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Cultural adaptation and validation of the Indonesian version of QUALEFFO-41 in patients with osteoporosis

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Abstract

Background: osteoporosis represents a growing public health concern in Indonesia and contributes substantially to morbidity through pain, functional decline, and vertebral and nonvertebral fractures. Despite the widespread international use of the Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO-41), a fully validated Indonesian version has not previously been available. This study aimed to conduct a rigorous cultural adaptation and psychometric validation of the Indonesian version of the QUALEFFO-41.

Methods: we conducted a cross-sectional study among 204 Indonesian-speaking patients diagnosed with osteoporosis or osteopenia. Cross-cultural adaptation followed the standardized guidelines proposed by Beaton et al., including forward and backward translation, expert panel review, and cognitive debriefing. Psychometric evaluation included internal consistency (Cronbach α), test-retest reliability (intraclass correlation coefficient [ICC]), convergent validity (average variance extracted [AVE] and composite reliability [CR]), and construct validity using confirmatory factor analysis (CFA).

Results: internal consistency was excellent for pain (α = 0.93) and physical function (α = 0.90), acceptable for social function (α = 0.73), moderate for mental function (α = 0.79), and marginal for general health perception (α = 0.65). Test-retest reliability demonstrated good to excellent ICC values across domains (0.66-0.87), with an exceptionally high ICC for the total score (0.999). Convergent validity was satisfactory across all domains (AVE > 0.50; CR > 0.70). CFA showed perfect model fit for general health perception, marginal fit for activities of daily living and household work, and poorer fit for pain, mobility, social function, and mental function.

Conclusions: the Indonesian QUALEFFO-41 demonstrates robust reliability and satisfactory validity, supporting its use as a culturally relevant instrument for assessing quality of life in Indonesian patients with osteoporosis. Although several domains showed suboptimal CFA fit, likely reflecting cultural and linguistic influences, the instrument remains psychometrically sound for clinical practice and research. Further longitudinal and multigroup analyses are recommended to refine the factor structure and evaluate responsiveness across diverse Indonesian populations.

Keywords:
Osteoporosis.
Quality of life.
QUALEFFO-41.
Reliability.
Validation.

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INTRODUCTION

Osteoporosis is a major and growing public health concern in Indonesia. The progressive loss of bone mass and deterioration of bone microarchitecture characteristic of osteoporosis lead to increased bone fragility and fracture risk, imposing substantial clinical, social, and economic burdens. Early Indonesian studies have reported osteoporosis prevalence rates of 28.8 % in men and 32.3 % in women (1). In addition, the prevalence of vertebral fractures among Indonesian women has been estimated at approximately 9 % (2). Given the rapid growth of the aging population and the projected increase in fracture incidence, with predictions that half of all osteoporotic hip fractures will occur in Asia by 2050 (3), the burden of osteoporosis in Indonesia is expected to continue increasing.

Within this context, measuring health-related quality of life (HRQoL) in patients with osteoporosis is critically important. Conventional clinical parameters such as bone mineral density (BMD) and fracture counts capture structural changes but often fail to reflect the broader impact of osteoporosis on pain, functional limitations, social participation, and psychological well-being. Disease-specific patient-reported outcome measures (PROMs) therefore play a crucial role in assessing the subjective burden of osteoporosis, evaluating treatment effects, and monitoring longitudinal changes. However, the use of PROMs in Indonesia has been constrained by the lack of validated, culturally adapted instruments. Although generic HRQoL instruments are available, disease-specific, locally validated measures remain limited in the Indonesian linguistic and cultural context.

One of the most widely used osteoporosis-specific PROMs is the Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO-41). Developed by the European Foundation for Osteoporosis (now the International Osteoporosis Foundation), the QUALEFFO-41 consists of 41 items across five domains: pain, physical function, social function, general health perception, and mental function (4,5). The questionnaire has been translated into numerous languages and has demonstrated clinical utility in populations with vertebral fractures and osteoporosis (6).

A recent systematic review assessing the measurement properties of the QUALEFFO-41 found that the quality of evidence supporting structural validity, reliability, responsiveness, and cross-cultural validity ranged from very low to moderate (6). Despite the availability of a Bahasa Indonesia version in certain instrument repositories, no peer-reviewed publication has documented a complete psychometric validation of the Indonesian QUALEFFO-41, including appropriate translation and adaptation procedures, evaluation of factor structure, reliability testing, construct validity, measurement error, and responsiveness. This methodological gap limits its confidence in the use of the QUALEFFO-41 in clinical practice and research in Indonesia.

Therefore, the aim of the present study was to conduct a comprehensive cultural adaptation and psychometric validation of the QUALEFFO-41 in Bahasa Indonesia for use among Indonesian patients with osteoporosis, with or without vertebral fractures. By adhering to internationally accepted methodological guidelines for cross-cultural adaptation (7) and applying rigorous psychometric evaluation, this study aimed to produce a validated Indonesian QUALEFFO-41 capable of reliably assessing HRQoL among Indonesian patients with osteoporosis.

METHODS

STUDY DESIGN

This cross-sectional study was designed to translate, culturally adapt, and psychometrically validate the Indonesian version of the Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO-41). The study followed the cross-cultural adaptation process recommended by Beaton et al. (2000) and the psychometric evaluation guidelines proposed by Nunnally and Bernstein (1994) and Hair et al. (2019).

