Patient Preference and Adherence

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ORIGINAL RESEARCH

Development and Validation of the Treatment Adherence Scale for Non-Dialysis Chronic Kidney Disease Patients in China: A Mixed-Methods Study

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Purpose: Chronic kidney disease (CKD) is a global public health priority. Adherence to complex therapeutic regimens is crucial for non-dialysis patients. However, the absence of multidimensional assessment instruments has impeded precise adherence evaluation and targeted interventions. This study aimed to develop and validate a disease-specific Treatment Adherence Scale for Non-Dialysis CKD Patients (TAS-NCKD).

Methods: A cross-sectional mixed-methods study was conducted in China. Preliminary items were developed by a scoping review and two Delphi expert rounds. Three rounds of surveys (n=160, 350, and 370) were conducted for the construction and psychometric validation of the scale. Feasibility, reliability, validity, discrimination and difficulty, and optimal cutoff determination was verified.

Results: The third validation cohort consisted of 181 patients with CKD stage 1, 49 with stage 2, 59 with stage 3, 38 with stage 4, and 43 with stage 5. The final TAS-NCKD comprises 45 items across 5 dimensions. The scale demonstrated high feasibility with a completion rate of 92.5%, and a completion time within 18 minutes. The Cronbach's α, split-half reliability, test-retest reliability for the scale were 0.955, 0.968, and 0.836. The scale-level content validity index (CVI) and item-level CVI were 0.992 and 0.875–1. Confirmatory factor analysis showed a good model fit. Convergent and discriminant validity both met the standards. Item characteristic curves were ideal and the optimal cutoff was established at 179 points.

Conclusion: The TAS-NCKD is a valid and reliable instrument for assessing treatment adherence in Chinese non-dialysis CKD patients. This study provides targeted insights for improving patient self-management and may help slow disease progression.

Keywords: chronic kidney disease, non-dialysis, treatment adherence, scale development and validation, China

Introduction

Chronic kidney disease (CKD) is a lifelong condition characterized by high prevalence, disability rate, medical costs, and low public awareness.[1] It has emerged as a significant global public health issue that poses serious threats to human health. Currently, the median prevalence of CKD is 9.5% globally and 8.2% in China.[2,3] Notably, less than 1% of patients undergo dialysis, indicating that the majority of patients remain in the non-dialysis stage.[4] Poor early control drives multi-system complications, reducing quality of life, increasing the burden on the family and society, and elevating morbidity and mortality.[5] Therefore, targeting the non-dialysis intervenable window to slow kidney function decline is critical for improving patients' clinical outcome.

The 2024 KDIGO Clinical Practice Guidelines for CKD Assessment and Management emphasize delaying disease progression as the core treatment goal.[6] The optimal management has shifted from disease-centered to patient-centered

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integrated team-based care, and that in addition to medication, dietary, exercise, other lifestyle changes are the cornerstones of long-term CKD control. Good treatment adherence is essential to achieve effective outcomes and preserve renal function.[7] The World Health Organization (WHO) defines it as patients' adherence to the recommendations of healthcare providers, such as medication intake, dietary control, and lifestyle modification.[8] This definition emphasizes behavioral orientation and multidimensional construct focused on actionable practices rather than attitudes or willingness alone. Studies have shown that good treatment adherence in non-dialysis CKD patients facilitates disease regression, prevents complications, and delays dialysis initiation.[9,10] Therefore, there is an urgent need for a disease-specific assessment instrument to quantify the drivers of treatment adherence and enable personalized interventions.

Emerging digital health technologies and artificial intelligence (AI) are reshaping chronic disease management, particularly for CKD patients requiring long-term adherence monitoring. Recent studies highlight that AI-driven nutritional risk assessment tools can identify high-risk non-adherent patients by analyzing real-time biomarker and dietary log data,[11] while digital platforms improve medication adherence via personalized reminders and remote follow-up.[12] However, most digital interventions lack a validated, disease-specific adherence assessment instrument to anchor their strategies. Current adherence assessment instruments for non-dialysis CKD patients focus narrowly on dietary and medication, lacking holistic evaluation. Methods for assessing dietary adherence include dietary diary,[13] 24-hour recall,[14] urea nitrogen measurement,[15] and questionnaires such as Renal Adherence Attitude Questionnaire (RAAQ), Renal Adherence Behavior Questionnaire (RABQ),[16] and Diet History Questionnaire (DHQ).[17] Measurement of medication adherence includes indirect and direct measures. Indirect measures encompass detecting drug concentration,[18] calculating drug dosage and proportion of days covered (PDC),[19] Direct measures are mainly in the form of questionnaires, such as the Simplified Medication Adherence Questionnaire (SMAQ),[20] Medication Adherence Report Scale (MARS),[21] and 8-item Morisky Medication Adherence Scale (MMAS-8),[22] Whereas the End-Stage Renal Disease Adherence Questionnaire (ESRD-AQ) captures dialysis-specific barriers, it neglects cardinal adherence determinants in non-dialysis CKD patients.[23] Existing instruments fail to capture the multidimensionality of non-dialysis CKD adherence, including disease awareness, lifestyle adaptation challenges, and proactive self-monitoring behaviors. This gap underscores the necessity of developing a multidimensional, psychometrically sound scale that can integrate with digital health systems to enable precise CKD management.

The knowledge-attitude-practice (KAP) model, a classic health behavior theory, provides a valuable framework for conceptualizing treatment adherence dimensions in non-dialysis CKD patients.[24,25] Deficits in disease-specific knowledge and maladaptive attitudes compromise behavioral sustainability. For non-dialysis CKD patients, CKD-related knowledge fundamentally shapes adherence patterns, attitudes drive behavioral persistence, and observable practices constitute the ultimate manifestation of adherence. Thus, the KAP model offers a robust foundation for developing the Treatment Adherence Scale for Non-Dialysis CKD Patients (TAS-NCKD), which is designed to quantify concrete behaviors while assessing knowledge accuracy and attitude strength to comprehensively reflect treatment adherence levels.

The primary objective of this study was to construct a culturally adapted treatment adherence scale for Chinese non-dialysis CKD populations and conduct a preliminary psychometric evaluation of feasibility, reliability, validity, discrimination, difficulty, and optimal cutoff determination. We hypothesized that the TAS-NCKD would contain non-dialysis CKD-specific adherence items and exhibit good psychometric properties, providing a high-quality assessment tool and theoretical basis for targeted adherence interventions.

Materials and Methods

Study Design

This methodological study rigorously adhered to DeVellis'[26] scale development procedure, including the development of an instrument to measure treatment adherence in non-dialysis CKD patients and psychometric assessments of the developed scale's reliability and validity. To collect data for scale construction (first two rounds) and validation (third round), we conducted three rounds of cross-sectional surveys, all using convenience sampling with no data crossover across all phases. The cross-sectional section was reported following the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) guidelines (Table S1 in Supplementary materials).

Participants and Procedure

The study was conducted across three tertiary hospitals in Xi'an, China, from May 2024 to May 2025. In advance, the heads of the three hospitals' nephrology departments were contacted to recruit patients who were either hospitalized in the department or waiting in the outpatient clinics and who met the inclusion criteria. After explaining the study purpose, participants voluntarily signed an informed consent form. The research team then distributed paper-based questionnaires on site, collected them promptly upon completion, and checked for any missing or ambiguous responses. The study was approved by the Ethics Committee of the Second Affiliated Hospital of the Fourth Military Medical University (No. K202503-41) and strictly conducted in accordance with the principles of the Declaration of Helsinki.

