

Development and preliminary psychometric evaluation of the Diabetic Kidney Disease Prevention and Control Literacy Questionnaire for health-information use and decision-making: a multisite study

Yaqin Ren

Fujian Medical University

Huiqi Lai

Fujian Medical University

Shuizhen Chen

Fujian Medical University

Shuyi Zhang

Fujian Medical University

Huaxiang He

Fujian Medical University Union Hospital

Ting Lin

lt22862125@fjmu.edu.cn

Fujian Medical University

Research Article

Keywords: Diabetes mellitus, Diabetic kidney disease, Health literacy, Decision making, Health information, Questionnaire, Psychometrics

Posted Date: October 7th, 2026

DOI: <https://doi.org/10.21203/rs.3.rs-10793573/v1>

License: © ⓘ This work is licensed under a Creative Commons Attribution 4.0 International License. [Read Full License](#)

Additional Declarations: No competing interests reported.

Abstract

Background

Preventing and managing diabetic kidney disease (DKD) requires people with diabetes to understand disease-specific information, obtain information from different sources, communicate with healthcare professionals, appraise information quality and personal relevance, and use recommendations in health-related decisions. Existing general and kidney-specific health-literacy measures do not specifically assess this combined set of DKD-related information-use and decision-making competencies. This study aimed to develop and preliminarily evaluate the Diabetic Kidney Disease Prevention and Control Literacy Questionnaire (DKD-PCLQ).

Methods

This multisite, multiphase instrument-development and psychometric evaluation study was conducted in Fuzhou, China, in 2025. The DKD-PCLQ was developed and administered in Chinese. Candidate items were generated from a literature review and semi-structured interviews with people with diabetes and refined through two rounds of expert consultation and two rounds of cognitive interviewing. Item analysis was conducted in 266 participants. Psychometric properties were evaluated in 422 participants randomly divided into exploratory ($n = 212$) and confirmatory ($n = 210$) subsamples. Test-retest reliability was assessed in 20 participants after 14 days.

Results

The preliminary DKD-PCLQ contained 35 items. Eight items were removed during item analysis and one further item because of substantial cross-loadings, resulting in a 26-item questionnaire across functional, interactive, and critical health-literacy domains. Principal component analysis identified a three-component structure, and confirmatory factor analysis showed acceptable fit after limited model modification (chi-square/df = 1.839; CFI = 0.925; RMSEA = 0.063). Internal consistency was good for the total score (Cronbach's $\alpha = 0.898$) and all domains ($\alpha = 0.866$ – 0.912). Content validity was high (S-CVI/Ave = 0.979), and the total-score test-retest ICC was 0.96 (95% CI 0.91–0.98).

Conclusions

The Chinese-language DKD-PCLQ demonstrated good internal consistency and content validity, with preliminary evidence of structural validity and test-retest reliability. By integrating DKD-specific knowledge with competencies for health-information access, communication, appraisal, application, and decision-making, it may help identify needs for tailored education and decision support. External validation, measurement-error assessment, responsiveness, interpretability, measurement invariance, and electronic-mode equivalence should be examined before routine clinical or digital implementation.

Background

Diabetes affects hundreds of millions of adults worldwide, and diabetic kidney disease (DKD) is among its most common and clinically consequential microvascular complications [1–3]. DKD may involve progressive kidney damage and, when advanced, can lead to kidney failure and kidney replacement therapy, with substantial effects on morbidity, mortality, quality of life, and healthcare costs [2–9]. Because prevention and early management can modify important risk factors, timely recognition and sustained self-management remain central to reducing DKD-related harm [5,6,10].

Early DKD is frequently asymptomatic, so prevention and management depend less on symptom recognition alone and more on acting on health information [11]. People with diabetes may need to understand why kidney screening is performed, interpret or discuss albuminuria and estimated glomerular filtration rate results, weigh preventive and treatment recommendations, communicate uncertainties with healthcare professionals, and incorporate recommendations into medication, diet, monitoring, and follow-up decisions [5,6,10–13]. Previous studies have identified important gaps in DKD knowledge and awareness, particularly around early asymptomatic disease, diagnostic indicators, and preventive strategies [12,13]. From a decision-making perspective, these gaps concern not only what patients know, but also how they access, understand, appraise, communicate, and use information when making health-related choices.

These competencies are closely related to health literacy. Contemporary frameworks conceptualise health literacy as involving access to, understanding of, appraisal of, and use of health information and services in health-related decision-making [14–16]. In diabetes and kidney disease, disease-specific literacy also includes interpreting clinical information, communicating with healthcare professionals, navigating services, and applying information to self-management [17–21]. In contemporary information environments, patients may encounter disease-related information through digital, printed, and professional sources, making source selection, credibility appraisal, and verification relevant to informed health decisions. However, existing instruments primarily assess general health literacy, CKD-related knowledge or awareness, or selected self-management competencies. To our knowledge, no validated instrument specifically evaluates the integrated health-information and decision-making competencies required to prevent, recognise, monitor, and manage DKD in people with diabetes [17–21].

To address this measurement gap, we developed the Diabetic Kidney Disease Prevention and Control Literacy Questionnaire (DKD-PCLQ), guided by the hierarchical model of health literacy [15], and conducted a preliminary evaluation of its item performance and psychometric properties. The intended use is to identify domain-specific information and decision-support needs, support targeted patient education and self-management discussions, and provide a

measure for future intervention and digital-workflow research. The present study focuses on instrument development and preliminary measurement performance; it does not evaluate a clinical decision-support system, digital-health intervention, or electronic implementation.

Methods

This multisite, multiphase instrument-development study was conducted at a general hospital and a community health service centre in Fuzhou, Fujian Province, China, in 2025. The study was informed by established scale-development and content-validity guidance [22,23]. The Biomedical Research Ethics Review Committee of Fujian Medical University approved the study (approval no. [2023] Fu Medical Ethics Review NO. 175). The four study phases were as follows:

1. Conceptualisation of the target construct
2. Development of the preliminary questionnaire
3. Item analysis and selection
4. Psychometric evaluation of the final questionnaire

Phase 1: Conceptualisation of the target construct

The first step was to define the target construct, intended population, and context of use [22,23]. The literature review identified few studies treating DKD prevention and control literacy as a distinct construct and no established consensus definition. We therefore developed a disease-specific construct by integrating general health-literacy frameworks, chronic-disease prevention and management concepts, and competencies relevant to diabetes and kidney disease [14,16–21,24–26]. Particular attention was given to competencies that influence how people obtain, interpret, evaluate, communicate, and act on information when making decisions about DKD prevention and management.

Health literacy has evolved from an early health-education concept [27] to a multidimensional construct concerned with people's capacity to obtain and process health information and make appropriate health decisions [24]. The World Health Organization further emphasises personal knowledge and competencies that enable people to access, understand, appraise, and use information and services to promote and maintain health [16]. These definitions position information processing and application, rather than reading ability alone, at the centre of health-related decision-making [14,16,24].

In chronic disease, health literacy includes the skills required to access, comprehend, evaluate, communicate, and act on information over prolonged periods of self-management [25,26]. CKD-specific literature similarly emphasises understanding and using kidney-related information, communicating with healthcare professionals, following treatment recommendations, and performing self-management activities [17–19]. These competencies are especially relevant when patients must interpret laboratory indicators or recommendations in the absence of prominent symptoms.

Diabetes health-literacy research provides a complementary foundation. Early work focused on obtaining, processing, and understanding information and on literacy and numeracy tasks needed for diabetes self-management [20,21]. Later conceptualisations extended this to using information for medication management, dietary choices, blood-glucose monitoring, complication prevention, and appropriate use of healthcare services [20,21]. Thus, diabetes health literacy links information processing with practical decisions and behaviours.

DKD sits at the intersection of diabetes and CKD. Its prevention and management require people to combine disease-specific knowledge with risk recognition, interpretation of screening and monitoring information, communication with healthcare professionals, critical appraisal of information, and sustained self-management. Existing diabetes- or CKD-focused measures may capture parts of this process, but they do not fully represent the integrated competencies needed for DKD prevention and control [17–21]. This provided the rationale for a distinct DKD-focused measure.

