Title: The associations between diabetes distress and self-efficacy, medication adherence, self-care activities and disease control depend on the way diabetes distress is measured: comparing the DDS-17, DDS-2 and the PAID-5

Running title: Does type of diabetes distress measure matter?

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Abstract

Aims: To examine whether diabetes distress (DD), when measured by three different instruments, was associated differently with self-efficacy, self-care activity, medication adherence and disease control in people with Type 2 diabetes mellitus.

Methods: A cross-sectional study in three health clinics. DD was assessed with the 17-item Diabetes Distress Scale, the 2-item DDS-2 (DDS-2) and the 5-item Problem Areas in Diabetes Scale (PAID-5). Dependent variables included self-efficacy, self-care activities, medication adherence, HbA_{1c}, systolic and diastolic blood pressure (SBP, DBP). Multiple linear and logistic regression were used in analyses.

Results: In total 338 participants (56% women), with a mean age of 61 years and diabetes duration of 9.8 years, were included. DDS-2 was an independent determinant of SBP (β=1.89, 95% CI 0.14, 3.64), DBP (β=1.19, 95% CI 0.16, 2.21) and blood pressure target (OR=2.09, 95% CI 1.12, 3.83). PAID-5 was an independent determinant of medication adherence (adjusted β= -0.05, 95% CI -0.08, -0.01) and self-care activities (OR= 0.50, 95% CI 0.26, 0.99).

Conclusions: Associations of DD with important aspects of diabetes care are substantially influenced by confounders and depend on the way DD is measured. Our findings call for a judicious use of different DD measures in clinical practice and research.

Keywords: Diabetes Distress; Epidemiologic Measurements; Type 2 Diabetes Mellitus; Self-efficacy; Self-care Activities; Medication Adherence

Highlights

There are several instruments to measure diabetes distress (DD) in clinical practice and research.

Associations of DD with outcomes are influenced by confounders and depend on the instruments.

Findings call for a judicious use of different DD measures in clinical practice and research.

1. Introduction

Diabetes distress (DD) refers to the burden related to having diabetes, a chronic disease that requires daily self-management and can lead to burdensome complications. It clearly differs from depression or depressive symptoms, though both constructs are positively associated [1; 2]. High levels of DD are common in depressed people with diabetes, but not all depressed people with diabetes experience their diabetes as a source of distress. Studies have shown that DD is also moderately associated with lower self-efficacy [3], weakly to moderately with lower self-care [4] such as poorer diet adherence and physical inactivity, poor medication use [5], and moderately with suboptimal glycemic- but not blood pressure or LDL control [6]. The important effect of DD on self-management and disease control in people with Type 2 diabetes mellitus is recognized, and it is therefore not surprising that several instruments have been developed to measure DD in clinical practice and research [7]. The most commonly used measures are the PAID and the DDS. The 20-item Problem Areas in Diabetes (PAID-20) questionnaire and its shorter 5-item version [8] are more strongly associated with depressive symptoms and quality of life [9] than the 17-item Diabetes Distress Scale (DDS-17) and its shorter version DDS-2 [10]. Both DDS versions were associated with self-care activities and with glycemic control [9; 10]. Higher PAID-20 or DDS-17 levels were both in Australian and Dutch Type 2 diabetes mellitus adults associated with diabetes-related complications [11; 12]. In Asian people (Malay, Chinese and Indian) with Type 2 diabetes mellitus, the PAID-20 and DDS-17 were associated with diabetes self-care activities, directly by PAID-20 but indirectly by DDS-17 via self-efficacy [3; 13]. Both instruments were also associated with quality of life [13-15], but with medication adherence only an association was found with PAID-20 [13; 16]. In terms of disease control, PAID-20 was associated with poor glycemic control (HbA1c > 8%) [14; 17], while higher DDS-17 scores were associated with lower systolic blood pressure (adjusted B= -0.08, P=0.066), and no association was observed

with lipid profiles with DDS-17 but yet to be investigated with PAID [17]. To summarize, it is currently unclear whether the choice for a certain measure of DD will lead to different conclusions when used in the same population with regard to its association with patient-reported and clinical outcomes.

Knowing the associations between the different DD measures and important patient-reported and clinical outcomes is relevant to clinicians and researchers in choosing the type of DD measure or when interpreting the results of the different types of DD measures [18]. Shorter versions of DD scales may be more unidimensional in DD measurement [11], yet equally valid, and are potentially better and more useful in daily diabetes care [10].

We investigated whether associations between DD and self-efficacy, medication adherence, self-care activities and disease control (HbA1c, blood pressure and LDL) in adults with Type 2 diabetes mellitus were different for three DD scales, namely the DDS-17, the DDS-2 and the PAID-5.

2. Material and methods

2.1 Setting

This cross-sectional study was conducted in 2016 in three public health clinics in Malaysia, at Seri Kembangan, Dengkil and Salak, situated in urban, suburban and rural areas, respectively [2]. In these clinics, a multidisciplinary diabetes team consisting of resident doctors, a nutritionist or dietician, a pharmacist, a physiotherapist or an occupational therapist and specialized diabetes nurses provide primary diabetes care.

2.2 Study Sample and Procedures

Adults at least 30 years old, diagnosed with Type 2 diabetes mellitus more than three years ago and on regular follow-up with at least three visits in the previous year were invited to

participate. They were Malay, Chinese or Indian. Exclusion criteria were pregnancy or

lactating, having severe psychiatric disorders that could impair judgments and memory and

patients who cannot read or understand English, Malay or Mandarin. People were invited to

participate on their return to the clinics for medical follow-ups. Those who fulfilled the

criteria and wanted to participate gave written informed consent before answering

questionnaires according to the language they preferred. Trained research assistants

interviewed patients who were not able to self-administer the questionnaires. This study was

approved by the Medical Research Ethics Committee (MREC), Ministry of Health Malaysia

with the referent number (5)KKM/NIHSEC/P16-293 on 08/03/2016. The study is registered

on ClinicalTrials.gov (NCT02730754).

