Quality of Life in High-Risk Pregnancies: A Scale Development Study

Güleser Ada, PhD; Nazlı Ünlü Bıdık, PhD; Kevser İlçioğlu, PhD

Background and Objectives: The care process is crucial in improving quality of life and providing comfort during a high-risk pregnancy. This study aims to develop a "Quality of Life Scale in High-Risk Pregnancies" in order to identify the areas most affecting the quality of life of these women and to guide steps for improving their quality of life. **Methods**: This methodological study, a scale development study, was conducted in 3 stages. First, a draft scale was created with a 5-point Likert-type item pool consisting of 22 items, prepared in line with the literature. The items were then sent to 11 experts in the field for evaluation of their semantics and content. Following their feedback, 1 item was removed, and the scale items were finalized. After conducting factor and reliability analyses, with data from 210 pregnant women diagnosed with high-risk pregnancies, the scale was refined to 16 items. Data were collected face-to-face through a questionnaire developed by the researchers. **Results**: A total of 210 women with high-risk pregnancies, with a mean age of 29.41 ± 5.18 years, participated in the study. One item was excluded from the analysis based on expert opinion, and 5 items were removed during factor analysis because they overlapped, fell outside the theoretical dimensions, and had factor loadings below 0.30. The developed scale was determined to consist of 16 items and 3 sub-dimensions. The Cronbach's alpha internal reliability coefficient for the scale was 0.860, and the reliability coefficients for the sub-dimensions ranged from 0.817 to 0.844, indicating relatively high reliability. **Conclusion**: This study demonstrates that the Quality of Life Scale in High-Risk Pregnancies is a valid and reliable measurement tool. This scale, which can assist healthcare professionals in assessing the quality of life in high-risk pregnancies, can also be adapted to different cultures.

Key words: high-risk pregnancy**,** quality of life**,** scale development

Pregnancy is a joyful, exciting, and uncertain period for women and their families.[1,2] If an obstetric complication that threatens the life of the woman or fetus unexpectedly occurs during this period, the pregnancy is considered "high-risk."[3] For a woman diagnosed with a high-risk pregnancy and her family, this process becomes critical and concerning.[4] The woman may be negatively affected physically, psychologically, socially, and economically during this process.[5] In high-risk pregnancies with a high likelihood of maternal-neonatal death and disability, detecting risks at the earliest stage and providing appropriate healthcare services are crucial for the healthy continuation of both the pregnancy and the post-pregnancy period.[6]

Women with high-risk pregnancies are at an increased risk of depression and stress due to various factors, such as frequent antenatal follow-ups, hospitalization, intensive care needs, and separation from family.[6,7] In addition, they are likely to experience emotions such as fear, anxiety, restlessness, and anger, which can negatively affect their mood.[3,8,9] During this period, it is crucial to adopt woman-centered care, collaborate with health professionals, women, and their families in the treatment process, and make joint decisions.[1,10]

The World Health Organization (WHO) defines the quality of life as *"the individual's perception of his or her position in life in the context of the culture and value systems in which he or she lives, and in relation to his or her goals, expectations, standards, and concerns."*[11] The physical and psychological changes brought about by pregnancy are likely to positively or negatively affect a woman's perceptions of her position in life.[5] Pregnancy-specific diseases and disorders, such as gestational diabetes mellitus, hypertensive disorders, hyperemesis gravidarum, epigastric pain, and lumbopelvic pain[5,12-15] can continue to negatively affect women during the delivery and postpartum periods, further reducing their quality of life by introducing additional risks.[16] In addition to health problems, lifestyle changes and pharmacological treatments during pregnancy can also negatively affect women's quality of life.[5,13,17] Furthermore, sexuality during pregnancy is often limited due to sexual prejudices, such as the

Author Affiliations: *Bartin University, Faculty of Health Sciences, Department of Midwifery, Bartin, Turkey (Dr Ada); Sakarya University, Faculty of Health Sciences, Department of Midwifery, Sakarya, Turkey (Dr Ünlü Bıdık); and Sakarya University, Faculty of Health Sciences, Department of Gynecology and Obstetrics Nursing, Sakarya, Turkey (Dr İlçioğlu).*

Correspondence: *Güleser Ada, PhD, Bartin University, Faculty of Health Sciences, Department of Midwifery, Bartin, Turkey (Turkey.gada@bartin.edu.tr).*

The authors have no employment, financial, non-financial, or other competing interests to declare.

