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Validation of the Persian version of the summary of diabetes self-care activities scale (SDSCA) in pregnant women with gestational diabetes mellitus using a COSMIN methodology

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Abstract

Background Gestational diabetes mellitus (GDM) is a condition with significant prenatal and postnatal implications. This study aimed to validate the Summary of Diabetes Self-Care Activities (SDSCA) measure in Iranian women with GDM, focusing on its psychometric properties.

Methods The Persian version of the SDSCA was evaluated in 180 Iranian women with GDM. Following COSMIN guidelines, the instrument was translated into Persian, and its psychometric properties were assessed, including content validity, face validity, construct validity, internal consistency, test-retest reliability, measurement error, responsiveness, and interpretability. Floor and ceiling effects were also examined.

Results The validity assessments showed strong content validity, with a Content Validity Index (CVI) of 0.93 and a Content Validity Ratio (CVR) of 0.97. Face validity yielded an impact score of 4.38. Exploratory factor analysis (EFA) identified three factors—diet, exercise, and blood sugar testing—accounting for 57.4% of the variance. Confirmatory factor analysis (CFA) confirmed the model's excellent fit (CFI = 1.00, TLI = 0.99, NFI = 0.98, RFI = 0.96). The reliability analysis showed a Cronbach's alpha of 0.78 and a McDonald's omega of 0.91, with an intraclass correlation coefficient (ICC) of 0.92 (95% CI: 0.83–0.96). Ceiling effects were observed for blood sugar testing (26.7%), while floor effects were noted for exercise (6.7%) and blood sugar testing (6.1%). The Minimal Important Change (MIC) of 2.68 units exceeded the Smallest Detectable Change (SDC) of 1.11 units, indicating the tool's ability to detect clinically meaningful changes.

Conclusions The Persian version of the SDSCA demonstrates strong psychometric properties, including both reliability and validity, making it a suitable tool for assessing self-care behaviors in Iranian women with GDM. Its use in future research can enhance understanding of self-management in this population.

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Keywords Cross-Sectional studies, Self care, Psychometrics, Pregnancy, Diabetes, Gestational, Iran

Background

Diabetes is a metabolic disease marked by challenges in regulating blood sugar levels due to insufficient insulin production, insulin resistance, or both. It poses a significant public health issue, with projections indicating that nearly 1 in 10 adults globally will be affected by 2035 [1, 2]. Uncontrolled diabetes can lead to severe complications, including cardiovascular diseases, cognitive decline, and depression [3]. The condition is classified into several types, namely Type 1, Type 2, and gestational diabetes mellitus (GDM) [4, 5].

GDM, defined as glucose intolerance during pregnancy, affects approximately 14% of pregnancies worldwide, with its prevalence rising alongside obesity and Type 2 diabetes rates [6]. It is more widespread than previously recognized, impacting women across various body weights and regions, including Asia and Europe. In Iran, the prevalence of diabetes is around 7.6% in the general population [7].

Key risk factors for GDM include family history of diabetes, obesity, previous GDM, multiparity, and miscarriage history. Modifiable factors such as unhealthy diets and physical inactivity also play a role, with women from racial or ethnic minority groups at heightened risk [8, 9].

GDM is linked to negative outcomes for both mothers and their offspring, including preterm birth, cesarean delivery, and long-term metabolic risks for the child. Women with GDM are also more likely to develop Type 2 diabetes and cardiovascular diseases later in life [10, 11]. This condition imposes a substantial burden on healthcare systems due to the need for enhanced monitoring and management during and after pregnancy [12].

Management of GDM focuses on self-care practices like blood glucose monitoring, dietary changes, and increased physical activity [13]. Empowerment-based interventions have proven effective in improving self-care behaviors and maternal health outcomes [14]. The World Health Organization (WHO) emphasizes the importance of self-care in health maintenance [15]. Adherence to self-care is vital for effective diabetes management and glycemic control [16]. A personalized, patient-centered approach is essential for helping women maintain healthy behaviors and prevent future diabetes onset [17, 18].

