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Title: Health status based treatment of COPD patients in primary care – A randomized controlled pilot study

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Body: Introduction COPD treatment strategies are traditionally based on lung function impairment. In the GOLD 2013 guidelines health status is incorporated as measurement of severity and with that as disease management modulator. There is no evidence that management based on health status is superior. Aim To (pilot) test the hypothesis that health status based treatment is superior to pulmonary function based treatment. Methods We enrolled 53 COPD patients in a single blind randomized controlled pilot trial. GP's of patients in both groups received specific predefined treatment advices, based on either health status (measured by the Clinical COPD Questionnaire, health status group: HG) or regular GOLD 2009 based care (control group: CG). Included: diagnosed COPD, ≥ 10 packyrs. Excluded: asthma, severe comorbidities, regular oxygen use. Three visits in 6 months were completed. Each visit encompassed spirometry and questionnaires (disease specific health status (St. George's Respiratory Questionnaire (SGRQ))). The primary outcome was change in SGRQ after 6 mo. Univariate analyses were performed using the Mann-Whitney U test. Results Twenty eight patients were randomized to CG, and 25 to HG. 58% were male; mean 64yrs and 40 packyrs; GOLD I 38%, GOLD II 57%, GOLD III 6%. SGRQ changed 0,74 in HG and 3,4 in CG (ns). Treatment advices were implemented by the GP in 78,8 % of cases. Conclusion This pilot study showed no beneficial effect of 6 months treatment based on health status, possibly due to low n, but proved that health status based advices for treatment of COPD were acceptable to the GP. A much larger further developed follow-up study will show if these advices are also beneficial for patients.