PARTICIPANTS

A total of 204 participants diagnosed with osteoporosis or osteopenia were recruited from outpatient clinics and community health centers in Indonesia. Participants were aged 61-77 years and were able to read and understand Indonesian.

INSTRUMENT

The QUALEFFO-41 is a disease-specific quality-of-life questionnaire originally developed by the European Foundation for Osteoporosis to assess health-related quality of life in patients with vertebral fractures and osteoporosis. It comprises 41 items grouped into 5 domains:

1. Pain.
2. Physical function.
3. Social function.
4. Mental function.
5. General health perception.

Each item is scored on a 5-point Likert scale, with higher scores indicating poorer quality of life.

TRANSLATION AND CROSS-CULTURAL ADAPTATION

Translation and cultural adaptation of the QUALEFFO-41 into Indonesian were conducted according to the standard six-step process described by Beaton et al. (7):

1. *Forward translation:* Two independent bilingual translators translated the original English version into Indonesian.
2. *Synthesis:* The 2 translated versions were compared and synthesized into a single reconciled version following discussion among the translators and researchers.
3. *Backward translation:* Two additional translators who were blinded to the original instrument translated the Indonesian version back into English to assess conceptual equivalence.
4. *Expert committee review:* A multidisciplinary committee comprising methodologists, clinicians, and linguists reviewed all versions to evaluate semantic, idiomatic, experiential, and conceptual equivalence and produced a prefinal version.
5. *Pretesting:* The prefinal version was administered to patients to evaluate clarity, relevance, and cultural appropriateness through cognitive debriefing interviews.
6. *Final version:* Minor linguistic adjustments were made based on the feedback received, and the final Indonesian version was approved by the instrument developer, the International Osteoporosis Foundation (IOF).

CROSS-CULTURAL ADAPTATION AND LINGUISTIC VALIDATION

The cross-cultural adaptation of the QUALEFFO-41 questionnaire into Indonesian was conducted in accordance with internationally accepted guidelines for the adaptation of health-related quality-of-life instruments. Two independent bilingual translators whose native language was Indonesian performed forward translations of the original English version into Indonesian. One translator had a medical background, whereas the other had no clinical background, thereby ensuring both conceptual and lay-language equivalence. The 2 translated versions were then synthesized into a single reconciled Indonesian draft following discussion and consensus among the translators and research team. Subsequently, backward translation was performed by 2 independent professional translators who were blinded to the original instrument and had no prior knowledge of the QUALEFFO-41. The purpose of backward translation was to ensure semantic and conceptual equivalence with the original version.

The expert committee evaluated semantic, idiomatic, experiential, and conceptual equivalence and produced the prefinal Indonesian version. Cognitive debriefing (pilot testing) was conducted among patients with osteoporosis to assess clarity, comprehensibility, and cultural relevance. Minor wording adjustments were made based on participant feedback.

During the validation phase, participants completed only the Indonesian version of the QUALEFFO-41 questionnaire. No dual-language administration involving both the English and Indonesian versions was performed, and the same respondents did not complete both language versions. This approach was chosen to reflect real-world clinical use in the Indonesian population.

DATA COLLECTION PROCEDURE

Data were collected in Indonesia. Participants completed the Indonesian QUALEFFO-41 during routine clinical visits, either independently or with minimal assistance from trained research staff. To evaluate test-retest reliability, a subsample of 60 participants completed the questionnaire again after a 2-week interval, during which no clinical changes were expected. Sociodemographic data were also collected. The Indonesian-language version of the Qualeffo-41 questionnaire used in this study is publicly available through the International Osteoporosis Foundation (IOF) and can be accessed at: Indonesian version of the Qualeffo-41 questionnaire (https://www.osteoporosis.foundation/sites/iofbonehealth/files/2021-10/IOF-Qualeffo41-questionnaire-Indonesian.pdf).

STATISTICAL ANALYSIS

Psychometric analyses were conducted to assess the reliability and validity of the Indonesian QUALEFFO-41. Statistical analyses were performed using IBM SPSS Statistics, version 26.0; SmartPLS, version 4.0; and AMOS, version 24.0.

RELIABILITY

Internal consistency reliability was assessed using Cronbach α. Coefficients of $\alpha \geq 0.70$ were considered acceptable, $\alpha \geq 0.80$ were considered good, and $\alpha \geq 0.90$ were considered excellent. Test-retest reliability was assessed using the intraclass correlation coefficient (ICC) based on a 2-way mixed-effects model with absolute agreement. ICC values ≥ 0.75 indicated good reliability, whereas values ≥ 0.90 indicated excellent reliability.

CONVERGENT VALIDITY

Convergent validity was evaluated using factor loadings, average variance extracted (AVE), and composite reliability (CR). Values of AVE ≥ 0.50 and CR ≥ 0.70 were considered satisfactory evidence of convergent validity.

CONSTRUCT VALIDITY

Construct validity was examined using confirmatory factor analysis (CFA) with maximum likelihood estimation in AMOS. Model fit was assessed using χ^2/df, comparative fit index (CFI), Tucker-Lewis index (TLI), goodness-of-fit index (GFI), adjusted goodness-of-fit index (AGFI), and root mean square error of approximation (RMSEA). Model fit was considered acceptable when χ^2/df < 3.0, CFI and TLI ≥ 0.90, GFI ≥ 0.85, and RMSEA ≤ 0.08.