Despite the importance of self-care, standardized tools to assess these behaviors in women with GDM are lacking. While instruments like the Summary of Diabetes Self-Care Activities (SDSCA) have been validated for general diabetes populations [19–22], their suitability for GDM, particularly in diverse cultural contexts, remains underexplored. Recent studies have validated the SDSCA in Hindi [23] and Arabic [24] for women with GDM, highlighting its potential utility.

Utilizing validated instruments to measure health-related patient-reported outcomes (HR-PROs) is crucial for effective disease management [25]. The COSMIN (Consensus-Based Standards for the Selection of Health Status Measurement Instruments) checklist offers a framework for evaluating the psychometric properties of such instruments [25, 26]. Given the increasing prevalence of GDM and its complications, there is a pressing need for validated tools to assess self-care behaviors in specific populations. This study aims to psychometrically validate the Persian version of the SDSCA among Iranian women with GDM, following COSMIN guidelines to evaluate the scale's validity, reliability, and other psychometric properties for the target population.

Methods

Study participants and setting

Before using the SDSCA, the researchers obtained the necessary permissions from the SDSCA working group [22]. The study was approved by the Ethics Committee of Tabriz University of Medical Sciences in Iran. The validation was conducted with a sample of 180 pregnant women diagnosed with GDM. The participants were recruited from the outpatient clinics of three government-operated hospitals in Tabriz city, namely, Taleghani, Al-Zahra, and 29 Bahman, between February 23, 2024, and July 12, 2024. The sample was divided into two groups: 80 participants for exploratory factor analysis and 100 participants for confirmatory factor analysis. All women provided written informed consent before participating in the study.

The eligibility criteria included a GDM diagnosis, age ≥ 18 years, and gestational age ≥ 24 weeks. GDM was diagnosed if one or more of the following plasma glucose values were met or exceeded during a 75-gram oral glucose tolerance test (OGTT): fasting glucose ≥ 92 mg/dL (5.1 mmol/L), 1-hour glucose ≥ 180 mg/dL (10.0 mmol/L), or 2-hour glucose ≥ 153 mg/dL (8.5 mmol/L) [27]. The exclusion criteria were preexisting diabetes, fetal abnormalities, severe medical conditions, and maternal psychiatric disorders.

Instruments

Sociodemographic and obstetrics checklist

The sociodemographic and obstetric checklist collected information on the participants' age, occupation, education, family income, and obstetric history, including number of pregnancies and parity.

Summary of the diabetes Self-Care activities (SDSCA)

The SDSCA instrument was originally developed in the United States by Toobert and colleagues in 2000. It is a comprehensive 11-item measure that assesses various aspects of diabetes self-management, including dietary practices (4 items), exercise habits (2 items), blood glucose monitoring (2 items), foot care (2 items), and smoking behavior (1 item). Each item asks participants to report the number of days in the past week they engaged in a specific self-care behavior. Responses are recorded on a 7-point scale, ranging from 0 (no days) to 7 (every day). For this study [22], the Persian version of the SDSCA was adapted to include 7 items focusing on three key domains relevant to GDM: diet (3 items), exercise (2 items), and blood glucose testing (2 items). We excluded foot care and smoking from the SDSCA as they are less relevant to GDM management. Foot care primarily concerns those with chronic diabetes, while smoking's prevalence among pregnant women in Iran is low. Instead, we focused on key self-care behaviors like diet, exercise, and blood glucose monitoring that are more pertinent to GDM.

Sample size determination

The study adhered to recommended guidelines for factor analysis sample size [28], initially targeting 80 participants for exploratory factor analysis (EFA) based on 8 survey items. To ensure robust validation through both EFA and confirmatory factor analysis (CFA) on separate datasets, the total sample size was increased to 180 participants, with 80 allocated for EFA and 100 for CFA [28, 29]. The CFA sample size was determined by the rule of having at least 10 participants per free parameter, with 7 free parameters requiring a minimum of 70 participants [29]. The inclusion of 100 participants for CFA exceeded this requirement, ensuring sufficient statistical power.

Statistical analyses

Statistical analyses were performed using IBM SPSS Statistics 22 and STATA 14. Continuous variables with normal distributions were reported as means and standard deviations, while categorical variables were presented as frequencies and percentages.

