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Original Article

Development and validation of a comprehensive diabetes self-management scale

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1. Introduction

Diabetes mellitus is a chronic metabolic disorder characterized by hyperglycemia due to insulin deficiency and/or resistance [1]. It is a highly prevalent disorder worldwide and its prevalence and incidence was increased dramatically over the last 2 decades, especially in Iraq and other Arab countries. It is now considered as the 5th leading cause of death in the Arab world; this may be because uncontrolled hyperglycemia is associated with the development of many micro-and macro-vascular complications [2]. Diabetes self-management practices are considered as the cornerstone in managing diabetes and ensuring tight glycemic control [3,4]; these practices include healthy eating, physical activity, taking medications, monitoring of blood glucose, resolving problems, reducing diabetes risks and healthy coping with stress [5]. Many tools are available nowadays to assess diabetic patients' self-management practices, but only a few of them are valid and reliable. Additionally, most of the available tools were not designed to assess all of the 7 dimensions of self-management practices [6]. Furthermore, all of the available tools were developed and evaluated originally in countries at which patients have different health knowledge, beliefs, and practices from Iraqi patients. Therefore we aimed to develop a comprehensive tool to assess diabetes self-management practices that is specific for Iraqi diabetic patients.

2. Methods

2.1. Developing scale items

A comprehensive review of the literature was done using Google Scholar and PubMed to identify diabetes self-management scales. The following sets of keywords were used: Diabetes self-care scale, measuring diabetes self-care, diabetes self-management scale and measuring diabetes self-management. Only freely available scales that were written in English were chosen. Six relevant self-management scales were included, these scales include: The summary of diabetes self-care activities (SDSCA), diabetes self care scale (DSCS), Self-Care Inventory-Revised (SCI-R), The Diabetes Self-Management Questionnaire (DSMQ), Diabetes self management scale (DSMS) and The LMC Skills, Confidence & Preparedness Index (SCPI) [7–12]. The included scales were reviewed carefully by the main author of this study to find out items that can cover all of the 7 aspects of diabetes self-care behaviors [5] and on the other hand, be relevant to the Iraqi diabetic patients [13]. Fourteen questions were chosen to make a comprehensive diabetes self-management scale (CDSMS). Three items (3,4 and 5) aimed to identify the extent of healthy eating, two items (1 and 2) aimed to identify the extent of doing an exercise, one item (6) aimed to identify the extent of medication adherence, one item (7) aimed to identify the extent of blood glucose testing, four items (8–11) aimed to identify the practices to reduce diabetes risks, one item (12) aimed to identify patient behavior during stress and the final two items (13 and 14) are used to assess the patient's ability to solve major problems. 11 items were designed using multiple choice style with 5 different responses; 3 items (items 9, 11 and 14) have sub-questions with a dichotomous answer.

Scoring of All items ranged from 0 to 4; for all, zero was given for the no answer or the answer with the least accepted practice, while answers that ensure optimum practice was given 4 in items with multiple choices and 1 in dichotomous questions.

The score for items with sub-questions was calculated by summation of the scores for each of the 4 sub-question. All Items,

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except items (4, 5, 10, 11D and 14 B) are inversely calculated.

2.2. Translation

All 14 items were translated to Arabic using a strict forward and backward translation protocol, whereby 2 linguistic experts performed the translation independently. After the translation of these questions, they were modified to ensure easier understanding by the Iraqi patients. After writing the final version of CDSMS, all Arabic questions were translated to English using a strict forward and backward translation protocol, whereby 2 linguistic experts performed the translation independently.

2.3. Face and content validity

The developed scale, both the Arabic and English versions, was administered to a panel consisting of 7 Arab experts in the field of diabetes management including: one diabetologist, 2 diabetes educators, 2 clinical pharmacists, and one public health specialist. All experts were asked to review and rate all scale items to determine their eligibility for use to assess self-management practices among Iraqi type 2 DM patients. The panel came to a mutual agreement upon on clarity and relevance of all items in both versions.