Accordingly, DKD prevention and control literacy was operationally defined as an individual's ability to access, understand, appraise, communicate, and apply relevant health information; obtain and appropriately use health services; participate in disease monitoring and management; adopt and sustain health-promoting behaviours; and make informed health-related decisions to prevent or delay the onset and progression of DKD.

Phase 2: Development of the preliminary questionnaire

This phase comprised three steps: (1) generation of the questionnaire item pool, (2) expert consultation, and (3) cognitive interviewing with representatives of the target population [22,23].

Step 1: Generation of the questionnaire item pool

The initial item pool was generated on the basis of a comprehensive literature review and semi-structured interviews with representatives of the target population [22,23]. Under the guidance of an information specialist, the research team systematically searched nine electronic sources: China National Knowledge Infrastructure, Wanfang Data, the Chinese Biomedical Literature Service System, the VIP Chinese Science and Technology Journal Database, PubMed, Web of Science, CINAHL, PsycINFO, and the Ovid Embase platform. Searches covered the period from database inception to November 2024 and were restricted to Chinese- and English-language publications. Controlled vocabulary and free-text terms relating to diabetic kidney disease, diabetes, kidney disease, health literacy and related constructs, measurement instruments, and psychometric properties were combined using Boolean operators. Terms within each concept were combined with “OR”, whereas concept groups were combined with “AND”. Equivalent Chinese terms were used in the Chinese databases, and the search syntax was adapted to the indexing system and technical requirements of each database. Two researchers (YR and HL) independently screened the retrieved records at the title, abstract, and full-text stages. Disagreements between the two reviewers were initially resolved

through discussion. When consensus could not be reached, a third researcher (LT) was consulted to adjudicate the disagreement. From the included studies, the research team extracted information on DKD risk identification, screening and monitoring, treatment, self-management, and kidney-protective behaviours. Relevant items from existing instruments assessing diabetes-related constructs, CKD-related knowledge or competencies, and health literacy were also extracted, reviewed, and synthesised.

Concurrently, a qualitative study involving semi-structured interviews and directed qualitative content analysis was conducted with people with diabetes to explore their knowledge of DKD prevention and control, health information-seeking practices, health-related decision-making, self-management behaviours, and lived experiences [28]. Participants were eligible if they (1) were aged ≥ 18 years; (2) had a confirmed diagnosis of diabetes; (3) were eligible regardless of DKD status, with any DKD diagnosis verified from medical records or by a physician; and (4) had sufficient comprehension and communication ability to participate in the interview. The qualitative sample size was determined by thematic saturation, defined as the point at which additional interviews yielded no new themes or substantive information [29]. A total of 15 participants were interviewed. Following verbatim transcription and organisation of the interview data, the data were analysed using the hierarchical model of health literacy, which comprises functional, interactive, and critical health literacy [15]. The research team used a combined deductive–inductive approach, whereby the three predefined health literacy dimensions guided the initial analysis while additional categories were allowed to emerge from the interview data [28]. Evidence from the literature review and qualitative interviews was subsequently coded, categorised, and integrated. Candidate items with overlapping meanings, duplicate content, limited relevance, or ambiguous wording were merged, removed, or revised as appropriate [22,23]. This process yielded the initial item pool for the DKD-PCLQ.

Step 2: Expert consultation

A purposive sample of 15 experts with experience in diabetes, kidney disease, questionnaire development, or psychometric evaluation was recruited [30]. The experts were asked to evaluate the importance of the indicators at each hierarchical level, assess whether their content adequately represented the intended concepts, and provide recommendations for revision [22,23,31]. Experts recorded their proposed modifications in the designated “Comments and Suggestions” section of the consultation questionnaire. The importance of each indicator was rated on a 5-point scale from 1 (“not important at all”) to 5 (“very important”). Item relevance for calculating the I-CVI and S-CVI/Ave was rated separately using a relevance scale.

After each consultation round, the research team compiled and analysed the experts’ quantitative ratings and qualitative comments [31]. Based on the prespecified decision criteria, indicators and items were considered for retention if they had a mean importance score of > 3.5 and a coefficient of variation (CV) of < 0.25 . Indicators or items that did not meet these criteria but were considered to have substantial theoretical or clinical relevance were reviewed by the research team in conjunction with the experts’ comments before a final retention decision was made. Based on the experts’ quantitative ratings and written recommendations, the research team added, removed, merged, or revised questionnaire domains, subdomains, and items as appropriate [22,23,31].

Step 3: Cognitive interviewing with representatives of the target population

To evaluate the clarity, comprehensibility, relevance, and appropriateness of the questionnaire instructions, items, and response options, face-to-face cognitive interviews were conducted with representatives of the target population using a semi-structured interview guide [23,32,33]. The think-aloud technique and verbal probing were used concurrently during the interviews [32,33]. Participants were encouraged to explain how they understood each item, retrieved relevant information, formulated their responses, and selected a response option [32,33].

After each interview round, the data were transcribed, organised, and analysed by the research team. Based on participant feedback, items that were difficult to understand, ambiguously worded, or associated with difficulties in selecting an appropriate response were revised. The revised questionnaire was evaluated in the next round of cognitive interviews. This iterative process continued until no new problems relating to item comprehension, interpretation, or response selection were identified, no substantive recommendations for further revision emerged, and the item wording was considered stable [22,23,32,33]. This process resulted in the preliminary DKD-PCLQ, which was subsequently subjected to item analysis and selection in Phase 3.

Phase 3: Item analysis and selection

Questionnaire items were evaluated using extreme-groups analysis, item-response distributions, internal consistency statistics, corrected item–total correlations, and exploratory component analysis using principal component analysis (PCA) [22,34–38]. The specific analytical procedures and item-selection criteria were as follows.

1. Extreme-groups analysis based on the critical-ratio method

Participants were ranked in descending order based on their total DKD-PCLQ scores. Participants in the highest 27% of the total-score distribution constituted the high-score group, whereas those in the lowest 27% constituted the low-score group [34]. Independent-samples *t* tests were used to compare mean item scores between the high- and low-score groups. An item was considered to have inadequate discrimination between participants with higher and lower levels of DKD prevention and control literacy if the between-group difference in its mean score was not statistically significant ($P > 0.05$). Such an item was identified as a candidate for deletion [22,34].

2. Item-response distribution analysis

For each item, the frequency and percentage of responses in each response category were calculated to assess response-option utilisation and the distribution of item responses [22]. For items rated on a 5-point scale, the response distribution was considered insufficiently dispersed, with limited use of

the available response options, if three or more response categories each accounted for < 10% of responses. This threshold was established as a prespecified item-screening criterion for the present study. Items meeting this criterion were identified as candidates for deletion.

3. Item analysis based on classical test theory

3.1 Internal consistency analysis

Cronbach's α coefficients were calculated for the full questionnaire and each domain [35,36]. Cronbach's α if item deleted was examined for each item at both the full-questionnaire and domain levels. If deletion of an item produced a meaningful increase in Cronbach's α for the full questionnaire or its corresponding domain, the item was flagged for further review [22,35,36]. Final decisions regarding item retention or deletion were based on the item's theoretical relevance, contribution to construct coverage, and performance across the other item analyses, rather than on maximisation of Cronbach's α alone [22,36].

3.2 Corrected item-total correlation analysis

Corrected item-total correlations were calculated as Pearson correlation coefficients between each item score and the total DKD-PCLQ score after excluding that item from the total score [22]. A corrected item-total correlation coefficient of ≥ 0.30 was considered to indicate acceptable homogeneity between the item and the overall construct. An item with a corrected item-total correlation coefficient of < 0.30 was considered to have limited homogeneity with the overall construct and was flagged as a candidate for deletion [22].

3.3 Exploratory structural analysis

PCA with Varimax orthogonal rotation was used as an exploratory item-reduction procedure to examine the component structure of the preliminary DKD-PCLQ [22,37,38]. The primary component loading and cross-loadings of each item were examined to assess the clarity of its component assignment. An item was considered to have an ambiguous component assignment if its primary loading was < 0.40 or if it loaded > 0.40 on two or more components. Items meeting either criterion were flagged as candidates for deletion [22,37].

