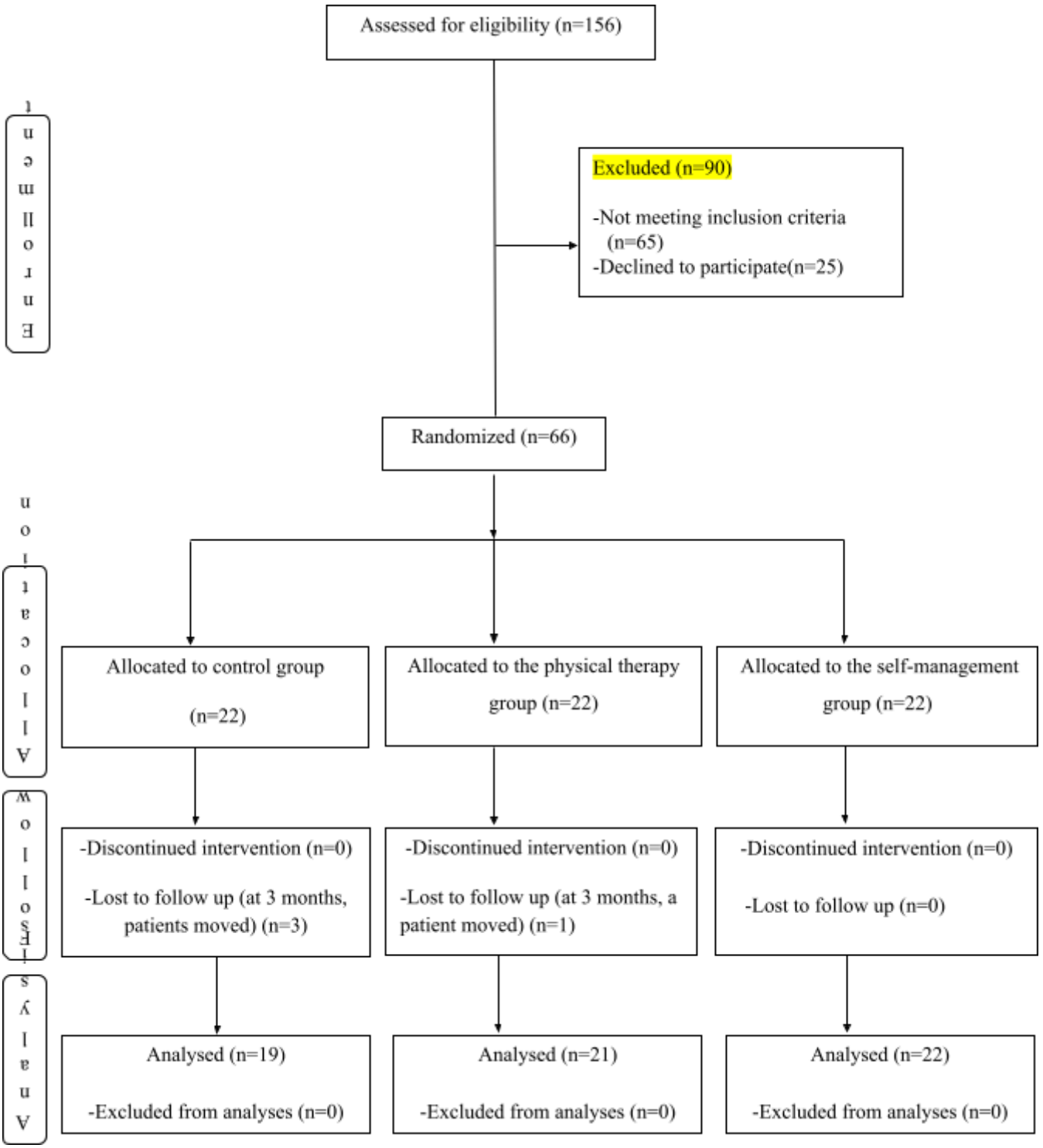
Assessed for eligibility (n=156)
Excluded (n=90)
-Not meeting inclusion criteria (n=65)
-Declined to participate(n=25)
Randomized (n=66)
Allocated to control group (n=22)
Allocated to the physical therapy group (n=22)
Allocated to the self-management group (n=22)
-Discontinued intervention (n=0)
-Lost to follow up (at 3 months, patients moved) (n=3)
-Discontinued intervention (n=0)
-Lost to follow up (at 3 months, a patient moved) (n=1)
-Discontinued intervention (n=0)
-Lost to follow up (n=0)
Analysed (n=19)
-Excluded from analyses (n=0)
Analysed (n=21)
-Excluded from analyses (n=0)
Analysed (n=22)
-Excluded from analyses (n=0)
Enrollment
Allocation
Follow-up
Analysis

