

University of Groningen

Distress and health-related quality of life in Indonesian type 2 diabetes mellitus outpatients

Arifin, Bustanul

IMPORTANT NOTE: You are advised to consult the publisher's version (publisher's PDF) if you wish to cite from it. Please check the document version below.

Document Version

Publisher's PDF, also known as Version of record

Publication date:

2018

[Link to publication in University of Groningen/UMCG research database](#)

Citation for published version (APA):

Arifin, B. (2018). *Distress and health-related quality of life in Indonesian type 2 diabetes mellitus outpatients*. [Thesis fully internal (DIV), University of Groningen]. University of Groningen.

Copyright

Other than for strictly personal use, it is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), unless the work is under an open content license (like Creative Commons).

The publication may also be distributed here under the terms of Article 25fa of the Dutch Copyright Act, indicated by the "Taverne" license. More information can be found on the University of Groningen website: <https://www.rug.nl/library/open-access/self-archiving-pure/taverne-amendment>.

Take-down policy

If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

Downloaded from the University of Groningen/UMCG research database (Pure): <http://www.rug.nl/research/portal>. For technical reasons the number of authors shown on this cover page is limited to 10 maximum.

2

Translation, revision, and validation of the diabetes distress scale for Indonesian type 2 diabetic outpatients with various types of complications

Bustanul Arifin, Dyah Aryani Perwitasari,
Jarir At Thobari, Qi Cao, Paul F. M. Krabbe,
Maarten J. Postma

Value in Health Regional Issues:

12C (2017) 63-73

HIGHLIGHTS

- i. ***What is already known about the topic?***
 1. To identify psychological problems and ensure that T2DM outpatients receive adequate intervention, it is strongly recommended that assessments be carried out on a regular basis.
 2. The DDS instrument has been translated and validated in many countries worldwide.
- ii. ***What does the paper add to existing knowledge?***
 1. The translated and reanalyzed instrument in this study is titled DDS17 Bahasa Indonesia. Support was provided for the initial psychometric validation study, factor structure and internal consistency of the newly translated DDS17 Bahasa Indonesia. Future research will be necessary to undertake a further examination of the reliability and validity of the newly translated version of DDS.
 2. Factor analysis with oblique rotation resulted in a better interpretable 4-factor structure in comparison to the orthogonal (varimax) rotation.
 3. During the data collection process, we developed an additional tool to help participants understand more clearly and to be able to respond accordingly. This tool is built around a simple graphic representation of the Likert scale of the DDS17 Bahasa Indonesia (from 1 to 6) with an extra-large font suitable for participants with impaired vision.
- iii. ***What insight does this paper offer for health-care related decision making?***

It is highly desirable to provide greater attention and support where patients are experiencing psychological problems and therefore it is recommended to extend these benefits to T2DM outpatients at primary and secondary health-care facilities in Indonesia with the use of the DDS17 Bahasa Indonesia.

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 facilities. The study itself was performed with forward and backward translations, an adaptation testing 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's alpha for each of the four domains of the DDS. The instrument resulting from this study was labeled DDS17 Bahasa Indonesia.

Results

324 participants (246 from hospitals and 78 from primary healthcare facilities) were involved in this study. To improve participant comprehension of the exact meaning of questions, examples of daily activities for T2DM outpatients (e.g. diet, exercise, and adherence to therapy) were added to some questions after the translation and revision procedure. 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 in the factor analysis was first interpersonal distress, followed by the emotional burden, physician distress, and regimen distress. The internal consistency for the four domains ranged from 0.78 to 0.83.

Conclusions

The DDS17 Bahasa Indonesia provides an initial psychometric validation study, factor structure and internal consistency for assessing the distress of T2DM outpatients in Indonesia. Use of this instrument in future research and clinical trials is recommended for the Indonesian context.