4. Integrated item-selection criteria

Items were flagged as candidates for deletion if they met one or more of the following statistical criteria:

- (1) The mean item score did not differ significantly between the high- and low-score groups in the extreme-groups analysis ($P > 0.05$);
- (2) Three or more categories on the 5-point response scale each accounted for < 10% of responses;
- (3) Deletion of the item increased Cronbach's α for the full questionnaire or its corresponding domain;
- (4) The corrected item-total correlation coefficient was < 0.30;
- (5) The item had a primary component loading of < 0.40 or loadings of > 0.40 on two or more components in the PCA.

Item-retention decisions were made by integrating the findings across all statistical analyses [22,37]. As a general rule, items meeting at least two deletion criteria were considered for removal. This rule was established as a prespecified integrated decision criterion for the present study. For items meeting only one criterion, the research team determined whether to retain, revise, or remove the item after considering its theoretical relevance, contribution to construct coverage, expert recommendations, and overall statistical performance. Items with substantial theoretical or clinical relevance were not removed solely on the basis of a single statistical criterion [22,37].

Phase 4: Evaluation of psychometric properties

1. Participants and data collection

Between June and July 2025, people with diabetes were recruited by convenience sampling from a general hospital and a community health service centre in Fuzhou, China. The inclusion criteria were as follows: (1) age ≥ 18 years; (2) a confirmed diagnosis of diabetes established at a secondary-level or higher healthcare institution; (3) eligibility regardless of DKD status; for participants reporting DKD, the diagnosis was verified using medical records, examination reports, or physician documentation; and (4) sufficient reading comprehension and communication skills to complete the questionnaire independently or with assistance from a researcher. The exclusion criteria were as follows: (1) severe cognitive impairment, psychiatric disorders, or other conditions likely to interfere with communication or questionnaire completion; (2) severe hearing or speech impairment that precluded participation in the survey; and (3) severe acute illness or an unstable clinical condition that precluded questionnaire completion. The DKD-PCLQ was developed and administered in Chinese, the language used by study participants. All psychometric analyses reported in this study therefore pertain to the Chinese-language instrument.

2. Data analysis

The psychometric properties of the DKD-PCLQ were evaluated within a classical test theory framework, focusing on content validity, structural validity, internal consistency, and test-retest reliability [22,23].

Statistical analyses were performed using SPSS version 27.0 and AMOS version 26.0. R version 4.5.2 was used for the reproducible random allocation of the psychometric-evaluation sample into exploratory and confirmatory subsamples.

2.1 Content validity

The content validity of the DKD-PCLQ was assessed using the item-level content validity index (I-CVI) and the average scale-level content validity index (S-CVI/Ave) [23,39–41]. Both indices were calculated from the experts' item-relevance ratings obtained during the second round of expert consultation. For each item, the I-CVI was calculated as the proportion of experts who assigned a relevance rating of 4 or 5. The S-CVI/Ave was calculated as the mean of the I-CVI values across all questionnaire items. An I-CVI of ≥ 0.78 and an S-CVI/Ave of ≥ 0.90 were considered indicative of acceptable content validity [40,41].

2.2 Structural validity

Structural validity was evaluated using exploratory component analysis based on PCA and confirmatory factor analysis (CFA) [22,37,38,42]. The 422 valid observations were divided into two non-overlapping subsamples using R version 4.5.2. A random seed was set to ensure reproducibility, and simple random sampling without replacement was used to create an approximately 1:1 split: 210 observations were allocated to the CFA subsample and the remaining 212 to the exploratory subsample. Using separate subsamples reduced the risk of confirming a structure in the same observations from which it was derived [22,37].

For exploratory analysis, components were extracted using PCA with Varimax orthogonal rotation [22,37,38]. Sampling adequacy and suitability of the correlation matrix were assessed using the Kaiser-Meyer-Olkin (KMO) measure and Bartlett's test of sphericity [43,44]. The component solution was evaluated using item loadings, cross-loadings, the cumulative proportion of variance explained, and the scree plot. Because PCA is a component-reduction method rather than a common-factor model, the exploratory findings were interpreted as preliminary structural evidence and were subsequently evaluated using CFA.

CFA was conducted using maximum likelihood estimation to evaluate the three-domain measurement model corresponding to the exploratory solution. Model fit was assessed using the chi-square statistic, chi-square/df, root mean square error of approximation (RMSEA), comparative fit index (CFI), incremental fit index (IFI), and Tucker-Lewis index (TLI) [42,45]. Fit indices were interpreted collectively rather than using a single statistic as a pass-fail criterion [42,45].

If the initial CFA model did not demonstrate acceptable fit, modification indices were reviewed. Parameters were modified stepwise only when the proposed relationship was considered substantively plausible given the item content, and model fit was reassessed after each change [42]. Because modifications were informed by the present sample, the modified model was treated as provisional and in need of external confirmation.

2.3 Internal consistency reliability

Cronbach's α coefficients were calculated for the full DKD-PCLQ and each domain to assess internal consistency [35,36,46]. Cronbach's α was interpreted as an indicator of the degree of interrelatedness among items within the full questionnaire and each domain. A Cronbach's α of ≥ 0.70 was considered indicative of acceptable internal consistency for the full questionnaire and each domain [36,46].

2.4 Test-retest reliability

To assess test–retest reliability, 20 participants completed the DKD-PCLQ on two occasions separated by a 14-day interval. Absolute agreement between repeated total and domain scores was evaluated using a two-way mixed-effects, absolute-agreement, single-measure ICC. ICC estimates were reported with 95% confidence intervals [47,48].

3. Use of generative artificial intelligence in manuscript preparation

During revision of this manuscript for journal submission, ChatGPT (OpenAI) was used for English-language editing, structural refinement, and journal-formatting support. It was not used to generate study data, conduct statistical analyses, or make study-design or item-retention decisions. The authors remain responsible for the accuracy, integrity, and final content of the manuscript.

Results

Development of the preliminary DKD-PCLQ

Generation of the initial item pool

Drawing on the literature review and qualitative content analysis of the semi-structured interviews, the research team generated and integrated candidate DKD-PCLQ items [22,23,28]. Literature-derived content covered DKD knowledge, risk recognition, screening and monitoring, treatment and self-management, and relevant health-literacy measures. Candidate items were designed to assess not only knowledge but also access to and comprehension of health information, patient-healthcare professional communication, appraisal of information, and decision-making related to DKD prevention and control.

Qualitative findings were incorporated to reflect participants' lived experiences and practical needs regarding DKD awareness, information seeking, interpretation of clinical information, self-management, and prevention and control decisions. Candidate items from the literature and interviews were iteratively compared and consolidated. Redundant, ambiguous, overlapping, or insufficiently relevant items were removed, and retained items were standardised for clarity and consistency [22,23].

The hierarchical model of health literacy guided the assignment of items to the functional, interactive, and critical health literacy domains [15]. Following several rounds of discussion and revision, the initial DKD-PCLQ item pool comprised three domains, seven subdomains, and 37 items.

Expert consultation

In the first consultation round, all items except item A1-6 met the predefined coefficient of variation criterion. The coefficients of variation (CVs) for the items ranged from 0.00 to 0.24, except for item A1-6, whose CV exceeded 0.25. The mean importance scores for the three domains, seven subdomains, and 37 items all exceeded 3.50, ranging from 4.27 to 5.00 (Table 1). Based on the experts’ quantitative ratings and written comments, selected indicators and items were removed or merged, and the wording of the retained items was refined in accordance with the prespecified consultation procedure [31]. Consequently, the item pool was reduced from 37 to 35 items after the first consultation round.

In the second consultation round, the CVs for all three domains, seven subdomains, and 35 items were below 0.25, ranging from 0.00 to 0.19. The mean importance scores for all domains, subdomains, and items exceeded 3.50, ranging from 4.33 to 5.00 (Table 1). All domains, subdomains, and items therefore met the predefined retention criteria, and the experts made no further substantive recommendations regarding item revision. Following the two consultation rounds, the resulting questionnaire framework comprised three domains, seven subdomains, and 35 items.