Inclusion in the study requires patients to satisfy the following criteria: (1) met the diagnostic criteria for CKD according to the clinical practice guideline;[27] (2) not on dialysis; (3) aged ≥18 years; (4) conscious, with normal communication skills and ability to complete the questionnaire; (5) informed and voluntary participation. Exclusion criteria: (1) cognitive impairment or comorbid psychiatric disorders; (2) comorbid serious cardiovascular, neurological, pulmonary, or other systemic disorders.

Phase I: Development of the Preliminary Items

To generate the initial item pool, we conducted a scoping review using the Joanna Briggs Institute (JBI) Scoping Review Guidelines in Australia as the methodological framework, strictly following its steps and the PCC (Participants, Concept, Context) principles.[28] The target population was non-dialysis CKD patients. The core concept was treatment adherence which typically covers core elements such as medication adherence, dietary adherence, lifestyle adherence, and follow-up adherence. The context focused on a practice pattern of specific behaviors whether in the context of inpatient or home-based care settings. Based on this, we developed search strategies and searched across English databases (PubMed, Embase, Cochrane Library, Web of Science, CINAHL, PsycINFO) and Chinese databases (CNKI, Wanfang Data Knowledge Service Platform, VIP Database, China Biology Medicine disc) and followed the Preferred Reporting Items for Systematic Review and Meta-analysis Protocols Extension for Scoping Reviews (PRISMA-ScR) to screen the literature. A total of 2638 records were initially retrieved, 490 duplicates were removed, 1685 records were excluded after title/abstract screening, and 463 full-text articles were assessed for eligibility, with 36 studies finally included. Guided by the KAP theory, we analyzed and categorized the knowledge, attitudes, and behaviors related to treatment adherence in non-dialysis CKD patients. On this basis, the preset dimensions and an item pool for the scale were drafted.

Following the scoping review, two rounds of Delphi expert consultation were conducted either face-to-face or by e-mail to revise items. A total of 17 experts, including five experienced nephrologists, five nurse specialists, four chronic disease management experts, two psychologists, and one questionnaire development expert, were consulted in the first round, and 16 experts, including one nephrologist withdrew due to scheduling conflicts, were consulted in the second round. Experts rated each dimension and item in terms of importance and relevance. The importance was evaluated using a 5-point Likert scale (5 = extremely important, 4 = important, 3 = moderately important, 2 = unimportant, 1 = extremely unimportant), while the relevance was assessed via a 4-point Likert scale (4 = highly relevant, 3 = moderately relevant, 2 = weakly relevant, 1 = irrelevant). Through scoping review and expert consultations, the preliminary dimensions and item pool for TAS-NCKD were determined.

Phase II: Preliminary Validation of the Draft Scale: 1st Survey

The preliminary validation commenced with a pilot survey of 50 CKD non-dialysis patients to eliminate items with ceiling or floor effects. Subsequently, 160 eligible participants were recruited from the nephrology department of a tertiary hospital in Xi'an for the first-round survey. Participants independently completed the draft scale with prompt collection by the research team. The data were used for preliminary item selection to construct a trial scale.

Phase III: Validation of the Trial Scale: 2nd Survey

Similar to the first-round survey, we still first selected 50 CKD non-dialysis patients to eliminate items with ceiling or floor effects. To ensure the validity of the results, the participants' sample size in the second-round survey should be 5–10 times the number of preset items,[29] considering a nonresponse rate of 10%-20%, in addition to the graded response model (GRM) parameter estimation in item response theory (IRT) requires a sample size of at least 250 cases,[30] and

finally 350 non-dialysis CKD patients were recruited from nephrology departments of three tertiary hospitals. This phase aimed to conduct further item selection and finalize the final scale.

Phase IV: Evaluation of the Final Scale: 3rd Survey

The third-round survey aimed to evaluate the final scale's feasibility, reliability, validity, discrimination, difficulty, and optimal cutoff determination. According to Tinsley's criterion, the sample size should be more than five times the number of items or at least 200 cases,[31] so we finally recruited 370 non-dialysis CKD patients. 56 patients (approximately 15% of those in the third round-survey) were randomly selected for retesting after 2 weeks to assess test-retest reliability. The flow chart illustrating the entire study process for scale development and preliminary validation is shown in Figure 1.

Statistical Analysis

Data were analyzed by SPSS 27.0, Mplus 8.3, and R 4.5.0 software. Normality was assessed using the one-sample Kolmogorov–Smirnov test. Quantitative data are presented as mean ± standard deviation (*SD*), and categorical data are presented as frequency and percentage.

The ceiling or floor effect was considered present if the responses of more than 15% of participants fell on the highest or lowest score. Item selection based on classical test theory (CTT) consists of the following five methods:[29] (1) discrete trend method: items with an $SD < 0.75$ were excluded; (2) critical ratio analysis method: participants were ranked according to their total scale scores. The top 27% and bottom 27% were classified into two groups. Independent samples *t*-test was used to analyze the differences between the items of the two groups and the items with a non-significant difference ($p > 0.05$) were excluded; (3) item-total correlation coefficient method:[32] the correlation coefficient between each item and the total scale score was calculated and the item with a correlation coefficient < 0.4 or $p > 0.05$ were excluded; (4) Cronbach's α coefficient method:[33] items with a corrected item-total correlation (CITC) < 0.4 and whose deletion resulted in an increase in the overall Cronbach's α coefficient were considered for exclusion; (5) exploratory factor analysis (EFA): items with a factor loading < 0.4 or multi-factor loadings > 0.4 were excluded. These five methods were used to statistically analyze each item of the scale in the first and second rounds of the survey, and the items that satisfied four or more of these methods were retained.

IRT is complementary to CTT, embodying the micro-assessment of scale items to improve the measurement instrument's precision.[34] Prior to IRT-based item selection, the unidimensionality of the scale must be assessed. If the ratio of the first to second eigenvalue > 3, it indicates that it is suitable for IRT analysis, which mainly includes the following three methods:[35] (1) discrimination (parameter *a*): this parameter reflects an item's ability to differentiate between respondents with varying levels of the latent trait. Items with *a* outside the range of [0.3, 3] were considered for deletion;[34] (2) difficulty (parameters *b*): higher *b* values indicate greater item difficulty. As the scale used a 5-point Likert format, four difficulty parameters (*b1, b2, b3, b4*) were estimated. These parameters were expected to be within the range [−5, 5] and exhibit a monotonically increasing order ($b1 < b2 < b3 < b4$). Items with the *b* parameters beyond these ranges can be deleted or modified;[36] (3) item characteristic curve (ICC): ideal ICCs for the endpoint response categories (category 1 and category 5) should show monotonic trends. ICCs for the middle response categories (categories 2, 3, and 4) should show a normal distribution. Items exhibiting flat ICCs or overlapping ICCs (indicating poor discrimination or indistinct category functioning) were considered for deletion.

