

Psychometric Evaluation of the EQ-5D-5L in Indonesia Patients with Type 2 Diabetes Mellitus

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ARTICLE INFO

Manuscript Received: 25 Jun, 2025

Revised: 12 Oct, 2025

Accepted: 15 Oct, 2025

Date of Publication: 04 Nov, 2025

Volume: 8

Issue: 11

DOI: [10.56338/mppki.v8i11.8406](https://doi.org/10.56338/mppki.v8i11.8406)

KEYWORDS

Type 2 Diabetes;
Quality of Life;
Instrument Development;
EQ-5D-5L

ABSTRACT

Introduction: Diabetes is a chronic disease affecting a significant portion of Indonesians populations with a substantial impact on the quality of life. Despite its widespread usage, the EQ-5D-5L remains a generic measure that may fail to capture condition-specific characteristics such as self-care obstacles, social support, psychological burdens, and complications in patients with type 2 diabetes mellitus. These constraints emphasize the theoretical gap and the need for a personalized remedy.

Methods: This study used a cross-sectional approach and was conducted at six community health centers (Puskesmas) in Yogyakarta City between October 2024 and February 2025. A total of 400 respondents aged 19-59 years who consented to participate were included in the study. Content validity testing was conducted by expert panel, who provided feedbacks on the relevance of the items, revisions prior to pilot testing of the instrument. Face validity was evaluated with 40 respondents. Model fit and construct validity were analyzed using Confirmatory Factor Analysis (CFA).

Results: The Cronbach's Alpha value for internal consistency reliability was 0.86. The majority of respondents were female (64.75%), had a moderate level of education (67.50%), and belonged to the low income bracket (61.75%). Hypertension was the most commonly reported complication (26.75%). Respondents' quality of life was categorized as fairly good. Confirmatory factor analysis (CFA) revealed that the social support dimension did not meet the validity threshold. After its removal, the five dimensional model—mobility, self-care, usual activities, pain/discomfort, and anxiety/depression showed satisfactory construct validity and reliability, with standardized loadings ranging. The Comparative Fit Index (CFI) was 0.923, while the Tucker-Lewis Index reached 0.885, RMSEA (0.125), and SRMR (0.069) suggesting a model fit that approaches, but does not fully meet, ideal thresholds.

Conclusion: The instrument exhibits acceptable reliability and preliminary validity consistent with the theoretical construct. However, revision of the social support items and further validation in broader populations are necessary before wider application.

Publisher: Fakultas Kesehatan Masyarakat Universitas Muhammadiyah Palu

INTRODUCTION

The chronic condition known as type 2 diabetes mellitus (T2DM) is becoming more common worldwide and impacts many facets of life, particularly the physical, psychological, and social aspects (1). Since 2006, only a small percentage of the populations under study have shown an increase in the prevalence of clinically diagnosed, in more than one-third of populations, the incidence has decreased during this time. The recent decline in the incidence of diabetes may have been attributed to preventive measures. There is a lack of data in middle-class and low-income nations, where patterns in the prevalence of diabetes may differ (2). Type 1 diabetes, type 2 diabetes, gestational diabetes, and other forms of diabetes mellitus are the several categories of diabetes (3). In 2024, 588.7 millions of individuals globally will have diabetes, with 80% of them living in middle-class and low-income countries (4,5). Noncommunicable diseases, such as diabetes, cardiovascular disease, cancer, and respiratory disorders, account for almost 70% of fatalities worldwide. In individuals between the ages of 40 and 60, diabetes typically lowers life expectancy by 4-10 years and increases the risk of dying from cancer, kidney disease, and cardiovascular disease by 1-3-3-0 times (1). Most cases of diabetes mellitus (DM) can be prevented, and can be potentially cured if identified and managed early in the course of the disease in some cases. However, all evidence suggests that the prevalence of diabetes is increasing worldwide, primarily driven by the rise in obesity caused by various factors, including lifestyle (6). Quality of life (QoL) is a widely used concept in healthcare albeit its lack of consensus in its definition. It is a concept generally associated with compliance, morbidity, and health outcomes (7).

The general management of DM attempts to raise the QoL for people with DM, long-term objectives include lowering the risk of acute complications, enhancing QoL, and eradicating DM symptoms of preventing and inhibiting how microangiopathy and macroangiopathy problems develop, as well as the ultimate objective of lowering DM morbidity and death (8). Diabetes affects patients' lives, often leading to a decline in QoL. When diabetes is present with other chronic, conditions, its adverse effects become even worse (9). By incorporating the quality of life considerations into clinical decision making, care can be tailored more effectively to meet individual needs and achieve the highest standard.