Q Manage Health Care
Vol. XX, No. XXX, pp. 1–9

DOI: 10.1097/QMH.0000000000000533

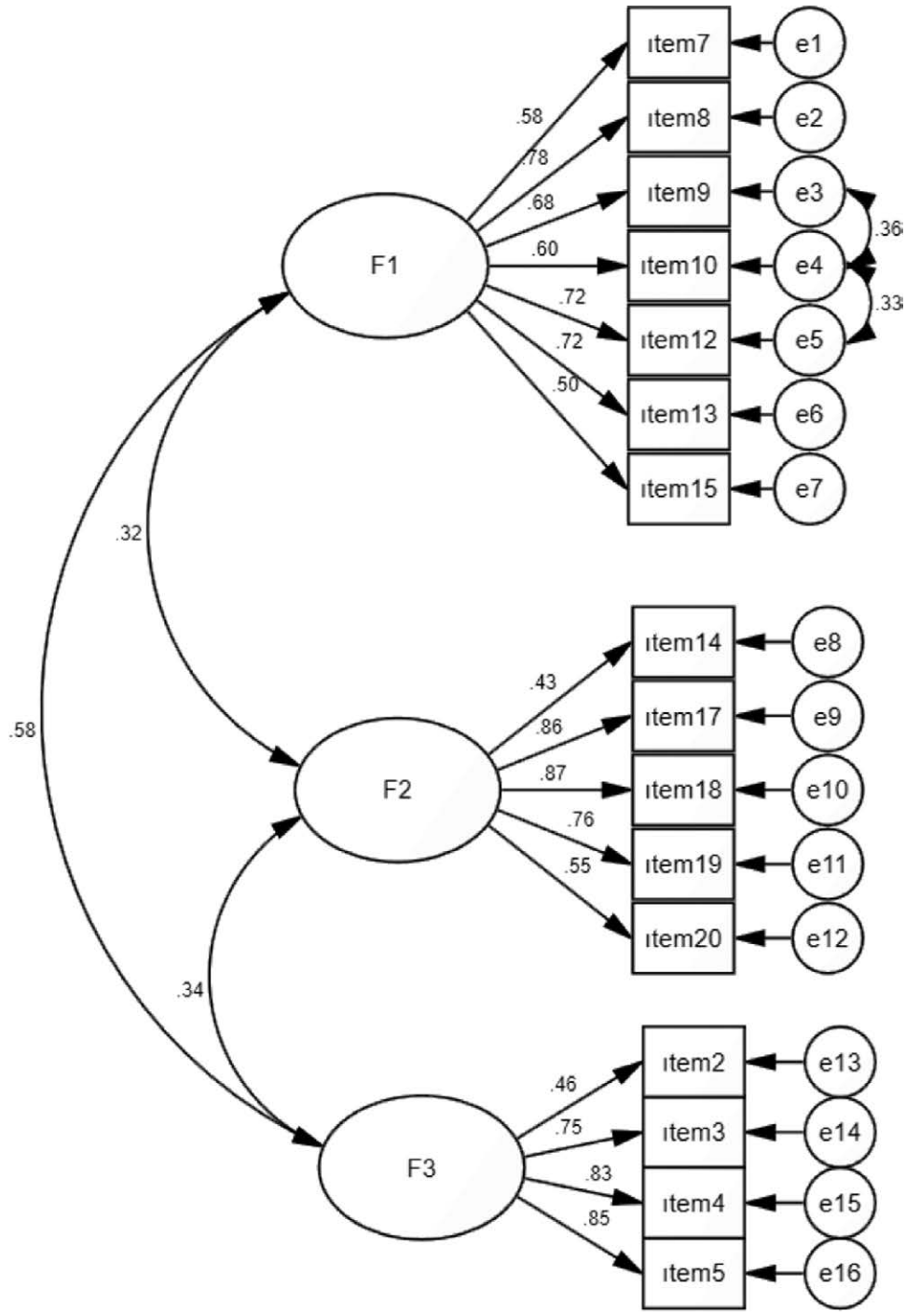

Figure. First level multifactor model confirmatory factor analysis of quality of life scale in risky pregnancies.

belief that it is dangerous and morally inappropriate.[18] This negatively impacts women's quality of life concerning sexuality during pregnancy.[19]

The care process is crucial in improving the quality of life and providing comfort in high-risk pregnancies. Providing comfort is an essential component of quality care. According to Kolcaba's Comfort Theory, comfort is addressed through physical, environmental, psychospiritual, and sociocultural dimensions.[20] It is expected that evaluating the specified dimensions and providing care services accordingly will increase individuals' quality of life and comfort.

In a study examining the relationship between health problems during pregnancy and quality of life, it was found that pregnancy brings many challenges, including psychological issues, that negatively affect quality of life. Further studies were recommended to measure quality of life more accurately.[21] A systematic review also noted the need for a specific scale to measure the quality of life of women with different

conditions during pregnancy and the postpartum period.[22]

Although the validity of instruments measuring the quality of life has been tested in previous studies, no instrument specifically designed to measure the quality of life of women during pregnancy and the postpartum period has been found. Therefore, there is a need for a scale that evaluates the quality of life of women during the high-risk pregnancy process. It is believed that developing a quality of life scale for high-risk pregnancies, in line with the comfort theory, will help identify the areas where women's quality of life is most affected and guide efforts to improve it.

Psychological, functional and social factors are important components that affect the quality of life.[23] The developed scale focuses on physical and psychological difficulties experienced during the risky pregnancy process as well as social support and communication problems. The scale items are grouped under the relevant factors and have the ability to measure and evaluate the physical, psychological, social, and communication quality of risky pregnant women.

This study aims to develop a scale with tested validity and reliability to assess the quality of life specific to high-risk pregnancies.

METHODS

Study design

This study is a methodological type of study.

Study procedure. The methodological study was conducted in 3 stages.