Translation procedure

The SDSCA questionnaire was translated into Persian following WHO guidelines. This involved forward translation by two Persian speakers, back-translation by two native English speakers, and reconciliation of discrepancies [30]. A pilot study with 10 eligible women assessed the comprehensibility and ease of use of the Persian version, with feedback incorporated into the final questionnaire [31].

Validity assessment

Content validity was assessed by 10 experts using content validity index (CVI > 0.79) and content validity ratio (CVR > 0.62) [32].

Face validity was evaluated by a separate group of 10 eligible women, with an impact score > 1.5 considered acceptable [33].

Construct validity was examined through EFA and CFA. We used both EFA and CFA following the two-step procedure outlined by Malik and Millsap [34, 35]. EFA was employed to explore the underlying factor structure and identify the appropriate number of factors, while CFA was used to confirm the significance of the relationships between the factors and observed variables, ensuring model fit and validity. EFA utilized principal axis factoring with promax rotation, and the Kaiser–Meyer–Olkin (KMO) measure was greater than 0.5, along with Bartlett's test of sphericity. The minimum cut-off point for factor loadings in the EFA was set at 0.3 [35]. CFA assessed model fit using the following criteria: RMSEA < 0.08, SRMR < 0.10, normed chi-square (χ^2/df) < 5, and comparative fit indices (CFI, NFI, RFI, TLI, GFI > 0.90) [35, 36].

Reliability assessment

Internal consistency was evaluated using Cronbach's alpha and McDonald's omega, with values ≥ 0.7 considered acceptable for all 180 participants [28, 37].

Test-retest reliability was assessed by administering the questionnaire to 30 participants twice, 14 days apart. Intraclass correlation coefficient (ICC) values > 0.7 indicated good reliability [38].

Additional analyses

Floor and ceiling effects were considered significant if > 15% of responses fell at the extremes [39].

Responsiveness was assessed by comparing SDC to the minimal important change (MIC), with SDC < MIC indicating adequate responsiveness [26].

Interpretability was evaluated by estimating MIC as half the standard deviation of instrument scores [40, 41].

Measurement error was evaluated using the standard error of measurement (SEM) and smallest detectable change (SDC), with lower SDC values indicating higher sensitivity [42].

Results

Descriptive characteristics of the participants

The researchers approached 207 women for participation in the validation study. Of these, 11 were excluded because they did not meet the eligibility criteria. Among the remaining 196 eligible participants, 16 declined to participate, resulting in a final sample of 180 women and a response rate of 91.8%. The study included a total of 180

Table 1 Demographic characteristics of the participants in the SDSCA ($n = 180$)

Characteristics	EFA ($n = 80$)		CFA ($n = 100$)	
	Mean	SD	Mean	SD
Age (year)	33.06	6.91	31.63	7.30
Spouse age (year)	38.3	7.22	36.41	7.13
Parity	0.98	0.86	0.96	0.92
Gravity	2.53	1.33	2.36	1.24
	Number	Percent	Number	Percent
Education level				
High school or below	39	48.9	46.0	46.0
Diploma and university	41	51.1	54.0	54.0
Job				
Housewife	76	95	83.0	83.0
Employee	4	5	17.0	17.0
Family history of diabetes	33	41.3	30.0	30.0
Income sufficiency				
Insufficient	15	8.3	13	13
Relatively sufficient	69	86.3	84	84
Completely sufficient	2	2.5	3	3

SD = standard deviation, EFA = exploratory factor analysis, CFA = confirmatory factor analysis, SDSCA = summary of diabetes self-care activities scale

Table 2 Results for the content and face validity of the SDSCA

Items	Impact score	CVI	CVR
1	5	0.90	1
2	3.70	0.86	1
3	3.60	0.93	1
4	4.10	0.90	1
5	4.60	1	1
6	5	1	1
7	4.70	0.90	0.80
Total	4.38	0.93	0.97

CVI = content validity index, CVR = content validity ratio, SDSCA = Summary of Diabetes Self-Care Activities Scale

women, who were randomly divided into two groups: an EFA group of 80 participants and a CFA group of 100 participants. The characteristics of the participants are detailed in Table 1. The women in the EFA group had a mean age of 33.1 years, with a SD of 6.9 years. In the CFA group, the women had a mean age of 31.6 years, with a SD of 7.3 years.

