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Effect of a structured integral intervention to stimulate selfmanagement and improve quality of life in people with chronic obstructive pulmonary disease (COPD), Randomised clinical trial

Maite Lopez Luque

Catalan Health Institute, Spain

hronic Obstructive Pulmonary Disease (COPD) is a great magnitude public health problem with an associated increased mortality and a high cost (consumption of health care resources and loss of health related quality of life (HRQoL)). The comprehensive approach to this complex disease, focusing self-care promotion, improves HRQoL and the patients" clinical status, as shown by several studies, although further investigation is needed to confirm these results in the field of Primary Care (PC) and to formulate clear recommendations on the more effective type of intervention. Hypothesis: In (moderate-severe) COPD patients, a structured self-management intervention plan in the setting of primary care, is more effective than usual treatment on the main outcomes associated with the disease: HRQoL, lung function, exacerbations and hospital admissions, at 6, 12 and 24 months of follow-up.

Objectives: To evaluate the impact of a comprehensive intervention plan to promote self-care and improve HRQoL in

people with COPD in PC.

Methods: Multicenter randomized controlled trial, conducted at PC centers in Barcelona.

Determinations: Specific standardized and validated questionnaires, as the St George's Respiratory for the HRQoL. Statistical analysis: Intention to treat analysis. Descriptive statistics of the variables of the intervention and the control group to assess their homogeneity at the beginning of the study. An analysis of variance (ANOVA) will be used to assess differences among intervention groups.

Expected results: A significant improvement in HRQoL attributable to the intervention performed in patients with COPD

Applicability and Relevance: To implement the intervention plan in clinical practice and to standardize its content.

tlopezl@gencat.cat

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