A pilot study was conducted on seven Iraqi DM patients; they were asked to read the Arabic version of CDSMS and then reply to the main author with their feedback on the clarity of each question in CDSMS. All patients agreed on the clarity of CDSMS questions.

2.4. Concurrent validity

An improved glycemic control can be achieved through the practicing of diabetic patient of self-management [14–16], and since HbA1c can effectively correlate with the patient's glycemic control during the last 2–3 months, besides that it doesn't affected by food [17,18]; therefore HbA1c value was chosen as comparator to confirm concurrent validity of CDSMS. HbA1c was measured using the point of care apparatus (i-chroma, UAE).

2.5. Study design

A cross-sectional study was conducted over 9 months starting from November 2017 in the National Centre for Diabetes, Baghdad, Iraq. Ethical approval for this study was obtained from the ethical committee at the National diabetes center.

2.6. Sample size

The sample size for this study was set at 140 since CDSMS has 14 items and it is well known that ten participants per item can provide a sufficient sample size for validation of a newly developed scale [19,20]. Anyhow, the target sample size was 147 patients by taking into account a 5% of no-response rate.

2.7. Patients' selection

A convenient sample of 147 patients was recruited by the main researcher in a private room for researches and educating patients at the National Centre for Diabetes, Baghdad, Iraq.

Only Arab patients older than 18 years, having type 2 DM and maintained on anti-diabetic medications for at least 3 months were included in this study. However, patients who had cognitive impairment, depression, and pregnant women were excluded.

All patients were interviewed by the main researcher to explain the purpose and the study protocol: only those who provided their informed consent were requested to fill in the questionnaire (CDSMS). The CDSMS was presented to patients with low educational level and to patients with visual difficulties via face-to-face interviews.

The participants need approximately 10-15 min to complete filling the CDSMS.

To examine reliability test–retest analysis, approximately one-fifth of the initial study sample was conveniently selected ($n = 28$) [21]. Additional 10 patients were also selected to counteract the expected escape rate which exceeds 30% in some other studies [22]. Thus 38 patients were asked to return back after 14–28 days, but only 25 patients (64%) returned back and filled in the CDSMS for the second time.

2.8. Statistical analysis

Data input and analysis was done using the Statistical Package for the Social Sciences (SPSS) version 17.

Categorical variables were presented as percentage and frequencies, while mean and standard deviation were used to present continuous variables.

Shapiro-Wilk test was used to test the normality of distribution for continuous variables.

Spearman rho correlation test was used to determine the correlation between abnormally distributed continuous variables.

Cronbach's alpha values were used to determine the internal consistency of the CDSMS. A Cronbach's alpha value of more than 0.7 was considered optimum. The value of any corrected item-total correlation which is higher than 0.2 is considered acceptable [23].

Test-retest reliability was assessed by using Wilcoxon signed ranks test to measure score difference for each item while Spearman's correlation coefficient test was used to test the correlation of CDSMS total score before and after retesting.

Receiver operating characteristic (ROC) curve analysis was done to determine the area under the ROC curve (AUC) and then to define the optimum cut-offs point for CDSMS that can predict good glycemic control; Sensitivity and specificity were also measured at the optimal cut-off point.

P value of <0.05 was considered statistically significant.

3. Results

A total of 147 participants were recruited in this study; however, only 141 patients completed this study (response rate 95.9%), patients' demographic and clinical data are presented in Table 1.

3.1. Psychometric properties of the CDSMS

3.1.1. Reliability analysis

The internal consistency of CDSMS was 0.704 which was measured using Cronbach's alpha. All items except item 10 had corrected total item correlation more than 0.2. Cronbach's alpha will be increased to 0.714 if that item was excluded (Table 2).

In Table 3, the Spearman's rho for the total score of test-retest reliability was 0.991 ($p = 0.000$). When the individual items in the CDSMS were analyzed, all items were not significantly different at test-retest ($P > 0.05$).