Table 1
Expert ratings of the questionnaire domains and subdomains across two consultation rounds

Evaluation indicator	Round 1 expert consultation				Evaluation indicator	Round 2 expert consultation			
	Mean	SD	CV	Maximum-score rate (%)		Mean	SD	CV	Maximum-score rate (%)
A. Functional health literacy	5.00	0.00	0.00	100.0	A. Functional health literacy	4.93	0.26	0.05	93.3
B. Interactive health literacy	4.87	0.35	0.07	86.7	B. Interactive health literacy	4.93	0.26	0.05	93.3
C. Critical health literacy	4.87	0.35	0.07	86.7	C. Critical health literacy	4.93	0.26	0.05	93.3
A1. Knowledge of basic information about DKD	4.67	0.49	0.10	66.7	A1. Knowledge of basic information about DKD	4.87	0.35	0.07	86.7
A2. Knowledge of DKD risk factors	4.73	0.70	0.15	86.7	A2. Ability to apply DKD prevention and control information	4.80	0.41	0.09	80.0
A3. Knowledge of DKD identification and response	5.00	0.00	0.00	100.0	A3. Knowledge of DKD identification and response	4.87	0.35	0.07	86.7
B1. Ability to obtain DKD prevention and control information	4.53	0.92	0.20	73.3	B1. Ability to obtain DKD prevention and control information	4.93	0.26	0.05	93.3
B2. Ability to use DKD prevention and control information	4.80	0.41	0.09	80.0	B2. Ability to communicate DKD prevention and control information	4.73	0.46	0.10	93.3
C1. Ability to evaluate and analyze DKD prevention and control information	4.60	0.63	0.14	66.7	C1. Ability to analyze and evaluate DKD prevention and control information	4.80	0.41	0.09	93.3
C2. Ability to make and implement decisions regarding DKD prevention and control	4.47	1.06	0.24	73.3	C2. Ability to make decisions regarding DKD prevention and control	4.73	0.46	0.10	93.3
Note: DKD, diabetic kidney disease; SD, standard deviation; CV, coefficient of variation.									

Cognitive interview findings

Two rounds of cognitive interviews were conducted, each involving 15 people with diabetes, to assess the clarity of the questionnaire instructions, the comprehensibility and relevance of the items, and the appropriateness of the questionnaire content and response options [32,33]. Interviews in both rounds lasted 15–30 minutes. In the first round, five participants reported difficulty understanding certain questionnaire items. After reviewing the participants’ feedback, the research team revised the wording of three items to improve clarity and comprehensibility.

In the second round, no participants identified further problems with the questionnaire instructions, items, or response options, and no additional recommendations for revision were provided. The item wording was therefore considered stable. The resulting preliminary DKD-PCLQ comprised 35 items and was subsequently subjected to item analysis and selection in Phase 3.

Item-selection results

Participant characteristics

Of the 280 returned questionnaires, 266 met the prespecified data-quality criteria and were included in the analysis (analysable proportion, 95.0%). The final item-analysis sample included 127 men (47.7%) and 139 women (52.3%). Participants were aged 27–77 years, with a mean (SD) age of 52.69 (15.14) years. The duration of diabetes ranged from 1 to 33 years, with a mean (SD) of 7.49 (6.39) years.

Questionnaire administration and scoring

The preliminary DKD-PCLQ contained 35 items with 5 response options. Higher scores indicated higher DKD prevention and control literacy. The total score ranged from 35 to 175, and domain scores were calculated by summing the relevant items. If a participant required assistance, trained research staff used a standardised procedure that described permitted assistance without interpreting items or influencing responses.

The full wording and response options of the final 26-item DKD-PCLQ are presented in Additional file 1 (Supplementary Table S1) as an English translation for international readers. The study participants completed the Chinese-language questionnaire; the English translation was not independently psychometrically validated in the present study and should not be interpreted as a validated English-language version.

Critical-ratio analysis

As shown in Table 2, independent-samples *t* tests indicated that the mean scores of items A2-2, A3-3, B2-3, and B2-4 did not differ significantly between the high- and low-score groups ($P > 0.05$). Accordingly, these four items were flagged as candidates for deletion.

Item-response distribution analysis

For each item, fewer than three response categories each accounted for $< 10\%$ of responses. Thus, no item met the prespecified deletion criterion for item-response distribution.

Item selection based on classical test theory

1. Internal consistency analysis

Cronbach's α for the overall questionnaire was 0.894. Deleting any one of items A3-2, A3-3, B1-3, B2-3, B2-4, or C2-4 individually increased the overall Cronbach's α . Accordingly, these six items were flagged as candidates for deletion. Detailed item-level results are presented in Table 2.

2. Corrected item-total correlation analysis

The corrected item-total correlation coefficients for items A2-2, A3-2, A3-3, B1-3, B2-3, B2-4, and C2-4 were < 0.30 . Accordingly, these seven items were flagged as candidates for deletion.

3. Exploratory component analysis

Items A2-2 and B2-4 had primary component loadings of < 0.40 . Item A2-3 exhibited substantial cross-loadings on Components 1 and 3 and was therefore also flagged as a candidate for deletion.

Integrated item-selection decision

After integrating the findings from the critical-ratio analysis, item-response distribution analysis, internal consistency analysis, corrected item-total correlation analysis, and exploratory component analysis, the research team removed items A2-2, A2-3, A3-2, A3-3, B1-3, B2-3, B2-4, and C2-4 from the item pool. Of these, A2-2, A3-2, A3-3, B1-3, B2-3, B2-4, and C2-4 met at least two prespecified deletion criteria. Items A3-2, B1-3, and C2-4 were removed because each exhibited both a corrected item-total correlation of < 0.30 and an increase in the overall Cronbach's α after deletion. Although item A2-3 met only the cross-loading criterion, it was removed after consideration of its ambiguous component assignment and its conceptual fit within the proposed questionnaire structure. Following item selection, 27 items were retained for subsequent psychometric evaluation.

Table 2
Item-analysis results and item-retention decisions (n = 266)

Item	Item score		t	P	Cronbach's α if item deleted	Item-total correlation	Factor loadings								
	High- score group	Low- score group					1	2	3	4	5	6	7	8	9
	(n = 72)	(n = 72)													
A1-1	3.86	2.14	10.844	<0.001	0.889	0.573**		0.736							
A1-2	4.03	2.26	12.028	<0.001	0.888	0.609**			0.601						
A1-3	4.15	1.88	15.444	<0.001	0.886	0.710**			0.675						
A1-4	3.86	2.58	8.954	<0.001	0.891	0.432**									0.427
A1-5	3.76	1.50	19.488	<0.001	0.885	0.767**		0.823							
A1-6	3.79	1.53	19.100	<0.001	0.885	0.768**		0.830							
A1-7	3.79	1.50	19.601	<0.001	0.885	0.771**		0.819							
A2-1	3.38	2.13	5.535	<0.001	0.892	0.388**						0.602			
A2-2	3.11	3.19	-0.407	0.685	0.899	-0.022			0.346						
A2-3	3.96	1.60	16.538	<0.001	0.886	0.714**	0.426		0.533						
A2-4	4.10	1.74	19.326	<0.001	0.885	0.751**	0.875								
A3-1	3.93	2.18	11.268	<0.001	0.888	0.613**			0.743						
A3-2	2.83	2.28	2.185	0.031	0.897	0.152*							0.568		
A3-3	3.18	2.97	0.814	0.417	0.898	0.092						0.754			
A3-4	3.42	2.06	6.826	<0.001	0.892	0.417**						0.736			
A3-5	4.15	2.13	11.017	<0.001	0.888	0.613**			0.721						
A3-6	3.71	2.10	10.464	<0.001	0.890	0.541**				0.407					
A3-7	4.10	1.89	17.497	<0.001	0.886	0.737**	0.875								
B1-1	4.07	2.60	9.233	<0.001	0.890	0.509**							0.531		
B1-2	4.04	2.44	10.147	<0.001	0.890	0.536**							0.628		
B1-3	3.33	2.32	4.274	<0.001	0.896	0.236**				0.420					
B1-4	4.10	1.89	17.286	<0.001	0.886	0.733**	0.876								
B2-1	3.82	2.51	6.623	<0.001	0.892	0.407**								0.758	
B2-2	3.74	2.10	9.032	<0.001	0.890	0.509**							0.549		
B2-3	3.60	3.32	1.269	0.207	0.900	0.004							0.589		
B2-4	3.18	3.29	-0.546	0.586	0.900	-0.094						0.155			

