Translation, Revision, and Validation of the Diabetes Distress Scale for Indonesian Type 2 Diabetic Outpatients with Various Types of Complications

By Dyah Aryani Perwitasari



Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.elsevier.com/locate/vhri



Translation, Revision, and Validation of the Diabetes Distress Scale for Indonesian Type 2 Diabetic Outpatients with Various Types of Complications



Bustanul Arifin S. Farm, Apt, MSc, MPH^{1,2,3,*}, Dyah Aryani Perwitasari, Apt, PhD⁴,

Jarir Aghobari, MD, PharmD, PhD⁵, Qi Cao, PhD¹, Paul F.M. Krabbe, PhD⁶, Maarten J. Postma, PhD^{1,3,6}

8 it of PharmacoTherapy, Epidemiology & Economics (PTE2), Department of Pharmacy, Faculty of Science and Engineering,

University of Groningen, Groningen, The Netherlands; ²RSUD Banggai Laut Hospital, Banggai Laut Local Government, Central Sulawesi, Indonesia; ³Institute of Science in Healthy Aging & healthcaRe (SHARE), University Medical Center Graningen (University of Pharmacy, University of Ahmad Dahlan, Yogya 14. Indonesia; ⁵Department of Pharmacology and Therapy, Medical Faculty, Universitas Gadjah Mada, Yogyakarta, Indonesia; ⁶Department of Epidemiology, University Medical Center Groningen, University of Groningen, Groningen, The Netherlands

ABSTRACT

Objectives: To translate, revise, and validate the Diabetes Distress Scale (DDS) instrument for Indonesian type 2 diabetes mellitus (T2DM) outpatients with various complications. Methods: Participants were recruited from four hospitals and two primary health care centers. The study was performed with forward and backward translations, an adaptatio 33 ing with a small subset of participants, and validation analysis. Factor analysis with maximum likelihood estimation and promax rotation was then used to investigate the instrument structure. Internal consistency among the items was estimated using Cronbach α for each domain of the DDS. Results: In total, 324 participants (246 from the hospitals and 78 from the primary health care centers) were involved in this study. To improve participant comprehension of the exact meaning of questions, examples of daily activities for patients with T2DM (e.g., diet, exercise, and adherence to therapy) were added to some questions after the translation and revision procedures. The factor analysis revealed a correlation among

the four factors ranging from 0.40 to 0.67. The factor loadings of selected items from the four factors ranged from 0.41 to 0.98. The order of the four fact 36 h the factor analysis was as follows: interpersonal distress, and regimen distress. The internal consistency for the four domains ranged from 0.78 to 0.83. The instrument resulting from this study was labeled "DDS17 Bahasa Indonesia." Conclusions: The DDS17 Bahasa Indonesia provides an initial psychometric validation study, factor structure, and internal consistency for assessing the distress of Indonesian T2DM outpatients. Use of this instrument in future research and clinical trials is recommended for the Indonesian context. Keywords: Diabetes Distress Scale, Indonesian type 2 diabetes, psychometric properties, validation.

© 2017 Published by Elsevier Inc. on behalf of International Society for Pharmacoeconomics and Outcomes Research (ISPOR).

Introduction

Diabetes mellitus (DM) represents a substantial burden on health care systems with prevalence steadily rising worldwide [1]. In 2015, an estimated 31 million people were suffering from DM [2]; of these, 77% w 26 ving in low- and middle-income countries [3]. It is estimated that by 2040, the number of people 10 th DM will rise to nearly 650 million [2], with 90% suffering type 2 diabetes mellitus (T2DM) [4].

In Indonesia, the prevalence of T2DM among people older than 15 years, representing a population of 177 million, mounted significantly from 1.1% in 2007 to 2.1% in 2015 [5]. A report by the Indonesian Ministry of Health [5] shows that a further 1% of the

population complained of T2DM symptoms during the most recent month at the time of interview, but could not confirm whether these persons suffered from T2DM itself. In 2007, urban areas accounted for the highest incidence of T2DM, but data from 2013 present a different picture with no significant difference between urban and rural areas [5]. In the analysis of sociodemographic characteristics, the number of persons suffering from T2DM increases with age, with the highest proportion found in people older than 55 years [5]. There was no significant difference by sex [5]. This report also states that in disaggregation by occupation, the highest proportions were identified among the unemployed (7.4%), followed by self-employed and sole proprietors (7.2%), farmers/fisherfolk/manual laborers (6.2%), and active

Conflicts of interest: The authors have indicated t 8 they have no conflicts of interest with regard to the content of this article.

* Address correspondence to: Bustanul 25 n, Unit of PharmacoTherapy, Epidemiology & Economics (PTE2), Department of Pharmacy, Faculty of Science and Engineering, University of Groningen, Antonius Deusinglaan 1, Building 3214, Groningen 9713AV, The Netherlands.

E- 2 il: bustanul.arifin.ury@gmail.com; ury.bustanul.arifin@gmail.com

2212-1099\$36.00 - see front matter © 2017 Published by Elsevier Inc. on behalf of International Society for Pharmacoeconomics and Outcomes Research (ISPOR).

http://dx.doi.org/10.1016/j.vhri.2017.03.010

employees (5.8%) [5]. Regarding clinical characteristics, it is reported that 60% of patients with T2DM in Indonesia experience at least one comorbidity caused by T2DM [5,6].

People with T2DM need to follow a strict program of selfmanagement, including a healthy diet, sufficient physical activity, and adherence to their medication [7]. This daily management plan can be especially challenging for patients with cardiovascular and kidney complications, eye disease, nerve damage, and diabetic foot complications [8]. Previous research [9] found that T2DM management plans in themselves are responsible for psychological distress in many patients with T2DM, which may then hinder successful therapeutic outcomes. Because of the prominence of effects from emotional distress, it is imperative that T2DM-specific psychological distress be regularly assessed to identify those individuals who are particularly at risk [7,9]. To ensure that daily management plans are effective, T2DM outpatients should be able to manage their individual concerns and address their essential aspects of diabetes distress. An important contribution to this can come from both patient and car 3 ver understanding of the distress.

32 he Diabetes Distress Scale (DDS) was developed by William H. Polonsky from the Problem Areas in Diabetes (PAID) instrument [10,11] and has since become well established and widely recommended for assessing the level of distress in patients with DM [10]. Both the PAID and the DDS have their particular advantages in measuring diabetes distress, but the DDS has a more precise and cross-culturally consistent factor structure compared with PAID as shown in a validation study [12]. The DDS consists of 17 items that measure patients' feelings in four general domains [10,11]. First, the interpersonal distress domain (3 items) reflects the psychological emotions and feelings of patients with DM during their interaction with families, friends, or people around them. Second, the physician distress domain (4 items) portrays the distress that patients with DM experience during interaction with their physician. The third domain, regimen distress (5 items), describes the distress felt by patients with DM because of the need to adhere to a therapy management plan. The last is the emotional burden domain (5 items), which describes the distress related to the personal emotions of the patients suffering from T2DM, including fear of the possibility of DM-related complications.