RESULTS

SOCIODEMOGRAPHIC AND CLINICAL CHARACTERISTICS OF PARTICIPANTS (TABLE I)

Table I. Sociodemographic and clinical characteristics of the participants

Characteristic	Category	Frequency (*n*)	Percentage (%)
Participant group	Prevalidation study	50	24.5
	Control	88	43.1
	Case	66	32.4
Current age (years)	60-64	13	6.4
	65-69	112	54.9
	70-74	57	27.9
	≥ 75	22	10.8
Age at osteoporosis onset (years)	≤ 59	7	3.4
	60-62	89	43.7
	63-65	81	39.7
	≥ 66	27	13.2
Body mass index (kg/m^2)	< 18.5 (underweight)	0	0.0
	18.5-22.9 (normal weight)	98	48.0
	23.0-24.9 (overweight)	77	37.7
	≥ 25 (obesity)	29	14.2
Educational level	No formal education	42	20.6
	Primary education	43	21.1
	Secondary education	71	34.8
	Tertiary education	48	23.5
Marital status	Married	98	48.0
	Widowed	106	52.0
Employment status	Employed	39	19.1
	Retired	165	80.9

RESULTS OF THE TRANSLATION AND ADAPTATION OF THE QUALEFFO-41 QUESTIONNAIRE INTO INDONESIAN

General information

The original QUALEFFO-41 (Quality of Life Questionnaire, 1997) was translated, culturally adapted, and validated into Indonesian by Z. N. and P. W. N. The translation was acknowledged and approved by the International Osteoporosis Foundation (IOF) on June 16, 2019.

Structure of the questionnaire

The Indonesian version of the QUALEFFO-41 comprises 41 items divided into 5 domains, identical to those of the original version. The pain domain includes 5 items assessing the frequency, duration, and intensity of back pain. The physical function domain is divided into three subdomains. The activities of daily living subdomain comprises 4 items evaluating respondents' ability to dress, bathe, use the toilet, and maintain sleep quality. The household work subdomain contains 5 items covering activities such as cleaning, cooking, washing dishes, shopping, and lifting objects. The mobility subdomain includes 8 items assessing the ability to stand, bend, climb stairs, walk, and maintain posture. The social function domain consists of 7 items assessing respondents' participation in hobbies, sports activities, visits to cinemas or theaters, and other social activities. The general health perception domain includes 3 items reflecting respondents' perceptions of their overall health and quality of life, whereas the mental function domain comprises 9 items assessing fatigue, hopelessness, loneliness, mood, and optimism.

Translation and cultural adaptation

The translation process emphasized semantic, idiomatic, experiential, and conceptual equivalence with the original instrument. Several linguistic and cultural adaptations were made to ensure clarity and relevance for respondents. Lexical adjustments and simplifications were introduced to improve readability, whereas unfamiliar or technical terms were replaced with more readily understood expressions. Cultural adaptations were made for items that might not fully correspond to the local context, such as activities involving cinema or theater attendance. Clarifying examples were added to improve comprehension, particularly for items involving specific weights or tasks. Semantic refinement was also undertaken to preserve the intended

psychological meaning of key terms, ensuring that the translated items accurately reflected the constructs assessed by the source version.

Scoring and interpretation

All response options were standardized according to the IOF scoring algorithm (2017):

1. Most items are rated from 1 (best quality of life) to 5 (worst quality of life).
2. Items 33, 34, 35, 37, 39, and 40 are reverse scored.
3. Domain scores are calculated as the mean of all items in the domain and then converted to a 0-100 scale.
4. If > 30 % of items are unanswered, the result is considered invalid.

Validation notes

1. The translation incorporated the official IOF scoring and conversion algorithm, ensuring methodological consistency.
2. The Indonesian version retains the original structure and psychometric intent while ensuring linguistic and cultural equivalence.
3. Official authorization was obtained from the International Osteoporosis Foundation, confirming approval of the adaptation.

The Indonesian version of the QUALEFFO-41 demonstrates semantic and conceptual equivalence with the original English instrument, with minor linguistic simplifications and contextual adjustments to accommodate Indonesian cultural norms. This version is suitable for assessing quality of life among Indonesian-speaking patients with osteoporosis.

Table II presents the internal consistency reliability of each domain as measured using Cronbach α. The pain domain, comprising 5 items, demonstrated excellent reliability (α = 0.930). The physical function domain, comprising 17 items, also showed a high level of reliability (α = 0.902). The social function domain demonstrated acceptable reliability (α = 0.725). The general health perception domain demonstrated marginal reliability (α = 0.653), indicating lower internal consistency than the other domains. The mental function domain demonstrated moderate reliability (α = 0.794). Overall, most domains demonstrated satisfactory internal consistency.