Table 1. Baseline characteristics of the subjects for each group.

Variables	Control Group (n=22)	Physical Therapy group (n=22)	Self-Management group (n=22)	F
Age (years)	71.35±9.88	71.20±11.53	72.63±7.37	0.369
BMI (Kg/m^2)	27.91±5.71	26.67±4.00	28.82±4.38	1.348
FEV_1%	34.50±19.59	36.58±16.79	38.77±17.87	0.730
Handgrip strenght(N)	265.63±98.36	270.67±104.51	275.68±88.47	5.433
5STS(sec)	39.06±20.53	38.92±18.82	36.14±19.73	0.250
Borg	5.86±2.61	5.10±2.63	4.19±3.01	6.818
Hospitalization days	9.51±4.22	9.47±3.02	9.48±5.65	0.364
Health-related quality of life				
Mobility subscore	1.93±0.53	1.80±0.61	1.85±0.59	0.619
Personal care subscore	1.96±0.76	2.00±0.72	1.93±0.77	0.081
Daily activities subscore	2.22±0.75	2.20±0.76	2.04±0.80	1.023
Pain subscore	1.65±0.80	1.60±0.75	1.67±0.72	0.455
Anxiety/depression subscore	1.94±0.81	1.80±0.83	1.93±0.82	0.238
VAS	46.50±21.30	54.90±16.62	46.55±20.67	1.465
Dyspnea-related functionality				
Personal care subscore	11.13±4.49	10.00±4.58	9.93±4.86	1.082
Domestic activities subscore	7.90±11.53	7.90±9.78	6.93±9.81	0.137
Physical activities subscore	6.36±2.73	5.55±1.93	5.74±1.66	1.543
Leisure activities subscore	6.98±2.89	6.65±2.66	5.96±2.41	2.104
Total score	32.44±14.25	30.10±12.90	28.19±12.21	1.479
General functionality	1.75±0.47	1.55±0.60	1.67±0.54	
Motor subscore	81.15±13.80	85.80±10.51	79.74±12.12	1.666
Cognitive subscore	33.48±5.00	34.50±1.31	33.56±2.16	0.618
Total score	114.63±16.99	120.30±11.14	113.30±13.30	1.652

BMI: Body mass index; FEV_1%: Forced expiratory volume in one second predicted; 5 STS: Five times sit to stand test; VAS: Visual Analogue Scale.