Reliability analysis was performed to assess the reliability and stability of the scale. This primarily involved the following three methods: (1) internal consistency reliability: Cronbach's α coefficient ≥ 0.70 was considered acceptable;[37] (2) split-half reliability: the scale items were split into two halves via odd-even allocation. The Guttman split-half coefficient was calculated to assess the correlation between the two halves. A split-half reliability coefficient > 0.6 was considered satisfactory; (3) test-retest reliability: the same scale was administered to the same participants on two separate occasions and the correlation coefficient between the scores of the two surveys > 0.7 was acceptable.[38]

Validity analysis was conducted to evaluate the accuracy and authenticity of the scale, including content validity, construct validity, criterion validity, convergent validity, and discriminant validity. Content validity was evaluated using the content validity index (CVI), which included both the item-level CVI (I-CVI) and the scale-level CVI (S-CVI). Content validity was acceptable if the I-CVI ≥ 0.78 and the S-CVI ≥ 0.90.[39] Construct validity was assessed via EFA and confirmatory factor analysis (CFA). The suitability of the data for factor analysis was determined by the Kaiser-Meyer-Olkin (KMO) measure of

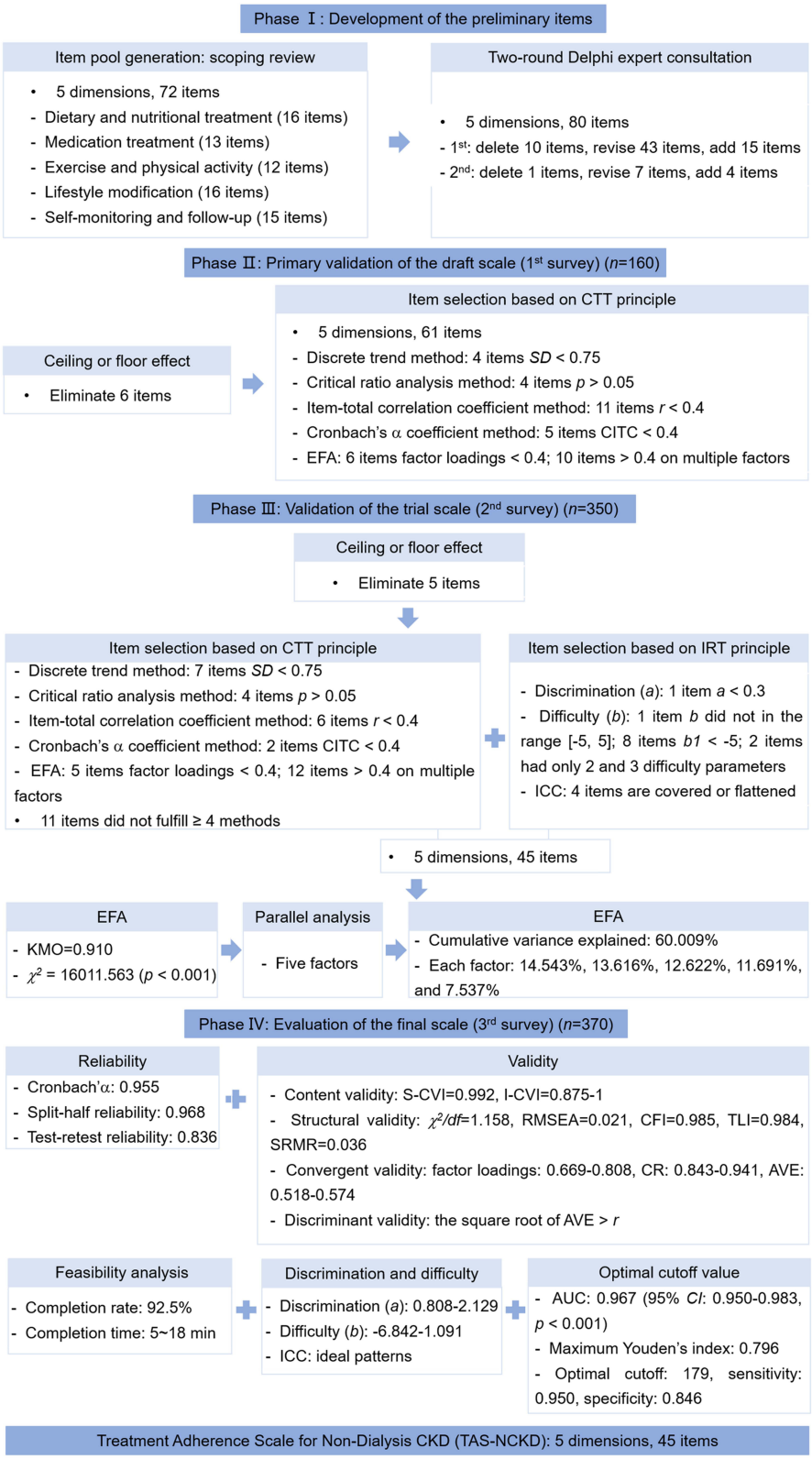

Figure 1 The scale development process.

Abbreviations: CTT, classical test theory; SD, standard deviation; CITC, corrected item-total correlation; EFA, exploratory factor analysis; IRT, item response theory; ICC, item characteristic curve; KMO, Kaiser-Meyer-Olkin; CVI, content validity index; RMSEA, root mean square error of approximation; CFI, comparative fit index; TLI, Tucker-Lewis index; SRMR, standardized root mean square residual; CR, composite reliability; AVE, average variance extracted; AUC, the area under curve.

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sampling adequacy and Bartlett's test of sphericity.[40] Factor analysis was considered appropriate when KMO > 0.9 and Bartlett's sphericity test was statistically significant ($p < 0.05$). The number of factors to retain was determined using parallel analysis. This involved comparing the scree plot of eigenvalues derived from the actual data with the curve representing the average eigenvalues obtained from randomly generated correlation matrices. The point where these two eigenvalue curves intersected indicated the absolute maximum number of factors to be extracted. Five indices were used to evaluate the degree of fit of the factors:[41] (1) chi-square/degrees of freedom (χ^2/df): ≤ 3 is considered to meet the standard; (2) root mean square error of approximation (RMSEA): ≤ 0.05 indicates that the model fit is good; (3) comparative fit index (CFI): > 0.90 indicates good fit; (4) Tucker-Lewis index (TLI): > 0.90 indicates good fit; (5) standardized root mean square residual (SRMR): ≤ 0.05 indicates good fit. Convergent validity and discriminant validity were evaluated using CFA. The following indicators were used to assess convergent validity: factor loadings (> 0.5), composite reliability (CR) (> 0.7), and average variance extracted (AVE) (> 0.5). Discriminant validity was established using the Fornell-Larcker criterion: for each latent dimension, the square root of its AVE must be greater than the absolute value of its correlation with any other latent dimension in the model.

Determining the cutoff score is a crucial step in the development and application of assessment instruments. Receiver operating characteristic (ROC) curve analysis was employed to determine the diagnostic accuracy of a test or to establish its optimal cutoff value. The ROC curve was plotted with sensitivity on the Y-axis and 1 - specificity on the X-axis and the area under curve (AUC) was calculated. The optimal cutoff score was determined as the point corresponding to the maximum Youden's index.[42] The larger the AUC is, the higher the accuracy; 0.90–1 is excellent accurate, and 0.80–0.89 is good accuracy. Ideally, the optimal cutoff score corresponds to high sensitivity and specificity (> 0.90).[43] Based on the optimal cutoff value, treatment adherence levels can be classified into two categories: good or poor. This classification framework enables clinicians and healthcare providers to quickly identify patients with poor treatment adherence.

In addition to good reliability and validity, it is essential to evaluate the feasibility of a scale, which is generally measured by the completion rate and the completion time. The scale is considered acceptable if the valid completion rate exceeds 85% and completion within 30 minutes.

