ORIGINAL ARTICLE

The reliability and validity of the Malay version 17-item Diabetes Distress Scale

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Abstract

Introduction: Diabetes-related distress (DRD) refers to patient's concerns about diabetes mellitus, its management, need of support, emotional burden and access to healthcare. The aim of this study was to translate and examine the psychometric properties of the Malay version of the 17-item Diabetes Distress Scale (MDDS-17) in adult patients with type 2 diabetes mellitus (T2D).

Methods: A standard procedure was used to translate the English 17-items Diabetes Distress Scale into Malay language. We used exploratory factor analysis (EFA) with principal axis factoring and promax rotation to investigate the factor structure. We explored reliability by internal consistency and 1-month test-retest reliability. Construct validity was examined using the World Health Organization quality of life-brief questionnaire, Morisky Medication Adherence Scale, Patient Health Questionnaire and disease-related clinical variables.

Results: A total of 262 patients were included in the analysis with a response rate of 96.7%. A total of 66 patients completed the test–retest after 1 month. EFA supported a three-factor model resulting from the combination of the regimen distress (RD) and interpersonal distress (IPD) subscales; and with a swapping of an item between emotional burden (EB; item 7) and RD (item 3) subscales. Cronbach's α for MDDS-17 was 0.94, the combined RD and IPD subscale was 0.925, the EB subscale was 0.855 and the physician-related distress was 0.823. The test–retest reliability's correlation coefficient was r = 0.29 (n = 66; p = 0.009). There was a significant association between the mean MDDS-17 item score categories (<3 vs ≥3) and HbA1c categories (<7.0% vs ≥7.0%), and medication adherence (medium and high vs ≥low). The instrument discriminated between those having diabetes-related complication, low quality of life, poor medication adherence and depression.

Conclusion: The MDDS-17 has satisfactory psychometric properties. It can be used to map diabetes-related emotional distress for diagnostic or clinical use.

Introduction

Diabetes-related distress (DRD) is defined as patient's concerns about diabetes mellitus, its management, need of support, emotional burden and access to healthcare.[1] Measuring DRD is important because it is a milder and more common emotional disorder that has significant effects on self-management and glycaemic control.[2,3] Therefore, DRD is manageable and should be intervened at primary care level and identified in a timely manner.[3,4]

Type 2 diabetes mellitus (T2D) patients with emotional distress (DRD and depression)[2] might not be capable of adequate self-care,[5] leading to poor glycaemic control and increased morbidity and mortality.[6–9] A general psychological distress was reported to be associated with gastro-intestinal complaints (bloating, abdominal pain, loose stools and urgency) among patients with diabetes mellitus.[10] Furthermore, untreated psychological disorders such as stress and distress, may lead to cardiovascular complications, depression and cognitive decline, which would aggravate the vicious cycles of self-care ability.[11–13]

Psychosocial problems that are related to diabetes, personal relationships and work, might begin early from the time of T2D diagnosis. Approximately half of the newly diagnosed patients with T2D often used negative coping

strategies and more frequently expected that diabetes would negatively affect their future.[14,15] International and local data have shown that many patients with T2D experienced psychosocial and emotional burden.[16–18] In Malaysian hospitals, more than half of these patients with diabetes mellitus felt burnt out from coping with increasingly difficult diseases.[18] Many patients worried about hypoglycaemia, worsening disease and insulin injection.[19] Majority of the patients felt tired of complying with their medication and reported that diabetes was preventing them from doing what they wanted to do.[18] Using the Depression, Anxiety and Stress Scale (DASS) 21 questionnaire, the prevalence of depression, anxiety and stress symptoms among patients with T2D in 12 Malaysian public primary care clinics were 11.5%, 30.5% and 12.5%, respectively.[20] Primary care patients treated with insulin had also been shown to report higher diabetes-related emotional distress compared to oral- or diet-treated patients.[21,22] Interestingly, Fisher L et al. reported that what has been widely called "depression" among patients with T2D in the literature may really be either major depressive disorder or/and DRD, with the latter displaying a more consistent and significant relationships with self-management, self-efficacy and glycaemic control.[2,23]

Local data showed increasing prevalence of T2D, diabetes-related complications and persistent poor disease control and management,[19,24–26] especially affecting the Malays.[27–31] Given the rising burden of T2D and its associated mood disorders in Malaysia, and the availability of emotional training program or behavioural intervention in these patients,[32–34] we translated and validated a Malay version of the 17-item Diabetes Distress Scale (MDDS-17) hoping that DRD could be rightly assessed in the Malay-literate patients in clinical practice. In this study, we analysed the data to address three major questions:

1. What is the reliability and efficiency of the MDDS-17 in clinical practice?
2. What are the operating characteristics of the MDDS-17?
3. What is the construct validity of the MDDS-17 in relation to glycaemic control, quality of life, medication adherence and depressive symptoms?

