Golestan University of Medical Sciences

Journal of Research Development in Nursing and Midwifery
(J Res Dev Nurs Midw)

Online ISSN: 2588-3038

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

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Abstract

Background: Health-related quality of life (HRQOL) refers to perceived physical, mental, emotional, and social well-being. The purpose of this study is to evaluate HRQOL in patients with chronic respiratory failure (CRF).

Methods: The present mixed methods study is conducted since 2020 by simultaneous implementation of quantitative and qualitative phases. The quantitative phase is cross-sectional research to determine HRQOL in patients with CRF. In this phase, 171 patients will be selected based on the inclusion criteria from the internal medicine, respiratory, and neurology wards of hospitals affiliated with the Golestan University of Medical Sciences (Gorgan, Iran). The stratified sampling method is applied by calculating the bed occupancy rate. To collect data in this phase, the Persian version of the HRQOL questionnaire will be used for patients with CRF. In addition, the questionnaire will be translated and evaluated in terms of psychometric properties. Data obtained from the quantitative phase are analyzed by descriptive statistics using SPSS 16 software. Simultaneously with the quantitative phase, the researcher will achieve an understanding of HRQOL in the patients by using the contractual content analysis method in the qualitative phase. In this phase, the subjects will be selected via Purposeful sampling. Data are collected through semi-structured interviews and sampling will continue until reaching data saturation. Data analysis is done by the Graneheim and Lundman method. In this regard, after extracting and categorizing the codes, subclasses and classes will be formed. Finally, the findings of the quantitative and qualitative phases will be compared and integrated for discussion and interpretation of the data.

Conclusion: Evaluation of HRQOL by implementing combined qualitative and quantitative approaches can provide a complete picture of this concept in patients with CRF. Moreover, the results of such studies can help predict outcomes and the efficacy of therapeutic interventions.

ARTICLE HISTORY

Received: Mar 16 2021
Received in revised form: Sep 05 2021
Accepted: Dec 23 2022
Published online: Jan 01 2023
DOI: 10.29252/jgbfnm.19.2.55

Keywords:
quality of life
Respiratory Insufficiency
Health
mixed methods study

Article Type: Original Article

Highlights:

What is current knowledge? Considering the combined structure of quality of life related to health, objective and subjective evaluation of this concept has not been done so far in patients with CRF.

What is new here? Evaluation of HRQOL by implementing combined qualitative and quantitative approaches can provide a complete picture of this concept in patients with CRF

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

The present study has been carried out since 2020 with a mixed methods design. The study has two quantitative and qualitative phases. The quantitative phase has a cross-sectional design in which data related to HRQOL in patients with CRF are collected using the Severe Respiratory Insufficiency Questionnaire (HRQOL-SRI). The Persian version of this questionnaire in Iran was not available; therefore, the German version was validated in this study. At the same time, the qualitative phase is carried out aiming at content analysis. Analysis of the data from the two phases is done separately, and the results are combined for interpretation and discussion. The present 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.

Quantitative phase

The quantitative phase is carried out to determine the HRQOL in patients with CRF. Based on the study of Masroor et al. (2012) (8) and considering the mean and standard deviation of HRQOL, the sample size was estimated at 171 using Cochran's formula, with a confidence of 95% and a maximum error of 0.15. The stratified sampling method based on the calculation of the bed occupancy rate is employed. Based on the sampling frame, the number of CRF patients requiring hospitalization in the respiratory ward (101 patients), general internal medicine (60 patients), and neurology (10 patients) are determined.

Inclusion criteria are having the age of ⩾20 years, confirmed diagnosis at least 6 months ago, history of frequent hospitalization due to shortness of breath, history of using long-term oxygen therapy or non-invasive ventilation for treatment, and not having an acute and unstable respiratory condition.

The psychometric-validated version of the HRQOL-SRI questionnaire will be used to collect data in the quantitative phase. The translation and psychometry analysis of this questionnaire was carried out as described below.

Translation and psychometric analysis of the tool

In order to measure HRQOL, translation, and psychometry of the HRQOL-SRI are done. Psychometric analysis of the instrument consisted of translation, face validity, content validity, construct validity and reliability. This instrument was 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, average variance extracted (AVE) and composite reliability (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.

Acknowledgements

The authors wish to express their gratitude to the Vice-Chancellor for Research and Technology of Golestan University of Medical Sciences for the financial support. The study has been derived from the results of a PhD dissertation in nursing.

Funding source

The study received financial support from the Nursing Research Center of Golestan University of Medical Sciences, Iran.

Ethical statement

The present consolidated study protocol was approved by the Ethics Committee of Golestan University of Medical Sciences (ethical approval code:

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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.