2.3 Measures

2.3.1   Socio-demographic Data

Age, gender, ethnicity, religiosity, marital status, educational level and occupation, life events

in the past six months, any family history of psychiatric illness and literacy (health and

general) were all measured by different items in a questionnaire. People's religious way of

life was reliably measured with item number 12 from the 20-items Beliefs and Values Scale,

on a 5-point Likert scale [2; 19]. Marital status categories included married, living with a

partner, divorced, widowed, separated and single. Educational levels assessed highest

educational level attained: no formal education, six years primary school, five to seven years

secondary education or tertiary education in college or university. Employment status

included the categories employed, unemployed, retired, home manager and student. The

following life events were asked for: death of a significant other, broken relationship with

loved ones, change in work or place of residence, all within the past six months. Family

history of psychiatric illnesses (yes or no) in parents, siblings or children was based on self-

report. General literacy was assessed by a question: "How would you rate your ability to read?" with five possible responses, ranging from excellent to very poor [20]. The Single-Item Literacy Screener (SILS) was used to assess health literacy "How often do you need to have someone to help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?" with five possible responses: 1-Never, 2-Rarely, 3-Sometimes, 4-Often, and 5-Always [21].

2.3.2 Diabetes Distress

The level of DD was measured in three ways. When using the DDS-17, DD is evaluated over the past month, each item is scored on a Likert scale from 1 (not a problem) to 6 (a very serious problem). It yields a total scale score, plus four sub-scale scores: emotional burden, physician-related distress, regimen distress and interpersonal distress. A mean item score ≥ 3 is considered high or severe distress that needs clinical attention [22]. The Malay [23] and English [24] versions were locally validated; and the Chinese version [25] was found acceptable by the local Chinese participants.

Like the validated original English 2-items DDS-2, the Malay and Chinese version consists of item 8 "Feeling that I am often failing with my diabetes routine" (regimen distress subscale) and item 14 "Feeling overwhelmed with the demands of living with diabetes" (emotional burden subscale) from the DDS-17 [10]. A cut-off score ≥ 3 requires further assessment with the DDS-17 [10].

The PAID-5 comprises items 3, 6, 12, 16, and 19 from the original PAID-20 [26; 27]. Each item scores on a 5-point Likert scale ranging from "not a problem" (score of 0) to "serious problem" (score of 4). The total score of the PAID-5 ranges from 0 to 20, higher scores implying greater emotional distress [28]. The Chinese and Malay PAID-5 are both extracted from the validated PAID-20 version [26]. A score ≥ 8 on the PAID-5 distinguishes

high DD from low DD [28]. We chose not to use the PAID-20 to confine the burden on the respondents included in the study. Besides, the PAID-5 demonstrated excellent psychometric properties as a one-factor scale and performed better than the full PAID-20 in people with Type 2 diabetes mellitus [8]. Supplementary material shows the items in the three DD measures used in this study.

2.3.3 Diabetes Management Self-efficacy

The 20-items Diabetes Management Self Efficacy Scale (DMSES) measures patients' confidence in managing their diabetes regarding optimal blood glucose measurement, healthy diet, and sufficient exercise. Total score ranges from 0 to 200, lower scores indicating low self-efficacy for coping with the activities listed [29]. The scores were categorized in three equal groups, yet with meaningful cut-offs. The lowest DMSES group has a mean item score of below 7 (total DMSES score $\leq$ 135), which indicates uncertain and low self-efficacy, while the highest group has a mean item score of above 8 (total DMSES score $\geq$ 166), which means high confidence. The Malay, Chinese and English versions are validated.

2.3.4 Diabetes Self-care Activities

Self-care activities were measured with validated versions of the Summary of Diabetes Self-Care Activities (SDSCA) questionnaires in Malay, Chinese and English [30]. Twelve items measure patients' daily activities in relation to diet, exercise, blood sugar and foot care. Items are rated from zero to seven, measuring how many days an activity is performed in the last week. The mean number of days was calculated based on the first 10 items. The summary scores were also categorized into three equal and meaningful groups, which are: $\leq$ 2.9, 3.0 to 3.8, and $\geq$ 3.9 [31].The 11th item measures smoking status (yes/no) and the number of cigarettes smoked in the last week is captured in item 12.

2.3.5 Medication Adherence

Medication adherence was measured with the 8-item Morisky Medication Adherence Scale (MMAS-8), validated questionnaires are available in Malay, Chinese and English [32-34]. It measures medication adherence during the past 2 weeks. Scores range from 0 to 8, resulting in the following levels of adherence: low (< 6), medium (6 to < 8) and high (= 8).

2.3.6 Depressive Symptoms

Depressive symptoms were assessed using validated measures of the 9-item Patient Health Questionnaire (PHQ-9) in Malay, Chinese and English [35], that evaluates depressive symptoms and grades the depression severity. Scores range from 0 to 27. Depressive symptoms are classified as minimal (score 0 to 4), mild (5 to 9), moderate (10 to 14), moderately severe (15 to 19), and severe (20 to 27).