INTRODUCTION

Diabetes mellitus (DM) represents a substantial burden on healthcare systems with prevalence steadily rising worldwide [1]. In 2015, an estimated 415 million people were suffering from DM [2]; of these, 77% were living in low and middle-income countries [3]. It is estimated that by 2040, the number of people with 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 aged over 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 presents a different picture with no significant difference between urban and rural areas [5]. In analysis of socio-demographic characteristics, the number of persons suffering from T2DM increases with age, with the highest proportion found in the above 55 age group [5]. No significant difference was evident in gender [5]. This report also states that in disaggregation by occupation, the highest proportions were identified among the unemployed (7.4%), following by self-employed and sole proprietors (7.2%), farmers/fishermen/manual laborers (6.2%) and active employees (5.8%) [5]. Regarding clinical characteristics, it is reported that 60% of T2DM patients in Indonesia experience at least one complication caused by T2DM [5,6].

People with T2DM need to follow a strict program of self-management, 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 T2DM patients, which may then hinder successful therapeutic outcomes. Due to 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 plan are effective, T2DM outpatients should be able to manage their individual concerns and address their essential aspects of diabetes distress (DD). An important contribution to this can come from both patient and caregiver understanding of the DD.

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

distress related to the personal emotions of the patients suffering from T2DM, including fear over the possibility of T2DM-related complications.

Although a generic instrument to measure psychological distress can be quite useful for recognizing distressed T2DM outpatients, a more specific diabetes-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]. However, this instrument 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 following step after translation. 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 at a family doctor in Wonosari, Yogyakarta and a Public Healthcare Centre (PHC) in Pakis, Surabaya, East Java. The overall validation phase lasted from February to July 2015. This study was approved by the Medical Ethics Committee of Universitas Gadjah Mada Yogyakarta Indonesia in document number

KE/FK/1188/EC on 12 November 2014. Permission to develop a version of the DDS for use with Indonesian T2DM outpatients was obtained from the original author (Assoc. Clinical Prof. William H Polonsky Ph.D., CDE, University of California San Diego, USA) in February 2015.

Participant selection

The selection process for participants enrolled in this study was carried out in the same manner as in the revision and validation phase. After enrolling in this study, T2DM outpatients aged 18 years or older were informed verbally about the context of the study. Following 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, based on 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 are 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 satisfied the sample selection criteria. The second group was made up of 10 healthy adults who volunteered to give their opinions on this initial DDS. During this phase, two specific points required attention: (i) whether both groups of participants would have the same difficulties in understanding the DDS questions, and (ii) 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 analysis. At the end of this phase, the DDS was revised as required, based on 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 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. Where differences

emerged among the translations, these issues were resolved by consensus.

Revision

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

Validation

Construct validity [16,17] was examined using factor analysis. We performed maximum likelihood estimation with both orthogonal (varimax rotation) and oblique (promax rotation). 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's alpha [16,17,20]. The estimations of floor and ceiling effects [21] were included to provide a description of the participants' most frequently selected answers. All statistical analyses were performed using IBM SPSS Statistics for Windows, version 23 (SPSS Inc., Cambridge, MA, USA). The final form was compiled after the data analysis was labeled "DDS17 Bahasa Indonesia".

