The validity and reliability test of the leprosy life quality questionnaire in leprosy patients [version 1; peer review: awaiting peer review]

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Abstract
Background: Leprosy is a public health problem because it potentially affects social life. In 2018, World Health Organisation (WHO) reported that Indonesia ranks third of new cases leprosy. Leprosy significantly influences patients' quality of life. Until now, there is still no specific questionnaire to assess the quality of life for leprosy patients. Leprosy Quality of Life Questionnaire (KUKUH) is a questionnaire to assess leprosy patients' quality of life, which includes questions about psychology, physical health, social environment, and treatment. The study aimed to assess the validity and reliability of the Leprosy Quality of Life Questionnaire (KUKUH) as a tool to assess the quality of life of leprosy patients in Indonesia.
Methods: The study was conducted at Saiful Anwar General Hospital in Malang, East Java. The validity analysis using construct validity with a minimum correlation coefficient value considered valid by 0.3. Internal consistency assessment for the questionnaire utilized the Cronbach α value where a value greater than or equal to 0.60 is acceptable, and a value greater than or equal to 0.80 is considered good.
Results: Based on the result of variable validity test, all items measuring each aspect have item correlation coefficient values with a total score (riT) > table correlation value (0.361). The results of reliability testing, the items that measure each aspect of the quality-of-life variable for leprosy patients have Cronbach's Alpha values greater than 0.6.
Conclusion: The validity test results of KUKUH Questionnaire are considered quite good, with a total score of 0.361 for the correlation coefficient for each question in KUKUH. The reliability test results were deemed satisfactory, with Cronbach's alpha > 0.6. The KUKUH questionnaire can be used to evaluate the quality of life of leprosy patients in Indonesia.
Introduction

Chronic infectious disease that is caused by *Mycobacterium leprae* is called Leprosy. This disease primarily affects the skin and peripheral nerves, resulting in sensory, motor, and autonomic dysfunction. *Mycobacterium leprae* can be found in high concentrations on the nasal mucosa of leprosy patients. Bacilli can survive outside the body for 36 hours to nine days. In 2019, 202,256 new cases of leprosy have been reported worldwide. India, Brazil, and Indonesia accounted for 79% of the most recent cases of leprosy patients globally. At the end of 2018, the South-East Asia region (SEAR) accounted for 71% of new leprosy cases globally, with India and Indonesia accounting for 92% of the location’s case load.

Leprosy is one of the infectious diseases that causes extremely complex problems, not only from a medical standpoint but also from a socioeconomic standpoint. The negative stigma from society persists, with people viewing leprosy as a frightening disease. Leprosy patients frequently experience psychosocial problems because of negative stigma. Delay in diagnosis and treatment of leprosy patients can result in permanent damage to the peripheral nerves and possibly lead to amputation and disability, this can occur due to many factors such as lack of awareness, poor access to leprosy diagnosis and treatment, neglect, poverty, social stigma, etc. Even today, many patients are diagnosed with leprosy after they become disabled.

Leprosy can cause physical disability, which can have severe psychological consequences and will almost certainly reduce one’s quality of life. Disability-related leprosy can cause economic, social, and psychological issues that have a negative impact on one’s quality of life.

The study’s findings also revealed that people with leprosy had lower mean quality of life scores than people without disabilities in all four domains of health relationships: physical, psychological, social, and environmental. Following this discovery, Tsutumi et al. (2007) and Dinesh et al. (2016) discovered that people suffering from leprosy have a low quality of life. A 2015 study in Brazil with 106 leprosy patients found a lower quality of life, particularly in leprosy patients with disabilities. Disability was associated with a decrease in quality of life (p = 0.001).

The European Academy of Dermatology and Venereology (EADV) believes that measuring quality of life in clinical practice can benefit patients, support physician decision-making, and contribute to the delivery of high-quality care. The goal of this Statement is to describe the various ways in which using quality of life measures can be beneficial in clinical practice.