Methods

This cross-sectional study comprised the questionnaire translation and validation of the MDDS-17. Approval was obtained from the original author to use the DDS English version. All subjects had provided written consent before participation. We reported this study according to an international consensus on taxonomy, terminology and definitions of measurement properties for health-related patient-reported outcomes.[35,36]

Description of the 17-item Diabetes Distress Scale (DDS-17)

The original 17-item DDS was tested by Polonsky et al. on patients with type 1 and T2D at both the primary care and specialist settings.[1] This instrument assesses problems and hassles concerning diabetes for 1 month on a Likert scale from 1 (not a problem) to 6 (a very serious problem).[1] Scoring of this scale involves summing up the patient's responses to the appropriate items and divide by the number of items in that scale. A mean item score of ≥ 3 is considered a level of distress worthy of clinical attention, whereas an overall mean score of less than 2.0 indicates little to no distress, a score between 2.0 and 2.9 indicates moderate distress.[37] The DDS-17 yields a total diabetes distress scale score plus 4 subscale scores, each addressing a different kind of distress: emotional burden subscale (EB) (e.g., "feeling overwhelmed by the demands of living with diabetes"), physician-related distress subscale (PD) (e.g., "feeling that my doctor doesn't take my concerns seriously enough"), regimen-related distress subscale (RD) (e.g., "feeling that I am not sticking closely enough to a good meal plan"), and diabetes-related interpersonal distress (IPD) subscale (e.g., "feeling that my friends/family don't appreciate how difficult living with diabetes can be"). Internal reliability of the DDS and the four subscales was adequate (α>0.87), and validity coefficients yielded significant linkages with the Centre for Epidemiological Studies Depression Scale, meal planning, exercise and total cholesterol.[1]

Setting

This study was conducted in a public health clinic, Klinik Kesihatan Salak, Selangor, Malaysia. Salak Health Clinic is a government health clinic that has resident doctors and headed by a family medicine specialist. The clinic is equipped with complete in-house facilities ranging from medical laboratory tests, plain x-rays and pharmacy. The clinic provides primary medical care services via a multi-disciplinary team approach involving nutritionist

or dietician, pharmacist, physiotherapist, occupational therapist and paramedics who have undergone specialised training in diabetes education and eye care.[38,39]

Study samples

A target sample size of 100–150 patients was estimated to give a good precision for reliability and validity study.[40] We doubled the sample size to 200–300 to account for missing data (incomplete returned questionnaires and unavailability of blood test results). A convenient sampling of 271 patients with T2D who fulfilled the inclusion and exclusion criteria were recruited by trained research assistants. Two patients declined to participate, and seven did not complete the questionnaires (often because there was inadequate time or for unknown reason).

Patients were included in the study according to following criteria: patients had to be a Malay, should be at least 30 years old or more, had been diagnosed with T2D for at least 1 year, had been on regular follow-up with at least three visits in the past 1 year, had recent blood test results within the past 3 months at the time of recruitment, and should be able to communicate in Malay language. Patients who were pregnant or breastfeeding an infant, or those with severe health problems or psychiatric/psychological disorders that caused cognitive impairments and could not complete interviews were excluded. Severe health problems such as life-threatening diseases, recent acute complications or injuries and recently discharged from hospital comprised the other exclusion criteria. The definition of T2D was as when the patient's case record fulfilled all these criteria: (i) either documented diagnosis of diabetes mellitus according to the World Health Organization criteria or (ii) those whose current treatment consisted of life-style modification, on oral anti-hyperglycaemic agent or insulin.