The majority of women in both groups were housewives, comprising 95% of the EFA group and 83% of the CFA group. Additionally, most participants reported relatively sufficient incomes, with 86.3% in the EFA group and 84% in the CFA group indicating income adequacy.

The mean (SD) scores for each factor were as follows: diet, 4.55 (1.55); exercise, 3.67 (2.10); and blood sugar test, 4.52 (2.33). For the overall SDSCA tool, the mean (SD) score was 4.29 (1.42).

Validity assessment

Content validity The CVI was 0.93 and the CVR was 0.97, indicating strong content validity (Table 2).

Face validity The impact score was 4.38, indicating strong face validity (Table 2).

Construct validity During the EFA process, one item (item 4) was excluded because its factor loading was less than 0.3 [35], ultimately reducing the number of items from 8 to 7 (KMO = 0.64, Bartlett's test of sphericity $p < 0.001$). The results presented in Table 3 show the extracted factors along with the corresponding questionnaire items. The first factor was labeled "diet." This factor contains 3 items and explains 20.2% of the total variance. The second factor, "exercise," consisted of 2 items and accounted for 17.5% of the overall variance. The third factor was "blood sugar testing." This factor also had 2 associated items and made up 19.7% of the total variance (Figs. 1 and 2).
We conducted a CFA to evaluate the three-factor structure from the previous EFA. The analysis revealed a chi-square to degrees of freedom ratio (χ^2/df) of 1.25 ($\chi^2 = 13.69$, $df = 11$), which falls within the acceptable range. This finding indicates that the model has a good fit with the data. Additionally, the key fit indices, including the TLI, CFI, NFI, GFI, and RFI, all exceeded the recommended threshold of 0.9, further confirming the overall goodness of fit of the model. Importantly, the RMSEA value of 0.04 and the SRMR value of 0.02 suggest that the model is valid and reliable, as these values are within the recommended thresholds for a well-fitting model (Table 4).

Reliability assessment

Internal consistency The reliability analysis revealed that the questionnaire had a Cronbach's alpha of 0.78 and a McDonald's omega of 0.91, indicating adequate internal consistency (Table 5).
Test-Retest Reliability: The ICC was estimated to be 0.92 (95% CI: 0.83–0.96) (Table 5).

Additional analyses

Floor and ceiling effects The ceiling effect on the overall SDSCA score was 0.6%. When the individual subdomains were examined, the ceiling effects were found to be 1.1% for the Diet component, 3.3% for Exercise, and 26.7% for the Test of Blood Sugar subdomain. Additionally, the analysis revealed a floor effect of 0.6% on the overall SDSCA score, whereas the specific subdomains presented floor effects of 1.1% for diet, 6.7% for exercise, and 6.1% for the test of the blood sugar component (Table 5).

Responsiveness and interpretability The MIC value of 2.68 units was greater than the SDC value of 1.11 units,

Table 3 Fracture structure of the SDSCA

Scale item	Factor 1	Factor 2	Factor 3
Factor1: Diet			
How many of the last seven days have you followed a healthful eating plan?	0.84		
On average, over the past month, how many days per week have you followed you're eating plan?	0.83		
On how many of the last seven days did you eat five or more servings of fruits and vegetables?	0.40		
On how many of the last seven days did you eat high fat foods such as red meat or full-fat dairy products?	0.07		
Factor2: Exercise			
On how many of the last seven days did you participate in at least 30 min of physical activity? (Total minutes of continuous activity, including walking).		0.83	
On how many of the last seven days did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work?		0.83	
Factor3: Blood Sugar Testing			
On how many of the last seven days did you test your blood sugar?			0.95
On how many of the last seven days did you test your blood sugar the number of times recommended by your health care provider?			0.95
% of variance observed	20.2	17.5	19.7
Total score	57.4		