Item	Item score		t	P	Cronbach's α if item deleted	Item-total correlation	Factor loadings								
	High-score group (n = 72)	Low-score group (n = 72)					1	2	3	4	5	6	7	8	9
B2-5	3.72	3.04	4.312	< 0.001	0.893	0.327**								0.503	
C1-1	3.67	2.43	6.384	< 0.001	0.891	0.447**				0.879					
C1-2	3.56	2.43	5.430	< 0.001	0.892	0.400**				0.886					
C1-3	3.78	2.19	9.790	< 0.001	0.889	0.555**				0.718					
C1-4	4.13	1.64	16.911	< 0.001	0.886	0.677**	0.816								
C2-1	3.99	2.47	9.726	< 0.001	0.890	0.537**					0.741				
C2-2	3.93	2.67	8.094	< 0.001	0.891	0.467**					0.776				
C2-3	3.36	2.32	5.958	< 0.001	0.892	0.386**					0.574				
C2-4	3.31	2.67	2.929	0.004	0.895	0.231**						0.614			

Psychometric evaluation results

Structural validity

All 440 distributed questionnaires were returned; 422 met the study's validity criteria and were included in psychometric evaluation (valid response rate, 95.9%). Using the prespecified reproducible simple-random-sampling procedure, the 422 observations were divided into non-overlapping exploratory (n = 212) and confirmatory (n = 210) subsamples.

In the exploratory analysis subsample, the Kaiser–Meyer–Olkin (KMO) measure was 0.897, and Bartlett's test of sphericity was statistically significant ($P < 0.001$), indicating that the data were suitable for component analysis. Principal component analysis (PCA) with Varimax orthogonal rotation was conducted on the retained questionnaire items. Following two iterative rounds of analysis, item A3-7 was removed because it exhibited substantial cross-loadings. The final PCA retained three components with eigenvalues > 1 , which collectively explained 63.957% of the total variance. The resulting questionnaire comprised 26 items distributed across three components.

The final 26-item DKD-PCLQ comprised 13 functional, 6 interactive, and 7 critical health-literacy items. Functional items addressed DKD knowledge, risk, screening and monitoring, symptoms, preventive behaviours, and treatment-related information. Interactive items addressed information seeking through the internet, books, and healthcare professionals together with clinician-patient communication. Critical items addressed source reliability, accuracy judgement, personal applicability, professional verification, health-action planning, treatment participation, and contextual treatment choice. The complete final questionnaire is presented in Additional file 1 (Supplementary Table S1).

CFA was conducted in the independent confirmatory subsample to evaluate the three-domain model corresponding to the exploratory solution. The initial model did not meet the prespecified fit criteria. After limited stepwise modification, the model showed acceptable fit (chi-square/df = 1.839, RMSEA = 0.063, CFI = 0.925, TLI = 0.915, and IFI = 0.926; Table 3), and all standardised factor loadings exceeded 0.40 (Fig. 1). Because these modifications were informed by the current data, the results are interpreted as preliminary evidence of structural validity requiring external confirmation.

Table 3
Fit indices for the initial and modified confirmatory factor models (n = 210)

Fit Indices	χ^2/df	RMSEA	GFI	CFI	TLI	IFI
Criteria	< 5	< 0.08	> 0.8	> 0.9	> 0.9	> 0.9
Initial Model	3.048	0.099	0.739	0.811	0.792	0.812
Proposed Model	1.839	0.063	0.838	0.925	0.915	0.926

Content validity

The item-level content validity indices (I-CVIs) for the 26-item DKD-PCLQ ranged from 0.867 to 1.000, and all values exceeded the prespecified acceptability threshold of 0.78. The average scale-level content validity index (S-CVI/Ave) was 0.979, exceeding the prespecified threshold of 0.90. Collectively, these

findings supported the satisfactory content validity of the DKD-PCLQ.

Reliability

Cronbach's α for the overall 26-item DKD-PCLQ was 0.898. The corresponding Cronbach's α values for the functional, interactive, and critical health literacy domains were 0.912, 0.866, and 0.899, respectively.

To assess test–retest reliability, 20 participants completed the DKD-PCLQ twice, with a 14-day interval between administrations. The two-way mixed-effects, absolute-agreement, single-measure ICC was 0.96 (95% CI [0.91–0.98]) for the total score. The corresponding ICCs for the functional, interactive, and critical health literacy domains were all 0.9 or above (Table 4).

Table 4 Test–retest reliability of the DKD-PCLQ		
Dimension	ICC	95% CI
Functional health literacy	0.90	0.75–0.96
Interactive health literacy	0.98	0.95–0.99
Critical health literacy	0.96	0.91–0.98
Note: ICC, intraclass correlation coefficient; CI, confidence interval.		

Discussion

This study developed and preliminarily evaluated the DKD-PCLQ, a 26-item questionnaire designed to capture functional, interactive, and critical competencies relevant to DKD prevention and control. The development process combined a theoretical health-literacy framework with literature review, interviews with people with diabetes, expert consultation, cognitive interviewing, item analysis, and independent exploratory and confirmatory subsamples. The resulting instrument addresses disease-specific knowledge together with the acquisition, interpretation, appraisal, communication, and application of health information in DKD-related decisions.

This framing is important for the decision-making context. Early DKD is often not symptom driven, and many preventive actions depend on understanding risk, interpreting screening information, communicating with healthcare professionals, and deciding how to act on recommendations [2,6,49]. The final item set operationalises this pathway across three domains: functional items address foundational DKD knowledge and its application; interactive items address information seeking and clinician-patient communication; and critical items address source appraisal, verification, personal applicability, action planning, treatment participation, and contextual treatment choice. This is consistent with multidimensional health-literacy frameworks in which information is converted into health decisions and action [14,15].

Internal consistency was good for the total score (Cronbach's α = 0.898) and for the functional, interactive, and critical domains (α = 0.912, 0.866, and 0.899, respectively). These coefficients support interrelatedness of items within the proposed scale and domains [36], but they should not be interpreted as evidence of unidimensionality or structural validity on their own.

The total-score test-retest ICC was 0.96 (95% CI 0.91–0.98) using a two-way mixed-effects, absolute-agreement, single-measure model, with domain ICCs of 0.90 or higher. These estimates suggest good short-term score stability over 14 days [47,48]. However, the retest sample was small (n = 20), and measurement error was not quantified using the standard error of measurement or smallest detectable change. Test-retest findings should therefore be regarded as preliminary.

Content validity was supported by expert ratings (I-CVI 0.867–1.000; S-CVI/Ave 0.979) and by the broader development process. In line with content-validity guidance, the literature review and theoretical framework informed construct coverage, interviews with people with diabetes contributed disease- and context-specific content, expert consultation addressed relevance and comprehensiveness, and cognitive interviewing evaluated comprehensibility and response processes [22,23,32,33,39–41].

Exploratory PCA identified a three-component solution, and CFA in a separate subsample provided preliminary support for the corresponding three-domain model. The modified CFA model showed acceptable fit (CFI = 0.925; RMSEA = 0.063), with all standardised loadings above 0.40. Nevertheless, the evidence remains preliminary for two reasons: PCA with orthogonal rotation was used for exploration, and the CFA required sample-informed modifications. Independent replication using common-factor exploratory methods where appropriate, prespecified confirmatory models, and larger samples is needed before the three-domain structure can be considered established [37,38,42,45].

The DKD-PCLQ differs from generic and disease-specific health-literacy instruments in its intended target. Generic measures such as the All Aspects of Health Literacy Scale and Health Literacy Questionnaire assess broad literacy domains and interactions with healthcare systems [50–52], whereas kidney-focused work has often emphasised CKD knowledge, awareness, communication, or self-management [17–19]. The DKD-PCLQ was designed specifically for the intersection of diabetes and kidney disease, where people must integrate diabetes self-management with kidney-risk recognition and monitoring.

Its potential added value lies in combining DKD-specific knowledge with information-use and decision-making competencies. The final questionnaire spans risk recognition, screening and monitoring, preventive and management strategies, information seeking through the internet, books, and healthcare professionals, communication of symptoms and treatment effects, source-credibility and accuracy appraisal, assessment of personal applicability,

professional verification, and application of information to health actions and treatment decisions. This broader information-to-action pathway is consistent with contemporary health-literacy concepts [14,15,17,50,51]. Direct comparisons with established instruments are still needed to determine incremental validity and whether DKD-PCLQ scores explain clinically meaningful variation beyond general health literacy or disease knowledge.