Study procedures

Patients self-administered the socio-demographic and MDDS-17 questionnaires, and for those who could not, face-to-face interviews were performed by the trained research assistants. Additionally, they completed the World Health Organization Quality of Life-brief version (WHOQOL-BREF),[41] the eight-item Morisky Medication Adherence Scale (MMAS-8)[42,43] and the nine-item Patient Health Questionnaire (PHQ-9).[44,45] Malay versions were used for all these questionnaires. WHOQOL-BREF has 25 items measuring quality of life over the past 4 weeks in four domains: (1) physical domain, (2) psychological domain, (3) social relationships domain and (4) environment domain. It scores from 25 to 100 and the scores are scaled in a positive direction (i.e. higher scores denote higher quality of life).[41]

The MMAS-8 measures medication adherence during the past 2 weeks. It scores from 0 to 8 and the levels of adherence were considered based on the following scores: medication adherence (<6), medium adherence (6 to <8) and high adherence (8).[42,43]

PHQ-9 evaluates depressive symptoms and grades the depression severity. It scores from 0 to 27, which can be classified as 0–4 (minimal), 5–9 (mild), 10–14 (moderate), 15–19 (moderately severe), and 20–27 (severe).[44,45]

Almost all the participating patients self-administered the questionnaires. Medical records were reviewed to obtain the latest haemoglobin A1c (HbA1c) and fasting lipid profiles within the past 3 months. This study received approval from the Medical Research Ethics Committee (MREC), Malaysia. The study registered ID is NMRR-12-1167-14158, the approval date was 11 March 2013 with the reference number of the notice: (2) dlm. KKM/NIHSEC/800-2/2/2/P13-68.

Instrument translation

Figure 1 shows the translation process of the DDS-17 from its original language (English) to Malay. It was conducted according to standard guidelines for cross-cultural adaption of self-report measures.[46,47] The translation and cultural adaptation process included 10 steps: (1) preparation, (2) forward translation, (3) reconciliation, (4) back translation, (5) back translation review, (6) harmonisation, (7) cognitive debriefing, (8) review of cognitive debriefing results and finalisation (9) proofreading and (10) final report.

Forward translation of the original questionnaire was undertaken by translation from English to the Malay language to produce a version that was semantically and conceptually as close as possible to the original questionnaire. Translation was done independently by two people: one was a medical officer in practice as a general practitioner and the other one was a qualified

linguistic translator; both were native speakers of Malay and proficient in English. Each translator produced a forward translation of the original questionnaire into the target language without any mutual consultation. Backward translation from Malay to English was carried out by another two translators, also consisted of a medical officer in practice as a general practitioner and a qualified linguistic translator. The principal researcher, who is a Malaysian, organised a meeting to review the two primary versions and compared them with the original. Repeated discussion between the four translators and researcher were done to resolve inconsistencies in the consensus meeting and a final version, ready for testing, was generated.

The translated questionnaire was first distributed to four experts cum investigators in this study. All experts agreed that the MDDS-17 was adequately relevant and comprehensive in assessing DRD. Later the translated questionnaire was also distributed to 10 Malay patients of similar inclusion and exclusion criteria for comment. These individuals were not included in the later validity and reliability study. The patients' comments on the MDDS-17 were that the items were easily understood and acceptable with regards to their cultural background. The final MDDS-17 version was accepted without modification and made available for the validity and reliability study. The MDDS-17 questionnaire took about 5–10 minutes to complete.

Test–retest reliability

To examine one-month reliability test–retest analysis, approximately one-fifth of the initial study sample was randomly selected (n = 48), and another group of patient was invited when they came back for medicine re-supply (n = 25). In total, we had 66 (41 + 25) patients who completed the test–retest after 1 month. Seven patients who participated in the initial study and agreed to participate in the 1-month reliability test–retest did not turn up.