3.2. Concurrent validity

There was an inversely significant correlation between CDSMS score and HbA1c (Spearman's rho = - 0.460, $P = 0.000$); this inverse correlation was significant among all type2 DM patients without regard to the type of treatment they use (Table 4). Additionally, all CDSMS subscales, except for the physical activity, were negatively correlated with HbA1c values (Table 5). Furthermore, there was a

Table 1
Demographic data of the participants.

Parameter	Value
Age (years) mean ± SD (Range)	57.23 ± 8.75 (36–74)
Gender	
Male	87
Female	54
Educational level	
None or Primary	21
Secondary	62
Diploma or college	50
Postgraduate	8
Duration of DM (years) mean ± SD (Range)	12.04 ± 7.28 (1 year-31 year)
Type of medication	
Oral	56
Insulin	36
Combination	49
HbA1c mean ± SD (Range)	9.2 ± 1.94 (5.11–16)

Table 2
Reliability of CDSMS.

Item number	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
1	0.421	0.673
2	0.458	0.667
3	0.410	0.674
4	0.382	0.681
5	0.283	0.692
6	0.259	0.696
7	0.231	0.703
8	0.388	0.688
9	0.352	0.685
10	0.088	0.714
11	0.260	0.694
12	0.314	0.688
13	0.267	0.694
14	0.416	0.676

Table 3
CDSMS test retest reliability.

Parameter	Z value	P value
Q1	−0.108	0.914
Q2	−1.414	0.157
Q3	0.000	1
Q4	0.000	1
Q5	−0.816	0.414
Q6	−0.463	0.644
Q7	−0.061	0.951
Q8	−0.557	0.577
Q9	−1.134	0.257
Q10	−1	0.317
Q11	−1.890	0.059
Q12	−1.732	0.083
Q13	−0.577	0.564
Q14	−1.633	0.102
Total mean score correlation	0.991	0.000

significant difference in CDSMS score between patients with different glycemic control (Table 6).

3.3. CDSMS cut-off point

ROC analysis showed that area under the curve is 0.723 (0.592–0.854) (95% CI) (P = 0.008) and the optimal cut-point score of CDSMS to predict good glycemic control is ≥ 15.04 points, this score has 76.9% sensitivity and 50.8% specificity to predict patient with good glycemic control. Further details are given in Fig. 1.

4. Discussion

This study showed that CDSMS has acceptable internal consistency, stable reliability, concurrent validity, good sensitivity, and specificity.

The Cronbach's alpha coefficient of CDSMS was more than 0.7 which indicates that CDSMS had an excellent internal consistency that met the standard criteria required for acceptance of the designed scale [24]. All the items except one item showed good corrected item-total correlations. In this regard, Cronbach's alpha value can be increased slightly if the aforementioned item was excluded from the scale; however, many researchers recognized this item as an important variable and accordingly, this item was retained in the designed CDSMS [7,25]. Meanwhile, the reported improvement in the Cronbach's alpha by deletion of this item was found to be marginal and non-significant [26,27].

All items in the CDSMS were not statistically different at test-retest. In addition, Spearman's rho for the total scores of the CDSMS showed an excellent correlation between the test-retest. This indicates a stable reliability for CDSMS.

The present study also demonstrated a fair and significant inverse correlation between HbA_{1c} values and the total CDSMS scores of the patients; similarly many other scales that assess diabetes self-management practices had a weak/fair but significant inverse

Table 5
Correlation of CDSMS subscales score with HbA1c.

CDSMS subscale	Correlation coefficient (R value)	P value
Exercise	−0.099	0.242
Diet	−0.416	0.000
Drug	−0.338	0.000
Blood glucose testing	−0.195	0.020
Reducing risks	−0.327	0.000
Healthy coping	−0.193	0.022
Resolving problems	−0.339	0.000

Table 6
Comparison of CDSMS values at different HbA1c levels.