The qualitative and cognitive-interview components also strengthened the intended patient-centred interpretation of the questionnaire. Participants' experiences highlighted difficulties not only with DKD knowledge but also with locating reliable information, communicating proactively, interpreting clinical indicators, and judging personal susceptibility. The retained items consequently include competencies that are especially relevant to information-rich care environments, such as locating online information, judging whether a source is reliable, evaluating whether information is accurate and applicable to one's own situation, and verifying information with healthcare professionals. These features support interpreting the DKD-PCLQ as a measure of information-use and decision-making needs rather than as a knowledge test alone [15,22,23,32,33].

These item-level features also provide a plausible bridge to future medical-informatics research. If externally validated and accompanied by interpretable score guidance, DKD-PCLQ responses could be represented as structured data for automated scoring, longitudinal tracking, or targeted delivery of vetted information within clinical workflows. Domain- or item-level profiles could then be evaluated as prompts for tailored discussion of kidney screening, laboratory results, medication or lifestyle recommendations, information reliability, or questions for healthcare professionals. Such use would be intended to support, not replace, clinical assessment, laboratory testing, or shared clinical judgement. The present study did not evaluate an electronic system or decision-support intervention, so these applications remain hypotheses for future implementation research.

The questionnaire may also support stratified education and self-management interventions. Rather than delivering uniform information, healthcare teams could use domain-level patterns to identify whether a patient primarily needs foundational DKD information, help interpreting monitoring results, support communicating with clinicians, or assistance appraising and applying information. Health-literacy-sensitive interventions can improve diabetes knowledge and selected self-management outcomes, although effects across outcomes are heterogeneous [53–55]. Prospective studies should test whether DKD-PCLQ-guided support improves information use, decision quality, self-management, healthcare use, or clinical outcomes beyond usual education.

For research use, the DKD-PCLQ could serve as an outcome or explanatory measure after responsiveness and interpretability are established [56,57]. Future studies could examine associations with kidney-screening uptake, medication-taking behaviour, glycaemic control, albuminuria, kidney function, and healthcare utilisation, while accounting for clinical and socioeconomic confounding. Longitudinal designs are particularly important because cross-sectional associations would not establish that literacy causes better outcomes. The questionnaire should therefore be viewed as a candidate measurement and decision-support tool whose clinical value still requires prospective validation.

Limitations

Several limitations constrain interpretation. First, the expert panel was relatively small and unevenly distributed across professional seniority and specialist fields, which may have limited the breadth of perspectives represented in content evaluation. Second, structural evaluation relied on PCA with Varimax orthogonal rotation rather than a common-factor exploratory model, and the CFA required modification based on the present confirmatory sample. Although the exploratory and confirmatory analyses used non-overlapping subsamples, the modified CFA model has not yet been replicated externally. Third, the test-retest sample was small and measurement error was not estimated. In addition, criterion validity, hypothesis-based construct validity against external measures, responsiveness, interpretability, and measurement invariance were not evaluated. These limitations support describing the current evidence as preliminary rather than definitive [22,23,37,38,42].

Generalisability is also limited by convenience sampling from only two sites within one city. Educational attainment, socioeconomic circumstances, access to healthcare and digital or non-digital health information, healthcare-delivery systems, language, and information-seeking behaviour may affect how items are understood and answered. Future validation should therefore include larger, geographically diverse hospital and community samples, urban and rural populations, different educational and socioeconomic groups, and people with and without diagnosed DKD. External CFA and measurement-invariance analyses should test whether scores are comparable across clinically relevant subgroups [22,23]. In addition, all development and validation data were obtained using the Chinese-language DKD-PCLQ. The English translation supplied in Additional file 1 (Supplementary Table S1) is provided for reporting and item-content inspection only; cross-cultural adaptation and independent validation would be required before it could be used as an English-language instrument.

Several retained items also contain context-dependent or time-sensitive clinical content, including a specific monitoring interval and named medication examples. Their relevance may vary with disease stage, local practice, treatment availability, and future updates to clinical recommendations. Periodic content review and cross-cultural adaptation will therefore be necessary, and any substantive item revision should be followed by renewed measurement evaluation rather than assumed to be psychometrically equivalent to the present version.

Implications for decision support, informatics, and future research

The immediate priority is external psychometric validation. Larger multisite studies should re-evaluate the component or factor structure, internal consistency, test-retest reliability, content validity, and item performance in independent populations rather than assuming the present structure is stable [22,23,42]. Measurement invariance should be examined across sex, age, education, healthcare setting, geographic context, and DKD status so that group comparisons are interpretable.

Longitudinal studies should then evaluate predictive and longitudinal validity. Baseline DKD-PCLQ scores could be examined in relation to subsequent kidney-screening attendance, clinical follow-up, self-management behaviours, glycaemic control, albuminuria, serum creatinine, and estimated glomerular filtration

rate, with appropriate adjustment for clinical and socioeconomic confounding. Responsiveness and meaningful change thresholds should also be evaluated before the questionnaire is used as an intervention outcome [56,57].

An electronic DKD-PCLQ is a plausible next step for medical-informatics research because the final instrument already includes information-access and appraisal content relevant to digital information environments. Digital administration could support automated scoring, structured storage, longitudinal tracking, and integration with hospital or community information systems. Electronic migration should preserve item wording, response options, order, scoring, and interpretation, and should be evaluated for usability, accessibility, completeness, and measurement comparability with the paper version [58]. Digital implementation should also account for older adults, people with limited digital literacy, and those who require assistance so that electronic administration does not introduce new access barriers.

After validation, structured DKD-PCLQ results could potentially trigger tailored decision-support actions. For example, difficulties with information access or appraisal could prompt vetted educational resources; communication-related needs could prompt question-prompt lists or clinician discussion; and difficulties interpreting screening indicators could prompt targeted explanation of kidney-monitoring results. Because the questionnaire also asks about personal applicability, professional verification, action planning, and treatment participation, future systems could investigate whether these item-level profiles help personalise the type and timing of decision support. These are proposed workflow uses, not outcomes demonstrated in the present study. Their feasibility, acceptability, safety, and effect on patient-clinician decision processes should be evaluated before implementation.

Future implementation studies should therefore compare questionnaire-guided pathways with usual education or self-management support. Relevant outcomes include DKD-PCLQ score change, decision quality, patient understanding, self-management behaviours, medication adherence, screening uptake, healthcare use, and kidney-related clinical indicators. Evaluation should also consider workflow burden, completion rates, digital accessibility, and whether automated recommendations remain understandable and appropriate across patient subgroups.

Conclusions

This study developed the 26-item DKD-PCLQ and provided preliminary evidence of internal consistency, content validity, structural validity, and test-retest reliability among people with diabetes. By integrating DKD-specific knowledge with health-information access, communication, appraisal, verification, application, and participation in health-related decisions, the questionnaire is positioned as a candidate measure of information-use and decision-making competencies relevant to DKD prevention and control. With external validation and interpretable scoring, it may support tailored patient education and decision-support research, including future electronic administration and workflow integration. The instrument should not be adopted for routine clinical or digital decision support until its structural stability, measurement error, responsiveness, interpretability, invariance, and external validity have been established.

Abbreviations

CFA
Confirmatory factor analysis
CFI
Comparative fit index
CKD
Chronic kidney disease
CV
Coefficient of variation
DKD
Diabetic kidney disease
DKD-PCLQ
Diabetic Kidney Disease Prevention and Control Literacy Questionnaire
eGFR
Estimated glomerular filtration rate
ESKD
End-stage kidney disease
ICC
Intraclass correlation coefficient
I-CVI
Item-level content validity index
IFI
Incremental fit index
KMO
Kaiser–Meyer–Olkin measure of sampling adequacy
MI _s
Modification indices
PCA
Principal component analysis

RMSEA
Root mean square error of approximation
S-CVI/Ave
Scale-level content validity index based on the average method
SD
Standard deviation
TLI
Tucker–Lewis index

Declarations

Ethics approval and consent to participate

This study was reviewed and approved by the Biomedical Research Ethics Review Committee of Fujian Medical University (approval no. [2023] Fu Medical Ethics Review NO. 175). All procedures performed in this study were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration and its later amendments. All participants provided informed consent to participate in the study.