One of the tools for evaluating the QoL in people living with diabetes is the EQ-5D-5L, introduced by the EuroQol Group in 2009 as an enhanced version of the EQ-5D-3L. It is developed to increase measurement sensitivity and reduce the ceiling effect observed in the EQ-5D-3L. the two pages that make up the EQ-5D-5L are the EQ visual analogue scale (EQ-VAS) and the EQ-5D descriptive system. Five categories make up the descriptive system: self-care, mobility, routine activities, pain/discomfort, and anxiety/depression. Each dimension is rated at five different levels: no issues, minor problems, moderate problems, severe problems, and extreme problems.

Several diabetes-specific tools have been created to capture characteristics of quality of life that are unique to living with diabetes. According to systematic reviews, the Audit of Diabetes-Dependent Quality of Life (ADDQoL) and the Diabetes Quality of Life (DQOL) questionnaire are among the most commonly used disease-specific tools, as they provide detailed, diabetes-centered domains such as treatment burden, diabetes-related worries, and the personal importance of affected life areas (10). Studies evaluating generic preference-based measures, most notably the EQ-5D-5L, report adequate reliability and validity in type 2 diabetes populations and emphasize its value for health economic evaluation and cross-disease comparisons, but also highlight limitations in sensitivity to some diabetes-specific concerns (e.g., treatment satisfaction, psychosocial burden) (11). Recent mapping of ADDQoL scores to EQ-5D-5L utility values indicates only small relationships between diabetes-specific and general preference measures, implying that ADDQoL captures features of patient experience not fully reflected in EQ-5D-5L indices (12). Furthermore, recent syntheses of EQ-5D-5L measuring features and minimally meaningful difference estimations enhance the interpretation of utility changes, but they do not replace the clinical and psychological detail supplied by disease-specific instruments (13).

Patients are asked to indicate their condition by checking the box next to the statement that best reflects their condition in each of the five dimensions. Every statement that is chosen correlates to a single-digit number that denotes the dimension's level. The patients's overall health status is described by combining the five numbers derived for the five dimensions into a five-digit number (14). Previous studies have validated quality of life instruments for patients with type 1 and type 2 diabetes, showing that the instruments are constructively valid (15). Separately Tondok et al. has developed a QoL measurement instrument for tuberculosis patients (16). Yet, measuring QoL remains inherently complex due to the subjective nature of the responses of the patients with individual perceptions

influencing the responses. Thus, instruments used for measuring QoL must be sensitive and relevant to the local cultural context, such as differences in ethnicity, perceived risk, and socioeconomic conditions.

Although the EQ-5D-5L is a well-validated and extensively used generic measure for assessing health-related quality of life (HRQoL), new research reveals that it may fail to capture important diabetes-specific categories, particularly psychosocial and social relational dimensions. For example, qualitative research among patients with type 2 diabetes has found that variables such as social/relational functioning are regularly identified as crucial to quality of life but are not explicitly included in the conventional EQ-5D-5L descriptions (17). Empirical studies reveal that social support has a direct and indirect effect on the quality of life of type 2 diabetes (T2DM) patients in rural China, which cannot be explained by standard physical or clinical criteria (18). Similarly, research in Vietnam reveals "unmet needs for social support" and substantial relationships between perceived social support and HRQoL, distress, and self-care behaviors in diabetes populations (19). As a result, there is a conceptual gap: while EQ-5D-5L excels at cross-disease comparisons and health economic evaluations, it may underrepresent or overlook specific aspects of the disease, particularly social support or relational dimensions, which have a significant impact on people with diabetes's life experiences. The goal of this study is to broaden the conceptual framework for measuring health-related quality of life (HRQoL) in type 2 diabetes (T2DM) by identifying and incorporating additional dimensions (social support) that are not adequately covered by current generic measurement tools such as the EQ-5D-5L, in order to improve sensitivity, relevance, and comprehensiveness in clinical and research settings.

Moreover, in Yogyakarta City, the prevalence of diabetes mellitus (DM) remains high, as evidenced by the results of the 2018 Basic Health Research (Riset Kesehatan Dasar, Riskesdas, 2018), which reported an increase from 6.9% to 10.9% among individual aged 15 years and older. The prevalence of DM based on medical diagnoses is 2% nationwide, while the rates in Yogyakarta Special Region and Yogyakarta City are notably higher, i.e., 3.11%, and 4.79% (20). This high prevalence has prompted researchers to develop a QoL assessment tool for patients with T2DM in Yogyakarta City, aiming to enable more targeted and accurate QoL measurement of T2DM patients. Therefore, the purpose of this study was to improve T2DM patients's quality of life.

