The Research Plan

The Official Title of the study：

A study of behavioural changes in long-term home oxygen therapy in elderly patients with chronic obstructive pulmonary disease combined with mild cognitive impairment

date of the document:

9 May 2022

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1 Research Background

Chronic obstructive pulmonary disease (COPD) is the fourth leading cause of death globally, affecting up to 14% of individuals over 65 years old[1]. This results in a significant burden on healthcare systems and the global economy, with the economic cost of COPD projected to exceed $4.3 trillion by 2050[2]. Persistent hypoxemia and systemic inflammation in COPD have been shown to accelerate lung function decline. Additionally, accumulating evidence suggests these factors may contribute to cognitive impairment through hypoxia-induced neuronal damage[1]. COPD has been identified as an independent risk factor for cognitive impairment, with disease duration correlating directly with an increased risk of developing mild cognitive impairment (MCI)[2] . Research indicates that 25% of COPD patients experience MCI, a rate notably higher than the 13% prevalence in the general population[3]. MCI, a precursor to dementia[4], is characterized by executive dysfunction, memory deficits, and impairments in attention, orientation, and executive function[5]. These cognitive deficits significantly affect the self-management capabilities of elderly COPD patients with MCI, influencing medication adherence and long-term oxygen therapy (LTOT) compliance. As a result, a detrimental cycle of hypoxemia and cognitive decline may be perpetuated[6].

LTOT, when administered for at least 15 hours daily, has been shown to significantly improve blood oxygen levels in elderly COPD patients with MCI[9]. This

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[3] Yohannes, A. M., Chen, W., Moga, A. M., Leroi, I., & Connolly, M. J. (2017). Cognitive Impairment in Chronic Obstructive Pulmonary Disease and Chronic Heart Failure: A Systematic Review and Meta-analysis of Observational Studies. Journal of the American Medical Directors Association, 18(5), 451.e1–451.e11.

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[1] Chen, S., Kuhn, M., Prettner, K., Yu, F., Yang, T., Bärnighausen, T., Bloom, D. E., & Wang, C. (2023). The global economic burden of chronic obstructive pulmonary disease for 204 countries and territories in 2020-50: a healthaugmented macroeconomic modelling study. The Lancet. Global health, 11(8), e1183–e1193.

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therapy effectively alleviates cognitive impairment, particularly in memory and attention, and may partially enhance comfort, exercise tolerance, and sleep quality[10]. However, adherence to LTOT remains suboptimal due to insufficient awareness of its benefits[11]. Health education interventions are essential for enhancing patient knowledge and improving COPD management[12]. Nurse-led educational interventions have been shown to provide personalized information, engage patients in decision-making, and improve treatment adherence and health outcomes. These interventions are also costeffective[7]. However, existing research typically focuses on a single condition (COPD or MCI) and neglects the interactions between co-morbidities. Additionally, many studies rely on "one-way" educational methods, such as brochure distribution, which are not grounded in behavioral change theories and fail to address cognitive-behavioral factors influencing LTOT adherence in MCI patients[8]. Consequently, the impact of these interventions is often short-lived[9]. Furthermore, contemporary educational interventions, grounded in traditional theoretical frameworks (e.g., health beliefs theory, knowledge-attitude-behavior theory), improve health behaviors and literacy but often overlook participants' physical and mental capabilities, including their ability to monitor health effectively[10].[11]

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[7] Michael Doherty,Wendy Jenkins,Hugh H. Richardson,Aliya Sarmanova,Abhishek Abhishek,Deborah Ashton,Christine Barclay,Sally Doherty,Lelia Duley,Rachael Hatton,Frances Rees,M Stevenson, & Weiya Zhang (2018). Efficacy and cost-effectiveness of nurse-led care involving education and engagement of patients and a treatto-target urate-lowering strategy versus usual care for gout: a randomised controlled trial. The Lancet, 392 (10156), 1403-1412.