2.3.7 Comorbidities and Clinical Measures

 Data about duration of diabetes, HbA_{1c}, blood pressure, LDL, diabetes-related complications, number and type of prescribed medications were retrieved from the patients' medical records. Diabetes-related complications consisted of retinopathy, nephropathy (micro-albuminuria, proteinuria, serum creatinine > 150 μmol/L or estimated glomerular filtration rate < 60 ml/min), diabetic foot problems (foot deformity, current ulcer, amputation, peripheral neuropathy or peripheral vascular disease), ischemic heart disease or cerebrovascular disease.

2.3.8 Data analysis

Data are presented as means (SD) for normally distributed variables or medians (IQR) for those with a skewed distribution. The three DD measures were the independent variables. The seven dependent variables were diabetes self-efficacy, medication adherence, self-care activities, HbA_{1c}, blood pressure (systolic and diastolic) and LDL. Possible confounding variables on the associations between DD and the dependent variables were based on the literature [2; 31; 36-38], they included socio-demographic variables (age, gender, ethnicity, religiosity, marital status, education, employment, life event and family history of psychiatric illness), general and health literacy, smoking, diabetes duration, presence of any diabetes complication, hypertension, dyslipidemia, medication use (oral anti-diabetic agents, insulin, anti-hypertensive and lipid-lowering agents) and depressive symptoms. Some categorical variables were dichotomized: marital status into married/ living with a partner and single; educational levels into none/primary and secondary/tertiary levels; employment status into employed/unemployed; general literacy into (very) good or okay/(very) poor, and health literacy into either good (never and rarely need help) or poor (sometimes, often or always need help when reading health-related material).

We analyzed the three DD measures and the seven outcomes both in continuous form and in categorical form. Also, the total scores of the DD measures were standardized to 0-100 to allow between scale comparisons. We used the pre-defined categories ≥ 3 or < 3 for the DDS-17 and DDS-2; ≥ 8 or < 8 for PAID-5 and < 6, 6 to < 8 and 8 for the MMAS-8. The DMSES and SDSCA summary scores were categorized in three equal groups as described earlier. HbA1c, blood pressure and LDL were dichotomized based on the recommended treatment targets of $< 7.0\%$ (53 mmol/mol), $< 140/90$ mmHg and < 2.6 mmol/L, respectively [39]. The models were adjusted for all potential confounders in multivariable analyses. We used Generalized Linear Models with linear distribution and identity link function to examine the variables in continuous forms, and used multinomial and binary logistic regression

analyses for the categorical outcomes. For HbA$_{1c}$, blood pressure and LDL, the multivariable analyses were separated into two; the first one without and the second one with the respective pharmacological treatments on top of the other potential confounders. Residuals from all final models were checked and found acceptable for normality, linearity and homogeneity.

Multiple imputation (with 10 runs) was used to handle missing data. All independent and dependent variables were imputed and used as predictor, with the exception of LDL because of 61.8% missing data. Percentages of missing other variables ranged from 0.3% (n= 1) (diabetes duration and general literacy) to 29.6% (n= 100) (HbA1c). Imputed variables were within a pre-defined clinically possible range, for example the range for duration of diabetes was between 3 and 50 years, for HbA1c was between 3 and 20%, and for SBP was between 80 and 300 mmHg. We report the estimates of the multivariable analyses based on the pooled results of the 10 imputed datasets. All data analyses were based on two-sided α of 0.05, and were completed using SPSS software version 22.0 (IBM Corp., Armonk, NY).

3. Results

3.1 Sample Characteristics

A total of 338 patients participated. Their mean (SD) age and diabetes duration were 61 (10.1) years and 10 (5.9) years, respectively (Table 1). Men and women were nearly equally represented. Most often them were Malay, married or living with a partner, religious, at least educated up to secondary school, not employed, and not having experienced any life event in the past six months (Table 1). Most patients (≥ 90%) were prescribed oral anti-diabetic, anti-hypertensive and lipid-lowering agents. The mean (SD) standardized scores of the three DD measures showed the highest scores of DD when measured with PAID-5 [40.1 (27.0)], followed by DDS-2 [29.2 (24.5)] and lowest with DDS-17 [27.3 (19.2)] (Table 1). Table 2

shows the characteristics of participants according to the different DD measures and categories of severe or high DD versus low DD.

3.2 Diabetes Self-efficacy

In the crude analyses, higher DD levels as measured by DDS-17 and DDS-2 but not PAID-5 were associated with lower scores on the DMSES (Table 3). However, both scales did not show a significant independent effect on DMSES after adjustment for potential confounders, neither as a continuous measure nor as a categorical one (Table 3 and Table 4).

3.3 Medication Adherence

All three DD measures were significant determinants of medication adherence in non-adjusted models, but only PAID-5 was an independent determinant after adjustment for potential confounders (adjusted β= -0.05, 95% CI -0.08, -0.01) (Table 3). People with low DD had 3.1 times higher chance on high medication adherence compared to those with high DD (adjusted OR= 3.08, 95% CI 1.43, 6.65) (Table 4).

3.4 Diabetes Self-care

Self-care activities were not clearly related to DD levels, neither in the crude nor in the adjusted analyses. Only PAID-5 showed a significant association with SDSCA (Table 3), between the low and mid SDSCA groups (adjusted OR= 0.50, 95% CI 0.26, 0.99), which means that people with high DD compared to those with low DD (measured by PAID-5) had a twice as high chance to report self-care activities 3.0 to 3.8 days per week if they were compared to those who report self-care activities ≤ 2.9 days per week (Table 4).

3.5 HbA1c

Table 3 shows that DD as measured by the DDS-17 and DDS-2 but not by PAID-5 was associated with HbA1c. However, none of the measures was significant after adjustment for potential confounders. The estimates of the associations between DDS-17 and DDS-2 with HbA1c were further reduced after oral anti-diabetic medication and insulin use were entered into the models. Whether people had a severe DD level or not did not influence whether they were well controlled (HbA1c < 7.0%) (53 mmol/mol) or not (Table 4).