METHOD

Study design

Cross-sectional approach was used in this quantitative investigation. Data used were primary data collected through questionnaires completed directly by respondents or through interviews. This study employed an instrument development approach to validate and refine an expanded version of the EQ-5D-5L for patients with type 2 diabetes mellitus. The instrument was adapted into a six-dimensional model encompassing mobility, self-care, daily activities, pain/discomfort, anxiety/depression, and social support to capture broader aspects of quality of life. Each dimension comprised three items developed through literature review, expert consultation, and content validation. The addition of the social support dimension was grounded in the biopsychosocial paradigm, highlighting the importance of interpersonal and emotional support in chronic disease management.

Population and Sample/Informants

Participants in this study comprised all patients diagnosed with T2DM who underwent examination in this study. A sample of 400 respondents was selected using nonprobability purposive sampling method. The inclusion criteria were: patients with type 2 diabetes examined in several Community Health Centers in Yogyakarta City, aged 19-59 years, and open to taking part in this research. Patients who were unable to respond or finish the questionnaire were among the exclusion criteria to the questions due to physical limitation, communication disorders, or unstable mental conditions. A pilot study was conducted with 40 respondents prior to this study.

Research Location

The study was conducted in several community health centers in Yogyakarta City, including Gondokusuman I Community Health Center, Umbulharjo I Community Health Center, Umbulharjo II Community Health Center, Ngampilan Community Health Center, Mantrijeron Community Health Center, and Mergangsan Community Health Center. For the pilot study, sample was collected at Gondokusuman I Community Health Center. Sample for construct validity and criterion validity were obtained from Umbulharjo I Community Health Center, Umbulharjo II

Community Health Center, Ngampilan Community Health Center, Mantrijeron Community Health Center, and Mergangsan Community Health Center.

Instrumentation

Variable outcome in this study is QoL especially EQ-5D-5L assessment tool created by the EuroQoL Research Foundation for people with chronic illnesses, was utilized in this investigation. It is divided into two primary sections: a visual analog scale and a descriptive portion with five dimensions. The five elements of mobility, self-care, routine activities, pain/discomfort, and anxiety/depression are all included in the descriptive part. Five severity levels are used to grade each dimension, with a score of 1 denoting "no problems" and a score of 5 denoting "very severe problems" or "unable to function." Respondents select one statement from each dimension that best reflects their health condition at the time of questionnaire completion. These will generate a five-digit code representing the individual's health status.

The EQ-VAS, which is the second component of the EQ-5D-5L instrument, is a visual vertical scale that is represented by a vertical line that goes from 0 (the worst possible health) to 100 (the best possible health). When filling out a questionnaire, respondents are asked to mark the number that best represents how they feel about their general health.

Other collected variables were namely age, sex, education, living with diabetes for, marital status, treatment, comorbidities, and index score QoL. The index score of QoL was measured by Indonesian set value of QoL with range 1-5. Then those index score was categorized into 3 levels (low, middle and high) by counting quantile.

Additionally, this study used informed consent obtained from respondents after they received clear, complete, and understandable explanations about this study. The prospective respondents were allowed to refuse or accept participation in this study without any coercion. This process is essential to protect the respondents' rights, safety, and privacy, and to ensure compliance to ethical research standards.

Data Collection Procedures

The developed instrument was distributed to eligible patients upon arrival at the selected community health centers during working hours. Respondents were provided with an informed consent form and signed it if they agreed to participate. Participants were then asked to complete the EQ-5D-5L instrument either independently or through an interview with a research assistant. This data collection process involved four research assistants who were recruited based on the following criteria: a minimum education level of an associate degree, effective communication skills, and prior experience in research data collection.

Data Analysis

Data analysis in this study was conducted through several validity tests. Content validity was calculated by experts using the Content Validity Index. Face validity was evaluated qualitatively using an expert review of the instrument items and participant feedback gathered during pilot testing. Cronbach's Alpha was used to evaluate the internal consistency reliability. Construct validity was evaluated using Confirmatory Factor Analysis (CFA). CFA was used to evaluate whether the factor structure of the developed instrument aligns with the expected theoretical constructs. Model fit was assessed using several fit indices, including chi-square (χ^2), CFI, TLI, Root Mean Square Error of Approximation (RMSEA), and Standardized Root Mean Square Residual (SRMR). Descriptive statistics were used to summarize the sociodemographic characteristics of the respondents. All analyses were performed using the R software (Lavaan package).