Results

Development of the Preliminary Items: 72 Items→ 77 Items→ 80 Items

Following the summarization of the literature included in the scoping review using the KAP theory and the referral to previous assessment instruments, we developed a preliminary item pool comprising 72 items across five dimensions, including dietary and nutritional treatment (16 items), medication treatment (13 items), exercise and physical activity (12 items), lifestyle modification (16 items), and self-monitoring and follow-up (15 items). In the first round of Delphi expert consultation, 17 questionnaires were distributed, with all 17 returned valid responses (valid response rate of 100%). This round resulted in the deletion of 10 items, revision of 43 items, and addition of 15 items. The revised scale retained 5 dimensions with 77 items. In the second round of Delphi expert consultation, 17 questionnaires were distributed, resulting in 16 valid responses (valid response rate of 94.12%). This round led to the deletion of 1 item, revision of 7 items, and addition of 4 items. The preliminarily scale comprised 5 dimensions and 80 items.

Primary Validation of the Draft Scale (1st Survey): 80 Items→ 74 Items→ 61 Items

The pre-survey eliminated 6 items with ceiling or floor effects, leaving 74 items. 170 questionnaires were distributed in the first round of survey and 160 valid questionnaires were recovered with the valid response rate of 94.12%. The mean age of the patients was 47.32 ± 13.38 years, and the remaining general information is detailed in Table 1.

In the first-round survey, item selection was performed on the draft scale based on CTT principle (Table S2 in Supplementary materials). A total of 13 items were ultimately eliminated, resulting in a trial scale containing 61 items.

Validation of the Trial Scale (2nd Survey): 61 Items→ 56 Items→ 45 Items

The second round of pre-survey eliminated 5 items with ceiling or floor effects, leaving 56 items. 365 questionnaires were distributed in the second round of survey and 350 valid questionnaires were recovered with the valid response rate of 95.89%. The mean age of the patients was 46.42 ± 13.88 years, and the remaining general information is detailed in Table 1.

Table 1 Demographic and Clinical Information for Non-Dialysis CKD Patients in the Evaluation of the Treatment Adherence Scale

Group	Sample 1 (n=160)		Sample 2 (n=350)		Sample 3 (n=370)	
	n	%	n	%	n	%
Age, y						
≤ 40	56	35.00	135	38.57	169	45.67
41–50	36	22.50	69	19.71	68	18.38
51–60	31	19.38	90	25.72	72	19.46
≥ 61	37	23.12	56	16.00	61	16.49
Gender						
Male	87	54.38	188	53.71	215	58.11
Female	73	45.63	162	46.29	155	41.89
Body Mass Index (BMI, kg/m^2)						
< 18.5 (Underweight)	6	3.75	10	2.86	23	6.22
18.5–24 (Normal)	76	47.50	166	47.43	162	43.78
> 24 (Overweight)	78	48.75	174	49.71	185	50.00
Marital status						
Unmarried	20	12.50	36	10.29	72	19.46
Married	130	81.25	296	84.57	287	77.57
Divorced	8	5.00	12	3.43	4	1.08
Widowed	2	1.25	6	1.71	7	1.89
Education						
Primary school and below	24	15.00	47	13.43	29	7.84
Junior high school	44	27.50	108	30.86	118	31.89
High school/Technical secondary school	32	20.00	70	20.00	92	24.86
Junior college	27	16.88	67	19.14	65	17.57
Bachelor's degree or above	33	20.62	58	16.57	66	17.84
Work status						
Employed	112	70.00	288	82.29	300	81.08
Unemployed	48	30.00	62	17.71	70	18.92
Residence						
Urban	92	57.50	191	54.57	184	49.73
Rural	68	42.50	159	45.43	186	50.27
Living situation						
Living with relatives	145	90.63	310	88.57	339	91.62
Living alone	15	9.37	40	11.43	31	8.38
Medical insurance						
Yes	158	98.75	343	98.00	357	96.49
No	2	1.25	7	2.00	13	3.51
Stage of CKD						
1	81	50.63	158	45.14	181	48.92
2	25	15.62	76	21.71	49	13.24
3	26	16.25	52	14.86	59	15.95
4	17	10.62	51	14.57	38	10.27
5	11	6.88	13	3.71	43	11.62
CKD etiology						
Chronic glomerulonephritis	25	15.62	82	23.43	93	25.14
Nephrotic syndrome	57	35.63	112	32.00	123	33.24
IgA nephropathy	35	21.88	81	23.14	45	12.16
Diabetic nephropathy	15	9.37	19	5.43	35	9.46
Hypertensive nephropathy	11	6.88	11	3.14	23	6.22

(*Continued*)

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Table 1 (Continued).

Group	Sample 1 (n=160)		Sample 2 (n=350)		Sample 3 (n=370)	
	n	%	n	%	n	%
Anaphylactic purpura nephritis	3	1.87	8	2.29	14	3.78
Lupus nephritis	10	6.25	24	6.86	22	5.94
Others	4	2.50	13	3.71	15	4.05
Disease duration, months						
≤ 6	60	37.50	58	16.57	96	25.95
6–12	18	11.25	98	28.00	28	7.57
13–36	31	19.38	76	21.71	121	32.70
≥ 37	51	31.87	118	33.72	125	33.78
Number of hospitalizations						
1	51	31.88	123	35.14	147	39.73
2–3	46	28.75	89	25.43	87	23.51
4–7	37	23.12	52	14.86	58	15.68
≥ 8	26	16.25	86	24.57	78	21.08
Number of comorbid chronic conditions						
0	53	33.13	107	30.57	133	35.95
1–3	104	65.00	235	67.14	228	61.62
≥ 4	3	1.87	8	2.29	9	2.43

In the second-round survey, further item selection was performed on the trial scale based on CTT and IRT principles (Table S3, S4 and Figure S1 in Supplementary materials). Ultimately, 11 items were excluded, resulting in a final scale comprising 45 items across 5 dimensions. EFA was conducted on this scale, and the KMO measure was 0.910 (> 0.6), and Bartlett's test of sphericity yielded $\chi^2 = 16{,}011.563$ ($p < 0.001$), confirming suitability for factor analysis.

When the number of factors was unconstrained, parallel analysis (Figure 2) revealed that eigenvalues of the first five factors from the observed data exceeded the mean eigenvalues of random data matrices. This supported retaining five