Although a generic instrument to measure psychological distress can be quite useful for recognizing distressed T2DM outpatients, a more specific DM-related identification of psychological distress may help to choose the appropriate intervention, which will ultimately improve prospects for adequate therapies and better outcomes [10,13]. This instrument, however, has yet to be introduced to the Indonesian population. To this end, our study purposes were to translate, revise, and validate the DDS instrument for Indonesian T2DM outpatients with various types of complications.

Methods

Study Setting

Our study was conducted in four hospitals and two primary care facilities on the island of Java. The revision phase represents the next step after the translation phase. We carried out the revision phase in the first week of February 2015 at only one hospital, the RSUD Kota Yogyakarta Hospital. In the validation phase, we also distributed this instrument to three other hospitals, PKU Muhammadiyah Hospital in Yogyakarta, Moewardi Hospital in Solo, Central Java, and BLUD Sekarwangi in Sukabumi, West Java, while continuing the data collection process at RSUD Kota Yogyakarta Hospital. At the primary care level, the instrument

validation process was performed by a family doctor in Wonosari, Yogyakarta, and in a public health center in Pakis, Surabaya, East Java. The 7 rall validation phase lasted from February to July 2015. This study was approved by the Medical Ethics Committee of the Universitas Gadjah Mada Yogyakarta Indonesia in document number KE/FK/1188/EC on November 12, 2014. Permission to develop a version of the DDS for use with Indonesian T2DM o 12 ients was obtained from the original author (William H. Polonsky, University of California, San Diego, CA) in February 2015.

Sample Selection

The selection process for participants enrolled in this study was carried out in the same manner as in the revision and validation phases. After enrolling in this study, T2DM outpatients aged 18 years or older were informed verbally about the context of the study. After this, they read and signed a statement of willingness to participate, inclusive of informed consent. Some participants with limited reading ability gave their informed consent orally with the approval of their caregiver. All participants were recruited in the locations previously described, thus forming the consecutive sample.

Study Procedure and Data Collection

Translation

The translation phase consisted of the two steps of forward and backward translations, on the basis of the specific recommendation guidelines and international criteria [14,15]. Initially, the original DDS instrument was translated from English to Bahasa Indonesia by two Indonesian professional translators, each working independently. The final version resulting from this step was labeled version 1. In the backward translation, the version 1 document was translated from Bahasa Indonesia to English by three Australian professional translators similarly working independently, all of whom were English native speakers and fluent in Bahasa Indonesia. The final version resulting from the backward translation was labeled version 2. The main purpose of the backward translation was to ensure that the forward translated documents were indeed correct, which we ascertained by comparing the original DDS with the three documents after backward translation. The final product of this process was the initial DDS in Bahasa Indonesia.

Revision

The initial DDS in Bahasa Indonesia was subsequently tested in two groups of participants. The first group consisted of the first 10 T2DM outpatients whom we encountered at random and who satisfied the sample selection criteria. The second group was made up of 10 healthy adults who volunteered to give their opinions on the initial DDS. During this phase, two specific points required attention: 1) whether both groups of participants would have the same difficulties in understanding the DDS questions and 2) the most frequently occurring problems with filling out the DDS. After this, we also asked their opinions about this phase. Some participants agreed to be recorded while stating their opinions, which provided helpful insights in subsequent analyses. At the end of this phase, the DDS was revised as required, on the basis of all comments received and issues observed. The final DDS resulting from this phase was subsequently taken to the validation phase.

Validation

This final form of the DDS was used for the remaining study participants in the validation phase. All participants involved were given information and an opportunity to ask questions. During this phase, we again recorded the conversations that took place with the consent of the participants. Figure 1 depicts the flowchart of our study procedure.

Analyses

Translation

The results of each step were analyzed by the core research team. Whenever differences emerged among the translations, these issues were resolved by consensus.

Revision

In this phase, we evaluated the difficulties experienced by participants on the basis of their reaction to specific items, when the participant would ask for additional information on a particular item. The items were then revised by one of the researchers and the results discussed together with another researcher. Furthermore, we took into account the input from 10 healthy volunteers who were also involved in this phase.

Validation

Construct validity [16,17] was examined using factor analysis. We performed maximum likelihood estimation with 6 h orthogonal (varimax) and oblique (promax) rotations. The aim of rotation is to simplify the initial factorization, thereby obtaining a solution that keeps as many variables and factors distinct from one to another as possible until a simpler structure is found [16]. We applied these two types of rotation to find the most appropriate structure for the questionnaire within the context of Bahasa Indonesia. The reference value for factor loading was 0.4, which reflects at least a moderately strong relationship [18,19]. Internal consistency between the items for each of the DDS subscales derived by factor analysis was estimated using Cronbach a [16,17,20]. The estimations of floor and ceiling effects [21] were included to provide a distription of the participants' most frequently selected answers. All statistical analyses were performed using IBM SPSS Statistics for Windows, version 23 (SPSS Inc., Cambridge, MA). The final form was compiled after the data analysis was labeled "DDS17 Bahasa Indonesia."

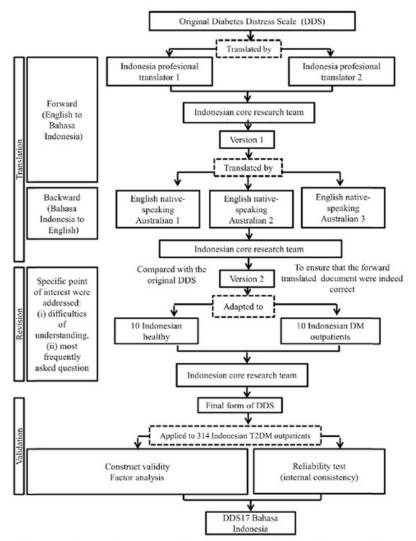


Fig. 1 - Study procedure. DDS, Diabetes Distress Scale; DM, diabetes mellitus.

Results

Translation

Differences between individual translators were detected in the translations of certain items. Our overarching concern was that the backward translation should reflect as best as possible the original English version of the DDS. We also discussed the most appropriate wording and sentencing on the basis of the formal style of Bahasa Indonesia, in which some discrepancies between translators were found. We present the complete processes of the translations, revision, and validation of the DDS17 Bahasa Indonesia in Appendix A.