Data on quality of life can aid in therapeutic strategy decisions and encourage patient participation in joint decision-making with doctors. Patients’ understanding of non-medical aspects of their illness supplements the physician’s knowledge of medical factors. Medication adjustments can be made while viewing the patient’s quality of life data, which can aid in clinical decisions such as dose adjustments and changes to follow-up therapy.

Leprosy can cause paralysis and deformity, which can lead to social stigma and exclusion, negatively impacting patients' quality of life. There is currently no specific quality of life assessment questionnaire available to assess the quality of life of leprosy patients. Information about people with leprosy’s quality of life is expected to be the foundation for overcoming the problem of leprosy, which focuses not only on the physical but also on other factors that may lead to a decrease in the quality of life of people with leprosy.

Leprosy Quality of Life (KUKUH) is a questionnaire that can be filled out by patients to assess the leprosy patients’ quality of life. It consists of ten questions on one sheet of paper and includes questions about aspects of psychology, physical health, social environment, and treatment. The Total Leprosy Quality of Life Score (KUKUH) is calculated by adding the scores for each question. Each question’s score has its own interpretation. KUKUH is a short and simple acronym that can be used in clinical practice and research. The Leprosy Quality of Life (KUKUH) questionnaire must be tested for validity and reliability before it can be used in the Indonesian leprosy population. The goal of this study was to determine the validity and reliability of the Leprosy Quality of Life Questionnaire (KUKUH) so that it could be used widely in Indonesian leprosy patients. Among the various types of validity, the construct validity is the most used for various types of research to test the validity of the questionnaire. The external validity test, which correlated a questionnaire with a valid measuring instrument, was not performed because there was no gold standard questionnaire for assessing the quality of life of leprosy patients in Indonesion. As a result, in this study, the construction validity is evaluated to assess the validity of all questions in the Leprosy Quality of Life (KUKUH) questionnaire. The instrument was tested for reliability with an internal consistency test on the research subject once. The Cronbach Alpha technique can be used to perform this test.
Methods

Research design

The research design tested the validity and reliability of the Leprosy Quality of Life Questionnaire (KUKUH) using a cross-sectional study design.

Patients diagnosed with leprosy/Morbus Hansen with the type of Pausibacillary and Multibacillary with a degree of disability 0-2 were controlled at the Dermatology and Venereology Polyclinic, Saiful Anwar Regional General Hospital, and at the Primary Public Health Center, Malang East Java. The sample size is 30 people.

The inclusion criteria were that patients had to be between the ages of 18 and 60, have a clinical diagnosis of leprosy, be able to communicate in Indonesian, read, and be willing to participate in research by signing informed consent. Patients with psychiatric disorders were excluded from the study.

The researchers recorded the identity, diagnosis of leprosy type, and the degree of disability of patients who had signed the consent form. Research subjects were asked to fill out the Quality-of-Life Leprosy (KUKUH) Questionnaire after receiving an explanation on how to fill out the questionnaire. The research subjects filled out the questionnaires themselves, but the researchers accompanied the process of filling out the questionnaires to provide explanations if needed.

Using the Pearson product-moment correlation technique formula, validity analysis uses construction validity by calculating the correlation between each statement and the total score. The minimum correlation coefficient value that is considered valid is 0.3. Correlation numbers below the minimum value indicate an invalid argument, perhaps due to the arrangement of words or sentences that are not good, or the sentences give different interpretations that require evaluation. The corrected statement must be tested again for validity on a diverse sample until valid results are obtained.

Internal consistency is used to test the reliability of the Leprosy Quality of Life (KUKUH) Questionnaire. Internal consistency is assessed using the Cronbach value; a value greater than 0.60 is acceptable, and a value greater than 0.80 is considered good.

The data is recorded in a particular format then edited and coded. The data was entered in the SPSS worksheet and then processed using the SPSS v. 21 program. Univariate analysis was to determine the distribution of the characteristics of the research subjects. The construction validity assessment uses Pearson’s product-moment correlation technique to see the correlation value between each statement and the total score. Internal consistency is used to test the reliability of the Leprosy Quality of Life (KUKUH) Questionnaire and is assessed using the Cronbach α value.