References

1. Boer A, Geuskens GA, Bültmann U, Boot CR, Wind H, Koppes LL, et al. Employment status transitions in employees with and without chronic disease in the Netherlands. 2018;63(6):713-22. [View at publisher] [Google Scholar]
2. Siddharthan T, Grigsby M, Morgan B, Kalyesubula R, Wise RA, Kirenga B, et al. Prevalence of chronic respiratory disease in urban and rural Uganda. Bulletin of the World Health Organization. 2019;97(5):318. [View at publisher] [Google Scholar]
3. Pishgar E, Fanni Z, Tavakkolinia J, Mohammadi A, Kiani B, Bergquist R. Mortality rates due to respiratory tract diseases in Tehran, Iran during 2008–2018: a spatiotemporal, cross-sectional study. BMC Public Health. 2020;20(1):1-12. [View at publisher] [Google Scholar]
4. Massierer D, Alsowayan W, Lima VP, Bourbeau J, Janaudis-Ferreira T. Prognostic value of simple measures of physical function and muscle strength in COPD: a systematic review. Respiratory medicine. 2020;161:105856. [View at publisher] [Google Scholar]
5. Jang SM, Kim KU, Na HJ, Song SE, Lee SH, Lee H, et al. Depression is a major determinant of both disease-specific and generic health-related quality of life in people with severe COPD. Chronic respiratory disease. 2018;16:1479972318775422. [View at publisher] [Google Scholar]
6. Oga T, Windisch W, Handa T, Hirai T, Chin K. Health-related quality of life measurement in patients with chronic respiratory failure. Respiratory investigation. 2018;56(3):214-21. [View at publisher] [Google Scholar]
7. Karimi M, Brazier J. Health, health-related quality of life, and quality of life: what is the difference? Pharmacoeconomics. 2016;34(7):645-9. [View at publisher] [Google Scholar]
8. Masroor D, Rafii F, Fadaeeaghdam N, Hoseini F. Health-Related Quality of Life in Patients with Chronic Obstructive Pulmonary Disease. Iran Journal of Nursing. 2012;25.(76) [View at publisher] [Google Scholar]
9. Ghafari G, Karimi A, Nozari H, Iran Ri. Trend study of quality of life in Iran. Quarterly of Social Studies. 2013;1(3):107-34. [View at publisher] [Google Scholar]
.10. Valko L, Baglyas S, Kunos L, Terray-Horvath A, Lorx A, Gal J, et al. Validation of the Hungarian version of the SRI Questionnaire. BMC pulmonary medicine. 2020;20(1):1-9. [View at publisher] [Google Scholar]
11. Wild D, Grove A, Martin M, Eremenco S, McElroy S, Verjee-Lorenz A, et al. Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures: report of the ISPOR task force for translation and cultural adaptation. Value in health. 2005;8(2):94-104. [View at publisher] [Google Scholar]
12. Hajizadeh E, Asghari M. Statistical methods and analyses in health and biosciences a research methodological approach. Tehran: Jahade Daneshgahi Publications. 2011;395. [View at publisher] [Google Scholar]
13. Sharif Nia S, Sharif SP, Goudarzian AH, Haghdoost AA, Ebadi A, Soleimani MA. An evaluation of psychometric properties of the Templer's Death Anxiety Scale-Extended among a sample of Iranian chemical warfare veterans. Hayat. 2016;22(3):229-44. [View at publisher] [Google Scholar]
14. Taghizadeh Z, Ebadi A, Montazeri A, Shahvari Z, Tavousi M, Bagherzadeh R. Psychometric properties of health related measures. Part 1: Translation, development, and content and face validity. journal of the Iranian Institute for Health Sciences Research. 2017;16(3):343-57. [View at publisher] [Google Scholar]
15. Saber A, Tabatabaei SM, Akasheh G, Sehat M, Zanjani Z, Larijani B. Face and content validity of the MacArthur competence assessment tool for the treatment of Iranian patients. International journal of preventive medicine. 2017;8. [View at publisher] [Google Scholar]
16. Baghestani AR, Ahmadi F, Tanha A, Meshkat M. Bayesian critical values for Lawshe's content validity ratio. Measurement and Evaluation in counseling and Development.73-69:(1)52;2019[View at publisher] [Google Scholar]
17. Ayre C, Scally AJ. Critical values for Lawshe's content validity ratio: revisiting the original methods of calculation. Measurement and evaluation in counseling and development. 2014;47(1):79-86. [View at publisher] [Google Scholar]
18.Polit DF, Beck CT, Owen SV, health. Is the CVI an acceptable indicator of content validity? Appraisal and recommendations. Research in nursing. 2007;30(4):459-67. [View at publisher] [Google Scholar]
19. Salim S, Yamin M, Alwi I, Setiati S. Validity and reliability of the Indonesian version of SF-36 quality of life questionnaire on patients with permanent pacemakers. Acta Med Indones .6-10:(1)49;2017[View at publisher] [Google Scholar]