Test-retest reliability was assessed using the intraclass correlation coefficient (ICC) over a 14-day interval in a subsample of 60 participants. The pain domain showed good temporal stability (ICC, 0.8378), and the physical function domain also demonstrated good reliability (ICC, 0.8510). The social function domain

Table II. Integrated analysis of internal consistency, test–retest reliability, and construct validity across questionnaire domains

Domain			No. of items	Cronbach's Alpha (α)	Alpha interpretation	*n* (test-retest)	Time interval	ICC	ICC interpretation	AVE	CR	Validity interpretation
Pain			5	0.930	Highly reliable	60	14 days	0.8378	Good	0.721	0.928	Valid
Physical function	Activities of daily living		4	0.902	Highly reliable	60	14 days	N/A	N/A	0.831	0.980	Valid
		Household work	5					0.8510	Good			
		Mobility	8					N/A	N/A			
Social function			7	0.725	Acceptably reliable	60	14 days	0.6604	Moderate	0.584	0.787	Valid
General health perceived			3	0.653	Marginally reliable	60	14 days	0.7572	Good	0.695	0.830	Valid
Mental function			9	0.794	Moderately reliable	60	14 days	0.8664	Excellent	0.716	0.907	Valid
Total score			-	-	-	60	14 days	0.9994	Excellent	-	-	-

Note: Percentages are calculated based on valid responses (n = *204*).

showed moderate reliability (ICC, 0.6604). General health perception demonstrated good reliability (ICC, 0.7572), whereas the mental function domain showed excellent test-retest reliability (ICC, 0.8664). In addition, the total score exhibited an exceptionally high ICC of 0.9994, indicating nearly perfect temporal stability. The Bland-Altman plot used to assess agreement between the initial test and retest measurements and to provide an overview of agreement for the total QUALEFFO-41 score is shown in figure 1.

Convergent validity was assessed for each domain using average variance extracted (AVE) and composite reliability (CR). All domains met the conventional criteria for convergent validity, with AVE values > 0.50 and CR values > 0.70. Specifically, the pain domain demonstrated strong convergent validity (AVE, 0.721; CR, 0.928). Social function (AVE, 0.584; CR, 0.787), general health perception (AVE, 0.695; CR, 0.830), mental function (AVE, 0.716; CR, 0.907), and physical function (AVE, 0.831; CR, 0.980) also demonstrated satisfacto-

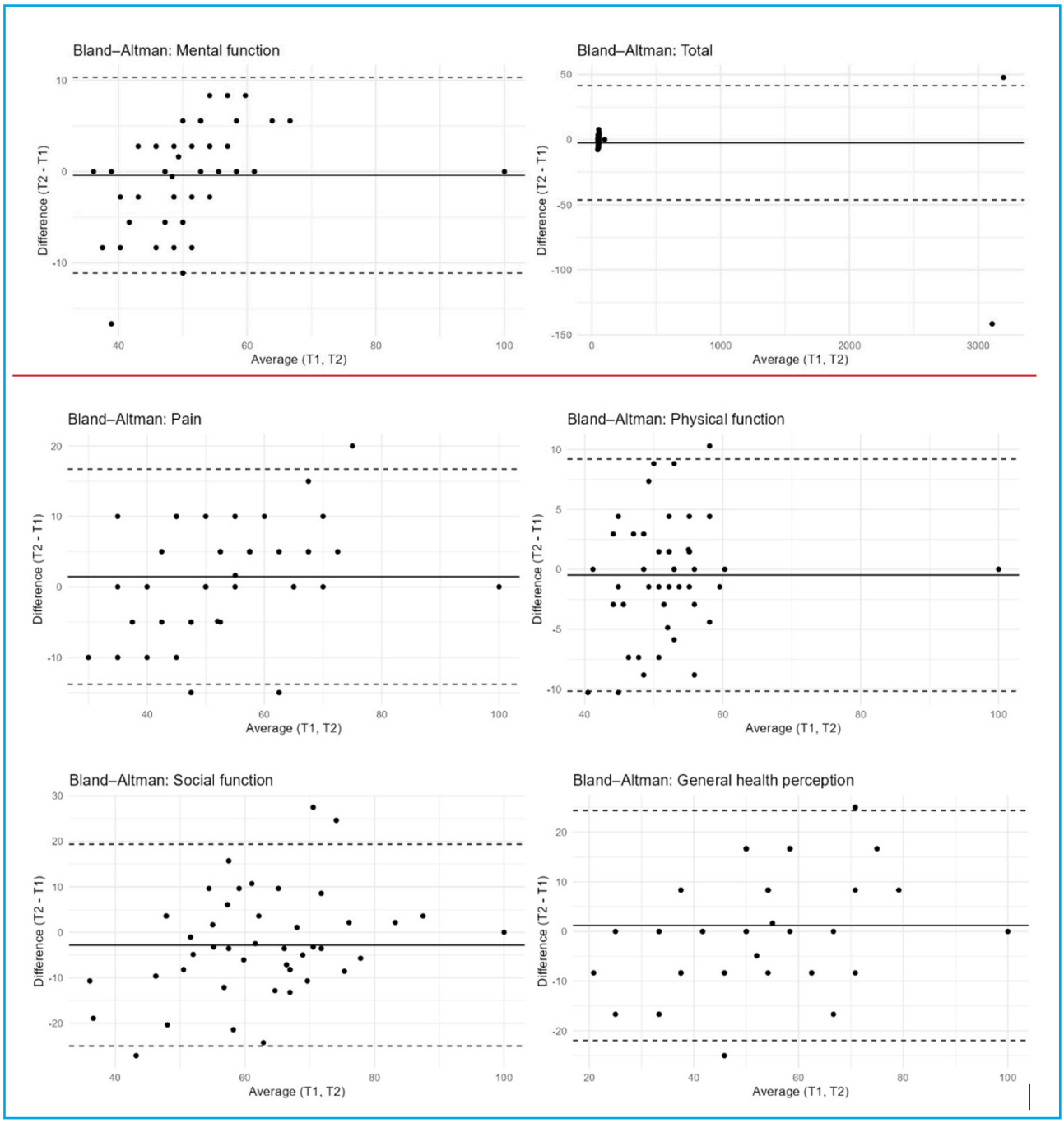

Figure 1. Bland-Altman plot for QUALEFFO-41 scores.

