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Health-Related Quality of Life in Patients with Chronic Respiratory Failure: A Mixed Methods Research Protocol

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Abstract

Background: The research was carried out to examine the effect of a parenting preparation course given to midwifery students during an academic semester on the preferred mode of delivery, fear of childbirth, and traumatic birth perception.

Methods: This was a quasi-experimental study with a pretest-posttest design that included 47 second-year students enrolled in the parenting preparation course. Students took the parenthood preparation course, 2 hours a week, for 14 weeks. Data were collected using a descriptive information form, the pre-pregnancy fear of birth scale, and the perception of traumatic birth scale. Paired t-test and chi-square test were used to evaluate intragroup and intergroup differences. The data were analyzed using SPSS 22.0 software at a statistical significance of 0.05.

Results: The mean age of the students was 20.13±0.67 years. The mean score of pre-pregnancy fear of childbirth was 40.46±9.37 in the pretest and 23.61±6.79 in the posttest. In addition, the mean score of traumatic childbirth perception decreased from 77.34±25.15 in the pretest to 39.44±13.78 in the posttest. The number of students who preferred cesarean section decreased significantly, while the number of students who preferred vaginal delivery increased after the preparation course.

Conclusion: Parenting preparation classes can contribute to the reduction of fear of childbirth and the perception of traumatic childbirth in women.

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Highlights:

What is current knowledge?

Surveys in some regions of Iran and other countries indicate that the patient safety culture is currently low and moderate, and efforts should be made to promote it. Patient safety culture training programs are useful for improving patient safety quality.

What is new here?

Collaborative learning is a non-traditional and innovative method that enhances mental processes by strengthening human characteristics. One of the strategies that has been most reinforced or that has accompanied the approaches to collaborative learning is what is known as mobile learning.

Introduction

In the 21st century, the increase in the number of people suffering from chronic diseases such as cardiovascular diseases, respiratory diseases, cancer, and diabetes has been considered a global health problem (1). Chronic respiratory failure (CRF) has been declared a health priority by the World Health Organization (WHO) (2). Although the exact statistics of CRF are not known in Iran, 9.8% of all deaths in 2019 were related to CRF (3). With the increase in the global population, the quality of life of those suffering from chronic diseases, especially chronic respiratory diseases, will also change dramatically (3). In fact, these patients might face difficulty in their social and personal life as well as physical performance and daily activities (4). These individuals are also more vulnerable to depression, anxiety, fear, dependence on others, and isolation, which causes an overall decrease in health-related quality of life (HRQOL) (5). This concept is an important clinical issue that could affect disease progression or outcomes (6). According to the WHO, the concept of HRQOL refers to a person's perception of individual expectations and standards within the framework of the society in which they live (7). It is a subset of quality of life and includes mental, emotional, social, and physical well-being that reflects the mental state of patients and their response to the disease (8). This concept is a composite structure that measures the objective conditions of people's lives by evaluating their mentalities (9); therefore, the evaluation of HRQOL should be done by combining both quantitative and qualitative aspects simultaneously. This study aimed to determine the HRQOL in patients with CRF.

Methods

designed by Professor Windisch in 2003 in German (10) and comprised 49 items and 7 subscales including respiratory complaint (8 statements), physical function (6 statements), social relations (7 statements), anxiety (5 statements), accompanying symptoms and sleep (7 statements), social function (8 statements) and mental well-being (9 statements) that are scored based on a 5-point Likert scale, ranging from completely false (-2 points) to always true (2 points). First, permission was obtained from the designer of the instrument for translation, and then the translation was done based on the model described by Wild et al (2005) (11). The questionnaire was translated from German to Persian by two bilingual translators and later checked by the research team for clarity of meaning and differences. This version was translated into German by a third translator, and the original and translated versions were reviewed by the designer. After incorporating the opinions of the original designer, the translated version was subjected to psychometric analysis.

Face validity

Face validity is done in two qualitative and quantitative ways. For qualitative face validity, the target group is asked to express their opinions about the level of difficulty, appropriateness, and ambiguity of the statements through face-to-face interviews (12). For quantitative face validity, the translated version of HRQOL-SRI is provided to a target group (6 women and 6 men) with chronic obstructive pulmonary disease, neuromuscular diseases, stable asthma, and pulmonary fibrosis. The statements are scored in terms of importance based on a 5-point Likert scale, ranging from very important (5 points) to not at all important (1 point). Quantitative face validity is done by measuring the impact score of each phrase (impact score = frequency (%) × importance); an impact score greater than 1.5 is considered acceptable (13).

Content validity

Content validity is also done in two qualitative and quantitative ways. For qualitative content validity, 15 people from a panel of professional experts and neuro-respiratory disease specialists, nursing lecturers, and researchers are asked to give their corrective views on the language and choice of words. Content

validity can lead to changes in the Likert scale and the deletion of a statement (14). Quantitative content validity is first done using the content validity ratio (CVR) and content validity index (CVI) (15). To determine the CVR, the same panel of experts is asked to express their opinions on the necessity of the HRQOL-SRI items. The minimum acceptable value for CVR in the Lawshe table is 0.49 (16). In general, CVI is essential for the assessment of quantitative content validity in instrument development (14). It can be calculated using item-CVI and scale level-CVI. The experts are asked to evaluate the relevance of each statement. A CVI score higher than 0.79 is considered appropriate (17). A scale level-CVI value greater than 0.9 indicates excellent content validity (18).

Convergent validity

To check the convergent validity between the statements of the instrument and related areas, AVE and CR indices are used.