Ethical Approval

The Ahmad Dahlan University Research Ethics Committee (KEP) granted ethical approval for this study Number 012406146.

RESULTS

The psychometric test of the respondent characteristics revealed that most respondents in this study were female, aged 45-59 years, with a moderate level of education (junior high school and high school). The majority had been diagnosed with T2DM for 1-5 years and were married. Economically, most respondents in this study reported a low income (< Rp 2,000,000.00/month). The most common treatment received was oral medication, while the most common comorbid condition was hypertension. The subjective quality of life score, as measured by the VAS indicated that the majority of respondents were in the low quality of life category. In contrast, while the majority of index scores were in the high category.

Table 1. Sociodemographic, Clinical, and Quality of Life Characteristics of Patients with Type 2 Diabetes Mellitus (N = 400)

Characteristic	Frequency (n = 400)	Percentage (%)
Sex		
Man	141	35.25
Woman	259	64.75
Age (year)		
Adult (19-44)	48	12.00
Pre elderly (45-59)	352	88.00
Education		
Low	59	14.75
Middle	270	67.50
High	71	17.75
Living with diabetes for		
< 1 year	105	26.25
1-5 years	222	55.50
> 5 years	73	18.25
Marital status		
Single	7	1.75
Widowed/divorced	80	20.00
Married	313	78.25
Income		
Low	247	61.75
Middle	21	5.25
High	132	33.00
Treatment		
Oral	386	96.50
Insulin	9	2.25
Combination	5	1.25
Comorbidities		
Gout	7	1.50
Asthma	2	0.50
Hypertension	107	26.75
Heart disease	5	1.25
Cholesterol	9	2.25
None	270	67.50
EQ-VAS		
≤ 70	152	38.00
71-80	196	49.00

81-100	52	13.00
Index score		
< 0.7	15	3.75
0.7 – 0.8	185	46.25
≥ 0.9	200	50.00

Note: EQ-VAS = EuroQol Visual Analog Scale; EQ-5D = EuroQol 5 Dimensions.

EQ-VAS scores were categorized as low (≤ 70), moderate (71–80), and high (81–100).

EQ-5D index scores were categorized as low (< 0.7), moderate (0.7–0.8), and high (≥ 0.9). Percentages are based on the total number of respondents (N = 400).

The assessment of QoL using this instrument also incorporated the Visual Analogue Scale (VAS) score as one of the indicators to assess respondents' subjective perceptions of quality of life. Descriptive analysis revealed a mean VAS score of 74.94 with a standard deviation of 9.88. To categorize the QoL levels, the researchers used the quantile division method on the scores. Quantiles divide data into equal parts and are useful for classifying data and identifying distribution patterns.

Based on the calculated tertiles, the first tertile of the VAS score was 70 and the second tertile was 80. Quality of life scores were categorized into three categories: low (VAS score ≤ 70), moderate (VAS score 71–80), and high (VAS score > 80). The majority of VAS scores in this study fell within the 71–80 range, classified as moderate. This suggested that most respondents in this study had a positive perception of their health condition. The relatively small standard deviation further indicated that the perception of quality of life among respondents were fairly homogeneous.

Of the 18 items assessed, not all met the criteria for construct validity. Four dimensions (mobility, daily activities, pain or discomfort, and anxiety or depression) presented strong factor loadings. The self-care dimension consisted of three items: 4, p5, and p6. Item 4 had a loading of 0.486, indicating the need for revision in terms of relevance and phrasing within the context of diabetes patients. The construct validity of the social support dimension showed significant issues in construct validity, due to very low loading values. This indicates that the items did not adequately represent the social support construct, necessitating a complete revision of the social support dimension.

Table 2. Descriptive statistics and internal consistency reliability for each dimension of the instrument (N = 400)

No	Dimension	Item	Mean	Standard Deviation (SD)	Internal Consistency Reliability (Cronbach's α)
1.	Mobility	P1, p2	2.31	1.07	0.799
2.	Self-Care	p5, p6	2.11	0.74	0.646
3.	Usual activities	p7, p8, p9	3.22	0.89	0.917
4.	Pain/ Discomfort	p11, p12	3.40	1.51	0.840
5.	Anxiety/ Depression	p13, p14, p15	4.15	1.89	0.843
Overall Reliability					0.809

Note: Cronbach's α = Cronbach's alpha coefficient. Descriptive statistics represent the mean score and standard deviation for each dimension of the revised instrument.