Table 2. Mean and secondary outcomes values at discharge

Variables	Control Group (n=22)			Physical Therapy group (n=22)			Self-Management group (n=22)			F
	Discharge	95% CI	Within group p value	Dircharge	95% CI	Within group p value	Discharge	95% CI	Within group p value	
FEV1%	41.25±21.09	(1.36, 11.4)	0.029	43.02±12.52	(1.36, 11.4)	0.003	45.73±17.9	(5.08, 15.4)	0.001	0.523
Handgrip strenght(N)	246.07±85.71	(-16.5,13.7)	0.487	257.25±64.5	(-21.8,20.7)	0.552	262.67±47.3	(-32.5,33.7)	0.305	4.651
5STS(sec)	31.27±11.22	(-4.6, 5.4)	0.195	29.06±20.53	(-11.6, -3.4)	0.033	24.5±6.82	(-6.6, -1.85)	0.025	2.321[a],c
Borg	3.10±2.34	(-2.3, -0.47)	0.011	2.60±2.31	(-3.7, -1.07)	0.006	2.85±3.37	(-3.1, -1.47)	0.004	0.562
Health-related quality of life										
Mobility subscore	1.59±0.63	(-0.19,0.50)	0.073	1.35±0.60	(-0.76,-0.13)	0.001	1.19±0.61	(-0.83,-0-49)	0.008	7.547a,b,c
Personal care subscore	1.69±0.80	(-0.08,0.46)	0.101	1.40±0.68	(-0.78,-0.11)	<0.001	1.23±0.76	(-0.19,-0.11)	<0.001	6.492a,c
Daily activities subscore	1.83±0.87	(-0.18,0.60)	0.062	1.55±0.98	(-0.18,1.11)	0.184	1.30±0.75	(-0.93,-0.54)	<0.001	9.488a,c
Pain subscore	1.21±0.77	(-0.26, 0.63)	0.056	1.30±0.73	(-0.43,0.64)	0.208	1.27±0.74	(-0.60,-0.20)	0.027	0.147
Anxiety/depression subscore	1.51±0.79	(-0.64, -0.22)	0.007	1.35±0.87	(-0.06,0.76)	0.326	1.19±0.70	(-0.94,-0.53)	<0.001	5.577c
VAS	56.13±22.69	(15.08,24.18)	<0.001	65.75±17.80	(-19.18,2.51)	0.395	70.60±23.79	(10.56,37.58)	<0.001	5.466b,c
Dyspnea-related functionality										
Personal care subscore	9.07±3.80	(-3.64,-0.48)	0.025	6.10±4.59	(-5.48,-2.23)	0.003	6.09±4.49	(-4.59,-2.09)	0.004	4.618a,c
Domestic activities subscore	9.43±7.94	(-4.49,1.43)	0.258	5.97±6.48	(-3.13,-1.08)	0.011	5.09±6.12	(-2.14,-0.55)	0.032	0.587a,c
Physical activities subscore	5.26±3.46	(-0.19, 2.39)	0.354	3.81±1.23	(-2.48,-1.35)	0.004	3.90±1,47	(-2.43,-1.25)	<0.001	6.665a,c
Leisure activities subscore	5.85±2.68	(-3.13,- 1.53)	0.035	4.25±2.35	(-3.84,-1.31)	0.001	3.58±2.25	(-3.75,-1.01)	0.001	8.941
Total score	28.68±11.62	(-0.57, 8.10)	0.985	20.87±9.47	(-12.20,-6.69)	0.002	18.69±9.69	(-12.80,-6.19)	<0.001	4.488a,c

General functionality										
Motor subscore	77.75±2.51	(-0.28,6.51)	0.321	91.60±11.24	(1.13,11.06)	0.012	85.34±11.83	(1.13,6.62)	0.017	2.43a,c
Cognitive subscore	34.08±1.94	(-3.02,1.82)	0.604	35.20±0.67	(0.21,1.08)	0.036	33.96±0.68	(0.11,1.08)	0.042	2.288
Total score	111.83±3.03	(-0.96,6.56)	0.459	126.55±12.24	(1.71,10.27)	0.041	119.30±12.42	(1.81,8.18)	0.023	3.899a,c

FEV1%: Forced expiratory volume in one second predicted; 5 STS: five times sit to stand test; VAS: Visual Analogue Scale. P<0.05*,p<0.001**. a: Significant differences between Control Group and Physical Therapy group. b: Significant differences between Physical Therapy group and Self-Management group. c: Significant differences between Control Group and Self-Management group.

Table 3. 3 months follow up main and secondary outcomes.