Revision

The 10 healthy volunteers who evaluated the initial version of the translated instrument suggested that a rticipants might be confused if they had to respond on the six-point Likert scale, in which 1 indicates no problem and 6 indicates a very serious problem. They also believed that participants would ask for more explanation on items related to emotional burden and regimen distress. These issues were confirmed when we used the instrument with the 10 T2DM outpatients.

The mean age of the 10 participants in this phase, including 3 women, was 65.1 \pm 6.7 years. Seven of the participants were receiving oral therapy (either monotherapy or a combination of two drugs), and the three others took a combination of oral antidiabetic medication and insulin. Only two persons had a bachelor's degree, whereas seven were graduates of senior high school and one had completed junior high school. All participants were retired civil servants and reported that a caregiver accompanied them when visiting a health facility.

In particular, when completing the instrument, participants were unsure of what to do when asked to choose on the scale set out for them. They also wanted more detailed explanations on the exact differences between slight and moderate problems, and between serious and very serious problems. For this purpose, we developed an additional tool (Fig. 2) to facilitate understanding by the participants. Notably, this tool is a simple graphic representation of the scales of the DDS17 Bahasa Indonesia, including an extra-large font for participants with moderately impaired vision. Besides the graphic tool, we added some explanations about relevant instrument items to help participants understand the instrument correctly.

Validation

The study involved a total of 314 participants, 238 of whom were recruited from hospitals and 76 from primary health care centers.

Within the whole sample popular 10 one was illiterate and four were older than 80 years. The mean age of the participants was 60.1 ± 9.5 years, and 57% were female. Most of the participants (65%) were receiving oral medication (either monotherapy or combinations of two or three oral antidiabetic drugs). Sixty-three percent of the participants suffered from at least one complication. Within the whole sample population, 72% reported senior high school as their highest educational attainment. Most participants in this study stated that they did not know exactly when they first developed T2DM, so we did not capture this inform 30 m. Sociodemographic characteristics and clinical conditions of the participants are presented in Table 1.

Factor analysis

Promax (oblique) rotation delivered better results than varimax (orthogonal) rotation by producing four factors among which the items were divided fairly evenly. The percentages of variance (eigenvalues) explained by these four oblique factors were 40.2%, 8.7%, 4.0%, and 2.3% (for the varimax rotation 20 e percentages were 17.8%, 16.0%, 14.7%, and 6.8%). The total percentage of variance explained by the four extracted oblique factors was 55.3%. Table 2 depicts the factor loadings of the DDS17 Bahasa Indonesia. The factor analysis with maximum likelihood and promax rotation showed the correlation among the four factors ranging from 0.40 to 0.67 (Table 3). Labeling of the factors for the DDS17 Bahasa Indonesia was based on close inspection of the content of the items loading high on that specific factor. Factor 1 appeared to represent the interpersonal distress domain with three out of five involving items from this domain. Similarly, factor 2 was representative of the emotional burden. Factor 3 included three out of four items of physician distress, therefore representing the physician distress domain. Factor 4 was a combination of two items of regimen distress and one item of the emotional burden, thus representing the regimen distress domain.

Reliability

Internal consistency for each of the four domains was high. The highest values of Cronbach α were found for the interpersonal distress and physician distress domains (0.83), whereas the lowest value (0.78) was found in the regimen distress domain (Table 4). As presented in Table 4, the wide range of floor and ceiling effects was observed in all domains, with the largest difference detected in the interpersonal distress domain (64.5 vs. 0.6).

29 Discussion

The results of our study indicate that the DDS17 Bahasa Indonesia is a reliable instrument for use in a population of Indonesian T2DM outpatients. This study also provides initial corroboration for the

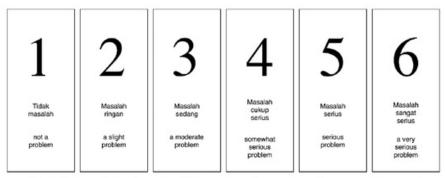


Fig. 2 - Graphical display of the six scales of the DDS17 Bahasa Indonesia. DDS, Diabetes Distress Scale.

Table 1 - Soci	odemographic ch	aracteristics and clini	cal conditions	Table 1 – Sociodemographic characteristics and clinical conditions of the participants (n $=$ 324).	= 324).		
Characteristic	Primary care (n =	care (n = 76)		Second	Secondary care (n = 248)		Overall N
	Family doctor of BPJS Boyolali Yogyakarta $(n = 35)$	Public health center in Surabaya, East Java (n = 41)	RSUD Kota Yogyakarta Hospital (n = 87)	PKU Muhammadiyah Hospital in Yogyakarta (n = 26)	Moewardi Hospital in Solo, Central Java $(n = 100)$	BLUD RS Sekarwangi Hospital in Sukabumi, West Java (n = 35)	3
, , , , , , , , , , , , , , , , , , ,			Socioder	Sociodemographic characteristics			
Age (y)	60 00 + 9 51	51 24 + 9 25	62 70 + 7 90	5051 + 9.61	58 90 + 10 73	100	60 14 + 0 52
<65 = 3D	26 (74.3)	24 (58.5)	51 (58.6)	19 (73.1)	75 (75)	33 (94.3)	228 (70.4)
> 65 Sex	9 (25.7)	17 (41.5)	36 (41.4)	7 (26.9)	25 (25)	2 (5.7)	96 (29.6)
Female	16 (45.7)	34 (82.9)	51 (58.6)	16 (61.5)	45 (45)	21 (60)	183 (56.5)
Male	19 (54.3)	7 (17.1)	36 (41.4)	10 (38.5)	55 (55)	14 (40)	141 (43.5)
Education							
Up to senior	26 (74.3)	41 (100)	52 (59.8)	19 (73.1)	64 (64)	32 (91.4)	234 (72.2)
Illigii sciiooi	1/2 2/10	8	35 (40.2)	7 (26 9)	36 (36)	9 6	19 70/ 00
degree	6 (23.7)	(0) 0	33 (40.4)	(6.03)	(oc) oc	(0:0) c	(0.72) 06
20.00			Ü	Clinical characteristics			
Therapy							
Diet	4 (11.4)	3 (7.3)	0 0	(0) 0	4 (4)	1 (2.9)	12 (3.7)
OAD	29 (82.9)	31 (75.6)	65 (74.7)	16 (61.5)	43 (43)	26 (74.3)	210 (64.8)
Insulin or	2 (5.7)	7 (17.1)	22 (25.3)	10 (38.5)	53 (53)	8 (22.9)	102 (31.5)
insulin + OAD							
Complications							
No	19 (54.3)	19 (46.3)	30 (34.5)	10 (38.5)	26 (26)	15 (42.9)	119 (36.7)
One	13 (37.1)	15 (36.6)	36 (41.4)	15 (57.7)	48 (48)	15 (42.9)	142 (43.8)
Two or more	3 (8.6)	7 (17.1)	21 (24.1)	1 (3.8)	26 (26)	5 (14.3)	63 (19.4)
Caregiver				Others			
No	14 (40)	23 (56.1)	25 (28.7)	4 (15.4)	44 (44)	9 (36.7)	119 (36.7)
Yes	21 (60)	18 (43.9)	62 (71.3)	22 (84.6)	26 (560)	26 (74.3)	205 (63.3)
Transportation							
Walk	5 (14.3)	19 (46.3)	13 (14.9)	5 (19.2)	1(1)	1 (2.9)	44 (13.6)
Bike/motor-	30 (85.7)	22 (53.7)	74 (85.1)	21 (80.8)	(66) 66	34 (97.1)	280 (86.4)
cycle/car/	1			(
public							
transport							
1707	44. 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1						