Construct validity

In order to check the construct validity and confirm the factorial structure of the questionnaire, first, exploratory factor analysis (EFA) is performed to extract the model and existing factors, and then, confirmatory factor analysis is used with AMOS-24 software to check the conformity of the model. The goodness of fit indices such as $\chi 2$, df/$\chi 2$, comparative fit index, root mean square error of approximation, normed fit index, and adjusted goodness of fit will indicate the model's validity. To determine the sample size in construct validity, the rule of thumb of 5 or 10 samples per statement will be used (22).

In this study, according to the prevalence of patients with CRF, 10 samples (490 people) will be obtained for each statement. Based on the inclusion criteria, the samples are collected from patients with chronic obstructive pulmonary disease, neuromuscular diseases with respiratory disorders, stable asthma, and pulmonary fibrosis. The required number of samples in each hospital ward will be based on the bed occupancy rate and the number of hospitalized patients.

In EFA, the Kaiser-Meyer-Olkin (KMO) test and Bartlett's sphericity test are used to confirm sampling adequacy (23). A KMO of more than 0.7 and the Bartlett's sphericity test with a P-value of <0.05 are acceptable (23,24).

Reliability and internal consistency

Cronbach's alpha coefficient and McDonald's omega coefficient are used to determine the internal consistency-reliability of the HRQOL-SRI instrument. Values above 0.7 indicate acceptable similarity and values close to 1 indicate similarity and greater capability of the tool. Stability reliability will also be evaluated through test and retest as well as the intra-class correlation coefficient. The stability reliability coefficient of 0.8 or more indicates satisfactory stability (26).

Data analysis

After the psychometric analysis of the HRQOL-SRI instrument, this questionnaire is used for patients with CRF. The data will be analyzed using descriptive statistics (mean and standard deviation) as well as absolute and relative frequencies.

Qualitative phase

The qualitative phase is a type of contract content analysis, which explains the perception of CRF patients about HRQOL. In this phase, the participants are CRF patients with maximum diversity in terms of age, sex, type of respiratory failure, history of illness, and history of hospitalization. The subjects are enrolled via purposeful sampling. Qualitative data are obtained using in-depth, semi-structured interviews, starting with open and general questions, followed by key questions such as "Tell me about a day's experience with shortness of breath", or "When I say shortness of breath, what comes to your mind?". Exploratory questions such as: "What does this mean?" "What do you mean?" "Please explain more?", "Can you share an experience or event so that I can better understand what you mean?", will be used to clarify the topic and obtain more information. Data management will be done via the MAXQDA10 software. The data will be analyzed with the method of Graneheim & Lundman (2004) (27). Researchers will listen to the recorded files and type them line by line and word by word, and then the texts will be reviewed and reread several times to get a general impression. After the first coding process, similar primary codes will be placed together in groups to create sub-classes and then main classes will emerge by categorization and continuous comparison of sub-classes.

In this study, the criteria of Lincoln and Goba are used to verify the accuracy of data (28). In order to increase credibility or acceptability, the researcher will be present at the place of study for continuous observation of the behaviors of patients with CRF. In order to achieve reliability, weekly meetings will be held in the presence of team members, and data analysis and extraction of semantic units will be done. In this study, to improve the verifiability of the findings, all steps including data collection and analysis, coding, and classification of concepts are documented for re-examination. Moreover, transferability will be guaranteed through a deep description of the desired phenomenon and obstacles and limitations, as well as the use of targeted sampling with maximum diversity.

Quantitative and qualitative data integration

In this study, the researcher will directly integrate the quantitative and qualitative findings data, thereby facilitating data interpretation and normalization.

Discussion

The HRQOL is a multi-dimensional physical, psychological, and social concept that is used in the evaluation of health or disease status as well as the treatment process of people and the well-being of patients (29,30). Patients with CRF suffer from a progressive and chronic condition, which lowers their quality of life, particularly following the exacerbation of respiratory symptoms (31). Gephin et al. (2021) considered activity intolerance, excessive fatigue, anxiety, and depression to be the most influential factors in HRQOL of patients with CRF (32).

In a previous study, the physical dimension of the disease was associated with symptoms such as shortness of breath, cough, and sputum (33). In a study by Masroor et al. (2012) using the general quality of life questionnaire (SF36), the lowest score was obtained in the dimension of role limitation due to physical reasons and physical functioning (8). Considering the widespread effects of respiratory failure, the evaluation of HRQOL helps to understand the effects of the disease on the body, mind, and daily and social activities of the patients (34). In other words, by simultaneously evaluating the objective and subjective dimensions of HRQOL, a more comprehensive view of the problems of these patients can be obtained (35). In addition, using an integrated approach and quantitative and qualitative data for HRQOL evaluation will improve clinical decision-making, the quality of medical and nursing care, predicting healthcare needs, and health policy choices (6, 36).

The present protocol described the integrated approach comprising quantitative and qualitative data integration for the evaluation of HRQOL in patients with CRF. One of the strengths of this study is the simultaneous collection of quantitative and qualitative data with large sample size. However, a possible prolonged sampling process and not using the spirometry test as a standard and objective indicator of respiratory problems due to the coronavirus disease 2019 pandemic are some limitations of the present study.

Conclusion

Mixed methods research is an applied and strong approach that provides researchers the opportunity to combine quantitative and qualitative data to achieve a sufficient understanding of problems. Using this integrated approach may be an effective method to achieve a better and deeper understanding of HRQOL in patients with CRF.

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Ethical statement

The present consolidated study protocol was approved by the Ethics Committee of Golestan University of Medical Sciences (ethical approval code: IR.GOUMS.REC.1399.097). Written informed consent will be obtained from all subjects before participation in the study.

Conflict of interest

The authors declare that there is no conflict of interest regarding the publication of this research.

Author contributions

All authors contributed to the design of the protocol. EHY, ShK, and LTY contributed to the implementation and analysis plan. EHY and ShK wrote the manuscript draft, and all authors read and approved the final manuscript.

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