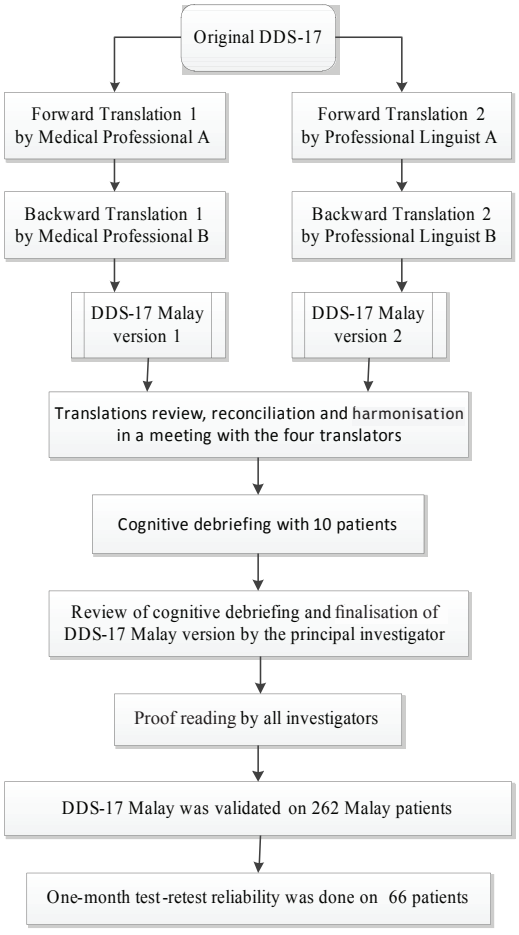

Figure 1. Translation process

Statistical analyses

The factor structure was investigated by exploratory factor analysis (EFA) using principal axis factoring and promax oblique rotation, as the factors were correlated.[48] We determined the number of factors from the criterion eigenvalue ≥1, supplied with judgment based on scree plots. We determined the allocation of items to factors by rotated factor loadings ≥0.5 in absolute value. Items with loadings below 0.5 in absolute value were not allocated to any factor.

Descriptive statistics were used to describe demographic and disease characteristics of the patients and their diabetes distress scores. Percentages and frequencies were used for the categorical variables, while means and standard deviations were calculated for the continuous variables. The characteristics of the whole sample and of the distress groups were presented. Chi square (χ^2), Spearman correlation and student t-test were carried out for MDDS-17 scores and categorical and continuous independent variables, appropriately. Mann–Whitney U test was used in the analyses of the total MMAS-8 and total PHQ-9 scores, as the distribution for these two variables were not normally distributed.

For most of the analyses, the MDDS-17 was divided according to the mean item score into <3 and ≥3. These categories were chosen based on the cut-off scores used by Polonsky for the original DDS-17.[33] Internal consistency was assessed using Cronbach's α, and Spearman's rank correlation was used to assess test–retest reliability. A Cronbach α of more than 0.70 indicates good internal consistency.[49] Correlations were interpreted using the following Cohen's criteria: 0–0.25 = little or no correlation, 0.25–0.5 = fair correlation, 0.5–0.70 = moderate to good correlation and >0.70 = very good to excellent correlation.

Construct validity was assessed through the association between MDDS-17 categories (mean score <3 and ≥3) and HbA1c levels (≥7.0% and <7.0%) and medication adherence categories (MMAS-8 score <6 vs MMAS-8 score = 6–8). These were done by using Chi square (χ^2) tests, assuming that patients with higher levels of distress also report poor diabetes control and low medication adherence, respectively. Construct validity of the MDDS-17 as a measure of distress was assessed by examining demographic and disease-related clinical variables, quality of life (WHOQOL-BREF), medication adherence (MMAS-8), depression (PHQ-9), blood pressure, lipid profiles and disease duration over the two MDDS-17 categories. Evidence to suggest the discriminative validities were examined by Pearson correlations of the relationships between the MDDS-17 scale scores and the PHQ-9 and WHOQOL-BREF total scores. This was possible considering the similarity between DRD and depression, and the difference between DRD and quality of life.[3,50] Criterion validity was not performed as a gold standard was absent for this health-related patient-reported outcomes.[46,47]

Statistical analyses were performed using Statistical Package for Social Science 21.0 (SPSS, Chicago, IL). The significance level was set at p <0.05.

Results

A total of 262 patients were eligible and included in the analysis with a response rate of 96.7% in which 66 patients had completed the test–retest after 1 month. The mean (SD) for age was 55.2 (9.74) years, duration of diabetes was 4.9 (4.39) years. The socio-demographic and clinical characteristics of the distress groups are shown in Tables 1 and 2. Of the 262 Malay patients with T2D, 26 (9.9%) were having significant distress (based on MDDS-17 scores of 3 or more). Higher proportion of patients with diabetes complications showed significant DRD (Table 1). There were no significant differences in DRD for the other variables tested (Tables 1 and 2).