Values are n (%) unless otherwise indicated. OAD, oral antidiabetic drug.

Table 2 - Factor loadings of the DDS17 Bahasa Indonesia for the four extracted factors with maximur	n
likelihood estimation and promax rotation $(n = 324)$.	

Item	Domain	Description Four extra				ctors
			1	2	3	4
17	ID	Feeling that friends or family don't give me the emotional support that I would like.	0.98			
13	ID	Feeling that friends or family don't appreciate how difficult living with diabetes can be.	0.68			
9	ID	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).	0.64			
15	PD	5 ling that I don't have a doctor who I can see regularly enough about my diabetes.	0.53			
16	RD	5 feeling motivated to keep up my diabetes self-management.	0.48			
4	EB	Heling angry, scared, and/or depressed when I think about living with diabetes.		0.78		
2	EB	Feeling that diabetes is taking up too muc 1 of my mental and physical energy every day.		0.73		
14	EB	Feeling overwhelmed by the demands of living with diabetes.		0.56		
7	EB	Feeling that I will end up with serious long-term complications, no matter what I do.		0.48		
3	RD	Not feeling confident in my day-to-day ability to manage diabetes.		0.41		
1	PD	Feeling that my doctor doesn't know enough about diabetes and diabetes care.			0.82	
5	PD	Feeling that my doctor doesn't give me clear enough directions on how to manage my diabetes.			0.78	
11	PD	3 ling that my doctor doesn't take my concerns seriously enough.			0.54	
6	RD	4-ling that I am not testing my blood sugars frequently enough.			0.41	
8	RD	Feeling that I am often failing with my diabetes routine.				0.71
12	RD	4 ling that I am not sticking closely enough to a good meal plan.				0.50
10	EB	Feating that diabetes controls my life.		0.46		0.48

validity of the DDS17 in this context. To our knowledge, our study is the first in Indonesia in which the DDS has been translated, revised, and validated. After factor analysis, a new instrument structure was developed, with the four factors arranged in the following order: interpersonal distress, emotional burden, physician distress, and regimen distress. Good internal consistency was obtained for reliability test for each domain with the corresponding measurements ranging between 0.78 and 0.83.

Our study showed a different direction in its results compared with two studies conducted in Norway [9] and Denmark [22]. All are similar in that the four factors are based on the results of factor analyses. Nevertheless, differences exist in the sequence of the DDS domains. In DDS17 Bahasa Indonesia, factor 1, which had the highest factor loading, contained three items of the interpersonal distress domain ranging from 0.64 to 0.98. In contrast, the studies on Norwegian DDS [9] and Danish DDS [22] found that these three items of that domain were loaded in factor 4.

In the other two studies, the DDS items were condensed into only three factors [23,24]. In a study conducted in Thailand [23], those three factors are emotional and regimen-related burden, physicia 28 d nurse-related distress, and DM-related interpersonal distress. In the Thai version of the DDS [23], the emotional burden and regimen distress domains were combined and renamed

Table 3 – Factor correlation matrix for the four extracted factors with maximum likelihood estimation and promax rotation (n=324).

Factor	1	2	3	4
1	1.00			
2	0.43	1.00		
3	0.67	0.40	1.00	
4	0.66	0.5 27	0.51	1.00

Factors: 1, interpersonal distress; 2, emotional burden; 3, physician distress; 4, regimen distress.

"emotional and regimen-related burden." The physician distress domain was also modified and renamed "physician- and nurse-related distress." Furthermore, the three factors formed 19 DDS validation study of the Chinese population [24] were emotional burden, regimen-related and social support-related distress, and physician-related 24 ress. The Chinese study [24] eliminated 2 items (item 12, "not sticking closely enough to a good meal plan," and item 15, "not having a doctor whom I can regularly see about my diabetes") from the original DDS and conducted the analysis on the basis of the remaining 15 items.

Our study ultimately involved a total of 324 participants. This number of participants is understood to comply with the standard numbers recommended in various literatures. Gorsuch stated that the sample size in a study with a statistical test applying four factors of analysis should not be less than 100 participants [17], whereas Reise and Comrey [25,26] found that a minimum of 200 participants is adequate for factor analysis (maximum of 40 items in the instrument). It is also recommended that the minimum sample size in a validation study should be adjusted for 5 to 10 times the number of instrument variables or items to be validated [16]. Our DDS has a total of 17 items, and so the minimum number on the basis of these statements should be 170. Our study, therefore, fulfilled the requirement by having almost twice the minimum number required as our sample size [16].

During the data collection process, we experienced difficulties in obtaining data on how long the participants in our research had suffered from T2DM. For the most part, participants reported that they were unaware that they had T2DM until comorbidities began to appear. This situation is also reported by McCall [6], who explains that people in Indonesia who suffer from T2DM usually found out about their illness when it was too late and that most T2DM inpatients suffer from at least one complication of the disease. The most common complications are kidney failure and visual problems [6]. An additional concern that stems from our observations during the data collection process is the need for improvement in the primary care and secondary care data integration process to enable the reporting system to support comprehensive and sustained monitoring of individual patients with T2DM.