3.6 Blood pressure

Only DDS-2 showed significant and independent associations with both SBP (adjusted β= 1.89, 95% CI 0.14, 3.64) and DBP (adjusted β= 1.19, 95% CI 0.16, 2.21). Taking into account potential confounders, a one point higher DDS-2 score was associated with about 2 mmHg and 1 mmHg higher SBP and DBP levels, respectively. PAID-5 showed significant associations with DBP in crude and adjusted models with an estimate of about 0.3 (Table 3). People with low DD levels had a twice as high chance to achieve a blood pressure level < 140/90 mmHg than those with a high DD level (adjusted OR= 2.09, 95% 1.12, 3.83), but only if DD had been measured with the DDS-2 (Table 4).

3.7 LDL-cholesterol

There were no significant associations between the three DD measures and LDL (Table 3 and 4).

4. Discussion

This study clearly demonstrated that DD is assessed in different ways when measured with DDS-17, DDS-2 and PAID-5, with the highest scores of DD found with the PAID-5 after standardization of the scores to a score ranging from 0-100. This was similarly observed in

other studies [12; 15]. DDS-17 and DDS-2 showed remarkably similar associations with many outcomes before adjustment for confounders, but only DDS-2 showed significant independent associations with SBP and DBP. On the other hand, PAID-5 showed significant independent associations with both medication adherence (MMAS-8 in continuous form) and self-care activities (SDSCA in categorical form). This suggests that the five PAID-5 items more successfully tap into the key distressing diabetes problems when compared to the DDS-2 and DDS-17. This difference may be supported by the difference in proportions of people with high DD according to PAID-5 (52%) compared to that according to DDS-17 (23%) or DDS-2 (40%). That a difference was substantially larger in our study compared to other studies [9; 11]. Using the PAID-20 (total score $\geq$ 40) and DDS-17 (mean score $\geq$ 3), Schmitt et al [9] reported 46.6% and 41.3% of high DD in participants with both Type 1 and Type 2 diabetes mellitus at a tertiary diabetes center in Germany; and Fenwick et al [11] showed that 19.1% and 12.2% of Australian adults with Type 2 diabetes mellitus had high DD in a national survey. PAID-5 focuses on emotional concerns, diet and diabetes complications, whereas the DDS scales more focus on self-care, treatment, opinion about physicians and interpersonal relationships. The significant, negative association between PAID-5 and medication adherence shows that those who were non-adherent to their medications were more often distressed by the disease and its therapeutic regimen or diabetes-related complications.

In agreement to a study among Taiwanese patients (8-item PAID) [40] but in contrast to non-Asian patients [4], we found higher DD levels in people who reported more days of self-care activities. This association could be bidirectional. High DD may motivate these people to increase self-care activities to three days or more per week. Alternatively, doing three days or more diabetes self-care activities per week could drain their mental and physical energy so much so that coping with diabetes self-care became a daily DD (PAID-5). The

small effect sizes of DD on self-care activities were not unexpected, knowing that these behaviors are affected by a wide range of personal and environmental factors [41].

DD was not associated with glycemic control in the present study. Many other studies reported otherwise [6; 37; 38; 42]. The reasons for this discrepancy may vary and include different cultural backgrounds of the studied populations such as family and social network members' involvement and influences on personal or health beliefs and decision making [43]. Another reason could likely be the differences in statistical modeling as elaborated further. A recent study [6] did not find significant associations between DD (measured with DDS-17) and blood pressure, which was similar to our study. In contrast, we demonstrated that high DD, defined by DDS-2, was associated with higher blood pressure levels; and low DD two times more likely to be related to achieved blood pressure targets. Similar to previous studies [6; 37], we did not find an association between DD and LDL levels.

Walker et al [37] showed that high DD when measured with DDS-17 was significantly associated with both medication non-adherence (MMAS-8) and higher HbA1c, but not SBP and LDL. Their models included socio-demographic and psychological factors but not clinical factors as in our study. The BENCH-D study [38] showed that higher DD (PAID-5) was associated with a higher HbA1c in the model adjusting for socio-demographic and clinical outcomes but not in the model that included psychological factors. Different or incomplete adjustment for confounding factors may have resulted in different associations between DD and outcomes. Alternatively, DD may be more subject to confounding in Asian people with Type 2 diabetes mellitus compared to people from Western countries because of larger variations in cultural and socio-economic background, healthcare services and treatment options. To the best of our knowledge, we adjusted for a considerable number of potential confounders; we also believe that we did not over-adjust, since we did not include potential intermediate factors. In our opinion, our results are robust and may emphasize the

different impact of different DD measures, and in Asian people compared to people from Western countries.

4.1 Strengths and Limitations

Besides the high number of analyzed confounders, one of the strength of this study is that the relatively large study sample is representative of semi-urban public primary care clinics in Malaysia. Some limitations should be taken into account as well. Although the Malay and Chinese versions of the DDS-2 and PAID-5 were not validated, they were extracted from the validated long scales [23; 24; 26]. Additionally, past studies had proven the robustness of the construct with the same items [8; 10; 28]. Nevertheless, data on validation and implementation of DDS-2 and PAID-5 are warranted.