Variables	Control Group (n=22)			Physical Therapy group (n=22)			Self-Management group (n=22)			F
	follow up difference	95% CI	Within group p value	follow up difference	95% CI	Within group p value	follow up difference	95% CI	Within group p value	
FEV1%	38.50±24.16	(-4.23, 7.5)	0.352	34.22±18.65	(-5.85, 6.3)	0.352	29.8±20.4	(-3.9, 6.12)	0.731	5.23
Handgrip strenght(N)	225.84±62.2	(-16.5,13.7)	0.409	219.25±57.1	(-15.36,12.8)	0.369	217.84±53.6	(-13.3,12.7)	0.258	4.651
5STS(sec)	28.14±12.58	(-4.6, 5.4)	0.532	22.90±16.3	(-11.4, 7.5)	0.308	20.08±11.69	(-13.6, 6.1)	0.270	2.321[a,c]
Borg	3.7±2.34	(-2.3, 0.47)	0.509	4.1±3.5	(-5.2, 2.77)	0.429	4.1±3.5	(-1.9, 2.7)	0.338	0.562
Health-related quality of life										
Mobility subscore	1.82±0.55	(0.12,0.45)	0.032	1.75±0.61	(-0.29,0.21)	0.351	1.03±0.40	(-0.26,0.59)	0.356	3.382[b,c]
Personal care subscore	1.93±0.72	(-0.53,0.39)	0.168	1.51±0.47	(-0.18,0.49)	0.874	1.07±0.40	(-0.26,0.59)	0.447	9.487[a,b,c]
Daily activities subscore	2.15±0.62	(0.05,0.46)	0.027	2.21±1.03	(-0.75,0.41)	0.816	1.53±0.89	(-0.54,0.07)	0.560	2.645[a,b,c]
Pain subscore	1.52±0.32	(0.03,0.24)	0.049	1.50±0.57	(-0.43,0.03)	0.351	1.27±0.00	(-0.23,0.56)	0.706	3.166[b,c]
Anxiety/depression subscore	1.75±0.72	(-0.43, 0.05)	0.385	1.61±0.75	(-0.75,0.12)	0.684	1.90±0.71	(-0.42,0.07)	0.433	4.221
VAS	53.13±28.28	(-8.67,14.6)	0.624	59.09±15.05	(-9.13,22.4)	0.952	63.72±31.57	(-4.13,17.9)	0.641	1.149
Dyspnea-related functionality										
Personal care subscore	9.55±3.43	(-3.19,2.08)	0.357	8.20±6.01	(-2.27,3.67)	0.841	6.86±3.71	(-0.59,5.53)	0.522	7.697[b,c]
Domestic activities subscore	7.55±19.93	(-3.88,6.77)	0.078	6.08±13.95	(-3.12,3.52)	0.746	4.52±6.50	(-2.09,2.44)	0.403	6.489[a,b,c]
Physical activities subscore	5.33±2.00	(-1.87, 1.20)	0.741	3.60±3.05	(-2.18,5.38)	0.259	3.79±1.80	(-0.51,0.74)	0.268	7.225[a,c]

Leisure activities subscore	6.88±2.47	(-2.78,1.01)	0.489	4.75±1.36	(-0.53,0.41)	0.752	3.18±3.71	(-3.21,6.01)	0.241	10.247[a,b,c]
Total score	27.33±15.41	(-21.79,11.12)	0.268	21.60±14.94	(-27.15,9.95)	0.225	16.22±10.39	(-4.15,5.09)	0.396	8.310[a,b,c]
General functionality										
Motor subscore	78.50±6.25	(-7.06,6.06)	0.362	88.85±5.50	(-8.00,1.50)	0.335	90.94±6.68	(-10.38,-0.81)	0.032	6.729[a,c]
Cognitive subscore	34.24±4.60	(-4.84, 1.51)	0.301	28.70±7.00	(-4.63,3.63)	0.649	30.16±3.42	(-0.10,0.50)	0.562	2.949[a,c]
Total score	110.83±7.77	(-7.15, 9.15)	0.528	118.05±17.67	(-13.32,4.32)	0.804	122.70±9.05	(-9.88,3.08)	0.225	7.259[ac]

FEV1%: Forced expiratory volume in one second predicted; 5 STS: five times sit to stand test; VAS: Visual Analogue Scale. P<0.05*,p<0.001**. a: Significant differences between Control Group and Physical Therapy group. b: Significant differences between Physical Therapy group and Self-Management group. c: Significant differences between Control Group and Self-Management group.