Table 2 shows that the highest average value was observed in the anxiety dimension (p13, p14, p15) with a standard deviation of 1.89, indicating that respondents reported relatively high levels of anxiety with considerable variation in responses among respondents. The average scores for usual activities and pain dimension were 3.22 and 3.14, respectively, suggesting that respondents experienced limitations in their daily activities and varying degree of pain intensity. The mobility and self-care dimension showed had generally lower scores of 2.31 and 2.11, respectively, indicating relatively better functioning in mobility and self-care compared to other dimensions, with less variations in responses. The reliability analysis showed that the alpha values across dimensions ranged from fair to very good category. The highest alpha value was found in the dimension of routine activities, indicating very good internal consistency among the items within the dimension. High reliability was also observed in the anxiety and pain dimensions. The alpha value for the mobility dimension remained in the good category, while the self-care dimension had the lowest alpha value, falling within the adequate range, when compared to other dimensions.

Table 3. Factor Loadings of The Validated Five-Dimensional Quality of Life Model for Patients with Type 2 Diabetes Mellitus

Dimension	Loading Factor Value
Mobility	
Item 1	0.759
Item 2	0.877
Self-care	
Item 5	0.829
Item 6	0.638
Usual activities	
Item 7	0.902
Item 8	0.932
Item 9	0.891
Pain/discomfort	
Item 11	0.738
Item 12	0.965
Anxiety/depression	
Item 13	0.816
Item 14	0.774
Item 15	0.819

Note: CFI = Comparative Fit Index; TLI = Tucker-Lewis Index; RMSEA = Root Mean Square Error of Approximation; SRMR = Standardized Root Mean Square Residual.

Table 3 shows that, overall, the items in the revised instrument exhibit strong factor loadings above 0.5, indicating that each item contributes significantly to the formation of its dimension construct. At the psychometric level, one item in the Self-Care dimension showed a relatively lower factor loading (0.638). This item was retained because it captured an essential theoretical aspect of self-management of diabetes. However, refinement may be necessary, and future validation studies should consider revising or expanding this item to strengthen its psychometric reliability. The Comparative Fit Index (CFI) for the revised instrument was 0.923, indicating that the model fit the empirical data well, although it had not yet reached an excellent level. The Tucker-Lewis Index (TLI) value of 0.885 is still below the ideal threshold (0.90), but it is close enough to be considered acceptable. The RMSEA value of 0.125 reflected good model fit. The SRMR value of 0.069 also indicated good model fit, as it was below the maximum limit of < 0.08.

In the present study, we explored both the original 5-dimension EQ-5D-5L structure and a modified 6-dimension version with an additional social support domain. While the inclusion of social support was conceptually justified given its importance for diabetes patients, the empirical evaluation showed that the 6-dimension model did not meet the criteria for acceptable fit. In particular, the RMSEA value was 0.125, which indicates poor fit according to conventional cut-offs.

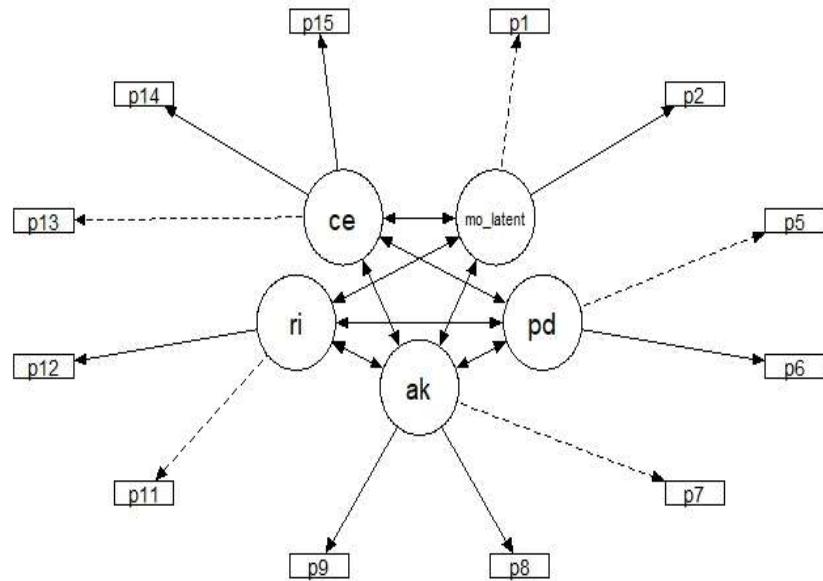


Figure 1. Final Confirmatory Factor Analysis (CFA) Model of The Validated Five-Dimensional Instrument