Phase 1: Evaluation of the content clarity and validity (item generation and selection). The scale was developed following the stages determined by DeVellis (2021).[24] Accordingly, as a first step, the characteristics of the concept to be measured were determined with the help of field experts and literature sources. Then, a draft form of 22 items, using a 5-point Likert scale, was prepared. The first draft of the scale was sent to 11 experts, including midwifery and nursing academics with expertise in scale development, for semantic and content evaluation. The experts were asked to evaluate the degree of measurement of each item on the scale (1: should be removed, 2: appropriate but should be corrected, or 3: appropriate) on a 1 to 3 point scale. At the end of the evaluations, items regarding language and expression were revised. In the statistical analysis, one item was removed, reducing the total number of items to 21. Expert opinions were evaluated by Kendall's W concordance analysis (number of experts: 11, Kendall's W: 0.247, $P > .05$).

The items, as determined by expert opinion, were applied to 10 women diagnosed with high-risk pregnancies, and the women were asked to mark the items they had difficulty understanding. Since no edits were made during this trial study, the number of items was not changed.

Phase 2: Selection of the population and sample for the implementation of the draft scale. Data were collected at Bartın Maternity and Children's Hospital, Obstetrics and Gynecology Department, between 13.10.2022 and 20.01.2023, using the face-to-face interview technique in 20 to 25 minutes.

Pregnant women who came to the hospital for follow-up were invited to the study by the principal investigator while waiting in line for the doctor's examination. One-on-one interviews were started with pregnant women who met the research criteria and agreed to participate in the study at a convenient time in an empty room of the outpatient clinic. The purpose of the study was first explained to the pregnant women, informed consent signatures were obtained and the interview was continued with research questions. There are different opinions in the literature regarding scale adaptation studies.[25] One of the most widely accepted methods is to calculate the sample size by taking at least 5 or 10 times the number of items in the scale (Tavşancıl, 2023; Özdemir & Buzlu, 2020). In this study, the sample consisted of 210 participants, which is 10 times the number of items in the 21-item scale. The inclusion criteria were women over the age of 18 with a diagnosis of high-risk pregnancy, while women who did not voluntarily participate in the study were excluded. In addition, the data of 19 pregnant women whose interviews were interrupted for any reason (the pregnant woman's turn to be examined, the pregnant woman not feeling well, the arrival of a third person in the room, etc) were not included in the study.

Phase 3: Scale construct validity and reliability (item reduction and investigation of factor structure).

Evaluation of the items

The most crucial step after creating the item pool is the evaluation of these items. At this stage, the items included in the scale are expected to correlate highly with each other.[26] Exploratory and confirmatory factor analyses were conducted for the scale's construct validity, and Cronbach's alpha internal consistency analysis was conducted for reliability.

Construct validity: Factor analysis can be used to find clues about the construct validity of the scale. The Kaiser-Meyer-Olkin (KMO) Sample Suitability Test and Bartlett's Sphericity Test, showing the correlation of the items with each other, were performed to determine the suitability of the data for factor analysis. After determining suitability, Exploratory Factor Analysis and Confirmatory Factor Analysis were conducted using Varimax rotation methods to test construct validity.

Reliability analysis: Cronbach's alpha reliability coefficient was calculated to assess the scale's internal consistency.

Data analysis

The data obtained were analyzed using SPSS (Statistical Package for Social Sciences) for Windows 25.0 and AMOS 24 software.[27,28] Reliability analysis tests whether

Table 1. Distribution of Participants in the Study According to Their Obstetric Characteristics

Variables		n	%
Number of pregnancies	1	69	32.9
	2	63	30.0
	3 and above	78	37.2
Risky pregnancy diagnosis	Hypertension	60	28.6
	Gestational diabetes mellitus	49	23.3
	Threat of premature birth	13	6.2
	Abortion	37	17.6
	Over 35 years old	20	9.5
	Other [a]	29	14.9
Last type of birth	I did not give birth	89	42.4
	Vaginal birth	71	33.8
	Cesarean section	50	23.8
Feeling ready for motherhood	Yes	108	51.4
	No	25	11.9
	Partially	77	36.7

[a]Multiple pregnancy (8), consanguineous marriage (2), vulvar and vaginal candidiasis (1), Rh incompatibility (8), cervical insufficiency (5), oligohydramnios (2), hyperemesis gravidarum (1), intrauterine growth retardation (3).

the items in the scale are consistent with each other and whether all items measure the same subject.[29] For the tests and results to be reliable, the measurements must be reliable. In addition, exploratory factor analysis and confirmatory analysis were performed to determine the scale's construct validity. The discriminative power of the items was examined with 27% sub-item analysis. The following fit indices were used: Comparative Fit Index ($0.90 \leq CFI \leq 0.95$), Goodness of Fit Index ($0.90 \leq GFI \leq 0.95$), Incremental Fit Index ($0.90 \leq IFI \leq 0.95$), Standardized Root Mean Square Residual ($0.05 \leq SRMR \leq 0.10$), Root Mean Square Error of Approximation ($0.05 \leq RMSEA \leq 0.08$), and $0 \leq \chi^2/df \leq 3$.[26,30] Internal consistency was determined using Cronbach's alpha for the subscales, and the overall scale, $\alpha > .88$, was considered acceptable. Descriptive statistical analyses (number, percentage, mean, and standard deviation) were used to obtain data in line with the sociodemographic and obstetric variables included in the descriptive information form for high-risk pregnancies. $pF \leq 0.05$ was accepted as a statistical significance value.