Indonesia.	23			
Domain (item number)	Mean ± SD	Floor effect	Ceiling effect	Cronbach
Emotional burden (2, 4, 7, 10, 14)	1.97 ± 1.03	19.4	0.3	0.81
Physician distress (1, 5, 11, 15)	1.48 ± 0.83	58.6	0.6	0.83
Regimen distress (6, 8, 3, 12, 16)	1.68 ± 0.83	30.3	0.3	0.78
Interpersonal distress (9, 13, 17)	1.44 ± 0.84	64.5	0.6	0.83

The substantial difference between the floor and ceiling effects in our study indicates that most of the participants chose 1 (not a problem) rather than one of the successive categories. There are several plausible explanations for this. First, most of the participants in our study were at retirement age (≥60 years). For these elderly people, lack of focus on the interview may have been an issue, even though an interview-based study appeared to be the optimal method in this group [27]. Furthermore, these participants were spending at least 7 hours in the hospital during their visits (registration, physician consultation, laboratory, and medicines pickup) and therefore participants may have been too fatigued to provide the desired level of response when interviewed. This may have caused them to choose 1 on the six-point Likert scale for ease and convenience rather than after careful consideration. Finally, many participants may have felt sympathetic toward the investigators, which might have led them to intentionally avoid reporting any problems that they may have actually had.

The DDS17 Bahasa Indonesia can be used as a reference for measuring distress in Indonesian T2DM outpatients. During our study procedure, some of the participants remarked that an instrument such as this should regularly be used to improve awareness among Indonesians about T2DM and related types of distress. Some specific practical issues must also be considered: scheduling to allow sufficient time, avoiding interviewing when participants are too tired, and emphasizing the need for accurate and realistic answers.

Regular application of the DDS17 Bahasa Indonesia will greatly assist the process of identifying psychological problems faced by Indonesian patients with T2DM, which will enable more precise targeting of psychological interventions. For example, for T2DM outpatients with a high score (≥3) [28] in the regimen distress domain, the importance of daily T2DM management (adherence, exercise, and diet) can be emphasized in personal communication. When patients have high scores in the emotional burden and interpersonal distress domains, a T2DM approach might be to provide information to family members about the importance of providing emotional support along with a reminder to the patients with T2DM to take their medication regularly. We recruited participants from various sources (public health centers, family doctor, and hospitals) to enhance the representativeness of our study. It was, however, not possible to assess the extent to which our study would be representative of Indonesian patients with T2DM in general.

The present study has strengths and limitations. The strengths lie in the representativeness and generalizability of the study. These are deemed to be good because the study was conducted in several locations (primary and secondary health facilities) on the island of Java, which covers 57% of the total population of Indonesia.

The limitations of this study concern two aspects. First, we did not compare the DDS17 Bahasa Indonesia with other DM-related health indicators. During the data collection process, patients were offered not only the DDS but also the EuroQol five-dimensional questionnaire [29]. Many participants, however, refused to complete two instruments because the necessary procedures while visiting the hospital already took up considerable time and energy. They

generally complained about the queuing at almost every stage, beginning with registration. After that, patients would have to wait for laboratory results, wait again to see a physician, and then sit patiently while a pharmacist prepared their medication. For these reasons, examination of the convergent and discriminant validity between these instruments was not possible. Two previous studies [9,23 22 prted comparable and consistent results between the DDS and the 36-item short form health survey [9] and between the DDS and the Geriatric Depression Scale [23] with regard to validity and reliability. Second, we involved five research assistants in distributing the instrument, which could have led to differences in information provided by different individuals. These assistants were, however, all very helpful in assisting participants gain a deeper understanding by communicating in the tribal languages. This benefit was thought to outweigh the possible disadvantage of differences in individual communication. In total, there were four research assistants who helped participants in the Indonesian language and elaborated meanings in a local language (Sundanese or Javanese). From our perspective, the use of a local language by research assistants helped to provide reassurance for the participants as well as demonstrate a higher level of respect during the interaction. In both local languages, respect is indicated in linguistic expression that must be adjusted to the social ranking of the person to whom one is speaking. Intonation and diction are also vital considerations when communicating with older people. Nevertheless, the delivery of each item in the DDS was still performed in the Indonesian language, and the local language served only to provide additional information when the participants asked for it, or when they replied in the local language.

Conclusions

The DDS17 Bahasa Indonesia provides the initial psychometric validation study, factor structure, and internal consistency for assessing the distress of Indonesian T2DM outpatients. We recommend it for use in future research, including in clinical tria notifical provided in the provided provided in the provided provided in the provided provided

Source of financial support. This research was supported by a grant from Beasiswa Pend 17 an Indonesia/Lembaga Pengelola Dana Pendidikan (the Indonesian Endowment Fund for Education, Ministry of Finance of Republic of Indonesia) and the University of Groningen, The Netherlands

Acknowledgments

We thank the hospital staff, patients, doctors, nurses, PERSADIA Jawa Timur, BPJS, members of the translation group, the Governor of Central Sulawesi and the Regent of Banggai Laut, Dr Muhamad Bambang Purwanto, Dr Supriyanto Kartodarso, Endang Prihatin, Nick Brown, Andrew F. Little, and our research assistants (Nurmutmainnah Saidah and Selly Ristya Ningsih) for their participation in this research.

Appendix A

Table	A1 – The complete instru	ment processes.		
Item	Original DDS	Final result of translation phase Forward: Version 1 Backward: Version 2 (applied to 10 volunteers of healthy people and 10 T2DM outpatients)	Result of revision phase Version 3 (applied to 314 participants)	DDS17 Bahasa Indonesia
1	Feeling that my doctor doesn't know enough about diabetes and diabetes care.	I felt that my doctor did not have enough knowledge on diabetes treatment.	I felt that my doctor didn't have enough knowledge on diabetes treatment.	17. Saya merasa bahwa teman-teman atau keluarga saya tidak memberikan dukungan emosional yang saya inginkan. Contoh dukungan emosional misalnya mereka selalu mengingatkan saya agar makan makanan yang baik, olahraga, mengingatkan minum obat dan menjaga kebersihan. (I felt that my friends or family didn't give enough emotional support that I wanted. Examples of emotional support, like that constantly reminded me to eat healthy food, exercise regularly, taking care of my medicine and keeping my cleanliness.)
2	Feeling that diabetes is taking up too much of my mental and physical energy every day.	I felt that diabetes has taken up too many energy and physics everyday.	I felt that diabetes has taken up too many energy and physics everyday.	13. Saya merasa bahwa teman-teman atau keluarga tidak menghargai bagaimana sulitnya hidup dengan diabetes. (I felt that my friends or family didn't appreciate how difficult life is with diabetes.)
3	Not feeling confident in my day-to-day ability to manage diabetes.	I didn't feel confident with my daily activities in handling diabetes problem.	I didn't feel confident with my daily abilities in handling diabetes problem. For example, I have to take care of my eating habit and cleanliness, take my medicine on time, and exercise regularly.	9. Saya merasa bahwa teman-teman atau keluarga saya tidak cukup mendukung usaha perawatan mandiri (contohnya: mereka mengajak saya makan makanan yang salah). (I felt that my friends or family didn't give enough support to my self-treatment [for example, taking me to eat
4	Feeling angry, scared, and/ or depressed when I think about living with diabetes.	I felt angry, afraid, and/or stressful thinking about life suffering from diabetes.	I felt angry, scared, and/or stressful when I think about life with diabetes.	unhealthy food].) 15. Saya merasa tidak mempunyai dokter yang bisa saya temui secara teratur untuk continued on next page