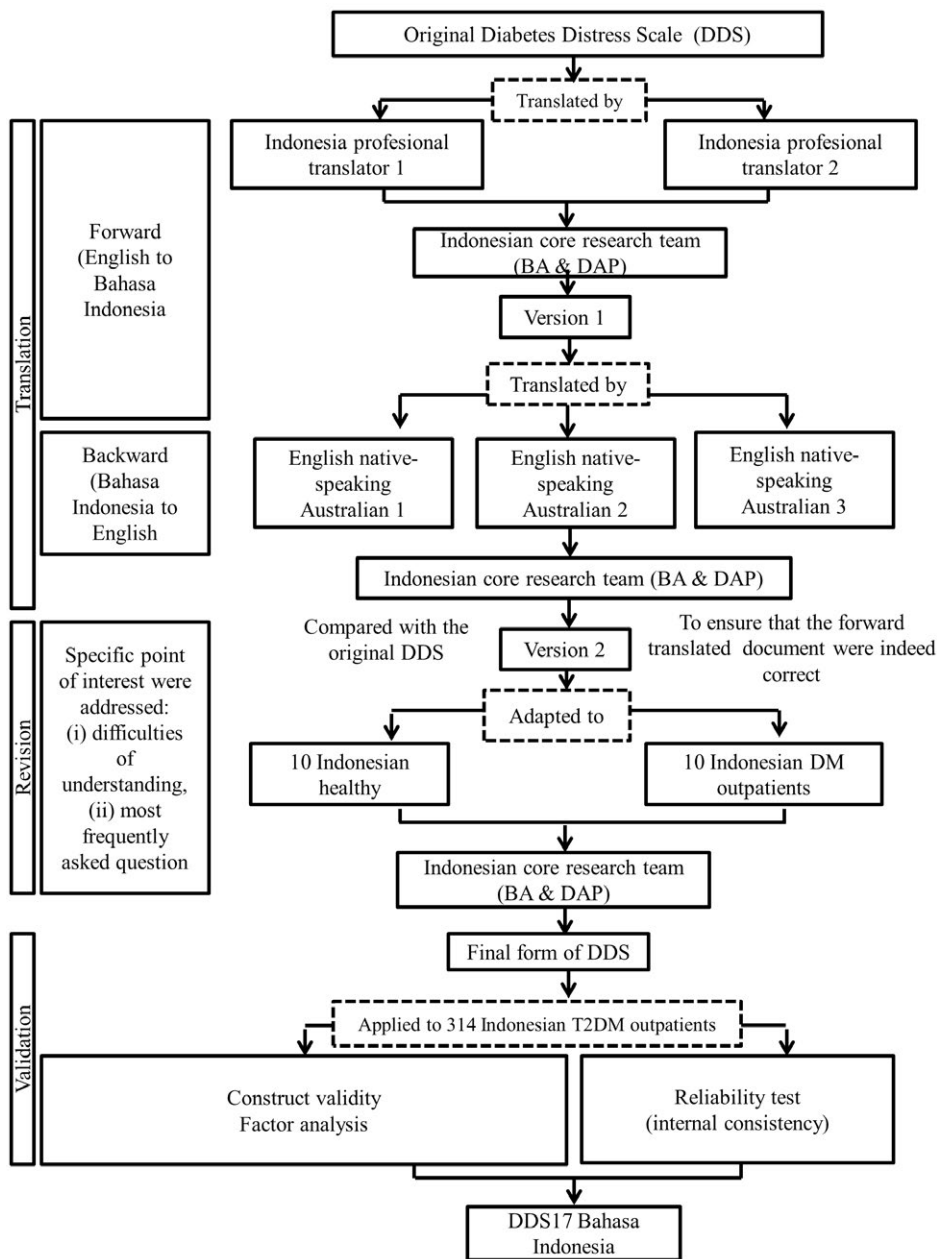


Figure 1. Diagram of the procedure of our study

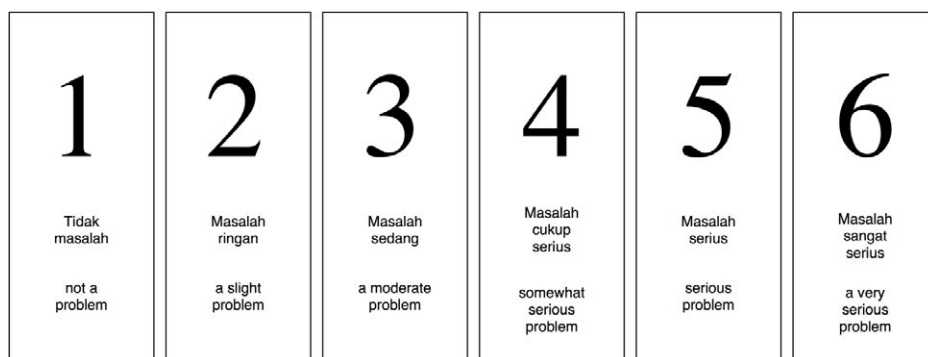


Figure 2. Graphical display of six scales of DDS17 Bahasa Indonesia

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 possible the original English version of the DDS. We also discussed the most appropriate wording and sentencing based on the formal style of Bahasa Indonesia, where some discrepancies between translators were found. We present the complete processes of the translations, revision, and validation of the DDS17 Bahasa Indonesia in the Appendix.

