

EMPIRICAL RESEARCH MIXED METHODS OPEN ACCESS

Designing and Psychometric Properties of Self-Care Tool for Adults With Pre-Diabetes: Exploratory Sequential Mixed Method

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ABSTRACT

Background: Self-care is one of the most critical factors in disease prevention. Adults with pre-diabetes are at 5 to 15 times higher risk of developing type 2 diabetes compared with others. Without self-care behaviours to promote health and prevention, more than 70% will ultimately develop type 2 diabetes during their lives.

Objective: This study aimed to design and psychometrically evaluate the self-care of adults with pre-diabetes.

Methods: This study was a sequential exploratory mixed-methods study. In the first phase of the mixed-methods study, a qualitative study was conducted with a directed content analysis approach according to Riegel et al.'s middle-range theory as a guide. This qualitative-directed content analysis was conducted on prediabetes from June 2023 to October 2023. The experiences of 39 adults with pre-diabetes and 6 healthcare workers were assessed through individual, face-to-face, semi-structured interviews. The data were analysed based on the Elo and Kyngäs's method. The psychometric properties of the primary tool were evaluated in the second phase. Face and content validity, item analysis, structural validity, internal consistency, relative and absolute reliability, interpretability, responsiveness, and feasibility were evaluated, and the scoring method was determined.

Results: The concept of self-care in prediabetes includes behaviours that are performed to return blood sugar to a normal state in a routine and usual way (self-maintenance) and behaviours in response (self-management) to the changes that have been detected following the follow-up and interpretation of symptoms, periodic examinations and tests (self-monitoring). The primary tool entered the psychometric evaluation phase with 57 items (blueprint). After performing face and content validity and item analysis, the number of items was reduced to 29 items. Exploratory factor analysis was performed with 29 items and 207 people with prediabetes, and finally, three subscales with 19 items were formed, which explain 38% of the total extracted variance. The results of confirmatory factor analysis with 200 samples indicated the acceptable fit of the model. The Cronbach's alpha of all subscales was higher than 0.7, and the intraclass correlation coefficient of the scale was higher than 0.90. The standard error of measurement was 1.340, the minimum detectable change was 6.57, and the minimal important change was 3.71. The total score of the questionnaire had no ceiling and floor effect; the percentage of unanswered items was within the acceptable range.

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Conclusion: The results show that the self-care questionnaire for prediabetes has good psychometric properties and can measure self-care in adults with pre-diabetes.

1 | Introduction

Pre-diabetes is the main but dormant incubator of future diseases (Lawal et al. 2020). Many interventions to control prediabetes aim to establish a healthy diet, increase physical activity, and reduce weight. Adults, independently or with the help of medical caregivers, assume responsibility for executing the programs (Marrero et al. 2008; Magalhães et al. 2010).

According to the self-care matrix, adults with prediabetes, a chronic condition characterised by elevated blood sugar that can progress to type 2 diabetes, must adopt self-care behaviours, including lifestyle modifications, preventive actions, and health-promoting behaviours. An individual with type-2 diabetes enters a long-term disease management trajectory, including disease, hospitalisation, and rehabilitation, each of which requires the individual to adopt self-care behaviours in various areas. Therefore, it is expected that self-care tools for diabetes be different from self-care tools for prediabetes (El-Osta et al. 2019).

Regarding this difference, it can be observed that the evaluation tools to assess diabetes self-care include behaviours concerning insulin injection or its long-term side effects while self-care guidelines do not have instructions for prediabetic adults, so the self-care for prediabetic adults is not evaluated (Ausili et al. 2017; Cosentino et al. 2020).

On the other hand, considering insulin injection and side effects specific to diabetes, self-care behaviours such as physical activities that are in the common scope of the self-care matrix for both conditions should be divided into two different types specific to each condition. For example, diabetic patients are expected to do light exercises daily for half an hour while prediabetic individuals should exercise with average intensity for 150 min per week (Pranata and Wulandari 2021; Rothenberger 2011).

Assessing the results and methods of the conducted studies about prediabetes in adults shows that the researchers have used primary and secondary indicators such as laboratory and physical indicators, including fasting blood sugar, glycolysis haemoglobin level, blood sugar two hours after breakfast, BMI, weight, and other anthropometric characteristics to assess the effect of interventions aimed at promoting health and preventing type 2 diabetes. Moreover, they have used various questionnaires to evaluate mental, social, and behavioural consequences in prediabetic adults (Alwashmi et al. 2019; Lim et al. 2022; Signal et al. 2020).

These questionnaires include the health-promoting lifestyle questionnaire, the Godin and Shephard leisure-time physical activity questionnaire (Taylor et al. 2011), the food frequency questionnaire, the fruit, vegetable, and low-fat food intake questionnaire (Rahmati-Najarkolaei et al. 2017), the international physical activity questionnaire, and the 24-h dietary recall questionnaire (Wilson et al. 2021).

None of the above is specific to adults with prediabetes, and their target population is healthy adults. Additionally, each of these questionnaires assesses one physical activity separately and cannot assess self-care in adults with prediabetes.

Moreover, a questionnaire like the health-promoting lifestyle questionnaire assesses various aspects and contains items about health-promoting behaviours in healthy individuals. For example, in the physical activity area, physical activity in leisure time is assessed, while in individuals with prediabetes, physical activity and its type are among the essential behaviours to control the condition, requiring more specific attention. As a result, different trials have been designed to promote physical activities in prediabetic individuals to reduce blood sugar (Rahmati-Najarkolaei et al. 2017; Chen et al. 2015; Færch et al. 2017).

After extensive research, no self-care tool was found specific to adults with prediabetes. Searching with wide parameters and general terms such as “questionnaire” and “prediabetes” revealed questionnaires specific to prediabetes that assessed awareness, perception, and performance in prediabetic individuals and healthcare workers (de Melo Ghisi et al. 2021; Hyder et al. 2021). The authors of the mentioned study assessing knowledge perception and performance in individuals with prediabetes stated that their tool had been designed according to tool-design principles, but no published article was found about its design process and the assessment of the tool psychometrics.

