

Health-related Quality of Life in Patients With Chronic Respiratory Failure; A Protocol for Mixed Methods Study

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Study protocol

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Abstract

Background: One of the major challenges of the present century is chronic respiratory failure with a complex, chronic, disabling, and progressive nature, which can gradually affect patient health-related quality of life and their individual and social activities. Therefore, studying its concept will help in recognizing changes in the disease process and predict the status of the disease. This study was prepared to determine health-related quality of life of patients with chronic respiratory failure using a mixed-method approach.

Methods and Analysis: The mixed-method approach, with a convergent parallel design, will be used to conduct the research in which the quantitative and qualitative study is performed simultaneously and with the same weight. In the quantitative study section, a cultural and psychometric adaptation of the Severe Respiratory Insufficiency Questionnaire is first translated for patients with severe respiratory failure and then the health-related quality of life dimensions of patients with chronic respiratory failure will be measured using a questionnaire pertaining to the culture of Iranian society in a descriptive-analytical study. Simultaneously with the quantitative study, the researcher will use a qualitative study to explain the perception of patients with chronic respiratory failure and health-related quality of life. Finally, the results of a quantitative study obtained from the analysis of descriptive statistics data (mean and standard deviation) and inferential statistics (analysis of variance, t-test, and regression) are integrated by SPSS software version 18. The results of a qualitative study are the results of conventional content analysis, by comparison and confrontation during interpretation.

Discussion & Conclusion: Due to the complexity of the research and for gaining in-depth understanding into the health-related quality of life of patients with chronic respiratory failure, this article will be based on a combination of quantitative and qualitative data. In this research, quantitative and qualitative methods overlap and add to the richness of the data so that the results, beyond the numbers and figures of a quantitative study, will be congruent with an explanation of the concept in a qualitative study and will be discussed and interpreted.

Background

One of the challenges of 21st-century health systems is the increase in the number of people suffering from chronic diseases such as cardiovascular disease, cancer, diabetes, and chronic respiratory diseases (CRF) (1). As one of the World Health Organization (WHO) priorities, CRF affects one billion people worldwide (2) and is the third leading cause of death in the world (more than 9.5 million deaths per year) (3, 4). Although CRF statistics in Iran are not accurate, in 2019 the mortality rate due to this disease was equal to 9.8% of the total mortality in this year (5, 6).

The WHO has estimated an increase in the trend of an elderly Iranian population by 2050, which means more exposure to CRF and the endurance of more socio-economic pressures on the society (7). Due to the chronic and progressive nature of CRF and the exacerbation of respiratory symptoms, patients with this

disease have impaired social and individual life, physical function, and daily activities (8, 9). They also experience a variety of psychological problems such as depression, anxiety, fear, dependence on others, and isolation that ultimately leads to a decrease in quality of life, especially in health-related quality of life (HRQOL) patients (10, 11).

The WHO has defined 'health-related quality of life' as a subset of the overall quality of life that includes feelings of mental, emotional, social, and physical well-being and reflects on patient mental evaluation and response to disease. (12) HRQOL has been an important topic of clinical research and researchers in this field have evaluated the various aspects by examining its various dimensions and characteristics (9). They know that by using this concept and using HRQOL measurement tools, by responding to and predicting these tools, and having differentiating properties we can help give more care and treatment of chronically ill patients and meet their needs (12). In other words, physicians and nurses can measure and evaluate HRQOL with such factors as 1) Differentiation of quality of life levels of different people from each other, 2) Measuring changes in the HRQOL process after receiving therapeutic care interventions and monitoring the severity and progression of the disease, and 3) Predict future outcomes such as mortality (13). In this study, a mixed-method approach has been used to evaluate HRQOL in patients with CRF and is considered a complex construct. This method also considers the objective conditions of the lives of people by assessing their mentalities. It seeks to provide a more comprehensive view of HRQOL by combining both quantitative and qualitative approaches (14). The researcher has valuable data from patients using a qualitative approach and inquiry by in-depth exploratory questions. A valid and reliable questionnaire will be used in the quantitative study to assess patient condition, and evaluate treatment-care programs and interventions. In the integration stage, which is the final stage, the different results of the quantitative and qualitative study will be merged by comparison and confrontation during interpretation.