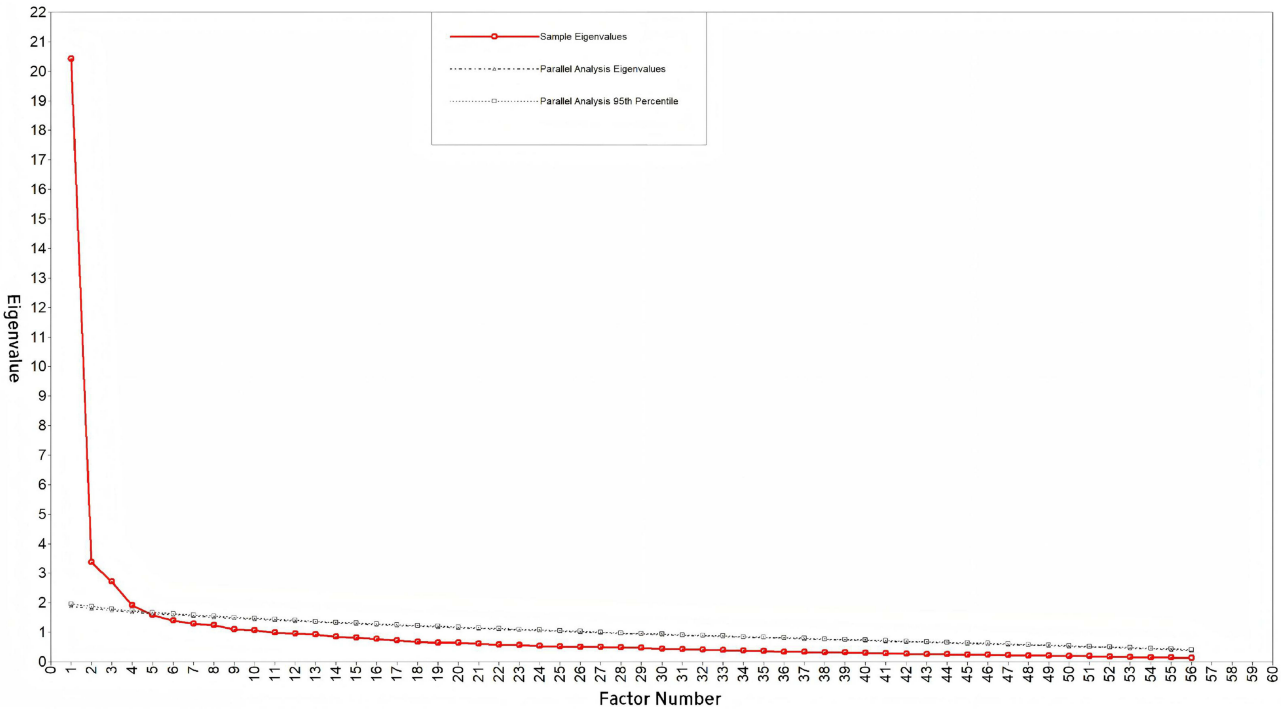

Figure 2 Scree plot of parallel analysis (2nd survey).

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factors, aligning with the scale's original theoretical structure. Subsequent EFA constrained to five factors demonstrated adequate explanatory power, with cumulative variance explained reaching 60.009%, and each factor percentage of variance explained were 14.543%, 13.616%, 12.622%, 11.691%, and 7.537%, respectively. All items exhibited factor loadings > 0.40 (Table 2), which indicated that the structure of TAS-NCKD is reasonable.

On the basis of the results of EFA and item content interpretation, the five factors were named: dietary and nutritional treatment (12 items) - assessing adherence to dietary recommendations for CKD; medication treatment (8 items) - evaluating adherence to prescribed medication regimens; exercise and physical activity (5 items) - measuring participation in physical activities per CKD rehabilitation guidelines; lifestyle modification (9 items) - assessing adjustments to daily habits closely related to CKD; self-monitoring and follow-up (11 items) - evaluating adherence to self-monitoring and scheduled clinical reviews. As a result, the TAS-NCKD consisting of 45 items in 5 dimensions was formally created (Figure 3). All items were scored on a 5-point Likert scale ranging from "Strongly disagree" (1) to "Strongly agree" (5). Higher scores indicate better treatment adherence in non-dialysis CKD patients.

Table 2 Rotated Factor Loading Matrix for the Final Scale (45 Items)

Dimensions and Items	Variance Explained (%)	Loading
Self-monitoring and follow-up	14.543	
5-A1. I understand what specific activities are required for self-monitoring and regular medical follow-ups.		0.501
5-A2. I understand edema can be assessed by checking for swelling in the eyelids, ankles, or fingers.		0.645
5-A3. I understand urine conditions can be evaluated by observing urine volume, color, and presence of froth.		0.609
5-A4. I understand symptoms like fatigue, weakness, and unusual paleness of lips/nail beds may indicate anemia.		0.572
5-B1. I believe self-monitoring and medical follow-ups enable early detection of health changes.		0.822
5-C1. I strictly adhere to physicians' schedules for check-ups and follow-ups.		0.825
5-C2. I measure and record my blood pressure daily at fixed times.		0.612
5-C3. I routinely monitor for signs of edema.		0.615
5-C4. I track and document daily urine output and characteristics.		0.820
5-C5. I monitor blood glucose regularly and complication.		0.801
5-C6. I watch for symptoms such as nausea or loss of appetite.		0.611
Medication treatment	13.616	
2-A1. I understand nephrotoxic drugs (eg gentamicin, streptomycin) can cause kidney injury.		0.829
2-A2. I understand some herbal medicines containing aristolochic acid or indeterminate components may damage kidney.		0.854
2-B1. I believe earlier medication adherence leads to better disease control.		0.818
2-C1. I strictly take prescription medications as prescribed (correct timing, dosage, and method).		0.716
2-C2. I consult professionals before using OTC drugs, supplements, or herbal medicines.		0.852
2-C3. I sometimes forget to take my medications.		0.829
2-C4. I discontinue medications when symptoms improve.		0.713
2-C5. I run out of medications without timely refills.		0.856
Dietary and nutritional treatment	12.622	
1-A1. I understand the need for a low-salt and low-purine diet with high-quality protein and light preparation.		0.488
1-A2. I understand a low-protein diet means 0.8–1.0 g/kg/day protein intake, reducible to 0.6–0.8 g/kg/day with keto acid therapy.		0.587
1-A3. I understand high-quality protein sources include animal foods (fish, poultry, eggs, dairy, lean meat) and plant proteins (soybeans/products).		0.476
1-A4. I understand during stable disease periods, daily vegetable intake should be 300–500g and fruit 200–350g (eg one medium apple ≈ 150–200g).		0.576
1-B1. I believe I can resist temptations from unhealthy foods.		0.815
1-C1. I select high-quality protein sources when eating.		0.542
1-C2. I choose high-calorie and low-protein staples (eg potatoes, lotus root starch, taro, and yam).		0.577

(*Continued*)

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Table 2 (Continued).

Dimensions and Items	Variance Explained (%)	Loading
1-C3. I avoid high-salt foods and seasonings (eg smoked, grilled, pickled items, soy sauce, Monosodium Glutamate).		0.542
1-C4. When hyperkalemic, I restrict high-potassium foods (eg mushrooms, spinach, bananas, nuts).		0.708
1-C5. When hyperphosphatemic, I limit high-phosphorus foods (eg squid, egg yolk, dragon fruit, persimmon).		0.810
1-C6. During hyperuricemia, I avoid high-purine foods (eg organ meats, seafood, red meat, broths).		0.659
1-C7. I use vegetable oils for cooking, limiting intake to ≤ 25 mL/day (≈ 2.5 ceramic spoonfuls).		0.511
Lifestyle modification	11.691	
4-A1. I understand smoking, alcohol, obesity, and constipation can harm kidney function.		0.478
4-B1. I believe I can maintain healthy habits like regular routines and tobacco/alcohol abstinence.		0.518
4-C1. I do not smoke or am actively reducing smoking.		0.689
4-C2. I abstain from alcohol or am quitting drinking.		0.739
4-C3. I consume fluids appropriately as advised.		0.648
4-C4. I use multiple methods to prevent constipation.		0.553
4-C5. I take precautions against infections (eg respiratory/urinary tract).		0.614
4-C6. I ensure 6–8+ hours of regular sleep nightly.		0.642
4-C7. I employ strategies to manage stress and emotions.		0.563
Exercise and physical activity	7.537	
3-A1. I understand suitable exercise types for my condition (eg brisk walking, Tai Chi, cycling, table tennis, badminton, jogging, swimming).		0.510
3-A2. I know the recommended regimen: 3–5 sessions/week, 30–60 min/session, with ≥ 150 min weekly moderate-intensity exercise.		0.584
3-B1. I believe regular exercise is essential.		0.854
3-C1. I actively perform prescribed exercises weekly.		0.852
3-C2. During exercise, I monitor my physical responses to prevent overexertion.		0.555

Evaluation of the Final Scale (3rd Survey)

400 questionnaires were distributed in the third round of survey and 370 valid questionnaires were recovered with the valid response rate of 92.50%. The mean age of the patients was 44.55 ± 15.43 years, and the other general information is detailed in Table 1. For test-retest reliability assessment, 60 questionnaires were distributed to a subsample, with 56 valid returns (valid response rate was 93.33%). The retest subsample had a mean age of 43.55 ± 13.79 years. There was no statistically significant difference in demographic characteristics between the retest sample and the third-round survey sample ($p > 0.05$).