Table	A1 – continued			
Item	Original DDS	Final result of translation phase Forward: Version 1 Backward: Version 2 (applied to 10 volunteers of healthy people and 10 T2DM outpatients)	Result of revision phase Version 3 (applied to 314 participants)	DDS17 Bahasa Indonesia
				berkonsultasi masalah diabetes. (I felt that I didn't have a special doctor whom I can meet regularly to consult
5	Feeling that my doctor doesn't give me clear enough directions on how to manage my diabetes.	I felt that my doctor didn't give enough instruction on how to handle diabetes.	I felt that my doctor didn't give enough explanation on how to handle diabetes.	about diabetes.) 16. Saya sendiri merasa tidak termotivasi untuk meneruskan penanganan diabetes. (I myself didn't feel motivated to continue my
6	3 Feeling that I am not testing my blood sugars frequently enough.	I felt that I didn't have enough tests on blood sugar.	I felt that I didn't have enough tests on blood sugar.	diabetes treatment.) 4. Saya merasa marah, takut dana tau tertekan ketika saya memikirkan tentang hidup dengan menderita dia 16 (I felt angry, scared, and/or
7	Feeling that I will end up with serious long-term complications, no matter what I do.	I felt that I will end up with serious long-term complication, no matter what I do.	I felt that I would end up with serious long-term complication, no matter what I do.	stressful when I think about life with diabetes.) 2. Saya merasa diabetes mengambil terlalu banyak energy jiwa dan fisik setiap 15 inya. (I felt that diabetes has taken up too many energy and
8	Feeling that I am often failing with my diabetes routine.	I 34 at I have often failed with my routine diabetes.	I felt that I have often failed with my routine diabetes.	physics everyday.) 14. Saya merasa kewalahan oleh tuntutan hidup dengan penyakit diabetes. (I felt overwhelmed with life pressure from diabetes.)
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).	I felt that my friends or family didn't give enough support for my own treatment (they gave me the wrong kinds of food).	I felt that my friends or family didn't give enough support to my self-treatment (for example, taking me to eat unhealthy food).	7. Saya merasa bahwa saya akan berakhir dengan komplikasi serius jangka panjang, terlepas dari apatan yang saya lakukan. (I felt that I would end up with serious long-term complication, no matter
10	Feeling that diabetes controls my life.	I felt that diabetes has controlled my life.	I felt that diabetes controlled my life.	what I do.) 3. Saya merasa tidak percaya diri dengan kemampuan keseharian saya dalam menangani masalah diabetes. Contohnya: menjaga pola makan dan kebersihan, minum obat tepat waktu dan olah raga teratur. (I didn't feel confident with my daily ability in handling diabetes problem. For example, taking my eating habit and cleanliness, taking regular continued on next page

Table	A1 - continued			
Item	Original DDS	Final result of translation phase Forward: Version 1 Backward: Version 2 (applied to 10 volunteers of healthy people and 10 T2DM outpatients)	Result of revision phase Version 3 (applied to 314 participants)	DDS17 Bahasa Indonesia
11	Feeling that my doctor doesn't take my concerns seriously enough.	13 I felt that the doctor wasn't serious enough in taking care of my concerns.	13 I felt that the doctor wasn't serious enough in taking care of my concerns.	medicine, and regular exercise.) 1. Saya merasa bahwa dokter yang menangani saya tidak cukup mengetahui tentang perawatan diabetes.
12	Feeling that I am not sticking closely enough to a good meal plan.	I felt that I wasn't very strict in preparing good healthy food.	I felt that I wasn't very strict in preparing good healthy food.	(I felt that my doctor didn't have enough knowledge on diabetes treatment.) 5. Saya merasa bahwa dokter tidak memberikan petunjuk yang cukup jelas tentang bagaimana menangani diabetes. (I felt that the doctor didn't give enough explanation on how to handle
13	Feeling that friends or family don't appreciate how difficult living with diabetes can be.	I felt that my friends or family did not appreciate how difficult life is with diabetes.	I felt that my friends or family did not appreciate how difficult life is with diabetes.	diabetes.) 11. Saya merasa dokter tidak cukup serius dalam memperhatikan kekhawatiran yang saya rasakan. (I felt that the doctor wasn't serious in taking care of
14	Feeling overwhelmed by the demands of living with diabetes.	I felt overwhelmed by the pressure coming from diabetes.	I felt overwhelmed by the pressure of living with diabetes.	concerns with diabetes.) 6. Saya merasa bahwa saya tidak cukup sering melakukan pengetesan gula darah. (I felt that I didn't have enough tests on blood
15	Feeling that I don't have a doctor who I can see regularly enough about my diabetes.	I felt that I didn't have a doctor whom I can meet regularly to consult about diabetes.	I felt that I didn't have a special doctor whom I can meet regularly to consult about diabetes.	sugar.) 8. Saya merasa bahwa saya sering gagal dengan rutinitas diabetes saya. (I felt that I have offen failed
16	Not feeling motivated to keep up my diabetes self- management.	I felt unmotivated to continue the treatment of diabetes.	I didn't feel motivated to continue the diabetes treatment.	with my routine diabetes.) 12. Saya merasa bahwa saya tidak ketat dalam menyiapkan makanan yang baik. (I felt that I wasn't strict in
17	Feeling that friends or family don't give me the emotional support that I would like.	I felt that my friends or family didn't give enough emotional support that I need.	I felt that my friends or family didn't give enough emotional support I wanted. For example, constantly reminding me to eat healthy food, to exercise regularly, to take my medication, and to be clean.	preparing healthy food.) 10. Saya merasa bahwa diabetes mengontrol hidup saya, dimana saya merasa bahwa aktivitas saya menjadi terbatas sejak menderita diabetes. (I felt that diabetes has controlled my life.)