4.2 Conclusion

In Asian adults with type 2 diabetes, different DD instruments may measure different forms of DD. High DD when measured by two questions (DDS-2) was associated with high blood pressure levels and not achieving the blood pressure treatment target. DD when measured by five questions (PAID-5) showed negative association with medication adherence and positive association with self-care activities. Both short instruments differentiate between different outcomes and each should be used judiciously in research, and could be used to assess DD in busy clinical settings. Obviously, medication adherence should be discussed as well.

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Table 1. Characteristics of participants. Number (percentage) of respondents or means (SD) or medians (IQR) for different categories of demography, clinical characteristics, psychological variables and diabetes distress

Characteristics	n	percentage, mean (SD) or median (IQR)
Demographics		
Age (years), mean (SD)	338	60.6 (10.1)
Gender: women (n= 336)	187	55.7
Ethnicity: Malay / Chinese / Indian (n= 333)	149 / 110 / 74	44.7 / 33.0 / 22.3
Religiosity: regarding themselves as religious (n= 329)	296	90.0
Marital status: married/ with partner (n= 333)	275	82.6
Education: none or primary education (n= 331)	159	48.0
Employment status: employed (n= 334)	116	34.7
Any life event: yes (n= 336)	59	17.6
Family history of psychiatric illnesses: yes (n= 331)	37	11.2
General literacy: very (good) and okay (n= 337)	175	51.9
Health literacy: good (n= 335)	191	57.0
Smoking in the past seven days: yes (n= 332)	35	10.5
Clinical characteristics		
Diabetes duration (year), mean (SD)	337	9.8 (5.9)
HbA1c (% & mmol/mol) mean (SD)	238	8.3 (2.0) & 67 (22.1)
HbA1c ≥ 7% (53 mmol/mol)	166	69.7
Systolic blood pressure (mmHg), mean (SD)	300	136.7 (16.3)
Diastolic blood pressure (mmHg), mean (SD)	300	76.4 (9.5)
Blood pressure ≥ 140/90 mmHg	129	43.0
LDL (mmol/L), mean (SD)	129	2.8 (1.0)
LDL ≥ 2.6 mmol/L	72	55.8
Prescribed oral anti-diabetic agent: yes (n= 301)	271	90.0
Insulin therapy: yes (n= 301)	143	47.5
Prescribed anti-hypertensive agent: yes (n= 301)	279	92.7
Prescribed lipid lowering agent: yes (n= 301)	272	90.4
Any diabetes complication: yes (n= 291)	59	20.3
Psychological variables		
Total DMSES score (0 – 200), median (IQR)	320	151.0 (46.5)
Total MMAS-8 score (0 – 8), median (IQR)	324	6.8 (2.8)
Mean SDSCA score (0 – 7), mean (SD)	313	3.4 (1.3)
Total PHQ-9 score (0 – 27), median (IQR)	328	4.0 (6.0)
Diabetes distress		
Mean DDS-17 score (1 – 6), median (IQR)	318	2.3 (1.4)
Mean DDS-17 score ≥ 3	74	23.3
Standardized DDS-17 score (0 – 100), median (IQR) / mean (SD)	318	25.1 (27.1) / 27.3 (19.2)
Mean DDS-2 score (1 – 6), Median (IQR)	329	2.0 (1.5)
Mean DDS-2 score ≥ 3	132	40.1
Standardized DDS-2 score (0 – 100), median (IQR) / mean (SD)	329	20.0 (30.0) / 29.2 (24.5)
Total PAID-5 score (0 – 20), Median (IQR)	328	8.0 (8.0)
Total PAID-5 score ≥ 8	171	52.1
Standardized PAID-5 score (0 – 100), median (IQR) / mean (SD)	328	40.0 (40.0) / 40.1 (27.0)

SD= standard deviation; DDS-17= the 17-item Diabetes Distress Scale; DDS-2= the 2-item Diabetes Distress Scale comprises items 8 and 14 from the DDS-17; DMSES= 20-item Diabetes Management Self Efficacy Scale; MMAS-8= 8-item Morisky Medication Adherence Scale; PAID-5= the 5-item Problem Areas in Diabetes Scale; PHQ-9= the 9-item Patient Health Questionnaire; SDSCA= the Summary of Diabetes Self-Care Activities. The MMAS (8-item) content, name, and trademarks are protected by US copyright and trademark laws. Permission for use of the scale and its coding is required. A license agreement is available from: Donald E. Morisky, ScD, ScM, MSPH, 14725 NE 20th St Bellevue, WA 98007, USA; dmorisky@gmail.com

Table 2. Characteristics of participants. Column percentage of respondents or means (SD) or medians (IQR) according to the different measures and categories of diabetes distress

