Title: Bubble PEP Training Among Patient With Chronic Obstructive Pulmonary Disease in Pulmonary Function Effects

Study Protocol

Principal Investigator : Szu-Yi Wang

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Material and Methods

Design and Participants

A randomized controlled trial with a single-blind study design was conducted. Using convenience sampling, data were collected from February 2021 to July 2021 at two teaching hospitals in northern Taiwan. Random serial numbers were generated by a research assistant using Random Allocation Software. The research assistant then put each serial number into an opaque envelope. After agreeing to participate in this study, each participant received an envelope and opened it to find out whether they belonged to the experimental group or the control group. The research assistant who assisted with recruitment did not engage in data collection or analysis.

The inclusion criteria were patients who diagnosed AECOPD and were 40 years old or older, conscious, could read articles, agreed to participate in the study, and signed an informed consent document. Exclusion criteria included patients who had used non-invasive PEP treatment before or during hospitalization, who had a mental disorder. The G*Power 3.1.9.7. software was used to estimate the sample size. A sample size of at least 26 has 80% power to detect the largest effect size of 0.5. An alpha level of 0.05 was used.

Measurements

The participants' demographics and clinical characteristics were collected, including gender, age, marital status, occupation, smoking history, chronic comorbidities (hypertension, diabetes mellitus, heart disease, lung cancer, and pneumothorax), COPD stage and dry powder bronchodilator use.

Chinese Version of the CAT

A total of eight items were used to assess the degree of dyspnea of the patients. Each item had a score ranging from 0 to 5 points, with the highest total score being 40

points. The higher the score, the higher the degree of dyspnea (Pothirat et al., 2015). The present study Cronbach's α was 0.88, and the Intraclass Correlation Coefficient (ICC) was 0.8.

CSSAQ

The CSSAQ was used to assess patients' cough and sputum symptoms. The content of the questionnaire was prepared with reference to published literature. The questionnaire consisted of 25 questions, including questions related to cough, sputum, and psychological symptoms and effects, on a four-point Likert scale with scores ranging from 0 to 4. The higher the score, the worse the cough or sputum symptoms (French et al., 2002). The index of content validity was 1, while Cronbach's α was 0.97.

PEFR

The patients' pulmonary ventilation was assessed using the TruZone peak flow meter. This device was also used to monitor FEV1. Several studies showed good internal consistency of this measurement instrument, with a Cronbach's α of 0.99 (Folgering et al., 1998; Martinez et al., 2017). In this study, Cronbach's α was 0.97.

Bubble PEP bottle

The bubble PEP device consisted of a 500cc water bottle and a short tube that was 0.8 cm in diameter and 45 cm in length. The tube was inserted into the water bottle, and 10 cm of the tube was placed underwater to form a breathing training water bottle with a positive pressure of 10 cmH_2O.

Bubble PEP training

The patients trained three times a day with a bubble PEP bottle, and each training session lasted 20 minutes. During the training session, each patient maintained a 90-degree sitting posture. After taking a deep inhalation, each patient held the bottle and blew air out through the tube into the water. The ratio of inhalation to blowing was 1 to

3 seconds. The patient rested for at least 1 minute after each bout of inhalation and blowing. After completing 10 blows, the patients exhaled 3 times, took deep breaths, and coughed. The breathing training continued for 30 days. The participants were advised to avoid training one hour before and two hours after meals.

Procedures

After the experimental and control groups agreed to participate in this study and completed the consent forms, the two groups took pre-tests, which measured the Chinese version of the CAT, the CSSAQ, and the PEFR, within 48 hours of hospitalization, which served as the baseline of the intervention (T0). Data were collected again on the 7th day (T1) and the 30th day (T2) of the intervention to evaluate the effect of the intervention on pulmonary function. Only the experimental group received bubble PEP training, while the control group had routine medical care. If participants were discharged from the hospital in the middle of the study, the investigator monitored the intervention effectiveness via weekly follow-up telephone calls.

The study procedures are shown in Figure 1. Of the 57 patients who met the criteria were invited to participate for study eligibility. 14 of the remaining 27 participants, 13 and 14 were assigned to the intervention and control groups, respectively. 7days follow-up (T1) data were obtained for 17 of the participants. 1M follow-up (T2) analyses were performed among the 14 participants with complete data. The attrition rates were 30% and 71% for the experimental and control groups, respectively, with an overall attrition rate of 52%.

Ethical considerations

The study protocol was reviewed and approved by the Institutional Review Boards of Fu Jen Catholic University Hospital and En Chu Kong Hospital (FJUH109078 & ECKIRB1091006). Participants were required to sign informed consent forms before

the study and were allowed to terminate or withdraw from the study at any time. Data collected from the participants were coded, de-identified, and kept in a locked cabinet (ClinicalTrials.gov number: NCT04828837).