Although assessing HbA1C as an objective indicator allows healthcare workers and the patient to evaluate the long-term effects of lifestyle changes, anything that can assess, monitor, and promote self-care behaviours and lifestyle changes will improve this factor along with other factors of blood sugar control (Modarresi et al. 2020; Babazadeh et al. 2023).

Knowledge about and monitoring of self-care behaviours can promote the interaction between patients and healthcare workers and increase the active participation of the patient in making decisions about their health by providing opportunities for personal goal-setting, acquiring knowledge about the contributing factors in self-care, and planning clinical interventions addressing the weak points in their self-care. In this way, the individual can direct their self-care and achieve consistency in caring for themselves (Evangelista and Shinnick 2008; Abd ElKareem Moghazy et al. 2020; Rezvan et al. 2018; Graffigna et al. 2017).

The reversibility of high blood sugar in adults to normal in prediabetes depends on the individual's self-care performance level. Therefore, due to the absence of a valid and reliable assessment tool specific to prediabetic adults' self-care, the current study aimed to design and define the psychometric properties of an assessment tool for self-care in adults with prediabetes.

1.1 | Theoretical Framework

According to Riegel et al.'s (2019) middle-range theory of self-care for chronic illness (2019), people perform a series of behaviours in a rotating process in three areas (self-preservation, self-monitoring, and self-management) during long-term conditions or chronic diseases. Since prediabetes can be a long-term condition that leads to type 2 diabetes, the above theory was used in the design of the qualitative phase of the study (preparation of the interview questions guide) and analysis of the obtained data (coding and categorisation) (Riegel et al. 2019).

2 | Methods

This is a mixed-methods study with an exploratory sequential design. It was performed in two phases: scale development and psychometric properties evaluation (Figure 1).

This study was approved by the Research Ethics Committee “REDUCTED” (IR.SBMU.RETECH.REC.1402.053). All participants were informed about the aim of the study, voluntary participation, and the confidentiality of the information. They were also informed that they could withdraw at any stage of the study, and written informed consent forms were obtained from

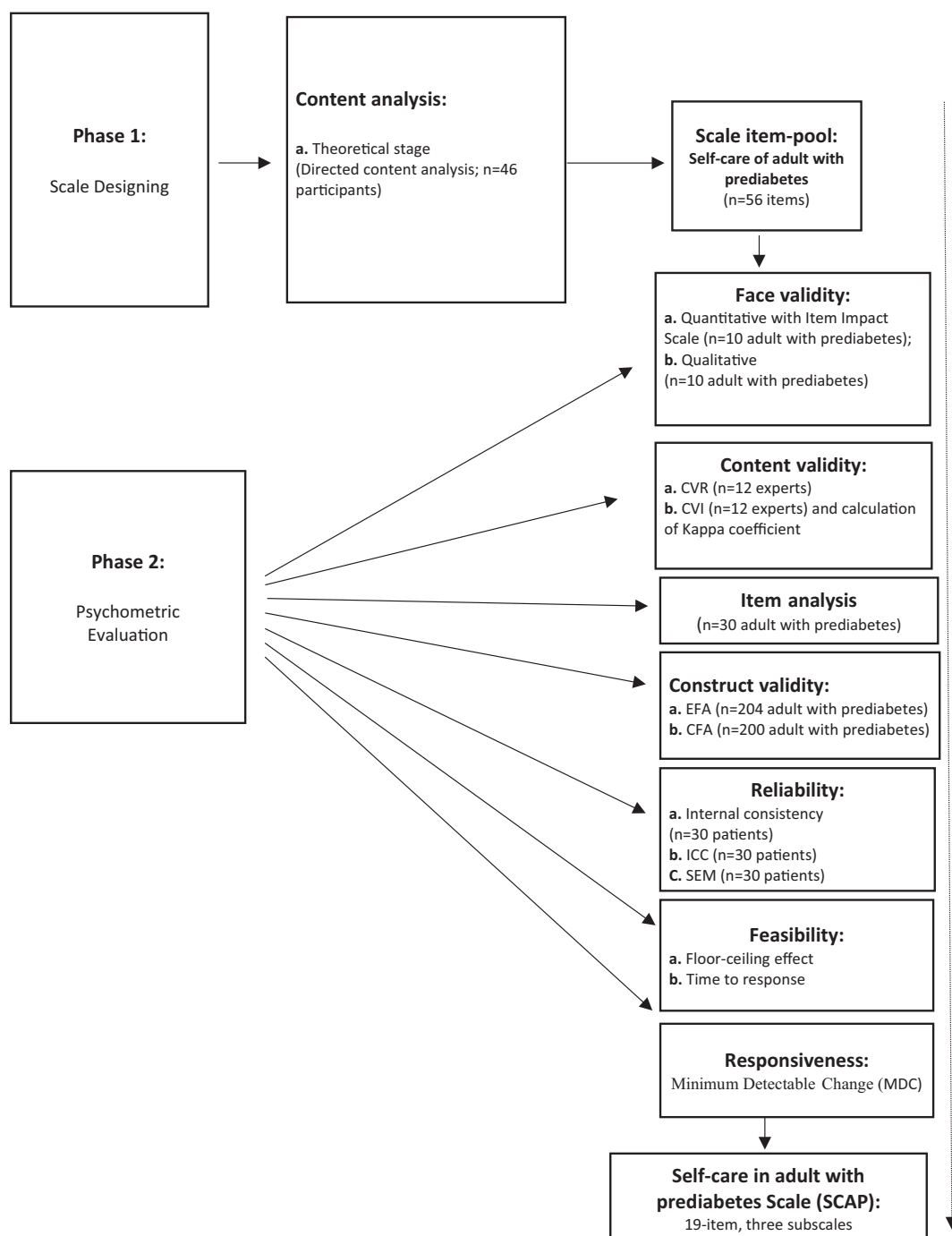


FIGURE 1 | The phases of the self-care in adult with prediabetes study for scale designing and psychometric analysis.

all participants. The SQUIRE guidelines were used to guide this study (See Data S1).

2.1 | Phase 1 (Qualitative Phase)

In this phase, a qualitative study on the directed content analysis method was conducted to explain the self-care experiences of adults with pre-diabetes based on Riegel et al.'s (2019) middle-range theory for self-care of chronic illness (Riegel et al. 2019).