Figure 1 illustrates the measurement model of the developed quality of life instrument for patients with T2DM, comprising five latent constructs: ce (anxiety), ri (pain), pd (self-care), ak (usual activities), and mo (mobility). Each construct was measured through several indicators represented by p1 to p15, and visually represented as rectangles. Arrows from the construct to the indicators indicate a reflective relationship, in which the construct accounts for variation in the indicators. Each indicator is linked by a one-way arrow originating from the construct, indicating its reflective nature. This relationship demonstrates the contribution of each indicator in explaining the measured quality of life construct.

Most of the items have good construct validity. However, several items were represented with dotted lines, indicating low loading values or less significant contributions to the construct. Inter-construct relationships were depicted using bidirectional arrows, indicating relationships between the quality of life dimensions being measured. The mobility dimension influenced anxiety, self-care, and usual activities, while anxiety and pain influenced usual activities. Self-care directly influenced usual activities.

Table 4. Distribution of Quality of Life Levels by Age Group Among Patients with Type 2 Diabetes Mellitus

Quality of life	Age		Total
	Adult	Pre-elderly	
Low	0	15	15
Middle	21	164	185
High	27	173	200
Total	48	352	400

The quality of life distribution of respondents by age group is displayed in the table 4. Of the 400 responders, 352 were categorized as pre-elderly and 48 as adults. While 15 pre-elderly respondents (3.8%) were deemed to have a poor quality of life, while none of the adults expressed this sentiment. In both age groups, the majority of responders fell into the midrange and high quality of life categories. In particular, 164 pre-elderly people (46.6%) and 21 adults

(43.8%) reported a middling quality of life, whereas 173 pre-elderly people (40.1%) and 27 adults (56.3%) reported a high quality of life. Overall, the percentage of adults and pre-elderly respondents who reported having a middling or high quality of life was comparable.

Table 5. Results of Validity Testing Between Age and Quality of Life

Variable	χ^2	df	p-value
Age vs quality of life	2.5453	2	0.2801

Note: χ^2 = Chi-square; df = degrees of freedom. The association between age and quality of life was not statistically significant ($p > .05$), indicating that age did not affect the distribution of quality of life categories among respondents.

This study provides preliminary evidence of validity and reliability for the five-dimensional instrument developed from the EQ-5D-5L framework. The validity of the criteria in this study was determined by measuring the validity of the age item as a criterion to assess the consistency of the age measurement results with the overall test results. Item validity was evaluated through the correlation coefficient between the item score and the total test score. The item validity used was based on the correlation between age and quality of life. Despite the apparent minor variation in the number of quality of life categories among age groups, the Chi-square test revealed no significant correlation between quality of life and age ($\chi^2 = 2.545$, df = 2, $p = 0.280$). This negative correlation was very weak and suggested that an increase in age was not strongly associated with a decrease in quality of life scores among respondents in this study.

DISCUSSION

Rukmini's study has identified that the most prevalent non-communicable diseases (NCDs) among depression, mental and emotional illnesses, and hypertension are prevalent among Indonesia's senior citizens, DM, and heart disease. Diabetes mellitus is more prevalent among people aged 60-69 years and is more common in women (21). Consistently, the present study also shows that the majority of respondents are female. A study conducted by Ghassab et al (2023) has reported that 56% of the total population of people living with diabetes are female, with a higher prevalence of type 2 diabetes among women (15.5%) compared to men (11.8%). Their simple logistic regression model revealed that age, high blood pressure, abdominal obesity, cholesterol level, and triglyceride level in both genders are significantly associated with the occurrence of type 2 diabetes (22).

Compared to men, women are more likely to develop T2DM, partly due to significant hormonal changes throughout the female life cycle, which can contribute to insulin resistance. Pregnancy causes fluctuations in insulin resistance, which might worsen in the second half of the pregnancy, especially in women with type 2 diabetes and gestational diabetes. Many factors influence insulin resistance during pregnancy, such as placental hormones, obesity, inactivity, unhealthy eating patterns, and genetic and epigenetic contributions; however, the underlying mechanisms are complex and not yet fully understood (23).