ry convergent validity. These results indicate that the items within each domain adequately represent their respective latent constructs.

Table III presents the results of the confirmatory factor analysis (CFA) for each construct. The pain construct showed poor model fit based on indices such as the goodness-of-fit index (GFI), adjusted goodness-of-fit index (AGFI), comparative fit index (CFI), Tucker-Lewis index (TLI), and root mean square error of approximation (RMSEA). Within the physical function domain, the activities of daily living (ADL) and household work subconstructs demonstrated marginal fit, whereas mobility showed poor fit across all indices. The social function and mental function constructs also showed poor fit, suggesting substantial deviations from the assumptions of the proposed measurement model. In contrast, the general health perception construct exhibited perfect fit, indicating complete agreement between the measurement model and the observed data. Overall, the CFA results demonstrate variability in construct validity across domains, with some domains requiring further refinement. A structural equation modeling (SEM) path diagram depicting the relationships between latent constructs and the contribution of each indicator to the overall model is shown in figure 2. This diagram provides a visual representation of the direction and strength of the structural relationships examined in the study. A CFA model of the QUALEFFO-41 latent construct, showing the factor loading of each item and the fit of the model to the theoretical structure, is shown in figure 3. Together, these complementary figures support interpretation of the psychometric findings discussed below.

DISCUSSION

The validation results for the Indonesian version of the QUALEFFO-41 in this study demonstrate an overall satisfactory psychometric profile. The high internal consistency observed in domains such as pain (α = 0.93) and physical function (α = 0.90) indicates that the items within these domains are highly cohesive and consistently measure the intended constructs. This finding is consistent with the Korean adaptation, in which Cronbach α values for the QUALEFFO-41 ranged from 0.733 to 0.942, indicating adequate reliability in the Korean population (8).

Although internal consistency was strong in several domains, the CFA results showed that not all domains conformed closely to the original factor structure. The general health perception domain demonstrated very good model fit, whereas pain, social function, mobility, and mental function showed poor to marginal fit based on indices such as CFI, TLI, and RMSEA. This finding indicates that, although the items may be internally consistent, the theoretically proposed latent structure may not fully correspond to the pattern observed among Indonesian respondents. The discrepancy between high internal consistency and suboptimal CFA fit can be explained by the fact that Cronbach α assesses item homogeneity, whereas CFI, TLI, and RMSEA assess how well the hypothesized factor structure corresponds to the empirical data. In other words, items may correlate strongly with one another without necessarily fitting a proposed unidimensional structure. A similar issue was reported in a recent systematic review, which found relatively strong evidence for construct validity but limitations in cross-cultural validity and factor structure (6).

Cross-cultural comparisons are particularly relevant when interpreting these findings. For example, in the Hebrew-language adaptation for postmenopausal women in Israel, the QUALEFFO-41 demonstrated good internal consistency (α = 0.88) and adequate construct validity, although several domains, particularly cognitive/mental and social domains, required refinement to improve their relevance within the Israeli sociocultural context (9). Similarly, the Serbian adaptation of the QUALEFFO-41 showed challenges related to translation and cultural adaptation despite the use of methodologically rigorous forward-backward translation procedures (10). In Malaysia, the Malay version of the QUALEFFO-41 demonstrated good internal consistency (0.752-0.925), although the social activity do-

Table III. Construct validity (Confirmatory Factor Analysis - CFA)

Construct		χ^2/df	GFI	AGFI	CFI	TLI	RMSEA	RMR	Fit conclusion
Pain		32.13	0.771	0.314	0.840	0.680	0.392	0.083	Poor fit
Physical function	Activities of daily living	8.19	0.963	0.815	0.969	0.906	0.188	0.059	Marginal fit
	Household work	7.49	0.941	0.822	0.935	0.871	0.179	0.101	Marginal fit
	Mobility	11.00	0.783	0.609	0.693	0.570	0.222	0.222	Poor fit
Social function		11.236	0.821	0.642	0.662	0.493	0.225	0.173	Poor fit
General health perceived		–	1.000	–	1.000	–	–	0.000	Perfect fit
Mental function		34.434	0.585	0.308	0.462	0.283	0.406	0.242	Poor fit

Source: Authors' primary data (2025).

