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**Title:** A multi-centre, randomised controlled trial of positive expiratory pressure mask therapy for inpatients with acute exacerbations of COPD and sputum expectoration

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Body: Background: Positive expiratory pressure (PEP) is an airway clearance technique used to enhance sputum clearance during acute exacerbations of chronic obstructive pulmonary disease (AECOPDs). The impact of PEP therapy on clinically important outcomes during AECOPDs has not been established. Aim: To determine the effect of PEP therapy on symptoms, quality of life and future exacerbations in patients with AECOPDs. Methods: 90 inpatients (58 male; mean age 68.6, FEV1 40.8% predicted) with AECOPDs and sputum expectoration were randomised to receive PEP therapy 3 times/day in addition to usual care, or usual care alone. Both groups underwent physical exercise. The Breathlessness, Cough and Sputum Scale (BCSS), St. George's Respiratory Questionnaire (SGRQ), exacerbations, hospitalisations and BODE index (Body mass index, airflow Obstruction, Dyspnoea, Exercise tolerance) were measured at discharge, eight weeks and six months following discharge. Longitudinal data were analysed using linear mixed models. Results: There were no statistically significant between-group differences in BCSS scores (p = 0.98), SGRQ scores (p = 0.87), or incidence of exacerbations (p = 0.99) or hospitalisations (p = 0.36) at any time. The PEP group showed a more rapid improvement in dyspnoea (p = 0.01) and exercise tolerance (p = 0.052, ns) over the first eight weeks, however these benefits were not observed at six months. Conclusion: PEP therapy during AECOPDs does not affect important clinical outcomes at discharge or six months later. There does not appear to be a routine role for PEP therapy in the management of inpatients with AECOPDs.