The following objectives will be considered below:

Quantitative study

1. Translation, cross-cultural adaptation, and evaluation of psychometric properties of the questionnaire
 - Translation and cultural adaptation of Severe Respiratory Insufficiency (SRI) questionnaire
 - Face validity assessment (quantitative and qualitative) of SRI questionnaire
 - Content validity assessment (quantitative and qualitative) of SRI questionnaire
 - Criterion validity assessment of SRI questionnaire
 - Construct validity assessment of SRI questionnaire (using exploratory factor)
 - Reliability assessment (internal consistency and stability reliability) of SRI questionnaire
2. Determination of HRQOL in CRF patients using SRI questionnaire by descriptive-analytical study
 - Determination of mean HRQOL score on the Respiratory Complaint subscale

- Determination of mean HRQOL score on the Physical Function subscale
- Determination of mean HRQOL score on the Social Relations subscale
- Determination of mean HRQOL score on the Anxiety and Worry subscale
- Determination of mean HRQOL score on the subscale of Sleep Disorder and Associated Symptoms
- Determination of mean HRQOL score on the Social Performance subscale
- Determination of mean HRQOL score on the Mental Health subscale
- Determination of mean HRQOL score on the Isolation and Dependency subscale

Qualitative Study

Explaining HRQOL patient perceptions of CRF using conventional content analysis approach

Combining quantitative and qualitative study results

Combining different results from the quantitative and qualitative study will be performed by comparison and confrontation during interpretation

Method/ Design

Study design

The mixed-method approach, with a convergent parallel design, will be used to conduct this research in which quantitative and qualitative study will be performed simultaneously and with the same weight. In the quantitative study section, a cultural and psychometric adaptation of the SRI questionnaire will be first translated for patients with severe respiratory failure and then the dimensions of the HRQOL of patients with CRF will be measured using a questionnaire related to the culture of Iranian society in a descriptive-analytical study. Parallel with the quantitative study, the researcher will use a qualitative study to explain the perception of patients with CRF of HRQOL. Both quantitative and qualitative data will be of equal value. Data analysis will be performed separately and the results will be combined in the data interpretation stage (15)(Fig. 1)

Quantitative Study

1) Translation, cross-cultural adaptation, and evaluation of psychometric properties of SRI questionnaire

In 2003, the Severe Respiratory Insufficiency Questionnaire was presented by Windisch in the German language (16). This questionnaire has been translated into different languages and has been used by different researchers to evaluate HRQOL in patients with CRF (13). In total, this questionnaire has 49 items and seven subscales including respiratory complaints (8 items), physical function (6 items), social relationships (7 items), anxiety and worry (5 items), accompanying and sleep symptoms (7 items), social functioning (8 items) and mental health (9 items). In this questionnaire, each item uses the Likert scale as

follows: Completely false (-2), Most of the time false (-1), Sometimes true (0), Most of the time false (+1), and Always true (+2).

Translation and cross-cultural adaptation

The first step in translating foreign questionnaires is the cultural adaptation of the meanings of the sentences (15). Usually, the translation and psychometric stages will begin after correspondence with the questionnaire designer and obtaining written permission. In this study, the Wilde et al. (2005) model will be used for making the translation. The questionnaires will be first translated from German to Farsi by two bilingual translators. Then a research team, or one of the translators, will examine the translations in terms of semantic clarity and correct the differences and contradictions between them. Eventually, the original translations will be merged and the final translation of the questionnaire will be approved. The final translation will be re-translated into the original language (German) by another translator (who is not involved in the translation process at the previous stage). The corresponding Farsi translations will be compared in the review and synchronization stages. In the continuation of this stage, the designer of the questionnaire will examine the original version and its translation and approve it in terms of conceptual and linguistic comprehension. A translated version of the HRQOL questionnaire will be used to perform the psychometric steps.