2.1.1 | Design and Setting

This study is a mixed-methods study with exploratory sequential design research. It was a methodological research conducted to explain the self-care experiences of adults with prediabetes.

The design and psychometric assessment of the scale were carried out through qualitative and quantitative phases. In the qualitative phase of the study, the directed content analysis approach based on Riegel et al.'s (2019) middle-range theory for self-care of chronic illness was used to design and generate items for the scale. In the quantitative phase, the psychometric properties of the scale were assessed.

2.1.2 | Qualitative Study

The qualitative phase of the study was conducted to explain the self-care experiences of adults with pre-diabetes based on Riegel et al.'s (2019) middle-range theory for self-care of chronic illness. Purposive sampling was done with maximum diversity in age (between 19 and 60 years), gender, marital status, religion, ethnicity, education, body mass index, duration of awareness of pre-diabetes, and family income level. The 46 participants of this study who had face-to-face interviews included 40 pre-diabetic adults within the age range of 22–60 years who were aware of their pre-diabetes for 6 months to 14 years with fasting blood sugar between 100 and 125 mg and body mass index of 20–42. The participants also included one diabetes nurse, one physician, three nutrition consultants, and one psychologist. Data were collected through semi-structured individual interviews from June to November. The interviews started with the general question, 'What behaviours have you adopted to control your blood sugar?' based on the interviewees' answers, the interview process was directed toward achieving the primary goal of the research. Exploratory questions were asked for a deeper understanding.

The interviews lasted 45 min on average. The data collection process lasted 3 months. Individual interviews continued until data saturation was reached, i.e., no new codes were extracted, and the codes were repetitive in the last two to three interviews.

The analysis of the data obtained from the structured individual interviews was done using Elo and Kyngäs's (2008) directed content analysis method (Hsieh and Shannon 2005; Assarroudi et al. 2018; Elo and Kyngäs 2008), according to the research

framework and Riegel et al.'s (2019) theory of self-care of chronic illness (Riegel et al. 2019):

The fundamental concepts of the theory of self-care in chronic illness, which include self-maintenance, self-monitoring, and self-management, were determined and selected as the main classes of the theory. Each concept in the model was then characterised and identified as a subclass. The interview texts were re-read, semantic units/codes were marked, and codes similar or related to each concept were placed in common subclasses.

2.1.3 | Trustworthiness

The validity and strength of the data were determined using Lincoln and Guba (1985) using four criteria: validity or acceptability, reliability, transferability, and confirmability (Polit-O'Hara and Yang 2016; Lincoln and Guba 1985). Data collection interviews were conducted quickly, and all participants were asked about the same topic. The researchers spent 4 months collecting the data. The research team reviewed the codes and data classification to achieve data saturation. The full text of all interviews along with coding and initial classifications were sent to the second author. The full text of the two interviews with coding was sent to the third and fourth authors. The comments were used throughout the process to help implement, code, and extract the sub-main categories. The results were submitted to two university faculty members and the Tehran Lipid and Glucose Study Center (for external review). Participant reviews were also done by three random participants to confirm the accuracy of the results. For this purpose, the interview text and the extracted codes were presented to the participants. In case of any discrepancy, they were reassessed. The researcher contacted the participants to clarify any ambiguities or misunderstandings through phone calls and email. Sampling was performed with maximum diversity (age, education, income etc.) to increase the transferability of data. In addition to a full report of all steps taken, a clear explanation of the analysis process and participant quotes were also recorded to demonstrate that the results were related to the data.

2.2 | Phase 2 (Item Generation)

According to the design stages (DeVellis 2016), to design items based on the definition of the concept of self-care in adults with prediabetes in the qualitative stage, the theoretical and practical definitions of each dimension were determined, and suitable items were created to measure each dimension. A blueprint (construction plan) was used to ensure that all the aspects of the concept were covered.

The initial item pool (created based on the results of interviews according to Riegel et al.'s (2019) middle-range theory for self-care of chronic illness) included three dimensions: self-maintenance (nutrition, physical activity, drug abuse, stress management, treatment adherence, complementary medicine, information, and resource seeking) with 40 items, self-monitoring (laboratory measurements, individual measurements, drug side effects, physical and mental symptoms, and interpretation of results) with 14 items, and self-management (physical activity changes,

nutritional changes, medication changes, information search, and consultation) with 32 items.

The initial item pool, which contained 86 items, was carefully refined by the research team, and 29 items were removed for reasons such as repetition or overlap with other items. Finally, 57 items remained (blueprint), all of which were extracted from the qualitative part of the study. The initial items were compiled at the end of this phase.

2.3 | Phase 3 (Psychometric Properties)

This phase lasted from March to August 2024. The scale validity was evaluated through face validity, content validity, and construct validity, and its reliability was evaluated through internal consistency and relative and absolute reliability.

2.3.1 | Face Validity

The face validity of the scale was assessed through quantitative and qualitative methods. Quantitative face validity was computed by determining the item impact scale (IIS) for each item of the scale with a satisfactory level of ≥ 1.5 (Polit-O'Hara and Yang 2016; Lenz 2010). Ten adults with prediabetes were asked to evaluate and score the importance of each item on a 5-point Likert scale. Next, the qualitative face validity of the scale was evaluated by 10 adults with prediabetes. The adults with prediabetes read the items and commented on their simplicity and clarity.

2.3.2 | Content Validity

The content validity of the scale was evaluated in both qualitative and quantitative methods. In the qualitative method, the scale was assessed based on the grammar, wording, item allocation, and scaling indices based on the opinions of 12 experts. Quantitative content validity was evaluated by content validity ratio (CVR), item-level content validity index (I-CVI), scale-level content validity and the index/averaging calculation method (S-CVI). A panel of specialist experts ($n=12$) was asked to determine the CVR by assessing the importance of each item using a three-point rating scale. The panel included methodological study experts and specialists working in the field of patient safety. Then, the CVR of each item was computed according to Lawshe's Table with the minimum acceptable value of 0.56 (Polit-O'Hara and Yang 2016; Lawshe 1975; Wilson et al. 2012). I-CVI was measured by 12 experts who assessed the relevance of each item based on a four-point Likert scale. For measuring I-CVI, the number of experts who gave a rating of three or four to the items was divided by the total number of experts. The acceptable CVI for the total scale (S-CVI/Ave) was 0.90. For items, if there was an item with I-CVI lower than 0.78, it was removed (Polit-O'Hara and Yang 2016).

