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## Study Protocol

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**We use this protocol and it's working**

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## Abstract

Adherence to treatment is critical to effective management of COPD and is key to addressing the growing burden of disease. So, this study protocol conducted to evaluate the effectiveness of a health education intervention on treatment adherence behavior of COPD outpatients and identify the level of health status improvement.

## Troubleshooting

## Participants and Sites

### 1 Participants

#### 1.1 Inclusion criteria

1.2 Patients were diagnosed with COPD according to GOLD 2018 criteria.

1.3 Received stable home treatment with inhaled medications.

1.4 No acute episodes, including acute episodes due to chronic diseases requiring hospitalization for at least 3 months.

1.5 Able to speak, read and understand Vietnamese.

1.6 Participants had and knew how to use a smartphone with an Internet connection.

1.7 Voluntarily participated in the study.

#### 1.8 Exclusion criteria

1.9 History of bronchial asthma, allergic rhinitis, lung surgery, or respiratory diseases.

1.10 People with mental disorders or other serious illnesses.

2 Research site: Examination Department of Da Nang C Hospital as the intervention site and Examination Department of Da Nang Hospital for Lung Disease as the control site.



## Research Time

- 3 The pre-intervention data collection period spans from April 2021 to October 2021.
- 4 Content development for the intervention occurs from November 2021 to April 2022.
- 5 The intervention itself takes place from April 2022 to June 2022, lasting three months.
- 6 Post-intervention assessments are conducted from July 2022 to August 2022.

## Study Population

- 7 All COPD patients receiving outpatient treatment at 3 hospitals in Da Nang City.
- 8 Selected the whole sample.
- 9 Sample size of phase 1 (before intervention): 420.
- 10 Stratified random sampling.
- 11 Sample size of phase 2 (intervention): 90.
- 12 Da Nang Hospital C — Da Nang Hospital of Lung Disease.
- 13 45 patients perform control group: Interventions by (1) regular treatment providing and monitoring, knowledge; (2) evaluation regular re-practice guide; (3) after 3 examination every track = phone and months month diary.

## Intervention Process

- 14 We used a randomized controlled intervention study design.
- 15 The two main research phases include:
  - 16 Phase 1: Pre-intervention assessment, cross-sectional description of treatment adherence and related factors of people with COPD who are receiving outpatient treatment at medical facilities in Da Nang City, specifically at the Outpatient Department of three hospitals: Da Nang C Hospital, Da Nang Hospital, and Da Nang Hospital for Lung Disease and related factors.
  - 17 Phase 2: Evaluation of intervention results after 3 months with the following steps:
    - 18 Step 1: Develop intervention content, and verify the acceptability, appropriateness, and feasibility of the intervention program through consulting experts and patients.
    - 19 Step 2: Implement the intervention.
    - 20 Step 3: Post-intervention assessment is performed comparing before and after intervention and comparing between the intervention group and control group.

## Develop an Intervention Program

- 21 Criteria and principles for developing intervention content.
  - 22 To ensure the effectiveness of intervention activities, the intervention model is built based on 3 criteria: (1) appropriateness and feasibility; (2) sustainability; and (3) applicability.
  - 23 Principles to ensure appropriateness and feasibility:
    - 24 Based on the existing system.
    - 25 In line with the national program for the prevention of COPD.

- 26 Acceptable funding.
- 27 Intervention content is easy to apply.
- 28 Principles to ensure sustainability:
- 29 In line with practical conditions, hospitals all have plans to build a model of periodic health education for patients, especially those with COPD.
- 30 In line with the psychological characteristics of patients, meeting the needs/deficiencies and desires of patients and their families.
- 31 Principles to ensure applicability:
- 32 Intervention content is presented clearly/briefly, with easy-to-understand words, convenient and easy to implement.
- 33 Compact/beautiful/attractive form to participants.
- 34 Intervention program.
- 35 Based on a review of various documents and the analysis of numerous studies from around the world and Vietnam, combined with Ajzen's Planned Behavior Theory model (1991), we identified several barriers that lead to non-compliance with treatment.
- 36 These barriers include a lack of awareness about the disease, a lack of confidence in the effectiveness of treatment medications, and insufficient understanding of the benefits of breathing exercises.
- 37 Many patients maintain a daily routine of breathing exercises but still hold incorrect attitudes toward treatment, resulting in poor adherence.
- 38 Additionally, some patients may be aware of their condition and trust the prescribed medications; however, they may still rely too heavily on their personal experiences,

leading to a subjective approach that hinders their adherence to the recommended treatment protocols.

## Measures to Limit Errors

- 39 In this study, the main errors encountered were sampling errors and data collection errors.
- 40 To ensure reliability and limit errors, we calculated the study sample size to be relatively large and representative of major hospitals in Da Nang city.
- 41 The selection of individuals participating in the study was carried out following the correct procedure.
- 42 To overcome errors in information collection, the research team took the following measures:
- 43 The toolkit was designed to be simple, easy to understand, and easy to answer, the contents were arranged logically and tested before use.
- 44 Selection of investigators to measure lung function: They are people with clinical experience. Lung function measurements are performed under the supervision of head nurses specializing in respiratory medicine.
- 45 Data collection was carried out by the graduate students themselves. Data collection was conducted strictly: (i) Graduate students reviewed and re-checked 100% of the questionnaires that had been interviewed; (ii) The researcher re-interviewed 10% of the surveyed questionnaires; Survey questionnaires that were assessed as not highly reliable for various reasons were checked and re-interviewed. If they did not meet the requirements, they were eliminated and not included in the data analysis.

## Ethical Consideration

- 46 The study was conducted in accordance with the thesis outline approved by the Outline Approval Council and the Medical Ethics Council of Nam Dinh University of Nursing, as per Decision No. 1681/GCN-HDDD dated August 2, 2021.
- 47 Approval was obtained from Da Nang C Hospital, Da Nang Hospital, and Da Nang Hospital for Lung Disease.
- 48 Participants were individuals with Chronic Obstructive Pulmonary Disease (COPD) who attended the outpatient clinics of the three hospitals mentioned above. They willingly



agreed to participate in the study by signing a consent form that provided by the researcher at the first-time meeting.

49 Since the study was conducted during the COVID-19 epidemic control period in Da Nang City, we took precautions to ensure the safety of all participants. This involved close coordination with the hospitals to screen and examine COVID-19 patients, organize patient flow, and create separate pathways for study participants.

50 Participants in the intervention group were informed about the importance of confidentiality and committed to not sharing the knowledge they gained during the study with others. After completing the intervention, all subjects in the control group participated in two health counseling sessions and received documentation containing similar information to that provided to the intervention group.