Table 1. Proportion of socio-demography according to MDDS-17 score categories

	Mean MDDS-17 score			X^2	*p*-value
	Total, *n* (%)[a]	<3, *n* (%)[b]	≥3, *n* (%)[b]		
Gender					
Female	136 (51.9)	120 (88.2)	16 (11.8)	1.07	0.41
Male	126 (48.1)	116 (92.1)	10 (7.9)		
Total	262 (100)	236 (90.1)	26 (9.9)		
Marital status					
Married/partner	218 (83.8)	196 (89.9)	22 (10.1)	0.35	0.78
Unmarried	42 (16.2)	39 (92.9)	3 (7.1)		
Total	260 (100)	235 (90.4)	25 (9.6)		
Educational status					
Never	5 (1.9)	5 (100.0)	0	1.57	0.46
Primary and secondary	205 (78.8)	186 (90.7)	19 (9.3)		
Tertiary	50 (19.2)	43 (86.0)	7 (14.0)		
Total	260 (100)	234 (90.0)	26 (10.0)		
Educational status					
Retired/home manager	138 (52.7)	124 (89.9)	14 (10.1)	3.71	0.16
Employed	122 (46.6)	111 (91.0)	11 (9.0)		
Unemployed	2 (0.8)	1 (50.0)	1 (50.0)		
Total	262 (100)	236 (90.1)	26 (9.9)		
Income (RM)					
<1000	95 (37.4)	85 (89.5)	10 (10.5)	0.66	0.72
1000–2999	135 (53.1)	124 (91.9)	11 (8.1)		
≥3000	24 (9.4)	21 (87.5)	3 (12.5)		
Total	254 (100)	230 (90.6)	24 (9.4)		
Do you exercise?					
No	127 (48.5)	112 (88.2)	15 (11.8)	1.69	0.43
I do at most 3 times in a week	94 (35.9)	85 (90.4)	9 (9.6)		
I do more than 3 times in a week	41 (15.6)	39 (95.1)	2 (4.9)		
Total	262 (100)	236 (90.1)	26 (9.9)		
Smoking					
Never	192 (73.8)	170 (88.5)	22 (11.5)	1.79	0.41
Stop >5 years	29 (11.2)	27 (93.1)	2 (6.9)		
Stop <5 years and active smoker	39 (15.0)	37 (94.9)	2 (5.1)		
Total	260 (100)	234 (90.0)	26 (10.0)		
Hypertension					
No	77 (29.5)	71 (92.2)	6 (7.8)	0.57	0.51
Yes	184 (70.5)	164 (89.1)	20 (10.9)		
Total	261 (100)	235 (90.0)	26 (10.0)		

Table 1. Proportion of socio-demography according to MDDS-17 score categories (Continued)

	Mean MDDS-17 score			X^2	*p*-value
	Total, *n* (%)[a]	<3, *n* (%)[b]	≥3, *n* (%)[b]		
Dyslipidaemia					
No	249 (95.8)	224 (90.0)	25 (10.0)	0.01	1.00
Yes	11 (4.2)	10 (90.9)	1 (9.1)		
Total	260 (100)	234 (90.0)	26 (10.0)		
Any diabetes complication					
No	244 (93.1)	223 (91.4)	21 (8.6)	6.89	0.02
Yes	18 (6.9)	13 (72.2)	5 (27.8)		
Total	262 (100)	236 (90.1)	26 (9.9)		
Oral hypoglycaemic agent					
No	31 (11.8)	28 (90.3)	28 (90.3)	0.002	1.00
Yes	231 (88.2)	208 (90.0)	208 (90.0)		
Total	262 (100)	236 (90.1)	236 (90.1)		
Insulin					
No	163(62.2)	145 (89.0)	18 (11.0)		
1 type	55 (21.0)	52 (94.5)	3 (5.5)	3.19	0.36
≥2 types	44 (16.8)	39 (88.6)	5 (11.4)		
Total	262 (100)	236 (90.1)	26 (9.9)		

[a]*Column %,* [b]*Row %*
MDDS-17, Malay version of the 17-item Diabetes Distress Scale

Table 2. Mean comparison of age, disease biomarkers, quality of life, medication adherence and depressive scores according to MDDS-17 score categories