2.3.3 | Item Analysis

After evaluation of the content validity of the scale, item analysis was performed to examine the internal consistency of the scale and to find unsuitable items. The scale was given to 30 adults

with prediabetes, similar to the main study sample (inclusion criteria: adults aged 19–60 years who were aware of their prediabetes status (fasting plasma glucose of 100–125 mg/dL) for at least 6 months since the diagnosis of their pre-diabetes status).

The initial reliability of the scale was first calculated using Cronbach's alpha coefficient. Then, the correlation of each item with other items was examined by the loop method. There should be a correlation between one item and at least two other items in the scale. A correlation of 0.30 or higher is accepted; otherwise, the item should be removed or revised. Moreover, items with a high correlation ($r \geq 0.70$) should be merged into one item, if possible (Polit-O'Hara and Yang 2016; DeVellis 2016).

2.3.4 | Construct Validity

The factorial validity of the scale was assessed by two methods as follows: exploratory factor analysis (EFA) and confirmatory factor analysis (CFA). For EFA, the scale was delivered to a convenience sample of adults with prediabetes ($n=204$) who met the inclusion criteria of the study. The appropriateness of the sample size was examined using the Kaiser-Meyer-Olkin (KMO) test (≥ 0.80) as well as Bartlett's test of sphericity. Items with communalities of 0.20 and above are suitable to enter the factor analysis (Plichta et al. 2013; Keszei et al. 2010; Munro 2005). The eigenvalues of one and higher and the scree plot were used to determine the number of extracted factors. To determine the structure of the scale, maximum likelihood factor analysis with promax rotation was assessed (Munro 2005). Items with factor loading 0.30 and above were retained.

In the next step for the evaluation of CFA, the scale was distributed among a new convenience sample of adults with prediabetes ($n=200$) who met the inclusion criteria of the study. CFA was performed using structural equation modelling (SEM). Nine fit indices were considered for estimated parameters, including CMIN/DF (minimum discrepancy function by degrees of freedom divided), RMSEA (root mean square error of approximation), SRMR (standardised root mean square residual), PNFI (parsimonious normed fit index), NFI (normed fit index), CFI (comparative of fit index), GFI (goodness of fit index), IFI (Incremental Fit Index), and NNFI (non-normed fit index) (Polit-O'Hara and Yang 2016).

2.3.5 | Reliability

The reliability of the scale was measured using three approaches in three different convenient patient groups ($n=30$). These approaches were as follows: internal consistency (criteria: $r \geq 0.70$), intraclass correlation coefficient (ICC) (criteria: $ICC \geq 0.80$), and standard error of measurement (criteria: the lower the value, the greater the reliability) (Hu and Bentler 1998; Schreiber et al. 2006).

2.3.6 | Feasibility

The feasibility of the scale was evaluated using the floor-ceiling effect and the average time to complete the scale (DeVellis 2016; Grove et al. 2012).

2.3.7 | Responsiveness

For the measurement of responsiveness, the minimum detectable change (MDC) in the scale items was measured. An MDC below 10% was considered excellent and an MDC less than 30% was considered satisfactory. MDC was measured by the following formulas (Polit-O'Hara and Yang 2016).

$$\text{MDC}_{95} = \text{SEM} \times \sqrt{2} \times 1.96 \text{ MDC \%} = (\text{MDC} \div \text{mean}) \times 100$$

2.3.8 | Data Analysis

The data were analysed using SPSS version 20 (IBM Corporation). Also, Lisrel version 8.8 was used for CFA analysis. Both item- and subscale-level analyses were conducted using descriptive statistics including frequencies, means, and standard deviations. The normality of the data, skewness, kurtosis, and outliers were assessed. The data showed normal distribution. The data were treated, outliers were removed, and missing values were replaced by the series mean in SPSS version 20. In both EFA and CFA, the amount of missing values was acceptable (< 5%).

3 | Results

3.1 | Scale Designing Results in Phase 1

3.1.1 | Theoretical Stage Results

After the directive qualitative study in response to the explicit meaning of self-care in adults with prediabetes, three main categories were extracted from 46 interviews during the qualitative study phase.

According to the results of the qualitative phase of the study, self-care of adults with prediabetes is a process during which adults with prediabetes strive to restore their blood sugar to a normal state in a routine and usual way through self-maintenance (nutrition, physical activity, stress, treatment adherence, complementary medicine, information search, and routine health care), self-monitoring (tracking and interpretation of signs, symptoms or clinical tests), and self-management, which includes directive (information seeking and consultation) and adaptive (nutritional changes, changes in physical activity, drugs and treatment changes) behaviours.

3.1.2 | Final Analysis and Scale Items Pool Results

After the directed qualitative study, three main categories were created: self-maintenance, self-monitoring, and self-management. Afterwards, the items were extracted from the main categories, and a scale item pool with 56 items was produced.

3.2 | Psychometric Properties Evaluation Results in Phase 2

3.2.1 | Face and Content Validity Results

In the qualitative face validity of the scale, no items were removed. After the qualitative face validity, ten items of the scale

were revised with adults with prediabetes in mind. For qualitative content analysis, the scale was assessed by 12 experts and a mild revision was done on the grammar and wording of several items. Five items were merged and a new item was suggested (56 to 53 items). Based on the opinions of a panel of 12 experts for estimation of the scale CVR, 24 of 53 items were removed leaving 29 items. The removed items had CVRs between 0 and 0.33 (< 0.56 in Lawshe's Table). Subsequently, based on the minimum acceptable value of CVI for each item, no items were removed, and thus 29 items remained on the scale. Also, the S-CVI/Ave of the scale was measured as 0.97.