Results

The Pearson Correlation (Product Moment) technique was used to test the instrument’s validity by correlating each score in each item with the total score. The Pearson Correlation technique test criteria state that if the correlation coefficient (riT) table correlation (rtable) is greater than one, the questionnaire item is declared valid or capable of measuring variables and can be used as a data collection tool.

Based on the results of validity test of the research variables (Table 1), all items which measuring each aspect, have coefficient correlation values with a total score (riT) > table correlation value (0.361). As a result, the questionnaire items that measure every aspect of leprosy patients’ quality of life are declared valid or capable of measuring these variables and will be used as a data collection tool in this study.

According to a summary of the research instrument’s reliability testing results (Table 2), the items that measure every aspect of the quality-of-life variable for leprosy patients have Cronbach’s Alpha values greater than 0.6. As a result, the questionnaire items that measure every aspect of leprosy patients’ quality of life have been declared reliable or consistent in measuring these variables and will be used as a data collection tool in this study.

Based on the summary of the correlation coefficient and the value of Cronbach’s alpha in each aspect (Table 3), the average value of the correlation coefficient in the psychological aspect is 0.862, and the value of Cronbach’s alpha is 0.885. Then, the average value of the correlation coefficient on the physical health aspect is 0.843, and Cronbach’s alpha value is 0.790. Furthermore, the average value of the correlation coefficient on social and environmental aspects is 1.000, Cronbach’s alpha value is 1.000, and the average value of the correlation coefficient on the treatment aspect is 0.926, and Cronbach’s alpha value is 0.828.
Discussion
Data on quality of life can help with therapeutic strategy decisions and encourage patient involvement in decision making. Patients’ understanding of non-medical aspects of their illness supplements the physician’s knowledge of medical factors. Medication adjustments made while viewing patient quality of life data can assist physicians in clinical decisions such as dose adjustments or changes to follow-up therapy, for example, to reduce the identified quality of life impacts more quickly. The treatment’s effect can also have an impact on the quality-of-life score.11

Regular quality of life measurements can aid in monitoring the progression of a condition or the efficacy of therapy. Changes in the score can be instructive and serve as a reminder to the doctor to reconsider changing treatment. For many patients and doctors, the most important outcome of care is improved quality of life. Quality of life measurement can be used as a screening tool to uncover “hidden” physical, psychological, and adjustment issues, as well as to identify patients who may need to be referred to other specialists or who may require additional support or care.11

Health questionnaires are generally designed to detect a psychological disorder and are reliable in dermatology patients. Quality of life measurement can show the effect of skin disease compared to other organ diseases.11

The European Academy of Dermatology and Venereology (EADV) summarizes at least 40 tools for measuring the quality of life and health status for skin diseases. Quality of life in dermatology is most often assessed with generic and
specialized instruments for dermatology-specific conditions. Researchers and clinicians have a wide choice of tools in which several parameters can influence therapy for a patient. Doctors and patients prefer short instruments and a short time to complete them. Another critical parameter in assessing the quality of life is validation. A well-validated tool has a better chance of being widely used.\textsuperscript{13}

An excellent measuring instrument or instrument must meet the requirements for testing its validity and reliability. Validity in the context of research instruments means that the validity of a study is related to the extent to which a researcher measures what is supposed to be measured. Moreover, the validity of quantitative research is rooted in empiricism, which emphasizes evidence, objectivity, truth, deduction, reason, facts, and numerical data. The measurement tools commonly used are questionnaires and tests. In this context, the questionnaire measuring instrument needs to be structured in such a way that it can be used as the right instrument to obtain, find, describe, explore, and compare various information, topics, and research variables.\textsuperscript{14} Construction validity relates to whether the research tools have been prepared based on an appropriate and relevant theoretical construct. Questionnaires with high construct validity are always based on the definition or limitations of experts on the concept, not on a dictionary definition. Based on these limitations, researchers can arrange appropriate statements and questions. With SPSS, questionnaires and test items need to be measured using factor analysis.\textsuperscript{15}