		Mean MDDS-17 score				t	*p*-value
	Total, *n*	<3		≥3			
		Mean (SD)	*n* (%)	Mean (SD)	*n* (%)		
Age (year)	262	55.5 (9.77)	236 (90.1)	52.9 (9.51)	26 (9.9)	1.31	0.19
Diabetes duration (year)	244	5.1 (4.46)	220 (90.2)	3.4 (3.65)	24 (9.8)	1.74	0.08
HbA1c (%)	228	8.5 (2.15)	205 (89.9)	7.7 (1.87)	23 (10.1)	1.66	0.10
Hypertension duration (year)	179	5.5 (5.48)	160 (89.4)	5.5 (6.05)	19 (10.6)	0.05	0.96
SBP (mmHg)	262	140.3 (18.17)	236 (90.1)	140.5 (17.77)	26 (9.9)	–0.07	0.95
DBP (mmHg)	262	81.9 (13.20)	236 (90.1)	83.0 (13.80)	26 (9.9)	–0.40	0.69
Dyslipidaemia duration (year)	11	5.6 (4.06)	10 (90.9)	4.0 (0)	1 (9.1)	0.38	0.72
LDL-C (mmol/L)	180	3.0 (0.92)	163 (90.6)	3.3 (0.86)	17 (9.4)	–1.22	0.22
HDL-C (mmol/L)	180	0.9 (0.28)	163 (90.6)	0.9 (0.26)	17 (9.4)	–0.86	0.39
Triglyceride (mmol/L)	180	2.1 (1.51)	163 (90.6)	1.8 (1.35)	17 (9.4)	0.70	0.48
Total cholesterol (mmol/L)	214	4.8 (1.23)	192 (89.7)	4.7 (1.11)	22 (10.3)	0.34	0.74
Total WHOQoL-BREF	262	56.6 (5.62)	236 (90.1)	51.0 (7.47)	26 (9.9)	4.73	< 0.001

Table 2. Mean comparison of age, disease biomarkers, quality of life, medication adherence and depressive scores according to MDDS-17 score categories (Continued)

		Mean Rank[a]	*n* (%)	Mean Rank[a]	*n* (%)	*U*	*p*-value
Total MMAS	244	128.8	225 (90.7)	82.9	23 (9.3)	1629.5	0.003
Total PHQ	228	119.8	231 (90.2)	208.5	25 (9.8)	4888.0	<0.001

[a]*Mann–Whitney U test*

Mean DDS score ≥3 indicates moderate to severe distress DBP, diastolic blood pressure; HDL-C, high-density-lipoprotein cholesterol; LDL-C, low-density-lipoprotein cholesterol; MDDS-17, Malay version of the 17-item Diabetes Distress Scale; MMAS, Morisky Medication Adherence Scale; PHQ, Patient Health Questionnaire; SBP, systolic blood pressure; U, Mann–Whitney U test statistic; WHOQoL-BREF, World Health Organization quality of life-brief

Exploratory factor analysis

The EFA supported a three-factor model instead of the four-factor in the original DDS-17 (Table 3). Kaiser–Meyer–Olkin (KMO) measure of sampling adequacy was 0.925, and the Bartlett's test of sphericity had the approximated Chi-Square value of 2915.83 (df = 136, $p<0.0001$). Subscales IPD and RD were merged as one factor. The other two subscales were more or less similar to the original subscales. Item 15 "Feeling that I don't have a doctor who I can see regularly enough about my diabetes" was allocated to this factor instead of PD subscale; item 7 "Feeling that I will end up with serious long-term complications, no matter what I do" was also allocated to this factor instead of EB subscale. Item 3 "Not feeling confident in my day-to-day ability to manage diabetes" was allocated to EB instead of RD subscale. The mean MDDS-17 score was 33.7 (SD 13.01). The lowest score was in physician-related distress (mean 4.7, SD 2.33) and the highest in combined RD and IPD subscale (mean 17.7; SD 7.67). Few data were missing (96% had complete data).

Reliability

High internal consistency was found (Cronbach's α = 0.940) for the 17 items in MDDS-17 version. Its item to total correlation coefficient ranged from 0.537 to 0.791. According to the original subscales, the Cronbach's α values for the EB, PD, RD and IPD subscales were 0.845, 0.856, 0.850 0.842, respectively. Following the three-model from the EFA in this study, the Cronbach's α for the combined RD and IPD subscale was 0.925, for EB subscale it was 0.855 and for PD it was 0.823.

The 1-month test–retest reliability value was r = 0.29 (n = 66, p = 0.009) with similar scores between the first and second assessment (34.0 SD 13.86 versus 35.6 SD 13.7).