3.2.2 | Item Analysis Results

After content validity, 29 items remained. The tool was administered to 30 adults with pre-diabetes. Cronbach's alpha coefficient and standardised Cronbach's alpha were 0.911 and 0.912, respectively.

In the results of the correlation of each item with the other items, none of the two items had a correlation greater than 0.7. Item 15 had zero variance and was automatically removed during the analysis process. Item 14 did not have a correlation above 0.3 with any of the items. In addition, two items, 14 and 15, had a correlation with a total score of < 0.3.

The research team retained item 14 because evidence has shown that smoking increases the risk of microvascular complications in prediabetes as well as diabetes (Durlach et al. 2022) and deleted item 15 (Limited consumption of alcoholic beverages in Iran). Items 13 and 24 had correlations between 0.2 and 0.3 with the total score, and these two items were removed by the research team.

3.2.3 | Construct Validity Results

The demographic characteristics of the samples in construct validity are presented in Table 1. For EFA, the 26-item scale was delivered to 204 patients who met the inclusion criteria. Skewness, kurtosis, the normal distribution of the data and outliers were assessed. The data were normally distributed. The KMO coefficient was 0.837, indicating the adequacy of the sample size. Bartlett's test verified that there is no redundancy between variables that would be summarised with some factors ($p < 0.001$).

Exploratory factor analysis was performed using 26 items. Using the maximum likelihood method and promax rotation, three factors with 19 items (factor loading between 0.360 and 0.996) were extracted, which explained 38% of the total extracted variance. According to the formula of Sharif-Nia et al. (2024), Proportion of variance = $\sum_{i=1}^N \frac{l_i^2}{N} = \frac{[(l_1^2 + l_2^2 + \dots + l_N^2)]}{N}$ Sharif-Nia et al. (2024). N is the number of variables (Items), and l_i is the factor load of the i th variable. No cross-loading was observed between the items. Items 16, 22, and 23 (in the self-maintenance and self-management dimensions) were included in Factor No. 3 after exploratory factor analysis.

Based on the results and after review by the research team, based on the items of each factor, the three extraction factors according to the theory of self-care of chronic disease by Riegel et al. (2019)

TABLE 1 | Demographic characteristics of the sample in the EFA and CFA.

Variables		EFA (<i>n</i> = 204)	Total (<i>n</i> = 404)
		<i>N</i> (%) Mean ± SD	<i>N</i> (%) Mean ± SD
Age (year)		(204) 45/95 ± 9/42	(404) 47/00 ± 9/52
BMI		(204) 25/64 ± 1/77	(404) 25/94 ± 1/63
Gender	Female	95 (46/6)	202 (50)
	Male	109 (53/4)	202 (50)
Marital Status	Single	6 (2/9)	14 (3/46)
	Married	198 (97/1)	390 (96/53)
Education	Elementary	3 (1/5)	3 (0/74)
	Secondary	10 (4/9)	19 (4/70)
	Diploma	73 (35/8)	154 (38/11)
	Advanced Diploma	10 (4/9)	19 (4/70)
	Bachelor	85 (41/7)	174 (43/06)
	Master	22 (10/8)	33 (8/16)
Job	Yes	96 (47/1)	260 (64/35)
	No	107 (52/5)	144 (35/64)
Health insurance	Yes	186 (91/2)	398 (98/51)
	No	18 (8/8)	6 (1/48)
Family income level	High	—	—
	Medium upward	14 (6/93)	28 (6/93)
	Medium	12 (5/9)	20 (4/95)
	Medium Downward	178 (87/3)	356 (88/11)
	Down	—	—
Family history of diabetes	Positive	108 (52/9)	222 (54/95)
	Negative	96 (47/1)	182 (45/04)
Ethnicity	Fars	143 (70/1)	309 (6/48)
	Turk	41 (20/1)	54 (13/36)
	Kurd	9 (4/4)	22 (5/44)
	Lor	6 (2/9)	11 (2/72)
	Arab	5 (2/5)	8 (1/98)

included self-maintenance behaviours (Factor 1), self-monitoring and tracking behaviours (Factor 2), and goal self-management behaviours (Factor 3). The results of the EFA are shown in Table 2.

Subsequently, CFA by SEM analysis was conducted to confirm the three-factor structure of the 19-item scale which was produced by the EFA. Therefore, the 19-item scale was given to 200 new adults with prediabetes. The SEM results showed that the model exceeded the sensitivity criteria of the goodness of fit. Six of the fit indices showed an acceptable value (Table 3). The factor loadings in the model showed that all 19 items of the scale were highly loaded on the respective factors (0.25–0.85) (Figure 2). Therefore, the construct validity of the self-care scale for adults with prediabetes with 19 items was confirmed in prediabetes.

3.2.4 | Reliability Results

Cronbach's alpha coefficient was 0.880 for the total scale and between 0.712 and 0.870 for its subscales. The ICC for the total scale and its subscales was 0.994 and 0.993–0.984, respectively. These results, in addition to the standard error of measurement results, are presented in Table 4.

3.2.5 | Feasibility Results

The floor and ceiling effects of the scale were 0% and 7% respectively (range 0–0.7). The time required to answer the scale was 6 min (including demographic questions).

TABLE 2 | Factors, items factor loading of the self-care in adults with prediabetes Scale in the EFA.