Evaluation of psychometric properties

Face validity

For qualitative face validity of translated version of SRI questionnaire, the lead researcher will perform face-to-face interviews of 12 patients (6 females and 6 males) of CRF patients (chronic obstructive pulmonary disease patients with neuromuscular disease and chronic respiratory failure, persistent asthma, and pulmonary fibrosis). These individuals will be asked to read the items formulated for the questionnaire and to express their understanding of the items. The level of difficulty, appropriateness, ambiguity of the items, and the need to delete or merge items in the questionnaire will be evaluated then the items will be edited according to the recommendations of this group.

Quantitative face validity will be achieved by measuring the impact score of the item (Impact score = Frequency (%) × Importance). At this stage, the selected target group will be asked to evaluate the items in terms of the importance of each item and according to their importance. The choices on the 5-point Likert scale will be as follows: Very important (5 points), to a significant extent (4 points), relatively important (3 points), slightly important (2 points), and not important at all (1 point) giving each item a score. The item will be deemed appropriate for subsequent analysis if the impact score exceeded 1.5, and will then be retained. (17)

Content validity

To evaluate the qualitative content validity of translated version of SRI questionnaire, 10 professional experts and related experts will include the following: Specialist in respiratory diseases, neurologists,

nursing teachers, and researchers in the field of internal medicine and respiration. They will be asked to submit their corrective views on the observance of language rules, the use of appropriate words, the placement of items in their proper place, and appropriate scoring. The scales of response to the item and the need to change or delete a item could also be asked (18).

Content validity ratio (CVR) and content validity index (CVI) will be used quantitatively to assess content validity (19).

To determine the CVR, 10 experts will be asked to comment on the necessity of each item in a 3-point Likert scale 3) is necessary, 2) is useful but not necessary, and 1) is not necessary.

The response of the experts will be quantified and the content validity ratio (CVR) will be determined and calculated based on the following formula (20):

NE = Number of specialists who selected the necessary option

N = Total number of assessor specialists

The numerical value of the content validity ratio will be determined with the help of the "determining the minimum value" table compiled by Lawshe (21).

With the existence of 10 experts, any items with a CVR greater than 0.62 will be acceptable.

In the development of the questionnaire, CVI will be the most widely reported indicator for the validity of quantitative content (18).

CVI could be calculated using Item-CVI (I-CVI) and Scale Level-CVI (S-CVI). Experts will be asked to rate the relevance of each expression on a four-point Likert scale from 1 to 4 (not relevant, somewhat relevant, quite relevant, and very relevant).

I-CVI will be calculated by summing the percentage of points for each item that scored 3 and 4 (highest score).

A CVI score above 0.79 will be considered appropriate (22). The mean of I-CVIs for all items on the scale will be evaluated by S-CVI by the mean scores of the Content Validity Index. The S-CVI values which are greater than 0.9 will have excellent content validity (23).

Criterion validity

A simultaneous criterion method will be used to realize the validity of the criterion. The criterion tool to be used in this research will be the short form of the questionnaire (SF36). The 36-item short-form was designed by War and Sherbon in the United States in 1992 to measure the health-related quality of life of healthy and sick people. (24) It is currently the most widely used tool for measuring health-related quality

of life in the world (25). The 36-item short-form was translated into Farsi by Montazeri et al. in Iran in 2005 and its validity and reliability were examined. (9)

Construct validity

To evaluate and confirm the factor structure of translated version of SRI questionnaire, first, exploratory factor analysis will be extracted from the existing model and factors, and then from the method of confirmatory factor analysis using the Amos program to answer the question: Does the existing model correspond to the Iranian research community or not? Confirmatory factor analysis and goodness indicators such as χ^2 , df / χ^2 , GFI, and CFI will be used.