Ethical aspects of the research

Approval (decision dated 12.05.2022 and numbered E-23688910-050.01.04-2200045899) was obtained from the Bartın University Social and Human Sciences Ethics Committee to conduct the study within the framework of ethical principles. Participants also provided informed consent before filling out the questionnaire. They were informed about their anonymity, their right to withdraw, and the voluntary nature of the study.

RESULTS

The study sample consisted of 210 pregnant women who met the inclusion criteria. The mean age of the participants was 29.41 ± 5.18 years, the mean gestational week was 23.50 ± 6.81, and the mean duration of marriage was 65.96 ± 50.16 months. The distribution of women according to obstetric characteristics is shown in Table 1.

Validity and reliability analysis of the scale

Construct validity. In our study, the Kaiser-Meyer-Olkin (KMO) value was 0.842. In line with this finding, it was concluded that the sample size and items were sufficient for factor analysis. In addition, when the results of the Bartlett Sphericity test were analyzed, the chi-square value obtained was significant ($\chi^2(120) = 1513.549$; $P < .01$). Accordingly, we accepted the proposition that the data followed a multivariate normal distribution.

Exploratory factor analysis (EFA). We conducted exploratory factor analysis was conducted using Principal Components Analysis and Varimax rotation methods to examine the scale's factor structure. As a result of the exploratory factor analysis, the compatibility between the revealed factors and the theoretical structure was investigated for suitability of the dimensions. In addition, the number of dimensions was examined by evaluating the eigenvalues and the contribution of each factor to the explained variance ratio. The researcher examined whether the items could be named as factors, the adequacy of the eigenvalues, and the explained variance ratios, ultimately concluding that the structure was appropriate. As a result of the analysis, when the factor pattern was examined for all items, it was determined that the scale showed a 3-dimensional ideal distribution. Therefore, the scale was accepted as 3 dimensions, and the factor pattern was acceptable. As a result of the factor analysis, items that were outside the theoretical

dimensions and had factor loadings below 0.30 were removed (M1, M6, M11, M16, M21). According to the exploratory factor analysis results, the developed scale explains 59.81% of the total variability. In addition, the first factor explains 22.10%, the second factor explains 19.38%, and the third factor explains 18.33% of the total variability (Table 2).

Confirmatory factor analysis. According to the confirmatory factor analysis in Table 3, it was determined that the structural equation modeling results for the scale were significant at the level of $P = .000$ and were related to the 16 items and 3-factor scale structure. Improvements were made to the model, including the allowing for covariance between the errors with high MI values (e3-e4; e4-e5).

According to the results of the first-level multifactor analysis, the goodness of fit indices of the Quality of Life Scale in High-Risk Pregnancies showed an acceptable fit with RMSEA = 0.071, AGFI = 0.861, and GFI = 0.899, and an excellent fit with χ^2 (Cmin/pdf) = 2.039. As a result, it was determined that the scale's construct validity was maximized (Figure).

Reliability studies. When the results were analyzed, it was found that the Cronbach's alpha for the Quality of Life Scale in High-Risk Pregnancies was 0.860, indicating that it is a highly reliable scale. In addition, sub-dimension reliabilities were found to be in the range of 0.817 to 0.844 (Table 4). Reliability analysis was performed with the split-half method, and the correlation between the 2 halves was calculated as 0.836. The Spearman-Brown coefficient was 0.910, and the Guttman split-half coefficient was 0.910, confirming that the scale was reliable.

Table 5 shows the independent group t-test results and item-total correlation, showing the discrimination power of all items. The minimum value required for the item-total test correlation to be considered sufficient is 0.30. Items with item correlations below 0.30 should not be included in the analysis. The item-total test correlation values of the participants' answers to the scale questions were examined, and it was determined that no items had a correlation below 0.30. The item-total test correlation values of all items vary between 0.397 and 0.836. As seen in the item-total test correlation table, all items were found to be correlated with each other. To determine the discrimination of the items on the scale, the raw scores obtained from the scale were ranked from highest to lowest, and the mean scores of the groups in the lower 27% and upper 27% were compared with the independent group t-test. As a result of the comparison, it was seen that there was a statistically significant difference between the means of the lower and upper group item scores. From this point of view, it can be concluded that the scale is distinctive in measuring the desired qualities.

Evaluation of the scale. Each item of the scale developed to determine the quality of life of women with high-risk pregnancies consists of 16 items, each graded on a 5-point Likert scale from 1 to 5: (1) strongly disagree, (2) partly disagree, (3) partly agree, (4) agree, and (5) strongly agree.