REFERENCES

- Wild S, Roglic G, Anders G, et al. Estimates for the year 2000 and projections for 2030. Diabetes Care 2004;27:1047–53.
- [2] International Diabetes Federation. IDF diabetes atlas, 7th edition. 2015.
 Available from: http://www.diabetesatlas.org/resources/2015-atlas.html.
 [Accessed February 21, 2016].
- [3] International Diabetes Federation. IDF diabetes atlas, 6th edition. 2014 update. Available from: www.idf.org/diabetesatlas. [Accessed February 2, 2016].
- [4] World Health Organization. Diabetes. 2014. Available from: http://www. who.int/mediacentre/factsheets/fs312/en/. [Accessed January 22, 2016].
- [5] Pusat Data dan Informasi Kementrian Kesehatan (PUSDATIN). Situasi dan analisis diabetes 2014. Available from: http://www.depkes.go.id/ resources/download/pusdatin/infodatin/infodatin-diabetes.pdf [Accessed April 07, 2016].
- [6] Mccall C. Country in focus: Indonesia struggles to pay for the increase in diabetes. Lancet Diabetes Endocrinol 2016;4:653-4.
- [7] Fisher L, Mullan JT, Skaff MM, et al. Predicting diabetes distress in patients with type 2 diabetes: a longitudinal study. Diabet Med 2009;26:622–7.
- [8] International Diabetes Federation. IDF diabetes atlas, 6th edition. 2013.
 Available from: www.idf.org/diabetesatlas. [Accessed October 14, 2015].
- [9] Graue M, Haugstvedt A, Wentzel-Larsen T, et al. Diabetes-related emotional distress in adults: reliability and validity of the Norwegian versions of the Problem Areas in Diabetes Scale (PAID) and the Diabetes Distress Scale (DDS). Int J Nurs Stud 2012;49:174–82.
- [10] Polonsky WH, Fisher L, Earles J, et al. Assessing psychosocial distress in diabetes: development of the diabetes distress scale. Diabetes Care 2005;28:626–31.
- [11] Polonsky WH, Anderson BJ, Lohrer PA, et al. Assessment of diabetesrelated distress. Diabetes Care 1995;18:754–60.
- [12] Schmitt A, Reimer A, Kulzer B, et al. How to assess diabetes distress: comparison of the Problem Areas in Diabetes Scale (PAID) and the Diabetes Distress Scale (DDS). Diabet Med 2016;33:835–43.
- [13] Fisher L, Glasgow RE, Mullan JT, et al. Development of a brief diabetes distress screening instrument. Ann Fam Med 2008;6:246–52.
- [14] Koller M, Aaronson NK, Blazeby J, et al. Translation procedures for standardised quality of life questionnaires: the European Organisation

- for Research and Treatment of Cancer (EORTC) approach. Eur J Cancer 2007;43:1810-20.
- [15] Sperber AD. Translation and validation of study instruments for crosscultural research. Gastroenterology 2004;126:S124–8.
- [16] Krabbe PFM. The Measurement of Health and Health Status: Concepts, Methods, and Applications from a Multidisclipinary Perpective. San Diego, CA: Elsevier/Academic Press, 2016.
- [17] Gorsuch RL. Factor Analysis (2nd ed.). Hillsdale, NJ: Lawrence Erlbaum Associates, 1983.
- [18] Fayers PM, Hand DJ. Factor analysis, causal indicators and quality of life. Qual Life Res 1997;6:139–50.
- [19] Revicki D, Ganguli A, Kimel M, et al. Reliability and validity of the Work Instability Scale for rheumatoid arthritis. Value Health 2015;18:1008–15.
- [20] Streiner DL, Norman GR. Health Measurement Scales: A Practical Guide to Their Development and Use (5th ed.). New York, NY: Oxford University Press, 2015.
- [21] Aaronson N, Alonso J, Burnam A, et al. Assessing health status and quality-of-life instruments: attributes and review criteria. Qual Life Res 2002;11:193–205.
- [22] Joensen LE, Tapager I, Willaing I. Diabetes distress in type 1 diabetes—a new measurement fit for purpose. Diabet Med 2013;30:1132–9.
- [23] Thanakwang K, Thinganjana W, Konggumnerd R. Psychometric properties of the Thai version of the Diabetes Distress Scale in diabetic seniors. Clin Interv Aging 2014;9:1353–61.
- [24] Ting RZW, Nan H, Yu MWM, et al. Diabetes-related distress and physical and psychological health in Chinese type 2 diabetic patients. Diabetes Care 2011;34:1094-6.
- [25] Reise SP, Comrey AL, Waller NG. Factor analysis and scale revision. Psychol Assess 2000;12:287–97.
- [26] Comrey AL. Factor-analytic methods of scale development in personality and clinical psychology. J Consult Clin Psychol 1988;56:754–61.
- [27] Lyons RA, Perry HM, Littlepage BN. Evidence for the validity of the Short-form 36 Questionnaire (SF-36) in an elderly population. Age Ageing 1994;23:182–4.
- [28] Fisher L, Hessler DM, Polonsky WH, Mullan J. When is diabetes distress clinically meaningful? Establishing cut points for the Diabetes Distress Scale. Diabetes Care 2012;35:259-64.
- [29] EuroQol Group, EQ-5D-3L self-complete version on paper. European Quality of Life 2016. Available from: http://www.euroqol.org/eq-5dproducts/eq-5d-3l/self-complete-version-on-paper.html. [Accessed April 07, 2016].

Translation, Revision, and Validation of the Diabetes Distress Scale for Indonesian Type 2 Diabetic Outpatients with Various Types of Complications

ORIGINALITY REPORT

10%

SIMILARITY INDEX

PRIMARY SOURCES

- Joensen, Lene E., Thomas P. Almdal, and Ingrid Willaing. "Associations between patient characteristics, social relations, diabetes management, quality of life, glycaemic control and emotional burden in type 1 diabetes", Primary Care Diabetes, 2016.
- www.ispor.org
- Kong, Lulu. "Psychological status and diabetes-related distress of Chinese type 1 diabetes patients in Jiangsu 57 words 1 % province, China", Journal of Biomedical Research, 2013.
- Fisher, L., D. Hessler, U. Masharani, and L. Strycker.
 "Impact of baseline patient characteristics on interventions to reduce diabetes distress: the role of personal conscientiousness and diabetes self-efficacy", Diabetic Medicine, 2014.

 Crossref
- peersforprogress.org 33 words < 1 %
- Fayers. "Factor Analysis and Structural Equation Modelling", Quality of Life, 03/03/2007

 Crossref 24 words < 1%
- Perwitasari, D. A., J. Atthobari, I. Dwiprahasto, M. Hakimi, H.