As shown in Table 1, the results of this study indicate that the highest proportion of type 2 diabetes patients are aged ≥ 45 years. Body tissues and organs are impacted by aging through a variety of physiological and pathological mechanisms. Adipose tissue, known for its high flexibility, undergoes significant changes with aging. In addition to increased lipotoxicity, aging modifies the location of adipose tissue, impacting adipogenesis, browning traits, inflammatory condition, and adipokine production. These alterations in adipose tissue that occur with age are among the key contributor to insulin resistance (24).

The most common educational levels among respondents in this study were intermediate (junior high school and high school) and higher (diploma and bachelor's degree). Education attainment is generally associated with a person's understanding of how to manage a disease, including the ability to access health services and the ability to maintain a healthy lifestyle. The QoL of DM patients is correlated with their educational attainment (25).

Most respondents in this study had suffered from DM for 1-5 years. This duration represents the early stage of the DM disease progression. Patients begin to experience lifestyle changes, including dietary patterns, medication consumption, and blood sugar monitoring. The duration of diabetes mellitus affects a person's quality of life. Patients who have lived with DM for ≥ 10 years tend to have significantly lower physical function compared to those with a shorter disease duration (26).

The quality of life of DM patients in the early stages is relatively good but may decline in the absence of social support, treatment adherence, and adequate knowledge (27). In theory, social support should play an important role in improving the quality of life for patients with type 2 diabetes mellitus. However, in this study, the social support component had lower factor loadings than the other dimensions. This disparity could be attributed to contextual variables, such as cultural differences in how social support is seen and reported, or to the small number and scope of items employed to operationalize the concept. While the dimension remains conceptually relevant, more refining and validation across larger and more diversified populations are required to better its psychometric performance. Most respondents in this study were married. Marital status is associated of various psychological and disease management aspects of the quality of life. Spouses can provide emotional support, especially when dealing with stress caused by chronic illness (26,28).

Most respondents in this study reported low income levels. Income is one of the key determinants that influence the quality of life among individuals living with diabetes mellitus. Access to health services for people with low incomes is limited. Limited financial resources can restrict access to health services and hinder the ability to maintain adequate nutritional intake tailored to the needs of DM patients. Consequently, income may significantly affect both the physical and psychological aspects of quality of life (29).

The most common comorbidity reported by respondents in this study was hypertension. People living with DM and hypertension tend to feel easily fatigued and experience muscle pain, which can reduce their quality of life. This finding aligns with that of Alshahrani et al, which identified a relationship between hypertension and declined quality of life in DM patients (26). High blood sugar levels in patients with type 2 diabetes can cause endothelial damage and vascular resistance, thereby worsening hypertension. Hypertension accelerates the progression of diabetes complications, especially microvascular complications (such as diabetic nephropathy) and macrovascular complications such as stroke and coronary heart disease (30).

Mobility is a key aspect in assessing the QoL of patients with T2DM. Research has shown that diabetes-related complications, such as muscle weakness, joint pain, and peripheral neuropathy, significantly impair patients' ability to move and function independently (31). This aligns with a study conducted by AbuAlhommos et al. which utilized the EQ-5D-5L dimensions and identified mobility as one of the most common issues faced by diabetes mellitus patients, with a significant impact on the quality of life of diabetes patients (32).

The results of this study show a standard deviation of 1.069 in the mobility dimension, indicating notable variation in respondents' responses. This means that while a portion of respondents reported good mobility, others reported significant mobility issues. Most respondents in our study experience moderate mobility constraints. Respondents' perceptions of mobility are relatively homogeneous, as indicated by the relatively small variation in scores. Overall, 83% of respondents did not experience any difficulties in moving (level 1), and 17% experienced mild to moderate difficulties (levels 2–4). One person reported severe difficulties (level 4). Despite the low prevalence of mobility issues as reported by respondents, this still warrant attention in the context of QoL of these patients.

A total of 96.5% of respondents in this study reported that they did not experience problems in performing their usual activities. However, the average score for the dimension of usual activities shows that most respondents have moderate limitations in performing daily activities. This value indicates that for the respondents in this study, impairments in daily activities are a significant aspect affecting individuals with type 2 diabetes mellitus. Consistent with the research conducted by Pramudya et al., there is a relationship between physical activity and the quality of life of elderly individuals with type 2 diabetes mellitus, thereby highlighting the need for support in providing knowledge about the significance of physical exercise (33).