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Michie et al. argue that successful behavior change requires both physical and

disease: effects ofexacerbation and long-term oxygen therapy [J]. Clin Respir J,2020,14(12):1137-1143. [10] Mermit Çilingir B, Günbatar H, Çilingir V. Cognitive dysfunctionamong patients in chronic obstructive pulmonary disease: effects ofexacerbation and long-term oxygen therapy [J]. Clin Respir J,2020,14(12):1137-1143. [11] Gauthier A, Bernard S, Bernard E, Simard S, Maltais F, Lacasse Y. Adherence to long-term oxygen therapy in patients with chronic obstructive pulmonary disease. Chron Respir Dis. 2019 Jan-Dec;16:1479972318767724. [12] Vincent S. Fan,Dennis E. Niewoehner, & Robert A. Lew (2012). A Comprehensive Care Management Program to Prevent Chronic Obstructive Pulmonary Disease Hospitalizations. Annals of Internal Medicine, 157 (7), 530-530.

mental capabilities, alongside the ability to perform the desired behavior. To address this, they developed the Behaviour Change Wheel (BCW) theory, based on the COMB model (Competence-Opportunity-Motivation)[12]. This model identifies competence, opportunity, and motivation as the primary drivers of behavior and provides a comprehensive framework for analyzing internal and external factors influencing behavior change. The BCW theory designs interventions aimed at fostering the emergence and modification of healthy behaviors. In a study by Chen et al., BCW theory was used to improve dietary adherence among patients with metabolic syndrome[13]. Similarly, Cavalieri et al. applied BCW theory to reduce sedentary behavior in COPD patients, achieving positive outcomes[14]. These studies further support the cross-disease applicability of the BCW theory, particularly for elderly COPD patients with comorbid MCI.

This study developed a nurse-led, BCW theory-based educational intervention to evaluate its impact on LTOT implementation. The intervention targeted adherence, equipment hygiene, safe oxygen use, and self-monitoring, while assessing health beliefs and multidimensional outcomes (cognitive function, ventilatory parameters, and activities of daily living) in elderly COPD-MCI patients.

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[14] Crayton, E., Fahey, M., Ashworth, M., Besser, S. J., Weinman, J., & Wright, A. J. (2017). Psychological Determinants of Medication Adherence in Stroke Survivors: a Systematic Review of Observational Studies. Annals of behavioral medicine : a publication of the Society of Behavioral Medicine, 51(6), 833–845.

2. Research Objectives

1. To investigate the problems and self - care needs of elderly COPD patients with MCI in using home oxygen concentrators.
2. To apply the BCW theory model to construct a health education model and explore its application effect in improving the self - management ability and compliance of elderly patients with MCI and COPD during long - term oxygen therapy with home oxygen concentrators.

3. Research Method

3.1 Object of Study

1. **Source of the study subjects and the sampling methods**: The study subjects will be selected from the respiratory department of a tertiary hospital in Xiamen,

   Fujian Province, and a community health service center in Tong'an District, Xiamen. The sampling method is convenience sampling.
2. **Inclusion criteria for the study subjects**: ○ Diagnosed as COPD by a physician. ○ $SpO_2 < 88\%$ or $PaO_2 < 60mmHg$.

   ○ Diagnosed with MCI. ○ Have a home oxygen concentrator.

   ○ No communication barriers.
3. **Exclusion criteria for the study subject**:

   ○ Complicated with asthma or lung cancer.

   ○ Long - term home oxygen therapy time ≥ 15h/d.

   ○ Participated in similar interventions.
4. **Samplesize estimation**: The sample size is calculated using the formula for comparing two - sample rates. Referring to the literature, the oxygen therapy compliance rate is 20%, and it is expected to increase by 40% after intervention. With a significance level of 0.05 and a Type II error probability of 0.1, 32 cases are required for each of the intervention group and the control group. Considering a 20% dropout rate, the final sample size is determined to be 39 cases per group, with a total of 78 cases.

3.2 Research Tool

（1） The execution of LTHOT was assessed using a self-designed Long-Term Home Oxygen Therapy Behavior Survey. Given that improper operational skills can affect the effectiveness of long-term home oxygen therapy, the survey primarily includes four dimensions: adherence to home oxygen therapy, cleaning and disinfection, safe oxygen use, and self-monitoring, with a total of 13 items. Each item has two response options: "Yes" and "No," where "Yes" indicates the behavior was performed, and "No" indicates it was not. A score of 1 is awarded for "Yes," and 0 for "No." The higher the total score, the better the patient's long-term home oxygen therapy behavior. The average daily oxygen use time was self-reported by the patient.