Parameter	CDSMS score	P value
Good glycemic control (n = 13)	18.46 ± 3.95	0.008
Bad Glycemic control (n = 128)	14.75 ± 4.43	

Table 4
Correlation of CDSMS score with HbA1c.

Parameter	Correlation coefficient (Rvalue)	P value
All diabetic patients (n = 141)	−0.460	0.000
Diabetic patients using oral anti-diabetics (n = 56)	−0.453	0.000
Diabetic patients using a combination of oral and injectable anti-diabetics (n = 49)	−0.395	0.005
Diabetic patients using Insulin (n = 36)	−0.536	0.001

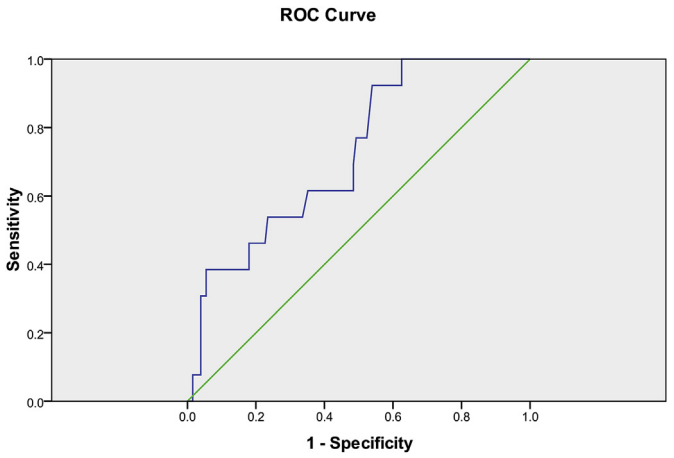

Fig. 1. ROC curve for CDSMS score.

correlation with HbA1c [9,11]. On the other hand, all subscales of CDSMS, except physical activity, had a significant inverse correlation with HbA1c. Similarly, physical activity subscale for the diabetes self-management questionnaire, which is one of the most commonly used questionnaires to assess diabetic patient self-management practices, had a very weak and non-significant correlation with HbA1c value [9]. This finding may be explained in that most Iraqi diabetic patients who do an exercise prefer to do so through walking [13] which can be considered as mild intensity exercise especially when walking is not brisk walking, since it is well known that mild-intensity exercise has the least benefit on improving glycemic control [28]. All of the previously mentioned findings confirmed the concurrent validity of the CDSMS and this was in tune with other studies that showed a positive correlation between self-management and glycemic control [29]. Furthermore, the present study showed that patients with good glycemic control had a significantly higher mean CDSMS score than those who had poor glycemic control, which provides strong evidence for the ability of the questionnaire to discriminate between patients' self-management behaviors.

ROC analysis for CDSMS showed that AUC was more than 0.7 which can be considered good [30]; a similar finding was obtained in many other scales that assess different parameters among diabetic patients [31,32]. Furthermore, a cut-off value of 15.04 which was obtained by ROC analysis, showed that CDSMS had a good sensitivity but with moderate specificity. Similarly, other reported data mentioned that specificity was poor-moderate for most of the patients reported scales that assess diabetic patient self-care behaviors [6].

The main limitation of this study was the small sample size of diabetic patients and the single-center recruitment pattern. In addition, CDSMS was only validated in Arabic and hence, only Arabic Iraqi patients could be included in the study. However, Iraq is a multiracial society with 4 ethnic groups: Arabs, Kurds, Assyrian, and Turkmen. Therefore, further studies to translate and validate the Kurdish, Assyrian, and Turkmen versions of the CDSMS are recommended. Furthermore, CDSMS was only validated for type 2 DM patients, so further studies are needed to confirm its validity among type 1 DM patients.

5. Conclusion

This study demonstrates that the developed CDSMS has good internal consistency and stable reliability. The psychometric properties of the CDSMS showed a significant correlation with HbA1c. Therefore, it seems to be a reliable and valid instrument and can be used for assessing self-management practice among Iraqi type 2 DM patients.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.dsx.2019.03.025.

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