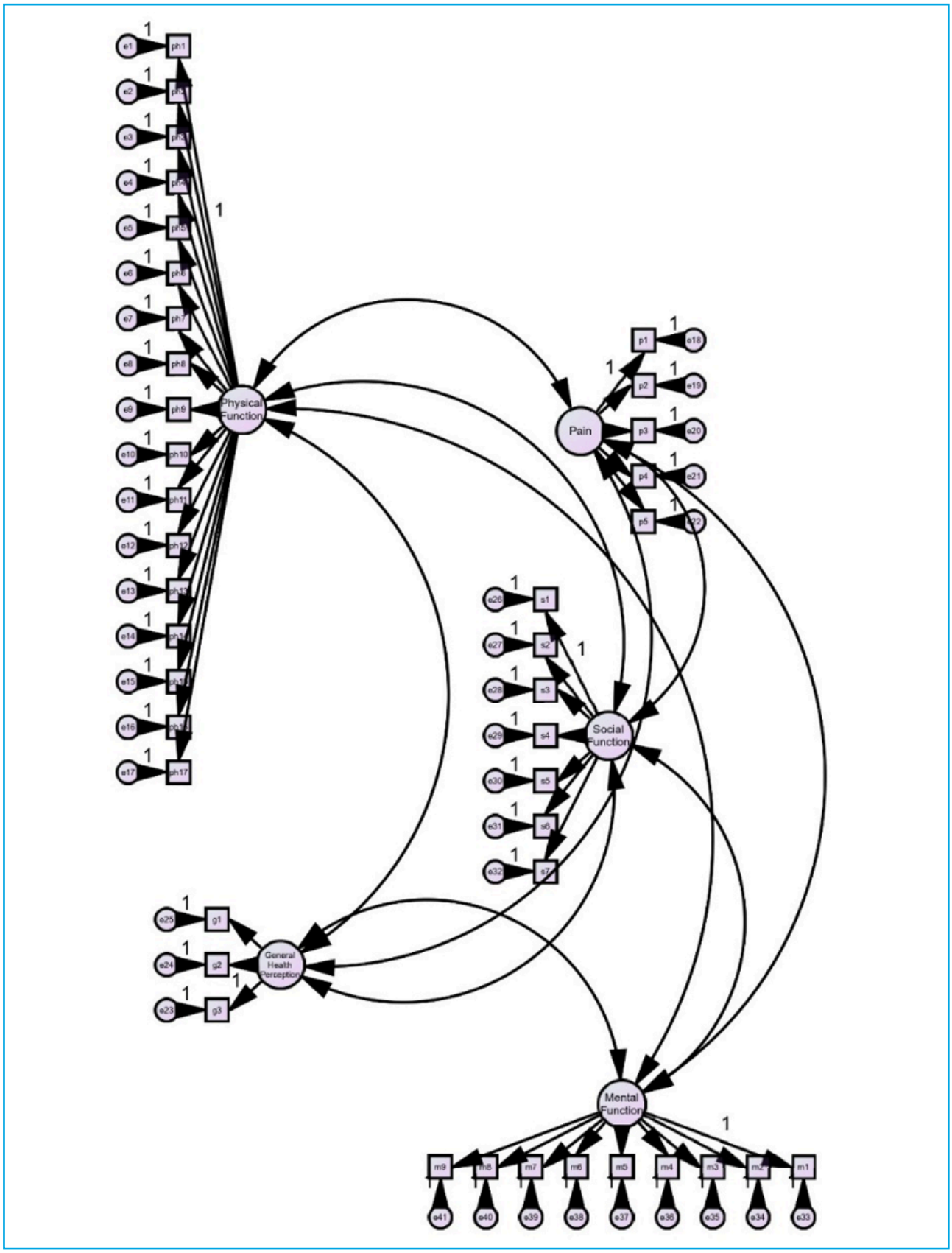

Figure 2. Structural equation modeling (SEM) path diagram.