Characteristics	DDS-17 [a]		DDS-2 [b]		PAID-5 [c]	
	≥ 3 (n= 74)	< 3 (n= 244)	≥ 3 (n= 132)	< 3 (n= 197)	≥ 8 (n= 157)	< 8 (n= 171)
Demographics						
Age (years), mean (SD)	60.3 (10.8)	61.1 (10.0)	58.9 (10.7)	61.8 (9.7) [†]	59.5 (10.6)	61.9 (9.5) [†]
Gender, women	64.9	53.7	59.1	53.8	59.1	53.5
Ethnicity: Malay	35.1	45.5	42.4	44.7	45.6	41.4
Chinese	36.5	34.4	31.1	35.5	28.1	40.1 *
Indian	28.4	20.1	26.5	19.8	26.3	18.5
Religiosity: regarding themselves as religious	91.9	87.7	92.4	86.3	93.0	84.7*
Marital status: married or with partner	91.9	78.7*	85.6	79.7	84.8	79.0
Education: none or primary education	52.7	49.2	46.2	51.3	48.0	51.0
Employment status: employed	37.8	32.8	38.6	32.0	37.4	31.8
Any life event: yes	21.6	16.8	19.7	16.8	18.7	16.6
Family history of psychiatric illnesses: yes	10.8	9.8	10.6	10.7	10.5	10.8
General literacy: very (good) and okay	77.0	79.9	81.8	78.7	78.4	80.9
Health literacy: good	25.7	32.4	24.2	35.5*	28.7	33.8
Smoking in the past seven days: yes	2.7	13.1*	7.6	12.7	8.8	12.7
Clinical characteristics						
Diabetes duration (year), mean (SD)	10.6 (6.8)	9.6 (5.7)	9.6 (5.0)	10.0 (6.5)	9.9 (5.8)	9.8 (6.1)
HbA1c (%), mean (SD)	8.7 (2.2)	8.1 (2.1) [†]	8.4 (2.1)	8.1 (2.0)	8.4 (2.2)	8.1 (2.0)
HbA1c ≥ 7% (53 mmol/mol)	74.3	67.4	70.2	69.4	70.6	69.2
Systolic blood pressure (mmHg), mean (SD)	138.7 (17.9)	136.4 (15.3)	138.1 (17.4)	136.0 (14.9) [†]	136.9 (16.6)	136.4 (15.4) [†]
Diastolic blood pressure (mmHg), mean (SD)	77.3 (9.4)	76.6 (9.8)	78.2 (10.1)	75.9 (9.7)	77.9 (9.2)	75.3 (10.0)
Blood pressure ≥ 140/90 mmHg	48.6	42.6	50.0	40.6	45.6	41.4
LDL (mmol/L), mean (SD)	2.8 (1.0)	2.9 (0.9)	2.8 (1.1)	2.9 (0.8)	2.8 (1.0)	2.9 (0.9)
LDL ≥ 2.6 mmol/L	50.0 [a]	58.2 [a]	50.9 [b]	60.0 [b]	53.0 [c]	61.0 [c]
Prescribed oral anti-diabetic agent: yes	89.2	90.6	88.6	91.4	90.1	90.4
Insulin therapy: yes	55.4	41.8*	51.5	40.6*	48.0	42.0
Prescribed anti-hypertensive agent: yes	89.2	90.2	88.6	89.8	89.5	88.5
Prescribed lipid lowering agent: yes	90.5	86.1	87.1	86.3	88.3	86.0
Any diabetes complication: yes	27.1	27.0	28.2	25.4	30.2	22.6
Psychological variables						
Total DMSES score (0 – 200), median (IQR)	140.0 (58.0)	152.0 (45.0)	140.0 (49.9)	155.0 (48.0) [‡]	145.0 (48.0)	153.0 (50.0)
Total MMAS-8 score (0 – 8), median (IQR)	6.0 (2.0)	6.8 (2.5) [‡]	6.5 (2.2)	7.0 (2.5) [‡]	6.0 (2.2)	7.0 (2.2) [‡]
Mean SDSCA score (0 – 7), mean (SD)	3.5 (1.2)	3.3 (1.3)	3.4 (1.2)	3.3 (1.3)	3.5 (1.2)	3.2 (1.4) [†]
Total PHQ-9 score (0 – 27), median (IQR)	7.0 (8.0)	3.0 (5.0) [‡]	7.0 (8.0)	2.0 (4.0) [‡]	6.0 (7.0)	2.0 (4.0) [‡]

[a] n= 121 (30 vs 91) for LDL within DDS-17; [b] n= 123 (53 vs 70) for LDL within DDS-2; [c] n= 125 (66 vs 59) for LDL within PAID-5

* Chi-square test with *p* < 0.05 (2-sided)

[†] Independent t-test with *p* < 0.05 (2-sided)

[‡] Non-parametric median test with Yates's continuity correction with *p* < 0.05 (2-sided)

SD= standard deviation; DDS-17= the 17-item Diabetes Distress Scale; DDS-2= the 2-item Diabetes Distress Scale comprises items 8 and 14 from the DDS-17; DMSES= 20-item Diabetes Management Self Efficacy Scale; IQR= inter-quartile range; MMAS-8= 8-item Morisky Medication Adherence Scale; PAID-5= the 5-item Problem Areas in Diabetes Scale; PHQ-9= the 9-item Patient Health Questionnaire; SDSCA= the Summary of Diabetes Self-Care Activities. The MMAS (8-item) content, name, and trademarks are protected by US copyright and trademark laws. Permission for use of the scale and its coding is required. A license agreement is available from: Donald E. Morisky, ScD, ScM, MSPH, 14725 NE 20th St Bellevue, WA 98007, USA; dmorisky@gmail.com

Table 3. Associations of diabetes distress and diabetes self-efficacy, medication adherence, diabetes self-care, HbA1c, blood pressure and LDL, n= 338 (otherwise specified)

DD Measures	DMSES (0 – 200)		MMAS-8 (0 – 8)		SDSCA (0 – 7)	
	Crude B (95% CI)	Adjusted B (95% CI)	Crude B (95% CI)	Adjusted B (95% CI)	Crude B (95% CI)	Adjusted B (95% CI)
DDS-17	**-0.54 (-9.44, -1.45)**	-0.99 (-5.60, 3.62)	**-0.30 (-0.48, -0.12)**	-0.10 (-0.31, 0.11)	0.13 (-0.03, 0.28)	0.11 (-0.07, 0.19)
DDS-2	**-0.50 (-8.16, -1.88)**	-2.90 (-6.49, 0.70)	**-0.24 (-0.38, -0.10)**	-0.09 (-0.26, 0.07)	-0.02 (-0.14, 0.09)	-0.09 (-0.23, 0.05)
PAID-5	-0.32 (-1.03, 0.40)	0.19 (-0.62, 1.00)	**-0.06 (-0.10, -0.03)**	**-0.05 (-0.08,-0.01)**	**0.03 (0.001, 0.05)**	0.02 (-0.02, 0.06)