Sub scales	Items	Factor loading	Eigenvalues	% of variance
Self-maintenance	1. I have refrained from buying junk food	./698	2/66	29/62
	2. I have replaced white bread (such as baguettes) with whole grain bread (whole wheat and barley bread)	./714		
	3. I have reduced the consumption of food with added sugar (such as jam, syrup, soda, ice cream, and all kinds of confections)	./360		
	4. I have used little liquid oil (seed oil) in my cooking	./456		
	5. I have not skipped any main meal or snacks between meals	./493		
	6. I reduced the amount of food in my meals	./533		
	7. I have done cardio (hiking, cycling, swimming, and aerobics) for 30 min daily at least 5 days a week	./494		
	8. I have refrained from smoking (cigarettes and hookah)	./425		
	9. I have acquired the information I needed from reliable and relevant sources (healthcare workers, educational networks and channels, and books)	./619		
Self-monitoring and tracking	10. In each visit to my doctor, I have updated my medications to reduce blood sugar, lipids, and blood pressure	./542	2/59	37/11
	11. I have followed up on my periodic blood sugar (fasting blood sugar and HA1c) and lipids tests according to the orders from my doctor	./388		
	12. I have measured my weight at regular intervals	./388		
	13. I have paid attention to any change in my physical symptoms (such as fatigue, dry mouth, and polyuria)	./538		
	14. I have followed up on abnormal changes in my lab results with the nurse or physician	./831		
	15. After periodic tests, I have attended my follow-ups with my doctor	./579		
	16. I have taken appropriate measures to control my blood pressure and lipids with the help of the health team	./801		
	17. I have followed a purposeful exercise program when I gained weight or had elevated blood sugar	./888		
Goaled self-management	18. I have followed my diet under the medical team's supervision when I gained weight or elevated blood sugar	./996	1/98	66/26
	19. Once I reached my healthy weight, I followed dietary recommendations to maintain my normal weight	./546		

Based on the results of the MDC, MIC, and LOA, the responsiveness of the scale was excellent (Table 4). Since MIC is not at the level of agreement, the scale can be responsive.

TABLE 3 | The goodness of fit indices in the CFA ($n=200$).

Goodness of fit indices	Value	Acceptable threshold
Chi-Square	414.50 ($p=0.0$)	$> 0/05$
Root mean square error of approximation (RMSEA) 90 percent confidence interval for RMSEA=(0.084; 0.11) p for test of close fit (RMSEA < 0.05)=0.00	0/095	0.1 $\geq$ weak, 0.1–0.08 medium, 0.08 $\leq$ good
Standardised Root Mean Square Residual (SRMR)	0/072	$< 0/1$
Parsimonious Normed Fit Index (PNFI)	0/77	$> 0/5$
Incremental Fit Index (IFI)	0/92	$> 0/9$
Comparative Fit Index (CFI)	0/92	$> 0/9$
Minimum Discrepancy Function by Degrees of Freedom divided (CMIN/DF)	2/77	Acceptable < 5 , good < 3

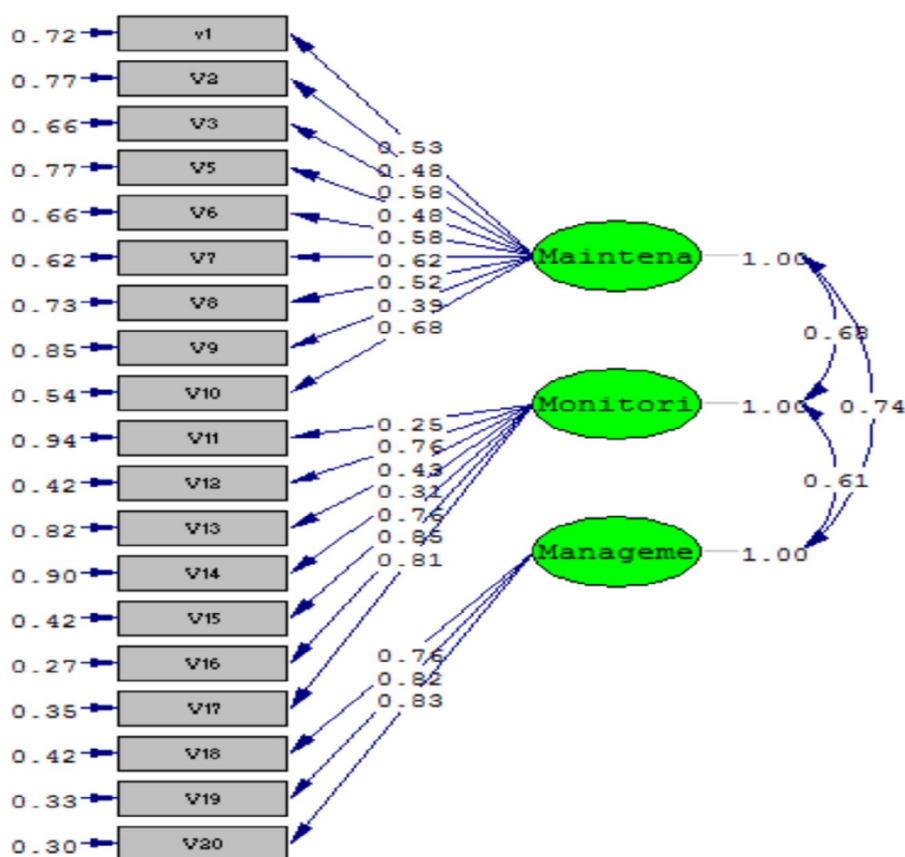
Since MIC is not within the agreed-upon range, the tool has potential responsiveness.

3.2.5.1 | Self-Care of Adults With Prediabetes Scale (SCAP). After conducting the two phases of the study, the 19-item scale was developed with the three subscales of ‘self-maintenance’ (9 items), ‘self-monitoring’ (7 items), and ‘self-management’ (3 items) on a 5-point Likert scale with 1–5 points (from always to never). The total range of raw scale scores is 19–95. After the transformation of the scores to the standard score, the scoring of the scale was changed to 0–100. The higher the score, the greater the self-care of adults with prediabetes.

4 | Discussion

This study aimed to design and assess the psychometric properties of the SCAP scale to measure self-care in adults with prediabetes in our context. First, the scale was developed by directed content analysis, and then the psychometric properties of the scale were examined.

The results of the validity and reliability assessment of the scale showed that the SCAP scale is a valid and reliable scale for measuring self-care in adults with prediabetes in our society. In the scale design phase, we conducted interviews with prediabetic individuals.



Chi-Square=414.50, df=149, P-value=0.00000, RMSEA=0.095

FIGURE 2 | The diagram of the self-care in adult with prediabetes Scale by the Structural Equation Modelling ($n=200$).

TABLE 4 | The reliability results for the self-care in adults with prediabetes Scale and its subscales.