SDSCA = Summary of diabetes self-care activities scale

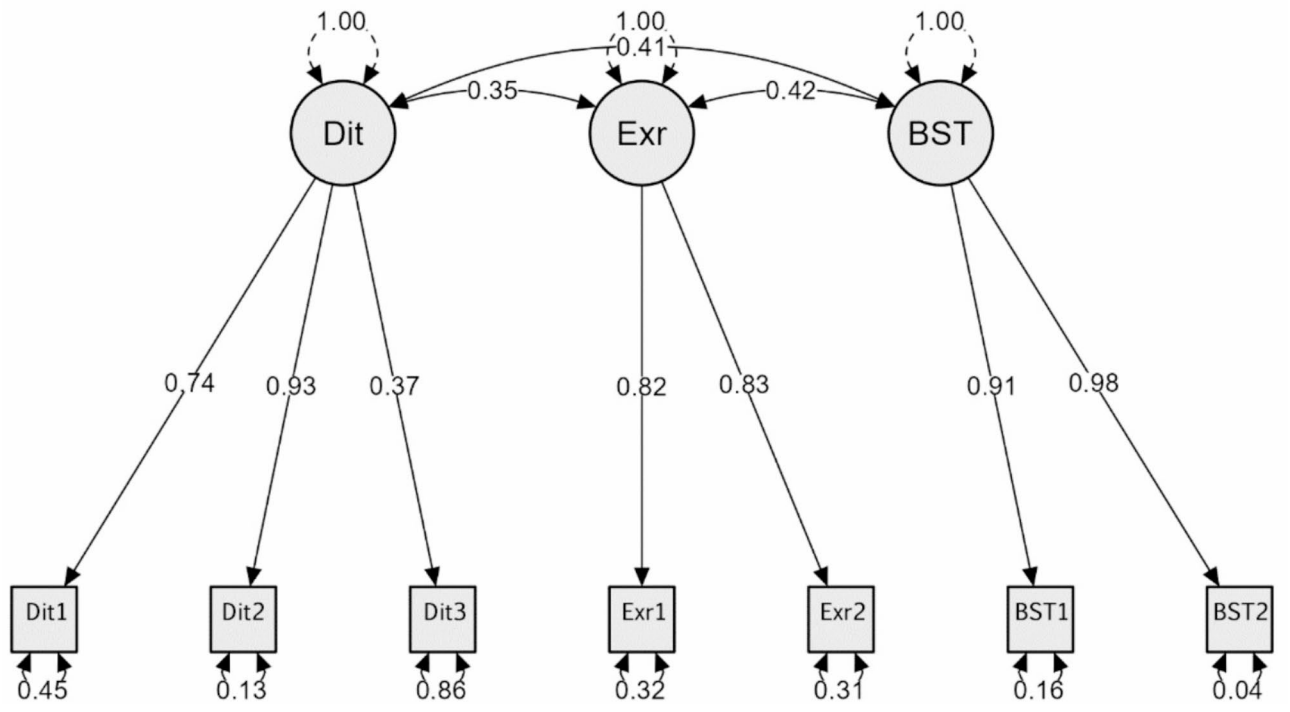

Fig. 1 Factor structure model plot of the SDCSCA based on CFA
Dit = diet, Exr = exercise, and BST = test of blood sugar

indicating that the measurement tool is able to accurately identify clinically or practically meaningful changes in the parameter being measured. This suggests that the tool has sufficient responsiveness and is able to consistently detect meaningful changes (Table 5).

Measurement error The SEM was calculated as 0.40, meaning that the recorded values are expected to fall within ± 0.40 units of the true score. The SDC was determined to be 1.11 units, indicating that any variation in the measured quantity less than this threshold may be imperceptible due to measurement uncertainties and can therefore be regarded as insignificant (Table 5).