Population and sample size in construct validity

According to the SRI questionnaire, which has 49 items and the breadth of the CRF condition, 10 samples (490 people) will be collected for each item in the internal medicine, general, specialized lung, and neurology departments. Samples for exploratory and confirmatory analysis are divided into two parts (245 samples for exploratory analysis and 245 samples for confirmatory analysis). Sampling in construct validity, in a stratified manner with appropriate allocation according to the inclusion criteria among patients with CRF, will include patients with COPD, persistent asthma, neuromuscular disorders, and pulmonary fibrosis hospitalized in hospitals affiliated to Golestan University of Medical Sciences, Gorgan, Iran.

Statistical data analysis in construct validity

The Kaiser-Meyer-Olkin (KMO) and Bartlett Sphericity tests will be used to confirm the adequacy of sampling in EFA. KMO over 0.7 will be interpreted as an acceptable and large sample suitable for EFA (19, 26). The Bartlett Sphericity test should show significant results ($P < 0.05$). To determine the best structure, the eigenvalue greater than 1 will be applied with a factor load equal to or greater than 0.4 (27). Cronbach's alpha model, Pearson correlation analysis, in-class correlation coefficient, exploratory factor analysis, and standard error measurement will also be used in statistical analysis (26).

Reliability

Internal consistency

Cronbach's alpha coefficient will be applied to determine the internal correlation in each of the subscales and the entire questionnaire. Cronbach's alpha represents the degree of appropriateness of a group of expressions that measure a structure. Values above 0.7 will indicate acceptable consistency and values close to 1 will indicate similarity and greater questionnaire capability (28).

Stability (or retest)

Thirty CRF patients will have to complete the SRI questionnaire two weeks prior. In this study, the calculation of the intraclass correlation coefficient (ICC) will be used to evaluate the reliability of the

questionnaire in the reproducibility dimension where the reliability coefficient (reliability) of 0.8 or more will indicate satisfactory stability (28).

2) Determining the amount of HRQOL in patients with CRF by descriptive-analytical study using thepersian version of SRI questionnaire

In this section, measurable, harmful, and contributing factors to HRQOL of patients with CRF will be identified, and evidence and the relationship between a large number of factors and HRQOL of these patients will be presented. A persian version of SRI questionnaire (P-SRI) will be used to measure HRQOL of patients with CRF in the form of a methodological, cross-sectional study. In this way, by a stratified sampling method with appropriate allocation in the research community and estimating the sample size, a persian version of SRI questionnaire will be provided to patients. After data collection, data analysis will be performed with descriptive statistics (mean and standard deviation) and inferential statistics (analysis of variance, t-test, and regression) using SPSS software version 18.

Population and research environment: The study population in this study will include patients with CRF; including those patients with Chronic obstructive pulmonary disease (COPD), persistent asthma, neuromuscular disorders, and pulmonary fibrosis hospitalized in hospitals affiliated to Golestan University of Medical Sciences.

Research sample: The samples in a quantitative stage will include a select group of patients in the research community who will be in the study according to the inclusion criteria and sample size.

Quantitative sample size: A total of 171 samples will be estimated based on the study of Fadaeeaghdam et al. in 2015 (12) and considering the mean and standard deviation of HRQOL in terms of total score, physical dimension, and psychological dimension (23.5 ± 23.5). Cochran's formula will be used with a 0.95 confidence and a maximum error of 0.15 maximum standard deviation score according to the following formula:

$$n = \frac{z_{\frac{\alpha}{2}}^2 \sigma^2}{d^2}$$

Inclusion criteria: Participants will have to be at least 18 years old, patients with a history of recurrent hospitalization due to shortness of breath, or patients on long-term oxygen therapy or non-invasive ventilation (patients with a history of at least 6 months or more reliance).

Exclusion criteria: Patients who self-report acute psychiatric disorder or case reports on file of patients with acute and unstable respiratory conditions will be the exclusions.

Qualitative Study

To explain the HRQOL of patients with CRF based on the narratives that these people give about their life experiences about the disease, at this stage a qualitative exploratory study will be performed with the approach of conventional content analysis.

Qualitative study participants

In this study, the participants will be selected purposefully by considering the maximum variation of participants in terms of age, sex, level of education, history of infection, number of hospitalizations, and location, and will be selected from among a few samples. This process will continue until the completion of the classes and the result of new data or duplication of previous data.