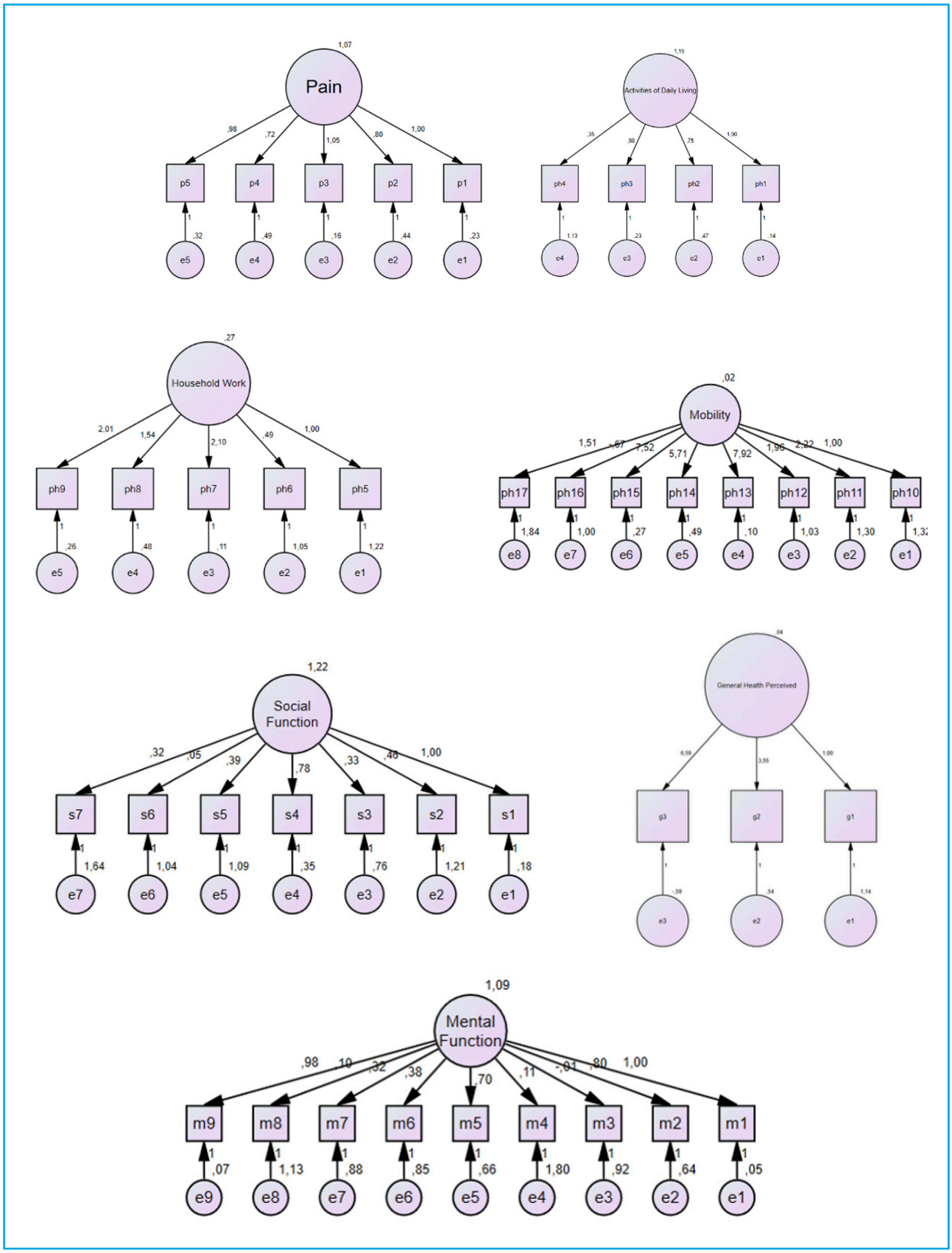

Figure 3. Confirmatory factor analysis (CFA) model for the QUALEFFO-41 latent construct.

main had a lower α value (0.692), possibly reflecting differences in the perception of social activity within the Malay cultural context (11).

Cultural and linguistic factors are likely to be major contributors to these differences. For example, the interpretation of household tasks in Indonesia may differ substantially from that in European or other Western contexts because Indonesian households often distribute such tasks among extended family members. This may lead respondents to rate the burden of household activities differently from how it was conceptualized in the original QUALEFFO framework. In addition, expressions related to "social function" and "mental function" may have different connotations in Indonesian; idiomatic expressions, emotional communication, and social roles, including family roles and social support, are strongly influenced by local cultural values. Linguistic adaptation that does not adequately account for these nuances may result in item cross-loading or high error covariance, which can adversely affect CFA model fit.

The high reliability and satisfactory convergent validity, including adequate AVE and composite reliability values across the major domains, indicate that the Indonesian version of the QUALEFFO-41 remains a useful disease-specific quality-of-life instrument for the Indonesian population with osteoporosis. Good internal consistency indicates coherent response patterns within domains, whereas convergent validity suggests that the items adequately reflect the constructs they are intended to measure. Collectively, these findings support the use of the Indonesian QUALEFFO-41 in clinical research, epidemiological surveys, and outcome monitoring in patients with osteoporosis in Indonesia.

The importance of the Indonesian version of the QUALEFFO-41 lies in its role as a locally adapted and validated instrument. It allows a more sensitive and contextually appropriate assessment of quality of life than generic instruments such as the EQ-5D in an Indonesian population that may differ in its perceptions of pain, mobility, social activities, and mental health. This provides practical benefits for clinical practice, including rehabilitation management and therapeutic interventions; research, including evaluation of treatment and rehabilitation effects; and health policy, such as assessment of the burden of osteoporosis-related impairment in quality of life in developing countries.

This study reinforces the view that health-related quality of life (HRQoL) is a critical clinical outcome in the management of osteoporosis, particularly among patients with vertebral fractures. Osteoporosis should not be conceptualized solely as a reduction in bone mineral density (BMD), but rather as a chronic, multifactorial condition with substantial physical, psychological, and social consequences. From a global epidemiological perspective, osteoporotic fractures represent a substantial and growing public health burden, particularly in aging populations (12). Vertebral fractures, although frequently underdiagnosed, are associated with chronic back pain, progressive kyphotic deformity, impaired mobility, reduced pulmonary function, and increased risk of falls. Collectively, these sequelae contribute to long-term deterioration in HRQoL that may not be adequately captured by radiological findings or densitometric parameters alone (13).

The development of the Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO) represented a paradigm shift in osteoporosis outcome assessment by emphasizing patient-reported outcomes (4). Unlike generic instruments, the QUALEFFO was specifically designed to detect the multidimensional impact of vertebral fractures, including pain severity, physical functioning, social participation, mental health, and general health perception. Subsequent validation studies confirmed its internal consistency, construct validity, and discriminative ability in distinguishing patients with and without vertebral fractures (14). The shortened version, QUALEFFO-41, further improved feasibility in clinical and research settings without compromising psychometric robustness.