20. Darvishpoor A, Abed S, Delavar A, Saeed O. Instrument development to measure elderly health-related quality of life (EHRQoL). Hakim Research Journal. 2012;15(1):30 7. [View at publisher] [Google Scholar]
21. Montazeri A, Goshtasebi A, Vahdaninia M, Gandek B. The Short Form Health Survey (SF-36): translation and validation study of the Iranian version. Quality of life research. 2005;14(3):875-82. [View at publisher] [Google Scholar]
22. Kolagari S, Tafreshi MZ, Rassouli M, Kavousi A. Psychometric evaluation of the role strain scale: The Persian version. Iranian Red Crescent Medical Journal. 2014;16.(10) [View at publisher] [Google Scholar]
23. Ebadi A, Taghizadeh Z, Montazeri A, Shahvari Z, Tavousi M, Bagherzadeh R. Translation, development and psychometric properties of health related measures-Part 2: construct validity, reliability and responsiveness. journal of the Iranian Institute for Health Sciences Research. 2017;16(4):445-55. [View at publisher] [Google Scholar]
24. Nikpour M, Tirgar A, Ghaffari F, Ebadi A, Nia HS, Nasiri-Amiri F. Development and psychometric evaluation of the women shift workers' reproductive health questionnaire: a sequential exploratory mixed-method study. Reproductive Health. 2020;17(1):1-10. [View at publisher] [Google Scholar]
25. Meyers LS, Gamst G, Guarino AJ. Applied multivariate research: Design and interpretation: Sage publications; 2016. [View at publisher] [Google Scholar]
26. Nikkhah M, Heravi-Karimooi M, Montazeri A, Rejeh N, Nia HS. Psychometric properties the Iranian version of older People's quality of life questionnaire (OPQOL). Health and quality of life outcomes. 2018;16(1):1-10. [View at publisher] [Google Scholar]
27. Alimoradi Z, Kariman N, Ahmadi F, Simbar M. Preparation for sexual and reproductive self-care in Iranian adolescent girls: a qualitative study. International journal of adolescent medicine health and quality of life outcomes. 2018;30.(1) [View at publisher] [Google Scholar]
28. Speziale HS, Streubert HJ, Carpenter DR. Qualitative research in nursing: Advancing the humanistic imperative: Lippincott Williams & Wilkins.2011 ; [View at publisher] [Google Scholar]
29. Golzarpour M, GHAEDAMINI H, Vameghi M, Sajjadi H, Tavangar F. Validity and reliability of Persian version of children's health-related quality of life. Journal of North Khorasan University of Medical sciences. 2016;8(3):447 59. [View at publisher] [Google Scholar]
30. Drotar D. Measuring health-related quality of life in children and adolescents: Implications for research and practice. 1 ed: Psychology Press; 2014. [View at publisher] [Google Scholar]
31. Sahni S, Talwar A, Khanijo S, Talwar A. Socioeconomic status and its relationship to chronic respiratory disease .Advances in Respiratory Medicine. 2017;85(2):97-108. [View at publisher] [Google Scholar]
32. Gephine S, Mucci P, Grosbois J-M, Maltais F, Saey D. Physical Frailty in COPD Patients with Chronic Respiratory Failure. International Journal of Chronic Obstructive Pulmonary Disease. 2021;16:1381.[View at publisher] [Google Scholar]
33. Fadaeeaghdam N, Montazeri A, Masroor D, Aliyari R, Hamidzadeh A. Factors associated with health-related quality of life in patients with chronic obstructive pulmonary disease. Journal of Isfahan Medical School. 2015;33(326):275-86. [View at publisher] [Google Scholar]
34. Mirshekari N ,Vali L. A survey on the health status of patients with chronic obstructive pulmonary disease (COPD) in Kerman in 2016. Journal of Military Medicine. 2018;20(4):391-401. [View at publisher] [Google Scholar]
35. Palinkas LA, Horwitz SM, Green CA, Wisdom JP, Duan N, Hoagwood K. Purposeful sampling for qualitative data collection and analysis in mixed method implementation research. Administration policy in mental health mental health services research. 2015;42(5):533-44. [View at publisher] [Google Scholar]
36. Henoch I, Strang S, Löfdahl C-G, Ekberg-Jansson A. Health-related quality of life in a nationwide cohort of patients with COPD related to other characteristics. European clinical respiratory journal. 2016;3(1):31459. [View at publisher] [Google Scholar]

How to Cite:
Elyas Hosseinzadeh Younesi , Zahra Sabzi , Mahmoud Khandashpour , Wolfram Windisch , Leila Teymouri Yeganeh, Shohreh Kolagari . Health-Related Quality of Life in Patients with Chronic Respiratory Failure: A Mixed Methods Research Protocol. *Journal of Research Development in Nursing & Midwifery*, 2022; 19 (2): 55-57