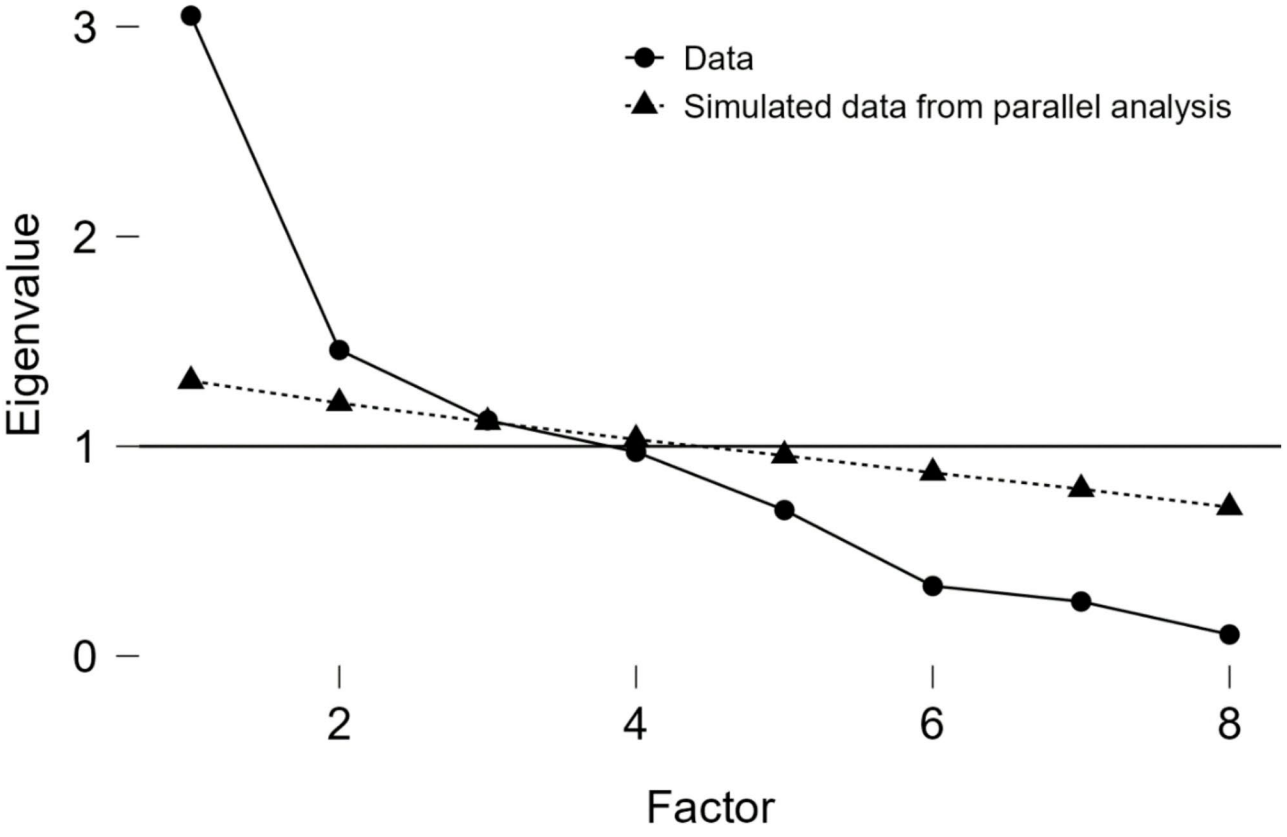

Fig. 2 Factor load scree plot of the items for determining the number of extracted factors of the Persian version of SDSCA (summary of diabetes self-care activities scale)

Table 4 Model fit indicators of the SDSCA

Goodness of fit indices	Value
χ2	13.69
df	11
Chi2/df	1.25
P value	0.25
CFI	1
TLI	0.99
NFI	0.98
RFI	0.96
GFI	1.00
SRMR	0.02
RMSEA	0.04

Df = degrees of freedom, χ2/df = normed chi-square, GFI = goodness-of-fit index, RFI = relative fit index, NFI = normed fit index, CFI = comparative fit index, TLI = Tucker–Lewis index, SRMR = standardized root mean square residual, RMSEA = root mean square error of approximation, SDSCA = summary of diabetes self-care activities scale

Discussion

This study is the first to evaluate the measurement properties of the SDSCA instrument in Iranian women with GDM, following the COSMIN checklist. The results confirm the validity, reliability, responsiveness, and interpretability of the SDSCA tool within this population.