Table 2. Explanatory Factor Analysis Results Regarding the Quality of Life Scale in Risky Pregnancies

	Factors		
Scale Items	**Factor 1**	**Factor 2**	**Factor 3**
My sleep pattern was disrupted because I had a high-risk pregnancy.	0.810		
My responsibilities have increased due to my high-risk pregnancy.	0.802		
I feel worn out and exhausted during my pregnancy.	0.730		
I can't spare time to think about the course of my pregnancy.	0.668		
I hesitate to travel because of my high-risk pregnancy.	0.645		
When I see a healthy pregnant woman, I feel sad thinking about why I didn't have a normal pregnancy.	0.590		
The risk of my pregnancy negatively affects my sexual life.	0.561		
After the diagnosis of high-risk pregnancy, my wife does not show interest in me.		0.864	
Our marital harmony was disrupted due to my high-risk pregnancy.		0.848	
My relatives (spouse, parents, siblings, mother-in-law, father-in-law, etc) do not support me during the risky pregnancy process.		0.819	
I cannot get sufficient information from the doctor/healthcare professionals regarding the risky situation in my pregnancy.		0.690	
I don't want to get pregnant again.		0.497	
I think the reason for my high-risk pregnancy is a mistake I made before.			0.846
I'm rebelling because I'm having a high-risk pregnancy.			0.833
I feel guilty for having a high-risk pregnancy.			0.821
I think my next pregnancy may also be risky.			0.553
Self-value	5401	2458	1711
Explained variance	22 097	19 380	18 333
KMO = 0.842; $\chi^2(120) = 1513.549$; Bartlett Test of Sphericity (p) = 0.000			
Total explained variance = 59 810			

Table 3. Findings Regarding Confirmatory Factor Analysis

Index	Perfect Fit Criterion	Criteria for Acceptable Fit	After Modification
X^2/SD	$0 \leq \chi^2/df \leq 3$	$3 \leq \chi^2/df \leq 5$	2.039
RMSEA	0.00 ≤ RMSEA ≤ 0.05	0.05 ≤ RMSEA ≤ 0.08	0.071
SRMR	0.00 ≤ SRMR ≤ 0.05	0.05 ≤ SRMR ≤ 0.08	0.069
CFI	0.95 ≤ CFI ≤ 1.00	0.85 ≤ CFI ≤ 0.95	0.929
NFI	0.95 ≤ NFI ≤ 1.00	0.80 ≤ NFI ≤ 0.95	0.871
IFI	0.95 ≤ IFI ≤ 1.00	0.80 ≤ IFI ≤ 0.95	0.930
TLI	0.95 ≤ TLI ≤ 1.00	0.80 ≤ TLI ≤ 0.95	0.913
GFI	0.90 ≤ GFI ≤ 1.00	0.80 ≤ GFI ≤ 0.90	0.899
AGFI	0.95 ≤ AGFI ≤ 1.00	0.80 ≤ AGFI ≤ 0.95	0.861

The minimum score on the scale is 16, and the maximum score is 80. The total score obtained from the scale indicates that the quality of life of high-risk pregnancies is relatively low. The scale is applied to pregnant women diagnosed with high-risk pregnancies.

DISCUSSION

Determining the quality of life in high-risk pregnancies is important for improving maternal and fetal health, enabling early diagnosis and treatment, planning prenatal care, preventing obstetric complications, enhancing quality of life, and monitoring the effectiveness of interventions.[31,32] However, the quality of life scale specific to pregnant women is lacking in the literature, making it difficult to quickly and affordably assess the quality of life in women with high-risk pregnancies and to identify their prenatal care needs.[31,33] The present results show that the scale's psychometric properties are satisfactory and support its use.

The analytic methods used in this study were carefully selected to ensure the validity and reliability of the developed scale. Factor analysis was used to confirm the structure of the scale and Cronbach's alpha coefficient was calculated to assess internal consistency and item compatibility. These analyses were preferred to show whether the scale has a statistically robust structure. A valid and reliable scale plays a critical role in the process of improving the quality of life of women with high-risk pregnancies. This scale will provide health professionals with an objective assessment tool to measure women's quality of life in a holistic way and help them identify the areas in which they need more support. By systematically assessing factors affecting quality of life, such as physical discomfort, emotional distress, lack of social support, and functional limitations, the scale will enable more targeted planning of health services. Furthermore, the integration of a validated quality of life scale into clinical practice will enable early identification of physical or psychological distress experienced by women, enabling individualized care processes. This scale will be an important resource not only in clinical assessments but also in research, enabling comparisons between different populations and evaluating the effectiveness of interventions to improve quality of life in high-risk pregnancies. Therefore, the quality of life scale for high-risk pregnancies has the potential to fill the gap in the literature. This research is discussed under the headings of validity and reliability.

Table 4. Quality of Life Scale in Risky Pregnancies Reliability Analysis

Scale and Sub-Dimensions	Number of Items	Cronbach Alpha
Quality of Life in risky pregnancies	16	0.860
Factor 1: Physical challenges	7	0.844
Factor 2: Social support and communication problems	5	0.816
Factor 3: Psychological challenges	4	0.817

Validity

In scale development studies, the literature is reviewed in detail, and an item pool is created through qualitative interviews. After the creation of the item pool, content validity is assessed.[34,35] For content validity, experts' opinions are consulted, and techniques such as those of Lawshe, Davis, and others are frequently used to gather feedback.[36,37] In this study, expert opinions were obtained using the Lawshe technique. Eleven experts evaluated the content validity of the adapted HRPW-QoL Scale, and according to the content validity calculation method, the Kendall Coefficient of Agreement analysis was found to be significant. This finding shows that the experts were generally in agreement on the scale items and that the developed scale was valid in terms of content.[38]

Construct validity refers to the degree to which the developed scales can accurately measure the construct and is an important type of validity.[39] The construct validity of the developed scale was examined

Table 5. Item Analysis Results for the Items of the Quality of Life Scale in Risky Pregnancies