（2） LTHOT Health Belief was assessed using the Long-Term Home Oxygen Therapy Health Belief Questionnaire designed by Yan, J [15]. The questionnaire consists of four dimensions and 26 items. Scores are based on the individual's understanding of their ability to engage in long-term home oxygen therapy behaviors. The total score ranges from 0 to 104, with higher scores indicating a higher level of perceived ability to perform long-term home oxygen therapy health behaviors.

（3） Activity of Daily Living (ADL): Daily living ability was assessed using the Activity of Daily Living scale[16], with a total score range of 14-56 points. A higher score indicates poorer functional ability. A total score greater than 16 points indicates varying degrees of functional impairment, while a score of 22 points or higher indicates significant functional impairment. If the score for any single item exceeds 3 points, or if two or more items score over 3 points, this suggests significant functional impairment.

（4） Ventilation Function Indicators: These include blood oxygen saturation (SpO2), arterial carbon dioxide partial pressure (PaCO2), arterial oxygen partial

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pressure (PaO2), pH, lung function (FEV1%), dyspnea score, and 6-minute walk distance (6MWD).

（5） Overall cognitive function The Montreal Cognitive Assessment (MoCA) is used to measure overall cognitive function[17], with a maximum score of 30. The cutoff scores for normal cognitive function are >13 for illiterate individuals, >19 for those with primary education, and >24 for individuals with middle school education or higher.

3.3 Data Processing and Statistical Analysis

1. After the data collection is completed, SPSS 20.0 software is used for statistical analysis.
2. The description of general demographic data and clinical data: Count data are described by frequency and percentage; measurement data are described by median.
3. Comparison of general demographic data and clinical data between the two groups of research subjects: Rank - sum test and X^2 test are used.
4. Comparison of the total scores of long - term home oxygen therapy beliefs at each time point between the two groups of research subjects: Repeated - measures analysis of variance is used.
5. Comparison of the scores of each dimension of long - term home oxygen therapy beliefs, long - term home oxygen therapy behavior scores, and average daily oxygen inhalation time at each time point between the two groups of research subjects: Generalized linear mixed - effect model is used for analysis.
6. Comparison between groups of the total scores and scores of each dimension of long - term home oxygen therapy beliefs, long - term home oxygen therapy behavior scores, and average daily oxygen inhalation time at different time points of the two groups of research subjects: If it conforms to the normal

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distribution, an independent - sample t - test is used; if it does not conform to the normal distribution, a two - independent - sample rank - sum test is used.

7. Comparison within groups of the total scores and scores of each dimension of long - term home oxygen therapy beliefs, long - term home oxygen therapy behavior scores, and average daily oxygen inhalation time at different time points of the two groups of research subjects: If it conforms to the normal distribution, a paired t - test is used; if it does not conform to the normal distribution, a paired rank - sum test is used.
8. Comparison of the differences in the scores of the Montreal Cognitive Assessment Scale, Mini - Mental State Examination, Geriatric Depression Scale, and Self - rating Anxiety Scale between the intervention group and the control group: An independent - sample t - test is used.

3.4 The Project Involves the Implementation Plan of the Ethical Par

1. **Voluntary Principle**: Ensure informed consent. Before participating in the study, patients are informed of the purpose, content, and procedures of the study. Patients can freely withdraw from the study during the process, and their relevant rights will not be damaged.
2. **Confidentiality Principle**: Seek the opinions of patients on the confidentiality of the research content according to the research questions. Adhere to the confidentiality principle for issues involving participants' privacy and personal safety.
3. **Beneficence and Non - maleficence Principle**: This study has no potential harm to the physical and mental health of patients. On the contrary, the intervention may be beneficial to the implementation of long - term home oxygen therapy and treatment outcomes of patients.

4. **Justice Principle**: Treat all research subjects equally. Whether in the control group or the intervention group, strictly follow the research design plan to conduct the research rigorously and fairly.