	HbA1c (%)			SBP (mmHg)		
	Crude B (95% CI)	Adjusted B (95% CI)	Adjusted B +ADM (95% CI)	Crude B (95% CI)	Adjusted B (95% CI)	Adjusted B +AHA (95% CI)
DDS-17	**0.33 (0.07, 0.58)**	0.29 (-0.010, 0.58)	0.14 (-0.12, 0.41)	0.28 (-1.85, 2.40)	1.82 (-0.59, 4.22)	1.81 (-0.59, 4.21)
DDS-2	**0.27 (0.06, 0.47)**	0.17 (-0.04, 0.39)	0.05 (-0.14, 0.24)	0.60 (-1.13, 2.34)	**1.86 (0.11, 3.61)**	**1.89 (0.14, 3.64)**
PAID-5	0.05 (-0.010, 0.10)	0.01 (-0.04, 0.07)	-0.01 (-0.05, 0.04)	0.13 (-0.23, 0.49)	0.29 (-0.09, 0.67)	0.31 (-0.08, 0.69)

	LDL (mmol/L)			DBP (mmHg)		
	Crude B (95% CI) (n= 129)	Adjusted B (95% CI) (n= 129)	Adjusted B + LLA (95% CI) (n= 108)	Crude B (95% CI)	Adjusted B (95% CI)	Adjusted B + ADA &AHA (95% CI)
DDS-17	-0.03 (-0.21, 0.15)	-0.10 (-0.31, 0.11)	-0.10 (-0.31, 0.11)	0.62 (-0.54, 1.79)	1.28 (-0.13, 2.69)	1.27 (-0.13, 2.67)
DDS-2	-0.01 (-0.14, 0.12)	-0.05 (-0.20, 0.10)	-0.05 (-0.19, 0.11)	0.80 (-0.16, 1.76)	**1.18 (0.16, 2.21)**	**1.19 (0.16, 2.21)**
PAID-5	<0.01 (-0.03, 0.04)	-0.02 (-0.05, 0.02)	-0.01 (-0.05, 0.02)	**0.26 (0.05, 0.46)**	**0.28 (0.05, 0.51)**	**0.29 (0.06, 0.52)**

Bold: the estimated coefficient is significant at $p < 0.05$ level

ADM= anti-diabetic medications including oral anti-diabetic agent and insulin; AHA= anti-hypertensive agent; DDS-17= the 17-item Diabetes Distress Scale; DBP= diastolic blood pressure; DDS-2= the 2-item Diabetes Distress Scale; PAID-5= the 5-item Problem Areas in Diabetes Scale; PHQ-9= the 9-item Patient Health Questionnaire; LDL= low density lipoprotein-cholesterol; DMSES= the 20-item Diabetes Management Self Efficacy Scale; MMAS-8= the 8-item Morisky Medication Adherence Scale; SBP= systolic blood pressure; SDSCA= the Summary of Diabetes Self-Care Activities. Potential confounders adjusted for included socio-demographic variables (age, gender, ethnicity, religiosity, marital status, education, employment, life event and family history of psychiatric illness), general and health literacy, smoking, diabetes duration, presence of any diabetes complication, hypertension, dyslipidemia, medication use (oral anti-diabetic agents, insulin, anti-hypertensive and lipid-lowering agents) and depressive symptoms.

Table 4. Diabetes distress category by different DD measures with categorical outcome measures, n= 308-329 (otherwise specified); and in multinomial and binary logistic regression analyses, n= 338 (except in models with LDL as the dependent variable)

DD Measures	DMSES (0 – 200) (n= 306-329) (Tertile), n (%)					MMAS-8 (0 – 8) (n= 308-318), n (%)					SDSCA (0 – 7) (n= 299-308) (Tertile), n (%)				
	Low (≤ 135)*	Mid (136 – 165)	High (≥ 166)	Crude OR (95% CI)	Adjusted OR (95% CI)	Low (< 6)*	Med (<8)	High (8)	Crude OR (95% CI)	Adjusted OR (95% CI)	Low (≤ 2.9)*	Mid (3.0 – 3.8)	High (≥ 3.9)	Crude OR (95% CI)	Adjusted OR (95% CI)
DDS-17, ≥ 3	31 (41.9)	24 (32.4)	19 (25.7)	0	0	35 (48.6)	30 (41.7)	7 (9.7)	0	0	24 (32.4)	23 (31.1)	27 (36.5)	0	0
< 3	81 (33.2)	82 (33.6)	81 (33.2)	1.31 (0.70, 2.44)[a] 1.64 (0.85, 3.16)[b]	0.71 (0.32, 1.59)[a] 0.95 (0.44, 2.15)[b]	73 (30.9)	99 (41.9)	64 (27.1)	1.58 (0.89, 2.81)[a] **4.38 (1.82, 10.55)**[b]	1.03 (0.51, 2.08)[a] 2.34 (0.84, 6.49)[b]	97 (39.8)	72 (29.5)	75 (30.7)	0.70 (0.35, 1.41)[a] 0.63 (0.33, 1.21)[b]	0.67 (0.30, 1.51)[a] 0.68 (0.30, 1.55)[b]
DDS-2, ≥ 3	59 (44.7)	40 (30.3)	33 (25.0)	0	0	55 (42.6)	55 (42.6)	19 (14.7)	0	0	46 (34.8)	43 (32.6)	43 (32.6)	0	0
< 3	56 (28.4)	67 (34.0)	74 (37.6)	**1.74 (1.01, 2.99)**[a] **2.37 (1.37, 4.12)**[b]	1.25 (0.61, 2.53)[a] 1.59 (0.80, 3.14)[b]	56 (29.6)	76 (40.2)	57 (30.2)	1.36 (0.82, 2.26)[a] **2.95 (1.56, 5.58)**[b]	0.92 (0.48, 1.76)[a] 1.54 (0.70, 3.42)[b]	79 (40.1)	54 (27.4)	64 (32.5)	0.67 (0.38, 1.21)[a] 0.84 (0.48, 1.47)[b]	0.63 (0.31, 1.27)[a] 1.02 (0.51, 2.07)[b]
PAID-5, ≥ 8	67 (39.2)	52 (30.4)	52 (30.4)	0	0	72 (43.4)	71 (42.8)	23 (13.9)	0	0	52 (30.4)	58 (33.9)	61 (35.7)	0	0
< 8	48 (30.6)	56 (35.7)	53 (33.8)	1.50 (0.88, 2.58)[a] 1.42 (0.83, 2.43)[b]	1.25 (0.64, 2.45)[a] 0.87 (0.45, 1.68)[b]	39 (25.7)	61 (40.1)	52 (34.2)	1.59 (0.94, 2.66)[a] **4.17 (2.23, 7.81)**[b]	1.36 (0.72, 2.57)[a] **3.08 (1.43, 6.65)**[b]	72 (45.9)	39 (24.8)	46 (29.3)	**0.47 (0.27, 0.83)**[a] **0.55 (0.33, 0.95)**[b]	**0.50 (0.26, 0.99)**[a] 0.62 (0.31, 1.22)[b]