Feasibility Analysis

The scale demonstrated excellent feasibility and high patient compliance, with a completion rate of 92.5% in this survey phase. The completion time of the scale ranged from 5–18 minutes, all within 30 minutes, indicating that patients could easily understand and complete the scale without excessive burden.

Reliability

The Cronbach's α coefficient for the scale was 0.955, and the Cronbach's α coefficient for the dimensions ranged from 0.842 to 0.941, all > 0.7. Split-half reliability yielded a coefficient of 0.968, with inter-subscale correlations at 0.938. Subscale split-half coefficients ranged from 0.828 to 0.942, all > 0.60. The test-retest reliability coefficient of the scale was 0.836, and the coefficients of the dimensions ranged from 0.804 to 0.865, all > 0.7.

Validity

Eight domain experts evaluated scale content validity and the S-CVI of this scale was 0.992 and the I-CVI was 0.875–1, as detailed in Table S5 in Supplementary materials. CFA was conducted to verify structural validity. Using maximum likelihood

Dimensions and items	Strongly disagree	Disagree	Not sure	Agree	Strongly agree
Dietary and nutritional treatment					
1. I understand the need for a low-salt and low-purine diet with high-quality protein and light preparation.					
2. I understand a low-protein diet means 0.8-1.0 g/kg/day protein intake, reducible to 0.6-0.8 g/kg/day with keto acid therapy.					
3. I understand high-quality protein sources include animal foods (fish, poultry, eggs, dairy, lean meat) and plant proteins (soybeans/products).					
4. I understand during stable disease periods, daily vegetable intake should be 300-500g and fruit 200-350g (eg one medium apple ≈150-200g).					
5. I believe I can resist temptations from unhealthy foods.					
6. I select high-quality protein sources when eating.					
7. I choose high-calorie and low-protein staples (eg potatoes, lotus root starch, taro, and yam).					
8. I avoid high-salt foods and seasonings (eg smoked, grilled, pickled items, soy sauce, Monosodium Glutamate).					
9. When hyperkalemic, I restrict high-potassium foods (eg mushrooms, spinach, bananas, nuts).					
10. When hyperphosphatemic, I limit high-phosphorus foods (eg squid, egg yolk, dragon fruit, persimmon).					
11. During hyperuricemia, I avoid high-purine foods (eg organ meats, seafood, red meat, broths).					
12. I use vegetable oils for cooking, limiting intake to ≤ 25ml/day (≈ 2.5 ceramic spoonfuls).					
Medication treatment					
13. I understand nephrotoxic drugs (eg gentamicin, streptomycin) can cause kidney injury.					
14. I understand some herbal medicines containing aristolochic acid or indeterminate components may damage kidney.					
15. I believe earlier medication adherence leads to better disease control.					
16. I strictly take prescription medications as prescribed (correct timing, dosage, and method).					
17. I consult professionals before using OTC drugs, supplements, or herbal medicines.					
18*. I sometimes forget to take my medications.					
19*. I discontinue medications when symptoms improve.					
20*. I run out of medications without timely refills.					
Exercise and physical activity					
21. I understand suitable exercise types for my condition (eg brisk walking, Tai Chi, cycling, table tennis, badminton, jogging, swimming).					
22. I know the recommended regimen: 3-5 sessions/week, 30-60 min/session, with ≥ 150 min weekly moderate-intensity exercise.					
23. I believe regular exercise is essential.					
24. I actively perform prescribed exercises weekly.					
25. During exercise, I monitor my physical responses to prevent overexertion.					
Lifestyle modification					
26. I understand smoking, alcohol, obesity, and constipation can harm kidney function.					
27. I believe I can maintain healthy habits like regular routines and tobacco/alcohol abstinence.					
28. I do not smoke or am actively reducing smoking.					
29. I abstain from alcohol or am quitting drinking.					
30. I consume fluids appropriately as advised.					
31. I use multiple methods to prevent constipation.					
32. I take precautions against infections (eg respiratory/urinary tract).					
33. I ensure 6-8+ hours of regular sleep nightly.					
34. I employ strategies to manage stress and emotions.					
Self-monitoring and follow-up					
35. I understand what specific activities are required for self-monitoring and regular medical follow-ups.					
36. I understand edema can be assessed by checking for swelling in the eyelids, ankles, or fingers.					
37. I understand urine conditions can be evaluated by observing urine volume, color, and presence of froth.					
38. I understand symptoms like fatigue, weakness, and unusual paleness of lips/nail beds may indicate anemia.					
39. I believe self-monitoring and medical follow-ups enable early detection of health changes.					
40. I strictly adhere to physicians' schedules for check-ups and follow-ups.					
41. I measure and record my blood pressure daily at fixed times.					
42. I routinely monitor for signs of edema.					
43. I track and document daily urine output and characteristics.					
44. I monitor blood glucose regularly and complication.					
45. I watch for symptoms such as nausea or loss of appetite.					

Figure 3 Treatment Adherence Scale for Non-dialysis Chronic Kidney Disease Patients (TAS-NCKD).
Note: *Indicates reverse-scored items.

estimation, the model fit indices met all criteria: $\chi^2/df = 1.158 \leq 3$, RMSEA = 0.021 ≤ 0.05, CFI = 0.985 ≥ 0.90, TLI = 0.984 ≥ 0.90, and SRMR = 0.036 ≤ 0.05. All 45 items demonstrated standardized factor loadings > 0.60 ($p < 0.05$), confirming excellent fit for the 5-factor model of the TAS-NCKD (Figure 4).

Convergent validity was confirmed by the factor loadings ranging 0.669–0.808 (all > 0.50), AVE values of 0.572, 0.556, 0.518, 0.566, and 0.574 (all > 0.50), and CR values of 0.941, 0.909, 0.843, 0.921, and 0.937 (all > 0.70). The square root of each dimension's AVE exceeded its correlation coefficients with all other dimensions, as detailed in Table 3.

Discrimination and Difficulty

The scale demonstrated unidimensionality for IRT analysis, with the ratio of the first-to-second eigenvalues (15.474/3.802 = 4.07) > 3. Discrimination parameters (*a*) ranged from 0.808 to 2.129 across all 45 items (all > 0.30). Difficulty parameters (*b*) ranged from −6.842 to 1.091. Although five items (A14, A15, A17, A18, A20) had *b1* values < −5, all other threshold parameters remained within [−5, 5] and satisfied monotonic ordering (*b1*< *b2* < *b3* < *b4*). ICCs showed ideal patterns with categories 1 and 5 exhibited monotonic trends and categories 2, 3, and 4 demonstrated unimodal distributions (Table S6 and Figure S2 in Supplementary materials).