People living with diabetes and physical limitations have a lower quality of life, including in terms of self-care. This decline in self-care abilities can lead to dependence on others, which in turn affects their psychological condition (34). QoL in patients with T2DM is often diminished, primarily due to pain/discomfort and mobility limitations associated with the disease (29). Evidence shows that diabetes is associated with various musculoskeletal disorders, and poor glycemic control can lead to persistent musculoskeletal pain over time. Neuropathic joints are often found in the feet and ankles of patients. Complications such as diabetic neuropathy, pain associated with rheumatoid arthritis (RA), and other musculoskeletal conditions are commonly observed in patients with diabetes. These complications contribute significantly to morbidity and have a substantial impact on patients' overall quality of life (35).

The dimension of anxiety has high consistency in the context of measuring the quality of life of people living with diabetes mellitus. Anxiety is closely related to physical aspects (disease management) and social aspects (i.e., family assistance) (36). In patients with T2DM, issues such as motivation, depression, and cognitive decline need to be addressed to prevent deterioration in quality of life (37). Anxiety or depression are the most frequent complaints in the severe to extreme scale (38).

Support from the community and reliable people in one's life is referred to as social support, both instrumentally and expressively. The significance of emotional and informational support from friends, family, and the community is emphasized by social support (39). Higher levels of social support are associated with reduced stress in both men and women. The aspect of social support in this study refers to a multidimensional concept consisting of material and psychological assistance from family, friends, and health workers(40).

A confirmatory approach using simple linear regression analysis showed a regression coefficient between age and quality of life of -0.0418 with a p-value of 0.603) and an R² value of 0.0007. This means that age only explains 0.07% of the variance in quality of life and is considered very small and insignificant. A high p-value indicates that age is not a significant predictor of quality of life in this population context. These results differ from several previous studies that found a stronger relationship between age and quality of life, particularly in elderly populations with chronic diseases. Physical and mental abilities as well as the capacity to carry out daily tasks are diminished with age, thus affecting QoL (41).

This study has several limitations. The data collection process for instrument development was time-consuming, and revisions may be required if data processing yields invalid results, requiring time and a large sample size. Future researchers are encouraged to reformulate items within the social support dimension and other dimensions that exhibit low correlation. External validity testing should also be conducted by linking the instrument results to clinical data or other objective indicators.

Despite these limitations, the study has been able to identify specific parts of the instrument that need improvement, providing clear direction for future instrument revisions and contributing to the development of quality-of-life instruments for people living with type 2 diabetes. It also emphasizes the importance of conceptual considerations in establishing criterion validity across instruments.

The study has significant drawbacks. A nonprobability purposive sampling strategy was used, which is methodologically suitable for the early stages of instrument development. However, this strategy may impair external validity and limit the generalizability of the results. Future study should examine using probability-based sampling strategies to improve representativeness and broaden the instrument's application to a larger sample of people with type 2 diabetes. In addition, the RMSEA value above the suggested threshold, probably due to the limited sample size and the model's complexity. To improve model fit and robustness, further refining and validation in bigger and more diverse datasets is advised.

CONCLUSION

The factor structure of the instrument is generally aligned with the theoretical construct and is considered acceptable. However, modification or revision of the items in the social support construct is needed, as all three item indicators in this dimension yields factor loadings below the minimum threshold (>0.50). The validity criteria for the dimensions in this study were not met, possibly due to differences in the scope of dimensions between instruments or the instrument items are not able to optimally represent the construct. The findings reveal acceptable psychometric qualities, confirming this instrument as a preliminary version that needs further testing in larger and more diverse groups before clinical or research application. The instrument shows acceptable reliability and partial validity evidence, though criterion validity remains to be confirmed in future research.

AUTHOR'S CONTRIBUTION STATEMENT

AS: conceptualization, writing-original draft, editing, data analysis. SS: methodology, writing-review, data analysis, supervision. S: writing-review, supervision. All authors have approved this manuscript.

CONFLICTS OF INTEREST

The authors declare no conflict of interest.

DECLARATION OF GENERATIVE AI AND AI-ASSISTED TECHNOLOGIES IN THE WRITING PROCESS

The author used AI as a tool for translation, grammar checking, and initial sentence development. The entire content and final wording of the text are the result of manual synthesis, review, and adaptation by the author to ensure compliance with academic standards. Therefore, the content of the text is not entirely dependent on AI results.

SOURCE OF FUNDING STATEMENTS

This study received financial support from the Ministry of Education and Culture of the Republic of Indonesia, through research funding grants No. 0609.12/LL5-INT/AL.04/2024 and No. 113/PTM/LPPM-UAD/VI/2024, administered by Universitas Ahmad Dahlan.

ACKNOWLEDGMENTS

The researchers would like to thank all respondents for their willingness to participate in this study.

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