Data collection: Qualitative data will begin with semi-structured in-depth interviews with open-ended and general questions and then will continue with key questions such as, "Can you tell me about the experience of a day with shortness of breath?" or "And when I say shortness of breath, what comes to your mind?" Exploration questions will be used to clarify the subject and gain rich information such as, "What does this mean?" "What do you mean?" "Can you please explain more?" and "Can you describe an experience or event so I can better understand what you mean?" In case of accidental and unplanned observation of events and events related to the subject of study, they will be recorded in the field as notes.

Data Analysis: Implementation information categorized and ranked at this stage after each interview. MAXQDA10 software will be used for data management. A constant comparison method will be used in the course of the research. To reduce the primary categories, after comparing them if possible, they will be merged and the similar categories will be placed around a common category. Qualitative data will be analyzed using conventional content analysis based on the Granheim-Landmann method (29). In this method, data is analyzed through repeated reading of the text to gain a full understanding of it. The texts are then read word-for-word to extract the code. First, the objective words that contain the main concepts are identified then the main codes are extracted. The classification of similar primary codes is more comprehensive and the codes are classified in the main themes and categories. Finally, sub- categories and main categories are extracted based on differences and similarities.

Scientific accuracy and strength of the Study

After commencement of the study, the researcher will be present at the study site for ascertaining the accuracy of the data and observations, and will evaluate patient behaviors during this period. To confirm the accuracy of the extracted codes and interpretations, after a few initial interviews and extracting the basic codes and concepts, this study will be prepared in the form of a typed text of the interview and the resulting codes will be provided to several participants.

In the present study, to achieve reliability, the texts were first reviewed in a limited way so as not to cause the researcher to be biased during data collection and analysis. The weekly session will be held with the presence of team members and the process of data analysis and extraction of semantic units will be evaluated.

Combination and interpretation of the quantitative and qualitative data

In this study, the researcher will directly compare and contrast the HRQOL statistical results (descriptive and inferential statistical results) of patients with CRF, with qualitative findings (specific information or quotes) from the interview by linking the data obtained from the two sets and bringing them together (side-by-side comparison), or it will expand and validate quantitative results with qualitative data. The integration of two quantitative and qualitative data sets took place in the interpretation of the results stage (discussion and conclusion).

Discussion

Health-related Quality of Life is a nursing-related concept in patients with CRF and nurses are always working to improve it. CRF affects all aspects of the life of a patient, such as physical, mental, and social conditions, and nurses should obtain comprehensive information using mixed-method approaches to HRQOL of patients with CRF. In fact, HRQOL measurement, especially based on the co-produced mixed-method approach, can measure the effect of the disease and the various associated factors that have an influence on patient health status, can describe and predict the consequences of treatment and care interventions, clinical management evaluation, clinical policy guidelines, and health resources. It can also be an indicator, or scale, to show the effect of CRF and its related factors in patients, which leads to better control of CRF (30). In addition, it is possible to provide a suitable framework and vision to provide services appropriate to various aspects of the lives of these people and to allocate the resources required to meet their needs by recognizing and measuring HRQOL in different populations.

Abbreviations

HRQOL: Health related quality of life, CRF: Chronic respiratory failure, COPD: chronic obstructive pulmonary diseases, WHO: World health organization, SRI: Severe Respiratory Insufficiency, EFA: Exploratory factor analysis, ICC: intraclass correlation coefficient, P-SRI: persian version of SRI questionnaire.

Declarations

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Authors' contributions

EHY, ZS, LTY, ShK contributed to the design of the protocol. EHY and SK contributed to the implementation and analysis plan. EHY and ShK has written the first draft of this protocol article and all

authors have critically read the text and contributed with inputs and revisions and all authors read and approved the final manuscript.

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Availability of data and materials

Not applicable.

Ethics approval and consent to participate

Written informed consent will be obtained from each participant, this protocol has been approved by the Ethics committee of Golestan University of Medical sciences, Gorgan, Iran (code number: IR.GOUMS.REC.1399.097).