Construct validity focuses on the extent to which a measuring instrument shows measurement results that conform to its definition. The definition of variables must be clear to facilitate the assessment of construct validity. The definition is derived from theory. If the definition is based on the correct theory and the question or item statement is appropriate, then the instrument is declared valid with construction validity.\textsuperscript{15}

Using the Pearson product-moment correlation technique formula, validity analysis uses construction validity by calculating the correlation between each statement and the total score. The minimum correlation coefficient value that is considered valid is 0.3. Correlation numbers below the minimum value indicate an invalid statement, perhaps due to the arrangement of words or sentences that are not good, or the sentences give different interpretations that require evaluation. The corrected statement must be tested again for validity on a diverse sample until valid results are obtained.\textsuperscript{16}

According to the results of testing the validity of this research variable, all items measuring each aspect have item correlation coefficient values with a total score (riT) greater than the table correlation value (0.361). As a result, the questionnaire items that measure every aspect of the quality-of-life variable of leprosy patients are declared valid or capable of measuring these variables, and will be used as a data collection tool in this study.

Trustworthiness, reliability, constancy, stability, and consistency are all synonyms for reliability. The main idea behind the concept of reliability is "the degree to which measurement results can be trusted." The term reliability refers to the degree to which measurement results can be trusted. Furthermore, the concept of reliability refers to the consistency of the scores on the questionnaire items, so that the reliability test evaluates the accuracy of the research instrument’s measurement scales.\textsuperscript{14}

Therefore, the main purpose of testing the reliability of research instruments is to measure the consistency of the measuring instruments used by quantitative researchers. In this context, the researcher wants to determine whether there is the accuracy of measurement results in the same sample at different times. A research instrument, such as a questionnaire, is reliable if it can provide consistent scores on each measurement. Then the measurement tool (items of statements/questions) still provides consistent measurement results at different times.\textsuperscript{14}

Re-measurement techniques, halving techniques, parallel techniques, and internal consistency can all be used to calculate reliability. Only questions with existing validity should be subjected to reliability calculations (Rahmatina, 2013). If the Cronbach’s Alpha reliability coefficient is greater than 0.70 (ri > 0.70), the instrument is said to be reliable, and if the Cronbach’s Alpha reliability coefficient is greater than 0.90 (ri > 0.9), the instrument is said to be unreliable. Tavakol and Dennick (2011) recommend revising or eliminating items with low correlations if the Cronbach’s Alpha reliability coefficient is less than 0.70 (ri < 0.70).\textsuperscript{17} A computer program can be used to quickly determine the object of the question. They also have suggestions if the Cronbach’s Alfa reliability coefficient is greater than 0.90 (ri > 0.90). They advocate for fewer questions with the same criteria, even if they are in different sentences.\textsuperscript{15}

According to a summary of the research instrument’s reliability testing results, the items that measure each aspect of the quality-of-life variable for leprosy patients have Cronbach’s Alpha values greater than 0.6. As a result, the questionnaire items that measure every aspect of leprosy patients' variable quality of life are declared reliable or consistent in measuring these variables, allowing them to be used as data collection tools.
Conclusion
The validity test results of the Indonesian language KUKUH Questionnaire to assess the quality of life of leprosy patients were considered good, with a total score of 0.361 for the correlation coefficient for each question. The reliability test results were deemed satisfactory, with Cronbach’s alpha > 0.6. The KUKUH questionnaire can be used to evaluate the quality of life of leprosy patients in Indonesia.

Data availability

Underlying data
Zenodo: The validity and reliability test of the leprosy life quality questionnaire in leprosy patients.18

https://doi.org/10.5281/zenodo.6817556

This project contains the following underlying data:

- Analytic Data Revised/Raw Data.xlsx
- Validity and Reliability Test Result.docx
- Validity and reliability test.sav

This project contains the following extended data:

- Quality of Life Questionnaire (KUKUH).docx

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References

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