Sub scales	ICC	95% CI	p
Self-maintenance	./993	./986–./997	< 0/001
Self-monitoring and tracking	./987	./973–./994	< 0/001
Goaled self-management	./984	./966–./992	< 0/001
Total scale	./994	./985–./997	< 0/001

Sub scales	MDC%	ICC	MIC	MDC ₉₅	SEM	LOA
Self-maintenance	5/87	./99	3/41	1/91	./692	–2/43 1/90
Self-monitoring and tracking	8/36	./98	2/80	2/20	./799	–2/69 –2/16
Goaled self-management	15/96	./98	1/63	1/22	./443	–7/74 –1/27
Total scale	5/53	./99	6/57	3/71	1/34	–4/76 –3/03

The results of the qualitative study clarified the concept of “self-care in adults with prediabetes” based on Riegel et al.’s (2019) middle-range theory of self-care for chronic illness (2019) (Riegel et al. 2019) in the cultural context of Iran. The results showed that self-care in adults with prediabetes is a concept with three dimensions.

The self-maintenance behaviours aspect involves behaviours related to physical activity, information and resource searching, smoking, and nutrition, which adults with prediabetes perform routinely to maintain their health.

The self-monitoring behaviours aspect involves attention to symptom changes following physical and laboratory changes, and follow-up involves actions such as tests to control blood sugar.

The self-management behaviours aspect involves responses of adults with prediabetes following signs and symptoms, monitoring their follow-up examinations and lab results, which manifest as purposive changes in the areas of physical activity, following a special diet, and weight control.

The items of the questionnaire elicited from this study are consistent with all self-care interventions and programs to reduce the prevalence of type 2 diabetes in adults with prediabetes. These items focused on following physical activity, a healthy diet, and a suitable diet along with regular control of blood sugar, periodical examinations, and following medication treatments if needed (Sun et al. 2023).

Comparing the self-care tools provided by Riegel et al. (2019) to the tool elicited from the current study, it can be stated that in the area of self-care behaviours, other tools contain disease-related routine behaviours besides the items about health-promoting behaviours, and in terms of self-care behaviours, they attempt to include the range of behaviours from health to disease condition, including public health, health promotion, prevention, and disease.

The items of the elicited tool focus on promoting health and preventing prediabetes from advancing to type 2 diabetes. This indicates that, generally, self-care is a self-protecting, self-monitoring, and self-management process, and the items of the tool are developed according to where the individual is on the health-disease spectrum, the type of the disease, and how chronic their condition is (Ausili et al. 2017).

The psychometric properties of the prediabetic adult self-care tool were assessed according to the COSMIN checklist, the self-care questionnaire for diabetic patients, and some studies that used a method similar to ours. Finally, a [Supplementary Discussion](#) about the results was provided (Mokkink, Terwee, Patrick, et al. 2010).

The face validity of the current study was established using qualitative and quantitative methods, while none of the following studies mentions establishing the face validity and the results of it: Ausili et al. (2017), Luciani et al. (2022), Matarese et al. (2020), Ausili et al. (2017), Luciani et al. (2022), Matarese et al. (2020).

The content validity of the tool was confirmed using qualitative and quantitative methods. The results were analysed under the research team’s supervision according to the COSMIN checklist. The mean content validity index of the entire tool was 0.97, which is acceptable.

In Ausili et al. (2017), where the content validity index was established for each item, and items of each scale of diabetic patients’ self-care tool were assessed according to the chronic disease self-care theory of Riegel et al. (2019), it was found that the Content validity index of the final version of each item and each scale was 100%. Although the changes were not mentioned in detail, to establish the validity of the qualitative content, the researchers included reviews and expert suggestions for each item (Ausili et al. 2017).

In Matarese et al. (2020), 12 items of the self-care tool in patients with chronic obstructive pulmonary disease (COPD) had

an unacceptable content validity index so they were omitted. In the remaining items, the total content validity index was 0.70 for each self-protecting subscale, 0.50 for each self-monitoring subscale, and 0.52 for each self-management scale. Also, to enhance the comprehensiveness of the tool, the experts were asked if they deemed it necessary to add any new item; however, no new item was added (Matarese et al. 2020).

In the current study, a group of experts established the qualitative content validity and any change that helped items to be clearer and simpler; any suggestion to integrate or add a new item was implemented on items before establishing the quantitative content validity of the tool.

Construct validity is achievable by factor analysis, hypothesis testing (validity of the known groups), convergent validity, discriminant validity, and intercultural validity. Construct validity was established by Luciani et al. (2022) by hypothesis testing (Luciani et al. 2022) and, by Matarese et al. (2020), by convergent and discriminant validity (Matarese et al. 2020). In this study, construct validity was established through exploratory factor analysis and confirmed using confirmatory factor analysis with maximum likelihood estimation and structural equation modelling (SEM). The final tool explains 38% of the variance of the main subject meaning the current tool can explain 38% of real situations, and the rest cannot be measured by this tool. Therefore, the exploratory factor analysis of the tools specific to diabetes explained 40% to 69% of the total variance (Lu et al. 2016).

In humanities and human-related studies, a variance of 50% is acceptable. Meanwhile, in studies whose data are objective, this should be 70% or higher (Munro 2005).

No fixed threshold exists, although certain percentages have been suggested. According to Hair et al., in the natural sciences, factors should be stopped when at least 95% of the variance is explained. In the humanities, the explained variance is commonly as low as 50%–60% (Williams et al. 2010). In this study, 38% of the variance may be due to medium range of factor loadings.

Matarese et al. 2020 stated that the absence of a valid and reliable self-care tool in chronic obstructive pulmonary disease was the reason for the inability to assess the factor validity. The same is true for the present study; as there was no suitable self-care tool in adults with prediabetes and it was not possible to simultaneously measure the glycolysis haemoglobin (HbA1c) of the participants in the laboratory, the factor reliability was not assessed (Matarese et al. 2020).

The internal consistency of the subscales of the current tool was assessed via Cronbach's alpha. Cronbach's alpha for all subscales was higher than 0.7. Matarese et al. (2020), who assessed the reliability of self-care tools for patients with chronic obstructive pulmonary disease, reported a Cronbach's alpha higher than 0.7 for all subscales and a correlation coefficient higher than 0.8 (Mokkink, Terwee, Patrick, et al. 2010). In the current study, Cronbach's alpha was higher than 0.7 and the intraclass correlation coefficient was higher than 0.9, which is indicative of the desired level of precision in measurements and reliability of the tool for adults with prediabetes.