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests

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Figures

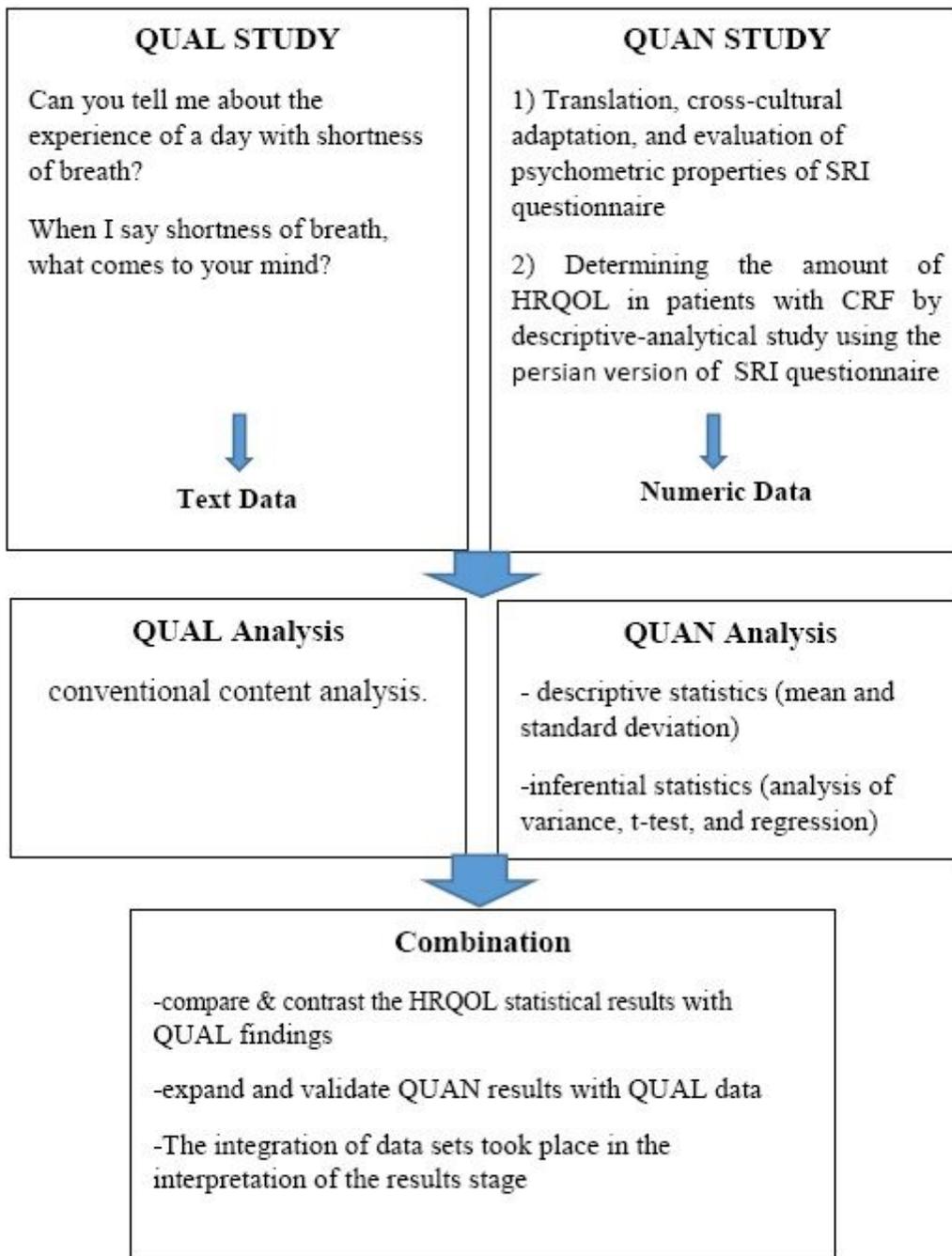


Figure 1

Study diagram