Items	Group	Mean	SS	r	Alpha Value When Item Is Deleted	t ([a]Upper-Lower 27%)	*P* Value ([a]Upper-Lower 27%)
Factor 1							
Item7	Top	4.11	0.56	0.519	0.836	10,798	.000[b]
	Lower	2.61	0.88				
Item8	Top	4.09	0.47	0.674	0.812	12,463	.000[b]
	Lower	2.46	0.87				
Item9	Top	4.23	0.54	0.669	0.814	11,705	.000[b]
	Lower	2.75	0.79				
Item10	Top	4.30	0.46	0.645	0.817	11,403	.000[b]
	Lower	2.86	0.83				
Item12	Top	4.23	0.54	0.669	0.813	11,626	.000[b]
	Lower	2.77	0.78				
Item13	Top	3.98	0.67	0.612	0.821	11,030	.000[b]
	Lower	2.46	0.80				
Item15	Top	4.09	0.76	0.488	0.848	12,686	.000[b]
	Lower	2.23	0.80				
Factor 2							
Item14	Top	3.67	0.85	0.397	0.846	11,988	.000[b]
	Lower	1.75	0.85				
Item17	Top	3.37	0.86	0.732	0.742	19,035	.000[b]
	Lower	1.09	0.29				
Item18	Top	3.49	0.76	0.743	0.739	21,056	.000[b]
	Lower	1.12	0.38				
Item19	Top	3.39	0.90	0.687	0.756	18,350	.000[b]
	Lower	1.09	0.29				
Item20	Top	3.04	0.94	0.515	0.806	13,544	.000[b]
	Lower	1.18	0.43				
Factor 3							
Item2	Top	4.12	0.38	0.429	0.852	9693	.000[b]
	Lower	2.84	0.92				
Item3	Top	3.98	0.52	0.701	0.739	15,975	.000[b]
	Lower	1.93	0.82				
Item4	Top	4.05	0.40	0.720	0.728	25,614	.000[b]
	Lower	1.53	0.63				
Item5	Top	3.91	0.66	0.716	0.730	17,311	.000[b]
	Lower	1.68	0.71				

n = 210
[a]n1 = n2 = 57
r = item total score correlation
[b]Significant values for P < .05.

through factor analysis. To conduct factor analysis, the sample size should be sufficient to ensure correlation reliability. Whether this adequacy is achieved is evaluated using the Kaiser-Meyer-Olkin (KMO) and Bartlett tests. The KMO test result ranges between 0 and 1, with values closer to 1 being desirable. For a valid factor analysis, it is recommended that the KMO value be above 0.60. The KMO value should be greater than 0.50, and the result of Bartlett's test of sphericity should be statistically significant to indicate that the sample size is appropriate for factor analysis.[40] In our study, it was concluded that the KMO value was sufficient (0.842), and the Bartlett's Sphericity Test result was significant ($P < .01$). These results indicate that

the sample size is suitable for factor analysis.[38] First-order CFA was examined for the model fit of the factors obtained as a result of EFA, and it was seen that the model fit indices of the scale were adequate, and the fit index values could be interpreted at an adequate level for model fit.[41,42] After determining that the model fit indices of the HRPW-QoL Scale were at an acceptable level, the sub-dimensions were named as difficulties experienced, social support and communication problems, and emotional and psychological difficulties, based on the literature review, and theoretical information about the 3-factor structure.

Reliability

Reliability in scale development studies refers to the accurate, consistent, and stable measurement of the feature to be measured.[34,40] The most frequently used analyses for scale reliability are item analysis based on item-total correlation and Cronbach's alpha coefficient if the item is deleted.[43,44] Reliability includes both internal and external reliability. Internal reliability is typically expressed by Cronbach's alpha coefficient and split-half reliability and is generally considered good when the coefficient is ≥ 0.8.[45] The scales's internal consistency coefficient, Cronbach's alpha, was found to be 0.86, and the reliability of the sub-dimensions ranged from 0.81 to 0.84. The higher the Cronbach's alpha coefficient of the scale, the more consistent the scale items are with each other, and it is assumed that the scale consists of items that measure the same characteristics.[46] In line with this information, the Cronbach's alpha value in the study (0.860) indicates that the scale is highly reliable. In the analysis conducted using the split-half reliability method, the Spearman-Brown correlation coefficient was found to be r = 0.91, the Guttman split-half value was r = 0.91, and the split-half reliability level of the scale was found to be at the recommended level of 0.83.[25] The evaluation of the correlation between the items of the test and its invariance over time are among the analyses used to assess reliability.

Strengths, limitations, and future directions

This study has several advantages: First, we strictly followed the process of scale introduction and the evaluation criteria[26,47-49] for developing and assessing the HRPW-QoL Scale, ensuring that the process was standardized. Second, the strength of the study lies in the fact that it is the first valid and reliable measurement tool to evaluate the quality of life in women with high-risk pregnancies, a subject not yet addressed in the literature, and that it can be adapted to other languages and cultures.

The validation of the questionnaire is a lengthy process, and there is a need for a larger sample size, as well as multiple studies and further expansion of the sample size in future research to test the questionnaire's usefulness and scientific validity. For effective prevention and intervention, it is crucial to deepen our understanding of the quality of life in high-risk pregnancies, assess their current quality of life, and analyze the influencing factors.