Table 3. Factor structure of the MDDS-17

MDDS-17	Subscales	Factors[a]		
		1	2	3
2. Feeling that diabetes is taking up too much of my mental and physical energy every day	Emotional burden	0.41	0.77	0.44
4. Feeling angry, scared and/or depressed when I think about living with diabetes		0.53	0.73	0.50
10. Feeling that diabetes controls my life		0.53	0.68	0.36
14. Feeling overwhelmed by the demands of living with diabetes		0.64	0.76	0.46
3. Not feeling confident in my day-to-day ability to manage diabetes		0.54	0.73	0.50
16. Not feeling motivated to keep up my diabetes self-management	Regimen distress (RD)	0.85	0.58	0.59
12. Feeling that I am not sticking closely enough to a good meal plan		0.73	0.48	0.44
8. Feeling that I am often failing with my diabetes routine		0.79	0.67	0.57
6. Feeling that I am not testing my blood sugars frequently enough		0.64	0.49	0.51
7. Feeling that I will end up with serious long-term complications, no matter what I do		0.72	0.63	0.60
13. Feeling that friends or family don't appreciate how difficult living with diabetes can be	Interpersonal distress	0.82	0.52	0.50
17. Feeling that friends or family don't give me the emotional support that I would like		0.82	0.49	0.56
9. Feeling that friends or family are not supportive enough of self-care efforts (e.g. planning activities that conflict with my schedule, encouraging me to eat the "wrong" foods)		0.72	0.47	0.42
15. Feeling that I don't have a doctor who I can see regularly enough about my diabetes		0.79	0.40	0.75
1. Feeling that my doctor doesn't know enough about diabetes and diabetes care	Physician-related distress	0.43	0.48	0.71
11. Feeling that my doctor doesn't take my concerns seriously enough		0.70	0.47	0.81
5. Feeling that my doctor doesn't give me clear enough directions on how to manage my diabetes.		0.55	0.50	0.84

DDS, 17-item Diabetes Distress Scale; MDDS-17, Malay version of the 17-items Diabetes Distress Scale

[a]*Rotated component matrix. Extraction method: principal axis factoring. Rotation method: promax with Kaiser Normalisation. Rotation converged in 6 iterations.*

Construct validity

The correlation between the total MDDS-17 scores and the total WHOQOL-BREF scores, MMAS scores and PHQ scores were $r = -0.41$ ($n = 253$, $p < 0.0001$), $r = -0.29$ ($n = 241$, $p<0.0001$) and $r = 0.56$ ($n = 247$, $p<0.0001$), respectively. The student t-test showed a significant relationship between MDDS-17 categories and WHOQOL-BREF, MMAS and PHQ (Table 2). Malay adult patients with T2D who were more distress also had lower quality of life, less adherent to medication and more depressed.

There was a significant association between the mean MDDS-17 score categories (<3 vs ≥3) and HbA1c categories (≥7.0% and <7.0%) ($\chi^2 = 4.20$; $p = 0.048$). Using medication adherence categories of high and medium adherence (MMAS-8 score = 6–8) vs low adherence (MMAS-8 score <6; $\chi^2 = 10.37$; $p = 0.001$).

Discussion

The main objective of this paper was to report the reliability and validity of the translated version of the MDDS-17 in a sample of adult Malay patients with T2D. This study was the first to systematically translate and validate the DDS-17 into the Malay language.

The factor model identified in our study is not exactly similar to Polonsky et al. (2005).[1] Although, IPD and RD were merged as one factor component, they could be representative of its own construct theoretically. Alternatively, these merged subscales can be known as therapeutic support distress in the MDDS-17. EFA did not support the allocation of some items according to the original subscales. The Norwegian version of the DDS also found that item 7 was allocated to RD instead of emotional burden subscale.[51] Item 15 is both conceptually and statistically appropriate to be kept in the PD subscale. Item 15 may be explained in the sense that having a doctor to see regularly might be due to the doctor being seen as a source of social support when they were distressed about their diabetes. Item 7 could reflect patients' hopelessness despite trying their best with the regimen, and thus might have resulted into the RD. Item 3, lack of confidence might be perceived as more of an emotional burden because of uncertainty and worry regarding their ability to manage their day to day diabetes. Hence, assessment of subscales of DRD should be used with some modification in the MDDS-17. The EB subscale in the MDDS-17 should include item number 3, and the item number 7 should be moved out from EB and include under RD. It is important to highlight that this new factor structure had better internal consistency reliability than the previous DDS-17. The internal consistencies of the original subscales were fairly good and in particular the total MDDS-17 score shows potential for use in clinical trials to capture DRD. However, more research in larger populations and different settings is needed to establish the relative strength and weaknesses of MDDS-17 and its subscales.