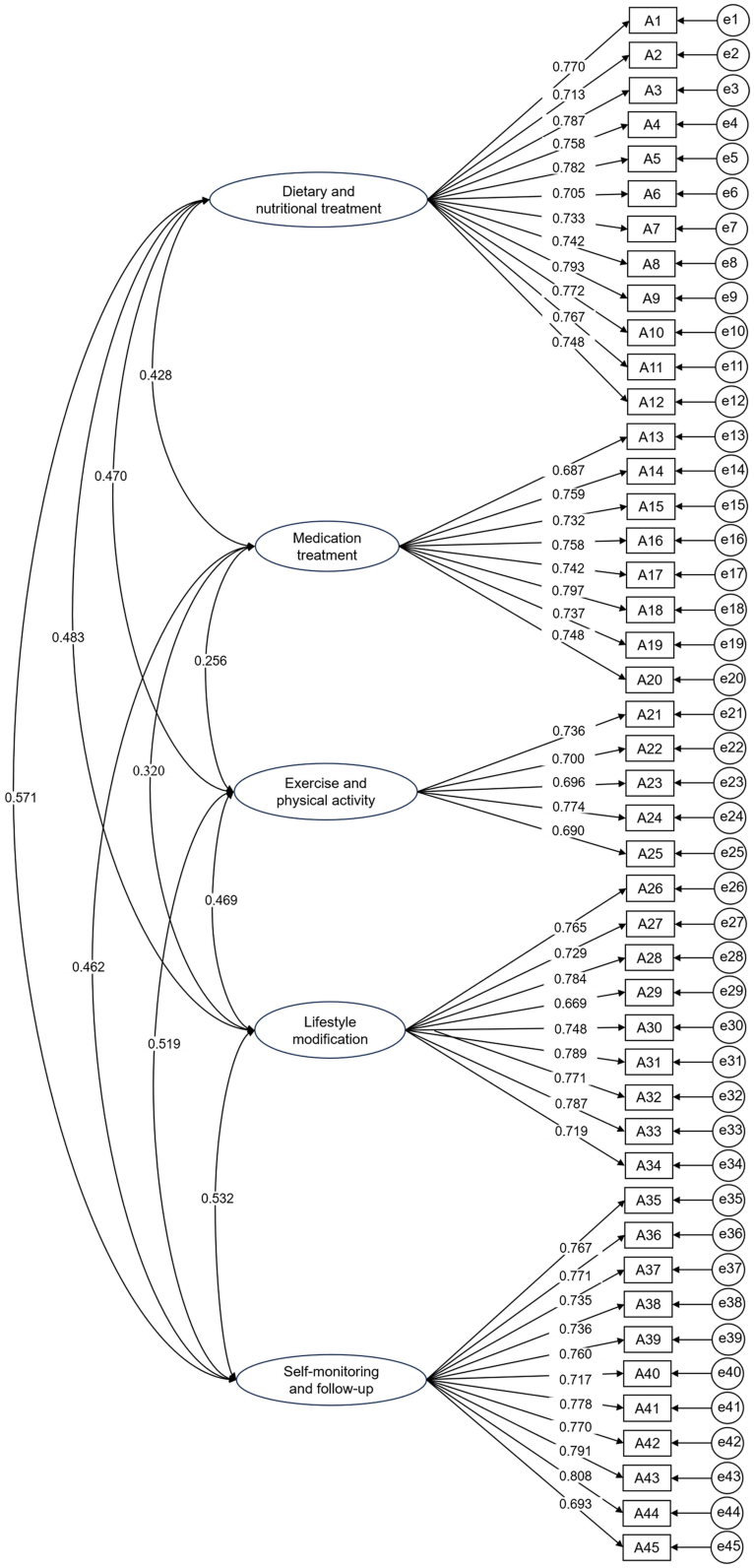

Figure 4 The proposed models of the scale by CFA.

Table 3 Fornell-Larcker Matrix for the TAS-NCKD

Dimensions	1	2	3	4	5
1 Dietary and nutritional treatment	**0.756**	–	–	–	–
2 Medication treatment	0.428	**0.746**	–	–	–
3 Exercise and physical activity	0.470	0.256	**0.720**	–	–
4 Lifestyle modification	0.483	0.320	0.469	**0.752**	–
5 Self-monitoring and follow-up	0.571	0.462	0.519	0.532	**0.758**

Notes: Bolded values on the diagonal represent the square root of AVE. Off-diagonal elements are inter-dimension correlation coefficients.

Optimal Cutoff Value

ROC curve analysis for TAS-NCKD yielded an AUC of 0.967 (95% *CI*: 0.950–0.983; $p < 0.001$). The maximum Youden's index was 0.796 (Table S7 in Supplementary materials), corresponding to a scale score of 178.5 points. Given that total scores are integers, the optimal cutoff was established at 179 points. At this threshold, sensitivity was 0.950 and specificity was 0.846 (Figure 5).

Discussion

This study strictly adhered to scale development principles by establishing an item pool, constructing a preliminary scale draft, selecting items to form the final scale, and conducting a psychometric evaluation. This process ensured scientific rigor in developing the TAS-NCKD, providing a disease-specific measurement instrument for assessing treatment adherence in non-dialysis CKD patients.

Currently, CKD is an incurable lifelong condition requiring long-term medication, regular follow-up and lifestyle management including diet, exercise, and rest to slow disease progression and reduce complications such as hypertension, diabetes, and cardiovascular events.[7] Enhancing treatment adherence in non-dialysis patients is thus pivotal to alleviating the burden on patients and their families and improving prognosis. Therefore, improving overall treatment adherence in non-dialysis CKD patients is imperative, and accurate adherence assessment is a fundamental prerequisite. Unlike previous unidimensional scales such as the RAAQ, RABQ, and MMAS-8 that focus only on diet or medication, the TAS-NCKD comprehensively covers five core dimensions: dietary and nutritional treatment, medication treatment,

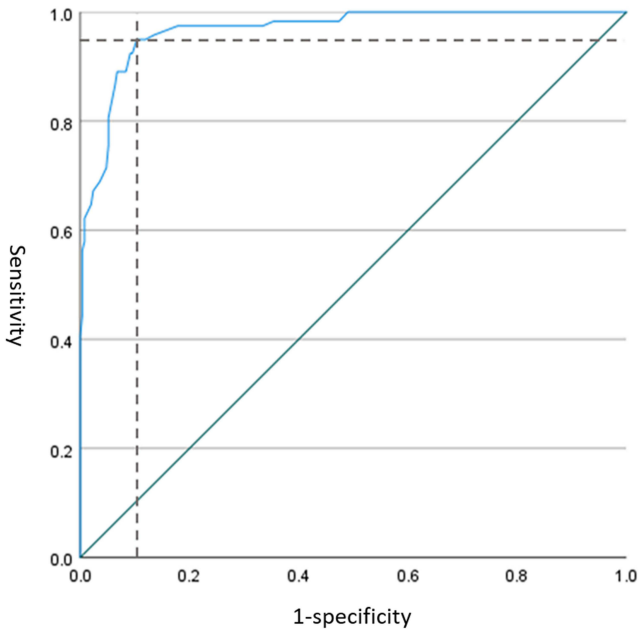

Figure 5 ROC curve for Tas-NCKD.

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exercise and physical activity, lifestyle modification, and self-monitoring and follow-up, each integrating knowledge, attitudes, and behaviors. Distinct from dialysis-targeted scales, it addresses the unique treatment needs of non-dialysis CKD patients, whose dietary, fluid, and monitoring requirements differ substantially from dialysis populations.[44] By addressing this unmet need, the TAS-NCKD responds to global kidney health initiatives and provides a foundation for targeted interventions and lifespan CKD management.

Notably, standardized adherence assessment tools remain underutilized in international nephrology practice, hindered by limited cross-cultural adaptability, clinical workflow constraints prioritizing acute complication management over adherence assessment, and weak links between tool results and actionable interventions.[45,46] The TAS-NCKD addresses these issues with its concise design (5–18 min completion time) and clear good/poor adherence classification, making it a feasible addition to routine outpatient care and a model for promoting adherence tool utility globally.