Future research has the potential to evaluate the quality of life of high-risk pregnant women in terms of physical, psychological, social and communication with the Quality of Life Scale in High-Risk Pregnancies, which has proven its validity and reliability. For future studies, it is recommended to address quality of life with different dimensions and to determine the factors thought to have the potential to affect these dimensions. Additionally, for future practical purposes, it is important to note that the scale is valid only within a specific country and language. Therefore, the scale's validity should be tested in other countries and languages.

CONCLUSION

As a result, it was concluded that the "Quality of Life Scale in High-Risk Pregnancies" is a valid and reliable tool that can be applied to women diagnosed with high-risk pregnancies. This scale can be used in studies that help prevent labor, a natural process, from deviating from its normal course and becoming high-risk for some individuals. At the same time, examining this scale in Turkish culture, with its sub-dimensions shaped by variables such as physical, social, and psychological difficulties, suggests that it will contribute to understanding the quality of life of women with high-risk pregnancies.

REFERENCES

1. Mirzakhani K, Ebadi A, Faridhosseini F, Khadivzadeh T. Well-being in high-risk pregnancy: an integrative review. *BMC Pregnancy Childbirth*. 2020;20:1-14. doi:10.1186/s12884-020-03190-6.
2. Rodrigues DB, Backes MTS, Delziovo CR, Santos E, Damiani P, Vieira VM. Complexity of high-risk pregnancy care in the health care network. *Rev Gaucha Enferm*. 2022;43:e20210155. doi:10.1590/1983-1447.2022.20210155.en.
3. Unlu Bidik N, Baskaya YH. Expectant fathers' perceptions towards high-risk pregnancy and experiences in this period: a study of hermeneutic phenomenology. *Appl Nurs Res*. 2022;68:151639. doi:10.1016/j.apnr.2022.151639.
4. Antunes M, Viana CR, Charepe Z 2022 Hope aspects of the women's experience after confirmation of a high-risk pregnancy condition: a systematic scoping review. *Paper presented at: Healthcare*
5. Holness N. High-risk pregnancy. *Nurs Clin*. 2018;53:241-251.
6. Chaharrahifard L, Motlagh AJ, Akbari-Kamrani M, Ataee M, Esmaelzadeh–Saeieh S. The effect of midwife-led psycho-education on parental stress, postpartum depression and parental competency in high risk pregnancy women: a randomized controlled trial. *J Caring Sci*. 2021;10(2):70.doi: 10.34172/jcs.2021.014.
7. Kent RA, Yazbek M, Heyns T, Coetzee I. The support needs of high-risk antenatal patients in prolonged hospitalisation. *Midwifery*. 2015;31(1):164-169.doi: 10.1016/j.midw.2014.08.003.
8. Shojaeian Z, Khadivzadeh T, Sahebi A, Kareshki H, Tara F. Perceived risk in women with high risk pregnancy: a qualitative study. *Iran J Nurs Midwifery Res*. 2021;26(2):168.doi: 10.4103/ijnmr.IJNMR_32_20.
9. Williamson SP, Moffitt RL, Broadbent J, Neumann DL, Hamblin PS. Coping, wellbeing, and psychopathology during high-risk pregnancy: a systematic review. *Midwifery*. 2022;116(2023):103556.
10. Badakhsh M, Hastings-Tolsma M, Firouzkohi M, Amirshahi M, Hashemi ZS. The lived experience of women with a high-risk pregnancy: a phenomenology investigation. *Midwifery*. 2020;82:102625. doi:10.1016/j.midw.2019.102625.
11. WHOQoL Group. The development of the World Health Organization quality of life assessment instrument (the