Some similar results were also noted by Polonsky et al. including the elevated DDS-17 total scores, which were associated with being younger, poorer self-care and more depressed, and none of the subscales were significantly related to patient sex, ethnicity, educational level or diabetes duration.[1] In contrast to this study, Polonsky et al. reported that more distressed patients were having elevated lipid levels and were using insulin. This might be due to their cohorts of patients, where majority were high school graduates (87.7%), most patients (50.4%) were using insulin and about half (46.2%) had come from highly specialised programs; suggesting that these individuals may have had more co-morbid conditions and complications. These same reasons would explain their higher mean total DDS-17 score (38.5) as compared to this study (33.8).

Our study among Malay patients with T2D showed that the MDDS-17 had high internal consistency (0.94), which is comparable to that of the original DDS-17 (0.93).[1] The rather moderate 1-month test–retest reliability could be due to the variability of DRD as experienced by the patients over the 4 weeks period. A shorter time interval between assessments for this test–retest reliability might result in a higher correlation. However, we chose the period of 1 month because of feasibility reason, that T2D is a chronic disease and DRD was expected to be more or less the same within 1 month. Persistence of DRD up to a period of 9 months and 18 months was observed elsewhere and was noted to be more persistence compared to the other affective disorders such as dysthymia, general anxiety disorder and panic disorder.[52]

The analyses indicated that the MDDS-17 is a valid instrument for measuring DRD, as the instrument was able to differentiate between patients who were clinically different. Besides showing that glycaemic control (HbA1c <

7.0%) was found to be significantly related with MDDS-17 scores <3, Malay adult patients with T2D who were more distressed were also having diabetes-related complication, leading to a lower quality of life, less adherent to medication and feeling more depressed. These significant associations of diabetes distress with quality of life and depression were also reported in Chinese and Persian adult patients with T2D.[53,54]

Patients with T2D who achieved glycaemic control were experiencing lesser distress in the study cohort. This finding suggested that patients with good glycaemic control had an overall lower distressing lifestyles and experiences. Association between the MDDS-17 categories and medication adherence categories represented an aspect of self-management in T2D.[2] We observed that patients with T2D and DRD were predisposed to medication non-adherence as observed in the other study.[33]

MDDS-17 will allow evaluation and study of DRD in clinical practice and trial, respectively. This is important because DRD could be more prevalent than and a precursor to other psychopathologies such as depression.[12,20,55] Further, DRD is more specific to the context of diabetes care and has the potential to explain the persistent and poor disease control in our healthcare setting.[2, 56] Life experience of the patients such as quality of life and aspects of self-management can also be investigated from this new perspective and modified through focused intervention on DRD.[34]

Strength and limitations

This study has limitations. The study population is homogeneously Malay and was collected from one setting of patients with T2D; this might affect the ability to generalise the scale to other ethnicities and for other diabetes types. However, we believe this study cohort was quite representative of the larger Malay population in Malaysia based on the socio-demographic and clinical characteristics.[24,56] The sample size could be underpowered to detect the associations between MDDS-17 with blood pressure; lipid profiles levels and insulin use. However, sensitivity analysis using objective criteria or a gold standard test is needed to precisely answer this question. Unfortunately, the present study was limited in this respect. Future work can be done in relation to construct validity, sensitivity and responsiveness of MDDS-17. This is very much an ongoing procedure that requires the performance of MDDS-17 in a range of settings, patient groups and quantifying its changes after certain intervention over specified periods of time.

Conclusion

The MDDS-17 has satisfactory psychometric properties and can be used to map DRD for clinical use. Assessment of sub-scales of DRD using the MDDS-17 in the local context should be used with some modification. The emotional burden subscale in the MDDS-17 should include item number 3, and the RD item number 7. Alternatively, RD and IPD subscales can be merged into a therapeutic support distress subscale. Although, future MDDS-17 with these modified constructs and subscales is supported by the psychometric evidence from this study, keeping both the RD and IPD subscales with the recommended items shift is valid and may be more desirable for wider comparison with other studies. The MDDS-17 seem to contribute uniquely in assessing DRD and are promising for use in clinical trials with adult patients with T2D.

Conflict of interest

The authors declare that they have no competing interests.

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How does this paper make a difference to general practice?

- This paper presented a new tool that may be used by clinicians to measure diabetes-related distress (DRD).
- This paper reported on the psychometric properties of the Malay version of the 17-item Diabetes Distress Scale (MDDS-17).
- There was a significant association between DRD (mean MDDS-17 score ≥3) and HbA1c ≥7.0%.
- The MDDS-17 discriminated well between adult type 2 diabetes mellitus (T2D) patients with diabetes-related complication, low quality of life, poor medication adherence and those who were more depressed.

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