The TAS-NCKD's item pool was derived from a scoping review aligned with the WHO's treatment adherence definition and refined via two rounds of Delphi consultation with multidisciplinary experts. A multi-tiered quantitative evaluation was then performed by synergistically integrating both CTT and IRT, enabling error reduction through macro- and micro-level psychometric analyses. The final items specify clinically actionable details (diet, medication, exercise, lifestyle, monitoring) for non-dialysis CKD patients beyond general principles, grounded in guidelines and practice. In terms of dietary and nutritional treatment, the sub-scale addresses both general principles and specific restrictions on high-sodium, high-potassium, high-phosphorus, high-purine, and high-fat foods, emphasizing that prohibitions are conditioned on biomarker abnormalities rather than blanket prohibitions. For medication treatment, building upon the MMAS-8, it supplements nephrotoxic medications (both Western and Chinese), medication-taking habits, and incorporates reverse-scored items to mitigate response bias and enhance data validity.[47] Exercise and physical activity assessment comprehensively examines exercise types, duration, frequency, intensity, and outcomes. For lifestyle modification, beyond conventional lifestyle factors like smoking cessation, alcohol restriction, and sleep hygiene, it specifically highlights bowel regularity, weight control, infection prevention, and stress management. Regarding self-monitoring and follow-up, the sub-scale investigates daily self-assessment of urine characteristics, edema, anemia, nausea/appetite loss, while emphasizing proactive tracking of blood pressure and blood glucose for early complication detection. Following rigorous psychometric evaluation, the final TAS-NCKD was established, comprising 5 dimensions and 45 items. The scale requires 5–18 minutes for completion, a feasible duration that is acceptable to adult participants in clinical settings.

The TAS-NCKD demonstrates robust psychometric properties, including satisfactory reliability, validity, appropriate item characteristics, and empirically derived optimal cutoff values. Specifically, Cronbach's α coefficients were > 0.70 for both the total scale and all subscales, indicating excellent internal consistency.[37] Split-half reliability coefficients were all > 0.6, confirming good scale homogeneity. Test-retest coefficients were > 0.7 across all dimensions, confirming temporal stability.[38] With an S-CVI of 0.992 and I-CVI ranging from 0.875 to 1, the scale exhibits excellent content validity, reflecting strong congruence between measured content and target constructs.[39] CFA demonstrated good model fit, supporting structural validity. All items displayed factor loadings > 0.50 with CR > 0.70 and AVE > 0.50 per dimension, establishing convergent validity for precise target concept measurement. Discriminant validity meets the Fornell-Larcker criterion, confirming distinct dimensionality.[48] All items demonstrated adequate discrimination (a >0.3). While the $b1$ parameters for several items were < −5, remaining threshold parameters remained within the acceptable range. ICCs exhibited appropriate psychometric properties, confirming the scale's ability to discriminate between respondents of varying trait levels. The observed threshold deviations may stem from cognitive interference with adjacent reverse-scored items, marginally increasing item difficulty.[49] Following expert panel deliberation, these items were retained due to their irreplaceable contribution to core construct domains, with all other psychometric indices meeting established standards. This decision aligns with methodological consensus that content representativeness outweighs minor statistical deviations when preserving measurement comprehensiveness.[50] The scale achieved strong predictive accuracy with an AUC of 0.967. At the optimal cutoff score of 179, the sensitivity and specificity were 0.950 and 0.846 respectively, indicating robust discriminatory power for identifying patients with suboptimal adherence. This threshold enables timely initiation of specialized interventions for patients scoring < 179, optimizing resource allocation and enhancing CKD management efficiency.

The TAS-NCKD demonstrates promising potential for clinical practice implication and can be further empowered by integration with digital health and AI technologies. Digitizing the scale into mobile applications allows patients to

complete assessments conveniently, with AI algorithms automatically analyzing results and generating personalized intervention recommendations. In routine practice, the scale can be administered by nurses or medical assistants while patients wait for consultations or when hospitalized. Brief verbal explanations of the scale's purpose can significantly improve participation rates among hesitant patients. In addition, the TAS-NCKD should be integrated into routine CKD follow-up protocols, where poor adherence classification triggers mandatory targeted interventions such as regular telephone reminders and dietary counseling sessions. Designed for multidisciplinary clinical use, its predictive validity can be longitudinally verified against eGFR decline trajectories and hospitalization rates. The scale bridges critical measurement gaps in CKD behavioral medicine, and the implementation may provide high-level evidence for integrating the TAS-NCKD scale into routine clinical practice for non-dialysis CKD management, ultimately inform targeted intervention strategies, enhance treatment adherence, slow disease progression and reduce disease burden.

Strengths and Limitations

This study provides a multidimensional and specific assessment instrument to quantify treatment adherence in non-dialysis CKD patients. Methodologically, we employed an integrated qualitative-quantitative approach for item development, utilizing complementary psychometric methods (CTT and IRT) across three survey rounds to ensure rigorous item calibration precision. Furthermore, the established optimal cutoff score reduces missed interventions for high-risk patients, facilitating practical implementation in clinical settings. Although the 45-item scale may appear lengthy, its concise phrasing and comprehensibility enabled completion within 18 minutes, demonstrating high acceptability.

Nevertheless, there are several limitations. First, mild positive selection bias existed. Patients volunteering for scale validation studies are typically more engaged, health-conscious, and inherently more adherent. Future studies should expand recruitment to community-dwelling patients and use stratified sampling to improve representativeness. Second, further prospective clinical validation is required to confirm its ability to improve patient-centered outcomes across diverse clinical and cultural contexts, where context-sensitive items may elicit differential responses. To facilitate international use, a three-step cross-cultural adaptation pathway is proposed: (1) standardized forward-backward translation by bilingual experts; (2) multi-center psychometric validation with context-specific item adjustments; (3) development of international normative data. Finally, when the GRM model of IRT is used for evaluation, a sample size of at least 500 is required for more accurate parameter estimation. While the present study combines the results of the CTT indicators with those of the EFA and CFA, expanding the sample size would improve the scale in the future.

Conclusion

In this study, a standardized Treatment Adherence Scale for Non-Dialysis CKD Patients was developed. The initial dimensions and item pool were grounded in the KAP framework, existing literature, and expert consultations. Through three survey rounds employing comprehensive psychometric evaluations including ceiling/floor effect analysis, integrated CTT-IRT item screening, reliability/validity testing, EFA, CFA, and optimal cutoff determination, the final 45-item scale with five dimensions was established. The TAS-NCKD demonstrates robust psychometric properties, representing a practical instrument for assessing treatment adherence in non-dialysis CKD populations. This study provides population-specific insights for enhancing adherence behaviors and facilitating active disease self-management. Clinically, the scale can support stratified adherence screening and targeted interventions in routine clinical care, while its potential for integration with digital health technologies and cross-cultural adaptation lays a foundation for broader application. Future research will further verify its long-term predictive value in CKD outcomes.

Data Sharing Statement

The datasets used during the study are available from the corresponding author Honghong Lv on reasonable request.

Ethics Approval and Consent to Participate

This study received approval from the Ethics Committee of the Second Affiliated Hospital of the Fourth Military Medical University (No. K202503-41). Ethical guidelines were strictly adhered to throughout the investigation. All participants were assured of their right to withdraw at any time, and the collected data were used solely for academic purposes.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors report no conflicts of interest in this work.

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