Effective self-care behaviors are essential for managing GDM, encompassing diet, exercise, medication adherence, and glucose monitoring. The role of healthcare providers in promoting these behaviors is critical to preventing complications associated with diabetes [43, 44]. Adherence to self-care practices allows women to exert greater control over their diet and body weight [45]. The self-care practices essential for managing GDM are largely analogous to those required for type 2 diabetes management. This similarity suggests that the components of the SDSCA scale, originally designed for type 2 diabetes, can be effectively adapted to evaluate self-care behaviors in pregnant women with GDM [46]. Despite the existence of self-care assessment tools for type 2 diabetes [47–54], there are currently no validated instruments tailored for Iranian women with GDM.

The CVI of 0.93 and CVR of 0.97 indicate that the SDSCA has excellent content validity for Iranian women with GDM. These findings align with previous studies by Al Hashmi et al. [24] and Singh et al. [23], which reported CVI values between 0.8 and 1 for the same tool in other populations. The high CVI and CVR values suggest that the tool's items are highly relevant and representative of the self-care challenges faced by women with GDM [28, 55]. Additionally, the Cronbach's alpha coefficient of

Table 5 Stability coefficients and interclass correlation coefficient SDSCA

Factor	Cronbach's α coefficient	McDonald's omega	ICC	(95% CI)	SEM	SDC	MIC	AVE	Floor effect (%)	Ceiling effect (%)
Diet	0.71	0.74	0.96	(0.92,0.98)	0.31	0.86	2.07	0.53	1.1	1.1
Exercise	0.81	0.81	0.95	(0.89,0.97)	0.46	1.27	3.08	0.69	6.7	3.3
Blood Sugar Testing	0.94	0.95	0.85	(0.69, 0.93)	0.90	2.49	6.03	0.90	6.1	26.7
Total	0.78	0.91	0.92	(0.83,0.96)	0.40	1.11	2.68	0.70	0.6	0.6

ICC = intraclass correlation coefficient, CI = confidence interval, SEM = standard error of measurement (SEM = SD√1-ICC), SDC = smallest detectable change (SDC = SEM1.96√2), MIC = minimal important change (SEM*sqrt(n)/2), AVE = average variance extracted (acceptable if AVE > 0.5, the threshold is 0.36–0.5), SDSCA = Summary of Diabetes Self-Care Activities Scale

0.78 demonstrates good internal consistency, consistent with the Hindi (α = 0.82) and Arabic (α = 0.74) versions of the tool [23, 24]. These results collectively support the robustness of the SDSCA across diverse cultural contexts.

The EFA revealed a three-factor structure, consistent with the primary self-care behaviors relevant to GDM management: diet, exercise, and blood glucose monitoring. Notably, Item 4 was excluded due to a low factor loading (< 0.3). This finding contrasts with studies by Singh et al. [23] and Al Hashmi et al. [24], where Item 4 performed adequately. However, similar issues with Item 4 have been reported in the German and Korean versions of the SDSCA for type 2 diabetes [48, 55], suggesting that its poor performance may not be unique to this study. One possible explanation is cultural differences in the interpretation of the item's content, which may not resonate equally across populations. Future research should explore the cultural and contextual factors influencing item performance to enhance the tool's cross-cultural applicability.

The factor structure identified in this study aligns with previous research on GDM self-care behaviors. For instance, diet emerged as the first factor, reflecting its central role in GDM management. Women with GDM often struggle with dietary control and require tailored recommendations from clinical nutritionists to manage carbohydrate intake and postprandial blood glucose levels [56, 57]. Exercise, the second factor, is equally critical, as physical activity improves glucose uptake by skeletal muscles and enhances glycemic control [58, 59]. However, adherence to exercise recommendations remains suboptimal among women with GDM [60]. Blood glucose monitoring, the third factor, is essential for preventing adverse pregnancy outcomes, yet adherence to self-monitoring practices is often inconsistent [51]. These findings underscore the importance of patient education and active involvement in self-care to improve outcomes and reduce long-term diabetes risk [61, 62].