	Gelderblom, H. Putter, J. W. R. Nortier, HJ. Guchelaar, and A. A. Kaptein. "Translation and Validation of EORTC QLQ-C30 into Indonesian Version for Cancer Patients in Indonesia", Japanese Journal of Clinical Oncology, 2011.	23 words — <	1 %
8	Antoñanzas, Fernando, Robert Terkola, and Maarten Postma. "The Value of Medicines: A Crucial but Vague Concept", PharmacoEconomics, Crossref	22 words — < 2016.	1%
9	Dunlop, William C. N., C. Daniel Mullins, Olaf Pirk, Ron Goeree, Maarten J. Postma, Ashley Enstone, and Louise Heron. "BEACON: A Summary Framew Overcome Potential Reimbursement Hurdles", PharmacoEconomics, 2016. Crossref		1%
10	"ABSTRACT BOOK EuroPRevent 2013 Rome, Italy", European Journal of Preventive Cardiology, 2013. Crossref	18 words — <	1%
11	ro-journal.biomedcentral.com	16 words — <	1%
12	onlinelibrary.wiley.com Internet	16 words — <	1%
13	Julie Askew. "A Qualitative Comparison of Women's Attitudes Toward Hysterectomy and Myomectomy", Health Care For Women Internation Crossref	14 words — < nal, 08/2009	1%
14	www.bmj.com Internet	13 words — <	1%
15	Glasgow, R.E "Using RE-AIM Metrics to Evaluate Diabetes Self-Management Support Interventions" American Journal of Preventive Medicine, 200601	12 words — <	1%

Crossref

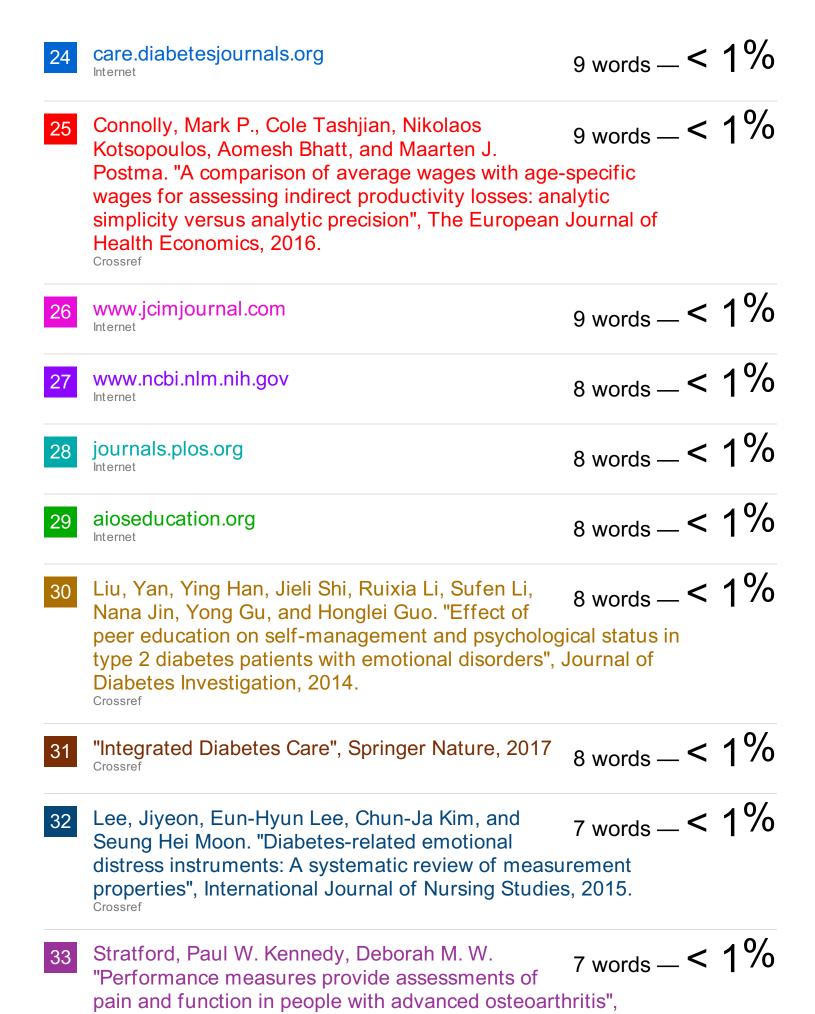


Crossref

- asch.uva.nl 11 words < 1 %
- Strandberg, Ragnhild Bjarkøy, Marit Graue, Tore Wentzel-Larsen, Mark Peyrot, and Berit Rokne.

 "Relationships of diabetes-specific emotional distress, depression, anxiety, and overall well-being with HbA1c in adult persons with type 1 diabetes", Journal of Psychosomatic Research, 2014.

 Crossref
- Sturt, Jackie, Kathryn Dennick, Danielle Hessler, Benjamin M. Hunter, Jennifer Oliver, and Lawrence Fisher. "Effective interventions for reducing diabetes distress: systematic review and meta-analysis", International Diabetes Nursing, 2015.
- $\frac{10}{10}$ iovs.arvojournals.org $\frac{10}{10}$ words -<1
- Lewis, J.E.. "Further psychometric property development of the Menopause-Specific Quality of Life questionnaire and development of a modified version, MENQOL-Intervention questionnaire", Maturitas, 20050314
- Guide to Assessment Scales in Parkinson's Disease, words < 1% crossref
- Gramm, Lukas, Erik Farin, and Wilfried H Jaeckel.
 "Psychometric properties of the German version of the MacNew heart disease health-related quality of life questionnaire", Health and Quality of Life Outcomes, 2012.



Physical Therapy, Nov 2006 Issue

- A Jacoby. "Development, validation, and evaluation of the PBC-40, a disease specific health related quality of life measure for primary biliary cirrhosis", Gut, 11/1/2005
- Martyn-Nemeth, Pamela, Laurie Quinn, Eileen Hacker, Hanjong Park, and Amber S. Kujath.

 "Diabetes distress may adversely affect the eating styles of women with type 1 diabetes", Acta Diabetologica, 2014.

 Crossref
- Beverly, Elizabeth A. Ivanov, Nedyalko N. "Is diabetes distress on your radar screen?(Report)", Journal of Family Practice, Jan 2017 Issue

EXCLUDE QUOTES OFF
EXCLUDE BIBLIOGRAPHY ON

Crossref

EXCLUDE MATCHES

OFF