WHOQOL) Paper presented at: Quality of Life Assessment: International Perspectives: Proceedings of the Joint-Meeting Organized by the World Health Organization and the Fondation IPSEN in Paris July 2–3 1993 1994.
12. Iwanowicz-Palus G, Zarajczyk M, Pięta B, Bień A. Quality of life, social support, acceptance of illness, and self-efficacy among pregnant women with hyperglycemia. *Int J Environ Res Public Health*. 2019;16(20):3941.doi: 10.3390/ijerph16203941.
13. Lagadec N, Steinecker M, Kapassi A, et al. Factors influencing the quality of life of pregnant women: a systematic review. *BMC Pregnancy Childbirth*. 2018;18(1):1-14. doi:10.1186/s12884-018-2087-4.
14. Sonmezer E, Özköslü MA, Yosmaoğlu HB. The effects of clinical pilates exercises on functional disability, pain, quality of life and lumbopelvic stabilization in pregnant women with low back pain: a randomized controlled study. *J Back Musculoskelet Rehabil*. 2021;34(1):69-76.doi: 10.3233/BMR-191810.
15. Türkmen H. The effect of hyperemesis gravidarum on prenatal adaptation and quality of life: a prospective case–control study. *J. Psychosom. Obstet. Gynecol.* 2020;41:282-289.
16. Minschart C, De Weerdt K, Elegeert A, et al. Antenatal depression and risk of gestational diabetes, adverse pregnancy outcomes, and postpartum quality of life. *Int J Clin Endocrinol Metab*. 2021;106(8):e3110–e3124.
17. Liu M-C, Kuo S-H, Chou F-H, Chan T-F, Yang Y-H. Transformation of quality of life in prenatal women with nausea and vomiting. *Women Birth*. 2019;32(6):543-548. doi: 10.1016/j.wombi.2018.10.009.
18. Ribeiro MC, de Tubino Scanavino M, Do Amaral MLSA, de Moraes Horta AL, Torloni MR. Beliefs about sexual activity during pregnancy: a systematic review of the literature. *J Sex Marital Ther*. 2017;43:822-832.
19. García-Duarte S, Nievas-Soriano BJ, Fischer-Suárez N, Castro-Luna G, Parrón-Carreño T, Aguilera-Manrique G. Quality of sexuality during pregnancy, we must do something—survey study. *Int J Environ Res Public Health*. 2023;20:965.
20. Kolcaba KY. A theory of holistic comfort for nursing. *J Adv Nurs*. 1994;19:1178-1184.
21. Karaçam Z, Özçelik G. Common complaints in pregnancy, physical, mental and sexual health problems, risk factors and relationships with quality of life. *J Ege Univ Faculty Nursing*. 2014;30:1-18.
22. Mogos MF, August EM, Salinas-Miranda AA, Sultan DH, Salihu HM. A systematic review of quality of life measures in pregnant and postpartum mothers. *Appl Res Qual Life*. 2013;8:219-250. doi:10.1007/s11482-012-9188-4.
23. Boylu AA, Paçaçıoğlu B. Quality of life and indicators. *J Acad Res Stud*. 2016;8:137-150.
24. DeVellis RF, Thorpe CT. *Scale Development: Theory and Applications*. Sage publications; 2021.
25. Tavşancıl E Measurement of attitudes and data analysis with SPSS. Ankara: Nobel Publishing House; 2010.
26. DeVellis RF. Scale Development: Theory and Practice. T. Totan (trans.). Ankara: Nobel Academic Publishing; 2014.
27. George D, Mallery P. *IBM SPSS Statistics 26 Step by Step: A Simple Guide and Reference*. Routledge; 2019.
28. Spss, I.SPSS for Windows Base 10.0 (10.0. 7). Chicago: SPSS. 2000.
29. Ural A, Kılıç İ. Scientific research process and data analysis with SPSS. *Ankara*. 2005.
30. Tabachnick BG, Fidell LS. Use of multivariate statistics [Using multivariate statistics]. *Trans M Baloglu Nobel*. 2015.
31. Felder JN, Lee KA. Insomnia during pregnancy. In H. Attarian & M. Viola-Saltzman (Eds.), Sleep disorders in women: A guide to practical management (3rd ed., 265-280). Humana, Cham; 2020. doi:10.1007/978- 3- 030- 40842-8_17.
32. Kaçar N, Özcan H. Coping with sleep problems in pregnancy and the role of midwifery. *Int J Gynaecol Obstet Neonatoly Med*. 2021;18:847-853.
33. Balserak BI, O'Brien LM, Bei B. Sleep and sleep disorders associated with pregnancy. Principles and Practice of Sleep Medicine. Sixth Edition. Elsevier; 2017:1525-1539. doi:10.1016/j.smrv.2017.09.003.
34. Büyüköztürk Ş. Data analysis handbook for social sciences. In: *Statistics, Research Design SPSS Applications and Comments*. PegemA Publishing; 2017
35. Ozdamar K. Scale and test development in education, health and behavioral sciences: structural equation modeling [Scale and test development in education, health and behavioral sciences: structural equation modeling]. *Eskisehir Nisan*. 2017.
36. Davis LL. Instrument review: getting the most from a panel of experts. *Appl Nurs Res*. 1992;5:194-197.
37. Lawshe CH. A quantitative approach to content validity. *Personnel Psychology*. 1975;28(4):563-575.
38. Kalaycı Ş. *SPSS Applied Multivariate Statistical Techniques*. Ankara, Turkey: Asil Publication Distribution. Volume 5; 2010.
39. Kartal M, Bardakci S. *Practical Examples of Reliability and Validity Analysis with SPSS and AMOS*. Academician Bookstore; 2018.
40. Alpar CR. Applied statistics and validity-reliability. Detay Publishing; 2016.
41. Kline P. *Handbook of Psychological Testing*. Routledge; 2013.
42. Schumacker RE, Lomax RG. *A Beginner's Guide to Structural Equation Modeling*. psychology press; 2004.
43. Karakoç AGDFY, Dönmez L. Basic principles in scale development studies. *World Med Educ*. 2014;13:39-49.
44. Özdamar K. Scale and Test Development: Structural Equation Modeling in Education, Health, and Behavioral Sciences. Eskişehir, Turkey: Nisan Publishing; 2016.
45. Tavakol M, Dennick R. Making sense of Cronbach's alpha. *Int J Med Educ*. 2011;2:53.
46. Erbil N, Bakır A. Developing inventory of professional attitude at occupation. *J Human Sci*. 2009;6:290-302.
47. Erkuş A. How functional are existing scale development methods and measurement theories in psychological scale development: a new proposal. *J Meas Eval Educ Psychol*. 2012;3:279-290.
48. Özdamar K. Scale and test development in health and behavioral sciences structural equation modeling. *April Bookstore*. 2016.
49. Şeker H, Gençdoğan B. *Measurement Tool Development in Psychology and Education*. Nobel; 2006.