The CFA results demonstrated an excellent fit for the proposed factor structure, with all key fit indices meeting or exceeding recommended thresholds. This represents a significant advancement over previous studies [23, 24], which did not conduct CFA. The rigorous evaluation of structural validity through CFA strengthens the evidence supporting the SDSCA's use in GDM populations.

Strengths and limitations

Our study has several strengths, including adherence to the COSMIN checklist, a comprehensive evaluation of psychometric properties, and the use of a relatively large and diverse sample of Iranian women with GDM. However, we acknowledge certain limitations. First, the lack of a gold standard measure for assessing criterion-related validity limits our ability to compare the SDSCA with an established benchmark. Second, the cross-sectional design precludes the assessment of the tool's responsiveness to changes in self-care behaviors over time. Third, the potential for response bias due to self-report measures cannot be ruled out. Finally, the cross-cultural validity of the Persian version was not examined, which should be addressed in future research.

Future research directions

Future studies should focus on several key areas to build on our findings. First, longitudinal studies are needed to assess the SDSCA's responsiveness to changes in self-care behaviors over time, particularly in response to interventions aimed at improving GDM management. Second, qualitative research could provide deeper insights into the cultural and contextual factors influencing self-care practices in women with GDM, helping to refine the SDSCA for use in diverse populations. Third, the cross-cultural validity of the Persian version should be evaluated in other populations to ensure its broader applicability. Finally, future research should explore the factors contributing to the poor performance of Item 4 and consider modifying or replacing it with culturally relevant items.

Clinical implications

The Persian version of the SDSCA demonstrates promising psychometric properties for assessing self-care behaviors in Iranian women with GDM. However, the clinical adoption of this scale should be approached with caution. The lack of evaluation of cross-cultural validity and the potential limitations in cultural adaptation highlight the need for further research before the scale can be confidently implemented in clinical practice. Future studies should rigorously assess the cultural appropriateness of the scale and its applicability to diverse populations. Until then, healthcare providers should consider these limitations when interpreting the results and use the scale as a supplementary tool rather than a definitive measure of self-care behaviors in this population.

Conclusion

The Persian version of the SDSCA demonstrates strong psychometric properties, making it a suitable tool for assessing self-care behaviors in Iranian women with GDM. Its use in clinical and research settings can enhance understanding of self-management behaviors and inform targeted interventions to improve outcomes for women with GDM and their children. Given the significant consequences of uncontrolled GDM, this tool represents a valuable contribution to diabetes care in Iran.

Abbreviations

CFA	Confirmatory factor analysis
CFI	Comparative fit index
COSMIN	Consensus-Based Standards for the Selection of Health Status Measurement Instruments
CVI	Content validity index
CVR	content validity ratio
DF	Degrees of freedom
EFA	Exploratory factor analysis
GDM	Gestational diabetes mellitus
GFI	Goodness-of-fit index
HR-PRO	Health-related patient-reported outcomes
ICC	Intraclass correlation coefficient
KMO	Kaiser–Meyer–Olkin
MIC	Minimal important change
NFI	Normed fit index
RFI	Relative fit index
RMSEA	Root mean square error of approximation
SD	Standard deviation
SDC	Smallest detectable change
SDSCA	Summary of diabetes self-care activities scale
SEM	Standard error of measurement
SRMR	Standardized root mean squared residual
TLI	Tucker–Lewis index
WHO	World Health Organization
χ2/df	Normed chi-square test

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Author contributions

The study design was developed collaboratively by MMi, MMa, SMAC, SGH, and FA. The initial version of the manuscript was drafted by MMi, MMa, and SMAC, while the data analysis was conducted by MAJ. All authors carefully reviewed the text, provided feedback and revisions, and approved the final submitted manuscript.

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Data availability

The study data are not publicly available due to patient privacy and ethical restrictions but can be requested from the corresponding author.

Declarations

Ethics approval and consent to participate

The study received ethical approval (IR.TBZMED.REC.1402.652/2023-12-04), and participant consent was obtained. The research methods adhered to relevant guidelines and regulations.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

Clinical trial number

Not applicable.

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