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## Design of a Randomized Controlled Trial (RCT) Evaluating Outcome and Cost-effectiveness of a Local Case-Management Intervention of Patients Suffering from Chronic Obstructive Pulmonary Disease (COPD)

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*Publication date:*  
2013

*Document Version*  
Early version, also known as pre-print

[Link to publication from Aalborg University](#)

*Citation for published version (APA):*

Sørensen, S. S., Pedersen, K. M., & Ehlers, L. H. (2013). *Design of a Randomized Controlled Trial (RCT) Evaluating Outcome and Cost-effectiveness of a Local Case-Management Intervention of Patients Suffering from Chronic Obstructive Pulmonary Disease (COPD)*. Poster presented at International Society for Pharmacoeconomics and Outcomes Research, Dublin, Ireland.  
[http://www.ispor.org/research\\_study\\_digest/list.asp?qs=34628](http://www.ispor.org/research_study_digest/list.asp?qs=34628)

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# A randomized controlled trial (RCT) evaluating outcome and cost-effectiveness of a local case management intervention of patients suffering from Chronic Obstructive Pulmonary Disease (COPD)

## BACKGROUND

In December 2011 the Danish Government issued a new plan of action for chronic disease management in the Danish counties and among other things granted DKK 100 mill to set up new positions as case managers to help vulnerable elderly patients. However, no precise job description was provided and the Danish counties still request further evidence for the effect of case management (CM).

*This study aims to investigate the consequences and costs of providing local CM to patients suffering from COPD.*

**STUDY DESIGN:** By use of the UK Medical Research Councils (MRC) framework for development of complex interventions<sup>1</sup>, the design of the case manager job description and the RCT was determined through a systematic literature review, interviews with key persons and discussions in a specialist-comprised steering group. CM was designed to encompass coordination of care, facilitation of relevant health- and social services and promotion of patient self-care through advocacy and education. The RCT was powered to detect the effect of CM on hospital admissions. Secondary measures include mortality, quality of life, self-care and cost-effectiveness of CM vs. usual care. 150 COPD patients are equally randomized into two groups after referral to pulmonary rehabilitation at the local rehabilitation center in Aalborg County, Denmark. The control group will receive usual care, whereas the interventional group will receive CM besides their usual care. Each patient is followed for 12 months.

**DATA COLLECTION:** The questionnaires SF-12, EQ-5D, Saint-George's Respiratory Questionnaire (SG-RQ) and The Patient-Activation-Measure (PAM-13) are completed at baseline and 12 months, and data for the economic evaluation are collected alongside trial. Prospectively collected data from national population-based medical registries; including the Danish National Registry of Patients, are used to estimate events and resource usage.

**PRELIMINARY STATUS:** The RCT terminates January 2014, and we hope to achieve a reduction in hospital admissions and overall mortality, see an improvement in the patient's quality of life and ability to provide self-care, and to demonstrate the cost-effectiveness of providing CM to COPD patients in a Danish setting. The study is expected to provide further insight to the future organization of CM, and if being cost-effective, the intervention could be applied to comparable healthcare settings.

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## PATIENT BASELINE CHARACTERISTICS:

	Intervention	Control	p-value
Male, n (%)	37 (48.7)	27 (37.0)	0.149
Age, years (±SD)	69.1 (8.3)	69.5 (8.5)	0.749
Living alone, n (%)	29 (38.2)	34 (46.6)	0.298
Employed, n (%)	11 (14.5)	4 (5.5)	0.101
Educational level, n (%)			
- Primary/secondary school or less	38 (50.0)	39 (53.4)	0.641
- Vocational education	22 (28.9)	18 (24.7)	
- Higher education	16 (21.1)	16 (21.9)	
Chronic comorbidities, n (%)			
- Diabetes	8 (10.5)	9 (12.3)	0.729
- Heart disease	47 (61.8)	39 (53.4)	0.298
- Osteoporosis	15 (19.7)	21 (28.8)	0.198
Smoking status, n (%)			
- Current	17 (22.4)	19 (26.0)	0.594
- Former	56 (73.7)	49 (67.1)	
Alcohol consumption> health guidelines, n (%) <sup>*</sup>	12 (20.7)	11 (22.9)	0.782
Level of physical activity, n (%) <sup>†</sup>			
- Sedentary/lightly active	11 (14.5)	12 (16.4)	0.304
- Moderately active	61 (80.3)	57 (78.1)	
- Very active	4 (5.3)	4 (5.5)	
BMI, kg/m <sup>2</sup> (±SD)	26.3 (5.3)	26.3 (5.6)	0.966
FEV <sub>1</sub> , l (median, P <sub>25</sub> -P <sub>75</sub> )	1.1 (0.9-1.6)	1.2 (0.9-1.5)	0.838
FEV <sub>1</sub> /FVC, % (±SD)	53.3 (12.8)	55.2 (13.4)	0.372
MRC dyspnea scale (median, P <sub>25</sub> -P <sub>75</sub> )	3 (3-3.5)	3 (3-3)	0.765
EQ-5D (median, P <sub>25</sub> -P <sub>75</sub> )	0.8 (0.7-1)	0.8 (0.6-0.8)	0.515
SGRQ (median, P <sub>25</sub> -P <sub>75</sub> ) <sup>‡</sup>			
- Symptoms component	56.0 (35.4-67.0)	52.6 (37.3-60.2)	0.329
- Activities component	67.6 (44.3-91.6)	67.6 (44.8-84.2)	0.793
- Impact component	27.3 (13.6-53.1)	30.3 (18.9-51.7)	0.648
PAM-13 (±SD) <sup>§</sup>	59.6 (12.4)	60.9 (14.5)	0.566
SF-12 (±SD) <sup>¶</sup>			
- Physical score	39.3 (9.6)	37.7 (9.6)	0.304
- Mental score	51.8 (10.5)	50.3 (10.3)	0.396

\*A weekly alcohol consumption of > 7 units for women and > 14 units for men poses a potential health risk<sup>2,3</sup>. <sup>†</sup>Sedentary/Lightly active= Light activity 0-4h/week; Moderately active = Light activity > 4h/week; Very active = strenuous activity 2-4h/week. <sup>‡</sup>SGRQ scores go from 0 (better health status) to 100 (worse health status). <sup>§</sup>PAM-13 scores are divided into four levels of activation; Level 1 - Starting to take a role (score ≤47.0), Level 2 - Building knowledge and confidence (score 47.1-55.1), Level 3 - Taking action (score 55.2-67.0), Level 4 - Maintaining behaviors (score ≥67.1). <sup>¶</sup>SF-12 scores go from 0 (worse health status) to 100 (better health status).