Consent for publication

Not applicable.

Availability of data and materials

The datasets generated and/or analysed during the current study are available from the corresponding author on reasonable request.

The authors declare that they have no competing interests.

Funding

The authors received no financial support for the research, authorship, and/or publication of this article.

Authors' contributions

Y.R., H.L., H.H., and T.L. contributed to the conception and design of the study. Y.R., H.L., S.C., and S.Z. contributed to the implementation of the study. All authors read and approved the final manuscript.

Acknowledgements

We thank all those who participated in this study.

References

1. International Diabetes Federation. IDF Diabetes Atlas. 11th ed. Brussels: International Diabetes Federation; 2025.
2. Alicic RZ, Rooney MT, Tuttle KR. Diabetic kidney disease: challenges, progress, and possibilities. *Clin J Am Soc Nephrol*. 2017;12:2032-45. doi:10.2215/CJN.11491116.
3. Hoogeveen EK. The epidemiology of diabetic kidney disease. *Kidney Dial*. 2022;2:433-42. doi:10.3390/kidneydial2030038.
4. Jha R, Lopez-Trevino S, Kankanamalage HR, Jha JC. Diabetes and renal complications: an overview on pathophysiology, biomarkers and therapeutic interventions. *Biomedicines*. 2024;12:1098. doi:10.3390/biomedicines12051098.
5. Kidney Disease: Improving Global Outcomes CKD Work Group. KDIGO 2024 clinical practice guideline for the evaluation and management of chronic kidney disease. *Kidney Int*. 2024;105(4S). doi:10.1016/j.kint.2023.10.018.
6. American Diabetes Association Professional Practice Committee for Diabetes. 11. Chronic kidney disease and risk management: Standards of Care in Diabetes-2026. *Diabetes Care*. 2026;49 Suppl 1. doi:10.2337/dc26-S011.
7. Francis A, Harhay MN, Ong ACM, Tummalapalli SL, Ortiz A, Fogo AB, et al. Chronic kidney disease and the global public health agenda: an international consensus. *Nat Rev Nephrol*. 2024;20:473-85. doi:10.1038/s41581-024-00820-6.
8. Jha V, Al-Ghamdi SMG, Li G, Wu MS, Stafylas P, Retat L, et al. Global economic burden associated with chronic kidney disease: a pragmatic review of medical costs for the Inside CKD Research Programme. *Adv Ther*. 2023;40:4405-20. doi:10.1007/s12325-023-02608-9.
9. Kim K, Crook J, Lu CC, Nyman H, Sarker J, Nelson R, et al. Healthcare costs across diabetic kidney disease stages: a Veterans Affairs study. *Kidney Med*. 2024;6:100873. doi:10.1016/j.xkme.2024.100873.

10. Zimbudzi E, Lo C, Misso ML, Ranasinha S, Kerr PG, Teede HJ, et al. Effectiveness of self-management support interventions for people with comorbid diabetes and chronic kidney disease: a systematic review and meta-analysis. *Syst Rev*. 2018;7:84. doi:10.1186/s13643-018-0748-z.
11. Kushner P, Khunti K, Cebrián A, Deed G. Early identification and management of chronic kidney disease: a narrative review of the crucial role of primary care practitioners. *Adv Ther*. 2024;41:3757-70. doi:10.1007/s12325-024-02957-z.
12. Badran A, Bahar A, Tammam M, Bahar S, Khalil A, Koni AA, et al. The relationship between diabetes-related knowledge and kidney disease knowledge, attitudes, and practices: a cross-sectional study. *BMC Public Health*. 2023;23:480. doi:10.1186/s12889-023-15390-8.
13. Radić J, Vučković M, Đogaš H, Grubić M, Belančić A, Tandara L, et al. Beyond blood sugar: low awareness of kidney disease among type 2 diabetes mellitus patients in Dalmatia-insights from the first open public call. *Medicina (Kaunas)*. 2024;60:1643. doi:10.3390/medicina60101643.
14. Sørensen K, Van den Broucke S, Fullam J, Doyle G, Pelikan J, Slonska Z, et al. Health literacy and public health: a systematic review and integration of definitions and models. *BMC Public Health*. 2012;12:80. doi:10.1186/1471-2458-12-80.
15. Nutbeam D. Health literacy as a public health goal: a challenge for contemporary health education and communication strategies into the 21st century. *Health Promot Int*. 2000;15:259-67. doi:10.1093/heapro/15.3.259.
16. World Health Organization. Health promotion glossary of terms 2021. Geneva: World Health Organization; 2021.
17. Wei CJ, Shih CL, Hsu YJ, Chen YC, Yeh JZ, Shih JH, et al. Development and application of a chronic kidney disease-specific health literacy, knowledge and disease awareness assessment tool for patients with chronic kidney disease in Taiwan. *BMJ Open*. 2021;11. doi:10.1136/bmjopen-2021-052597.
18. Jain D, Green JA. Health literacy in kidney disease: review of the literature and implications for clinical practice. *World J Nephrol*. 2016;5:147-51. doi:10.5527/wjn.v5.i2.147.
19. Shah JM, Ramsbotham J, Seib C, Muir R, Bonner A. A scoping review of the role of health literacy in chronic kidney disease self-management. *J Ren Care*. 2021;47:221-33. doi:10.1111/jorc.12364.
20. Cavanaugh KL. Health literacy in diabetes care: explanation, evidence and equipment. *Diabetes Manag (Lond)*. 2011;1:191-9. doi:10.2217/dmt.11.5.
21. Al Sayah F, Williams B, Johnson JA. Measuring health literacy in individuals with diabetes: a systematic review and evaluation of available measures. *Health Educ Behav*. 2013;40:42-55. doi:10.1177/1090198111436341.
22. Boateng GO, Neilands TB, Frongillo EA, Melgar-Quinonez HR, Young SL. Best practices for developing and validating scales for health, social, and behavioral research: a primer. *Front Public Health*. 2018;6:149. doi:10.3389/fpubh.2018.00149.
23. Terwee CB, Prinsen CAC, Chiarotto A, Westerman MJ, Patrick DL, Alonso J, et al. COSMIN methodology for evaluating the content validity of patient-reported outcome measures: a Delphi study. *Qual Life Res*. 2018;27:1159-70. doi:10.1007/s11136-018-1829-0.
24. Ratzan SC, Parker RM. Introduction. In: Selden CR, Zorn M, Ratzan SC, Parker RM, editors. National Library of Medicine current bibliographies in medicine: health literacy. Bethesda (MD): National Institutes of Health; 2000. NLM publication No. CBM 2000-1.
25. Poureslami I, Nimmon L, Rootman I, FitzGerald MJ. Health literacy and chronic disease management: drawing from expert knowledge to set an agenda. *Health Promot Int*. 2017;32:743-54. doi:10.1093/heapro/daw003.
26. Nie XQ, Li YH, Tao MX, Li L, Huang XG. Study on chronic disease literacy and its influencing factors in China [in Chinese]. *Chin J Health Educ*. 2015;31:108-11. doi:10.16168/j.cnki.issn.1002-9982.2015.02.003.
27. Simonds SK. Health education as social policy. *Health Educ Monogr*. 1974;2 Suppl 1:1-10. doi:10.1177/10901981740020S102.
28. Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. *Qual Health Res*. 2005;15:1277-88. doi:10.1177/1049732305276687.
29. Hennink MM, Kaiser BN, Marconi VC. Code saturation versus meaning saturation: how many interviews are enough? *Qual Health Res*. 2017;27:591-608. doi:10.1177/1049732316665344.
30. Palinkas LA, Horwitz SM, Green CA, Wisdom JP, Duan N, Hoagwood K. Purposeful sampling for qualitative data collection and analysis in mixed method implementation research. *Adm Policy Ment Health*. 2015;42:533-44. doi:10.1007/s10488-013-0528-y.
31. Hasson F, Keeney S, McKenna H. Research guidelines for the Delphi survey technique. *J Adv Nurs*. 2000;32:1008-15. doi:10.1046/j.1365-2648.2000.t01-1-01567.x.
32. Beatty PC, Willis GB. Research synthesis: the practice of cognitive interviewing. *Public Opin Q*. 2007;71:287-311. doi:10.1093/poq/nfm006.
33. Willis GB. Cognitive interviewing: a tool for improving questionnaire design. Thousand Oaks (CA): Sage Publications; 2005.
34. Kelley TL. The selection of upper and lower groups for the validation of test items. *J Educ Psychol*. 1939;30:17-24. doi:10.1037/h0057123.
35. Cronbach LJ. Coefficient alpha and the internal structure of tests. *Psychometrika*. 1951;16:297-334. doi:10.1007/BF02310555.
36. Tavakol M, Dennick R. Making sense of Cronbach's alpha. *Int J Med Educ*. 2011;2:53-5. doi:10.5116/ijme.4dfb.8dfd.
37. Worthington RL, Whittaker TA. Scale development research: a content analysis and recommendations for best practices. *Couns Psychol*. 2006;34:806-38. doi:10.1177/0011000006288127.
38. Fabrigar LR, Wegener DT, MacCallum RC, Strahan EJ. Evaluating the use of exploratory factor analysis in psychological research. *Psychol Methods*. 1999;4:272-99. doi:10.1037/1082-989X.4.3.272.
39. Lynn MR. Determination and quantification of content validity. *Nurs Res*. 1986;35:382-5. doi:10.1097/00006199-198611000-00017.
40. Polit DF, Beck CT. The content validity index: are you sure you know what's being reported? Critique and recommendations. *Res Nurs Health*. 2006;29:489-97. doi:10.1002/nur.20147.
41. Polit DF, Beck CT, Owen SV. Is the CVI an acceptable indicator of content validity? Appraisal and recommendations. *Res Nurs Health*. 2007;30:459-67. doi:10.1002/nur.20199.
42. Kline RB. Principles and practice of structural equation modeling. 4th ed. New York: Guilford Press; 2016.