Former studies have consistently demonstrated that vertebral fractures are a major determinant of impaired HRQoL. Oleksik et al. (15) reported that postmenopausal women with low BMD and prevalent vertebral fractures experienced significantly poorer HRQoL than women without fractures. Similarly, Jahelka et al. (16) found that patients with osteopenia or osteoporosis without fractures had relatively preserved quality of life compared with patients with fractures. These findings suggest that vertebral fracture represents an important clinical turning point in the course of osteoporosis and underscore the importance of fracture prevention strategies.

Disease-specific instruments such as the QUALEFFO demonstrate greater sensitivity than generic measures for detecting clinically meaningful differences and changes after treatment. Badia et al. (17) showed that the QUALEFFO had strong discriminative ability in women with vertebral fractures when compared with the Osteoporosis Quality of Life Questionnaire (OQLQ). Furthermore, Yilmaz et al. (18) demonstrated that disease-specific instruments had higher responsiveness indices than generic instruments when evaluating therapeutic interventions. This is particularly relevant in clinical trials assessing pharmacological treatments, physical rehabilitation, or combined interventions.

The association between HRQoL and functional parameters further strengthens the clinical relevance of disease-specific assessment. Bergland, Thorsen, and Kåresen (19) demonstrated significant correlations between HRQoL scores and measures of mobility and balance among women with osteoporosis and vertebral fractures. Spinal deformity and chronic pain not only impair physical performance but also increase the risk of falls, creating a vicious cycle of disability and further fracture risk. Therefore, integrating HRQoL assessment with functional mobility evaluation provides a more comprehensive framework for patient-centered osteoporosis management.

Moreover, rehabilitation guidelines emphasize the importance of monitoring quality of life as part of therapeutic evaluation (20). Treatment success should not be restricted to improvements in BMD but should also encompass functional recovery and psychosocial well-being. This reinforces the clinical utility of the QUALEFFO beyond research settings and supports its use as a valuable decision-support tool in routine care. HRQoL in osteoporosis is inherently multidimensional. Physical domains, particularly pain and activity limitation, often exert the greatest influence on total scores; however, psychological and social domains also contribute substantially to overall health perception (14,15). Chronic pain, fear of falling, reduced autonomy, and social withdrawal collectively shape the lived experience of osteoporosis. Consequently, a biopsychosocial framework is essential when interpreting HRQoL outcomes.

Several limitations should be acknowledged. First, the study sample may have been predominantly female, limiting the generalizability of the findings to men with osteoporosis. Sex-related differences in social roles, household responsibilities, and pain perception may produce different response patterns. Second, the cross-sectional design precludes assessment of changes in quality of life over time and causal inference. Third, although test-retest reliability was assessed, long-term temporal stability over months or years and measurement invariance across subpopulations, including age, sex, and geographic region, were not evaluated. Without measurement invariance analyses, it is difficult to determine whether the QUALEFFO-41 factor structure remains consistent across different segments of the Indonesian population. Subgroup analyses according to T-score severity and fracture type were not performed because of limited statistical power. Future studies with larger samples are warranted to assess the discriminative ability of the Indonesian QUALEFFO-41 across clinical severity groups.

Recommendations for future research include the following: (1) conducting item-level analyses, such as item response theory or communality analyses, to identify problematic items, including cross-loading, redundant, or culturally irrelevant items; (2) conducting cognitive interviews with respondents from diverse cultural and social backgrounds to ensure that item meaning is understood as intended; (3) considering modifications to the factor structure, including potential division of domains or subscales, based on local empirical data and cultural theory; (4) conducting multigroup CFA to assess measurement invariance across sex, geographic region, and age groups; and (5) implementing longitudinal studies to evaluate responsiveness to change and temporal stability of the Indonesian QUALEFFO-41.

Overall, although not all domains demonstrated optimal model fit in CFA, the strengths in internal consistency and convergent validity support the Indonesian version of the QUALEFFO-41 as a valuable, relevant, and contextually appropriate instrument for assessing quality of life in Indonesian patients with osteoporosis. Further adaptation and validation studies will help strengthen its utility in clinical research, population-based studies, and osteoporosis management interventions in Indonesia.

CONCLUSIONS

This study demonstrates that the Indonesian version of the QUALEFFO-41 is a valid and reliable instrument for assessing health-related quality of life in patients with osteoporosis, with satisfactory internal consistency across domains and evidence supporting several aspects of its construct validity. Although some CFA domains showed suboptimal model fit, the overall psychometric findings support use of the instrument within the Indonesian cultural context. Careful linguistic and cultural adaptation helped ensure that the instrument captures patients' lived experiences more appropriately than nonlocalized measures. The study is limited by its cross-sectional design, predominantly female sample, and absence of long-term longitudinal evaluation. Future research should assess longitudinal responsiveness, measurement invariance, and applicability across more diverse populations with osteoporosis.

AUTHORS' CONTRIBUTIONS

P. W. N. conceptualized the study, coordinated data collection, and performed the statistical analyses. Z. N. supervised the overall study design, provided methodological oversight, contributed to data interpretation, and critically revised the manuscript for important intellectual content. Both authors have read and approved the final version of the manuscript and are accountable for the accuracy and integrity of the work.

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