DD Measures	HbA1c (%), n (%)				Blood pressure (mmHg), n (%)				LDL (mmol/L) (n= 121-125), n (%)			
	≥ 7%*	< 7%	Crude OR (95% CI)	Adjusted OR (95% CI)	≥140/90*	<140/90	Crude OR (95% CI)	Adjusted OR (95% CI)	≥2.6*	< 2.6	Crude OR (95% CI)	Adjusted OR (95% CI)
DDS-17, ≥ 3	55 (74.3)	19 (25.7)	0	0	36 (48.6)	38 (51.4)	0	0	15 (50.0)	15 (50.0)	0	0
< 3	163 (67.4)	79 (32.6)	1.15 (0.63, 2.12)	1.35 (0.55, 2.97)[c] 0.93 (0.36, 2.41)[d]	104 (42.6)	140 (57.4)	1.22 (0.68, 2.18)	1.60 (0.81, 3.34)[c] 1.64 (0.81, 3.33)[d]	53 (58.2)	38 (41.8)	0.72 (0.31, 1.64)	0.77 (0.24, 2.16)[c] 0.74 (0.25, 2.21)[d]
DDS-2, ≥ 3	92 (70.2)	39 (29.8)	0	0	66 (50.0)	66 (50.0)	0	0	27 (50.9)	26 (49.1)	0	0
< 3	136 (69.4)	60 (30.6)	1.19 (0.70, 2.04)	1.43 (0.70, 2.80)[c] 0.95 (0.46, 2.15)[d]	80 (40.6)	117 (59.4)	1.32 (0.81, 2.16)	**2.02 (1.11, 3.77)**[c] **2.09 (1.12, 3.83)**[d]	42 (60.0)	28 (40.0)	0.69 (0.34, 1.42)	0.75 (0.27, 1.76)[c] 0.70 (0.29, 1.92)[d]
PAID-5, ≥ 8	120 (70.6)	50 (29.4)	0	0	78 (45.6)	93 (54.4)	0	0	35 (53.0)	31 (47.0)	0	0
< 8	108 (69.2)	48 (30.8)	1.19 (0.67, 2.10)	1.25 (0.56, 2.45)[c] 1.09 (0.50, 2.41)[d]	65 (41.4)	92 (58.6)	1.14 (0.72, 1.79)	1.35 (0.77, 2.29)[c] 1.32 (0.76, 2.33)[d]	36 (61.0)	23 (39.0)	0.72 (0.35, 1.47)	0.74 (0.27, 1.69)[c] 0.81 (0.32, 2.07)[d]

* Reference category in multinomial (DMSES, MMAS-8 and SDSCA) or binary (HbA1c, blood pressure and LDL) logistic regression analysis

[a] Mid compared to Low; [b] High compared to Low; [c] all confounding factors without medication; [d] all confounding factors with medication

Bold: the Odd's ratio is significant at $p < 0.05$ level. AHA= anti-hypertensive agent; DDS-17= the 17-item Diabetes Distress Scale; DBP= diastolic blood pressure; DDS-2= the 2-item Diabetes Distress Scale; PAID-5= the 5-item Problem Areas in Diabetes Scale; PHQ-9= the 9-item Patient Health Questionnaire; LDL= low density lipoprotein-cholesterol; DMSES= the 20-item Diabetes Management Self Efficacy Scale; MMAS-8= the 8-item Morisky Medication Adherence Scale; SBP= systolic blood pressure; SDSCA= the Summary of Diabetes Self-Care Activities. Potential confounders adjusted for included socio-demographic variables (age, gender, ethnicity, religiosity, marital status, education, employment, life event and family history of psychiatric illness), general and health literacy, smoking, diabetes duration, presence of any diabetes complication, hypertension, dyslipidemia, medication use (oral anti-diabetic agents, insulin, anti-hypertensive and lipid-lowering agents) and depressive symptoms.