43. Kaiser HF. An index of factorial simplicity. *Psychometrika*. 1974;39:31-6. doi:10.1007/BF02291575.
44. Bartlett MS. A note on the multiplying factors for various chi-square approximations. *J R Stat Soc Series B Stat Methodol*. 1954;16:296-8. doi:10.1111/j.2517-6161.1954.tb00174.x.
45. Hu LT, Bentler PM. Cutoff criteria for fit indexes in covariance structure analysis: conventional criteria versus new alternatives. *Struct Equ Modeling*. 1999;6:1-55. doi:10.1080/10705519909540118.
46. Nunnally JC, Bernstein IH. *Psychometric theory*. 3rd ed. New York: McGraw-Hill; 1994.
47. Qin S, Nelson L, McLeod L, Eremenco S, Coons SJ. Assessing test-retest reliability of patient-reported outcome measures using intraclass correlation coefficients: recommendations for selecting and documenting the analytical formula. *Qual Life Res*. 2019;28(4):1029-1033. doi:10.1007/s11136-018-2076-0.
48. McGraw KO, Wong SP. Forming inferences about some intraclass correlation coefficients. *Psychol Methods*. 1996;1(1):30-46. doi:10.1037/1082-989X.1.1.30.
49. de Boer IH, Khunti K, Sadusky T, Tuttle KR, Neumiller JJ, Rhee CM, et al. Diabetes management in chronic kidney disease: a consensus report by the American Diabetes Association and Kidney Disease: Improving Global Outcomes. *Diabetes Care*. 2022;45:3075-90. doi:10.2337/dci22-0027.
50. Chinn D, McCarthy C. All Aspects of Health Literacy Scale (AAHLS): developing a tool to measure functional, communicative and critical health literacy in primary healthcare settings. *Patient Educ Couns*. 2013;90:247-53. doi:10.1016/j.pec.2012.10.019.
51. Osborne RH, Batterham RW, Elsworth GR, Hawkins M, Buchbinder R. The grounded psychometric development and initial validation of the Health Literacy Questionnaire (HLQ). *BMC Public Health*. 2013;13:658. doi:10.1186/1471-2458-13-658.
52. Tavousi M, Mohammadi S, Sadighi J, Zarei F, Mozafari-Kermani R, Rostami R, et al. Measuring health literacy: a systematic review and bibliometric analysis of instruments from 1993 to 2021. *PLoS One*. 2022;17. doi:10.1371/journal.pone.0271524.
53. Dahal PK, Hosseinzadeh H. Association of health literacy and diabetes self-management: a systematic review. *Aust J Prim Health*. 2019;25:526-33. doi:10.1071/PY19007.
54. Butayeva J, Ratan ZA, Downie S, Hosseinzadeh H. The impact of health literacy interventions on glycemic control and self-management outcomes among type 2 diabetes mellitus: a systematic review. *J Diabetes*. 2023;15:724-35. doi:10.1111/1753-0407.13436.
55. Al Sayah F, Majumdar SR, Williams B, Robertson S, Johnson JA. Health literacy and health outcomes in diabetes: a systematic review. *J Gen Intern Med*. 2013;28:444-52. doi:10.1007/s11606-012-2241-z.
56. Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, et al. The COSMIN study reached international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes. *J Clin Epidemiol*. 2010;63:737-45. doi:10.1016/j.jclinepi.2010.02.006.
57. Mokkink LB, Terwee CB, de Vet HCW. Key concepts in clinical epidemiology: responsiveness, the longitudinal aspect of validity. *J Clin Epidemiol*. 2021;140:159-62. doi:10.1016/j.jclinepi.2021.06.002.
58. O'Donohoe P, Reasner DS, Kovacs SM, Byrom B, Eremenco S, Barsdorf AI, et al. Updated recommendations on evidence needed to support measurement comparability among modes of data collection for patient-reported outcome measures: a good practices report of an ISPOR Task Force. *Value Health*. 2023;26:623-33. doi:10.1016/j.jval.2023.01.001.

Figures

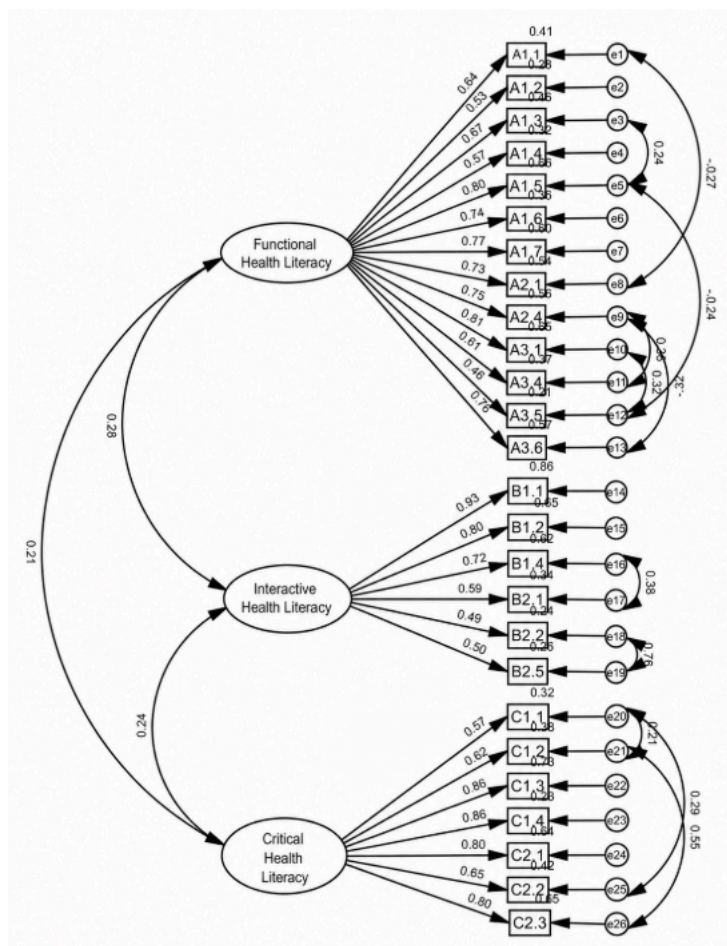


Figure 1

Standardised three-factor CFA model for the 26-item DKD-PCLQ after modification (n = 210)

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [Additionalfile1.docx](#)