Matarese et al. (2020) reported the reliability coefficient for each subscale using Cronbach's alpha coefficients for one-dimensional scales, composite reliability, and the global reliability index for multi-dimensional scales. The current study used Cronbach's alpha to assess the level of internal consistency of each subscale. In addition to that, the global reliability of the tools in Matarese et al. (2020) was established via confirmatory factor analysis, while in the current study, Cronbach's alpha was used to assess the global internal consistency of the tool.

Identical conditions for participants in the two stages of tool development are an important criterion in the COSMIN checklist (Mokkink, Terwee, Gibbons, et al. 2010). In this study, a pretest interview was conducted before the retest to ensure that no unexpected occurrence happened to influence the retest score. Test conditions were similar in both tests, and both were conducted in person. The time between the test and retest in two studies similar to ours was set at 2 weeks, which is acceptable according to the COSMIN checklist.

Matarese et al. (2020) also used the confirmatory factor analysis to assess the tool dimensions and the suggested model to develop a self-care tool in patients with chronic obstructive pulmonary disease (Mokkink, Terwee, Patrick, et al. 2010). The RMSEA for each subscale was in a good range. In the current study, confirmatory and exploratory factor analyses were used and the RMSEA was 0.095, which is mid-range. The RMSEA assesses how well the model fits the data, considering the complexity of the model and the sample size (Savalei 2018). In addition, general guides include Tabachnick's rule of thumb that suggests having at least 300 cases are needed for factor analysis. Hair et al. suggested that sample sizes should be 100 or greater. A number of textbooks cite the work of Comrey and Lee in their guide to sample sizes: 100 as poor, 200 as fair, 300 as good, 500 as very good, and 1000 or more as excellent (Williams et al. 2010). In this study, sample size for EFA (N : 200) may have affected REMSEA index. But Bollen also showed that the TLI and IFI are relatively unaffected by sample size (Bollen 1990). In this study, IFI has an acceptable value.

Jaccard and Wan state when at least three indices from each group of absolute fit, comparative fit, and parsimonious fit have acceptable values (Ebadi et al. 2017), we can claim that the model fit is acceptable. In the current study, the confirmatory factor analysis showed that six indices of model fit were in good range, resulting in confirmation of the model.

In the current study, absolute measurement error was calculated along with the intraclass correlation coefficient. This was a strong point for the current tool. Also, the tool's responsiveness, interpretability, and feasibility were assessed. None of the studies above reported the tool's responsiveness.

In the current study, it was not possible to implement a known intervention or follow-up with the patients and healthcare workers long-term to assess its effect on the level of self-care in adults with prediabetes and consequently, the tool's responsiveness. Therefore, the researcher assessed the tool's responsiveness according to indices with minimal detectable change within an agreed-upon range with minimum significant change; however,

the assessment of this index for the current study is considered a strong point.

The tool and each subscale were scored according to the linear transformation formula from 0 to 100. Also, in Matarese et al. (2020), each subscale score and the tool's total score were calculated from 0 to 100 using the linear transformation formula so that they may be compared with each other. In both studies, a high score indicates a good level of self-care (Matarese et al. 2020).

As an interpretation, it can be said that the results of the quantitative stage to an acceptable extent confirmed the universality and fitness of the elicited content from the qualitative stage. In the qualitative stage, there were three main themes and in the quantitative stage, there were three subscales, so the final tool's subscales somehow involved the content of the three main themes of the qualitative stage.

Finally, it can be concluded that in the current mix-methods study, the results from the quantitative stage were able to produce a more universalized perception of the self-care concept than the qualitative data alone, and the final product of the study was introduced as the first reliable and valid tool for assessing self-care in adults with prediabetes.

5 | Final Conclusions

The self-care tool for adults with prediabetes has acceptable psychometric properties according to the COSMIN checklist. The reliability and validity of the questionnaire were assessed from different points of view and the results indicated the good condition of this tool. The relatively low number of questions and the use of questions specific to prediabetes were the advantages of this questionnaire. The psychometric analysis of this tool was performed among various prediabetic adult populations and by different experts and to the extent of the researcher's knowledge, this is the sole tool for assessing self-care in adults with prediabetes.

6 | Strengthens and Limitations of the Study

One of the strengths of the present study is the use of a strong methodology, consisting of directed content analysis based on Riegel et al.'s (2019) middle-range theory of self-care for chronic illness (2019). Also, we evaluated the validity and reliability of self-care in adults with a prediabetes scale with a wide range of psychometric tests. The self-care in adults with prediabetes scale is a short scale specifically for prediabetes. It is important to mention that the self-care in adults with prediabetes scale was developed in the context of Iran.

The final tool explains 38% of the variance and medium range of REMSEA (despite the appropriate range of some other indicators) are limitations of this study. This result shows further studies are needed to develop the tool with a larger number of samples.

Thus, the applicability of the self-care in adults with prediabetes scale is unknown in other cultures. It is suggested that the

applicability of the self-care in adults with prediabetes scale be tested in other societies in future research.

7 | Relevance to Clinical Practice

The self-care in adults with prediabetes scale as a short scale can be easily applied in quality-of-healthcare research studies and accreditation of diabetes prevention programs.

Author Contributions

M.Z., A.E. and A.M. supervised this study. All authors designed the study and cooperated in composing, reviewing, and correcting the written version. M.Z., A.E. and M.J. prepared the interview guide. M.J. conducted the interviews. A.E., M.J. and M.S.Y. analysed the data. All authors contributed to the article and approved the submitted version.

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The authors have nothing to report.

Ethics Statement

The patients/participants provided written informed consent to participate in this study. The study was accepted by the research ethics committee 'REDUCTED' Sciences (IR.SBMU.RETECH.REC.1402.053).

Consent

The authors have nothing to report.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The original contributions presented in the study are included in the article/[Supporting Information](#); further inquiries can be directed to the corresponding author.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section. **Data S1:** nop270446-sup-0001-Supinfo01.docx.