Revision

The ten healthy volunteers who evaluated the initial version of the translated instrument suggested that participants might be confused if they had to respond on the 1-to-6 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 ten T2DM outpatients.

The mean age of the ten participants in this phase, including three women, was 65.1 (SD 6.7). Seven of the participants were

receiving oral therapy (either monotherapy or combinations of two), and the three others took a combination of oral antidiabetic medication and insulin. Only two persons had bachelor level education, while seven were graduates of the 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 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 (Figure 2) to facilitate understanding by the participants. Notably, this tool is a simple graphic representation of the scale of 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

Table 1. The socio-demographic characteristics and clinical conditions of the participants (n = 324)

	Primary care (n = 76)		Secondary care (n = 248)				Overall N (%)
	N (%)	N (%)	RSUD Kota Yogyakarta (n = 87)	PKU Muhammadiyah Hospital Yogyakarta (n = 26)	Moewardi Hospital Solo, Central Java (n = 100)	BLUDRS Sekarwangi Hospital Sukabumi, West Java (n = 35)	
Socio-demographics							
Age, years							
Mean age							
≤ 65	60.92 ± 8.51	61.31 ± 8.25	63.79 ± 7.89	59.51 ± 8.61	58.80 ± 10.73	53.19 ± 8.30	60.14 ± 9.52
>65	26 (74.3)	24 (58.5)	51 (58.6)	19 (73.1)	75 (75)	33 (94.3)	228 (70.4)
	9 (25.7)	17 (41.5)	36 (41.4)	7 (26.9)	25 (25)	2 (5.7)	96 (29.6)
Sex							
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 high school	26 (74.3)	41 (100)	52 (59.8)	19 (73.1)	64 (64)	32 (91.4)	234 (72.2)
University degree	9 (25.7)	0 (0)	35 (40.2)	7 (26.9)	36 (36)	3 (8.6)	90 (27.8)
Clinical characteristics							
Therapy							
Diet	4 (11.4)	3 (7.3)	0 (0)	0 (0)	4 (4)	1 (2.9)	12 (3.7)
Oral antidiabetic drug (OAD)	29 (82.9)	31 (75.6)	65 (74.7)	16 (61.5)	43 (43)	26 (74.3)	210 (64.8)
Insulin or Insulin + OAD	2 (5.7)	7 (17.1)	22 (25.3)	10 (38.5)	53 (53)	8 (22.9)	102 (31.5)
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)
Others							
Caregiver							
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)	56 (56)	26 (74.3)	205 (63.3)
Transportation mode							
Walk	5 (14.3)	19 (46.3)	13 (14.9)	5 (19.2)	1 (1)	1 (2.9)	44 (13.6)
Bike/ motorcycle/ car/ public transport	30 (85.7)	22 (53.7)	74 (85.1)	21 (80.8)	99 (99)	34 (97.1)	280 (86.4)

Table 2. Factor loading of the DDS17 Bahasa Indonesia for the four extracted factors with maximum likelihood estimation method and promax rotation (n=324)

Item	Domains	Description	Four extracted factors of DDS			
			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	Feeling that I don't have a doctor who I can see regularly enough about my diabetes.	0.53			
16	RD	Not feeling motivated to keep up my diabetes self-management.	0.48			
4	EB	Feeling angry, scared and/or depressed when I think about living with diabetes.		0.78		
2	EB	Feeling that diabetes is taking up too much 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	Feeling that my doctor doesn't take my concerns seriously enough.			0.54	
6	RD	Feeling 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	Feeling that I am not sticking closely enough to a good meal plan.				0.50
10	EB	Feeling that diabetes controls my life.		0.46		0.48

EB: emotional burden, PD: physician distress; RD: regimen distress; ID: interpersonal distress

and 76 from primary health care centers. Within the whole sample population, one was illiterate, and four were over 80 years of age. The mean age of the participants was 60.1 (SD: 9.5), while 57% were female. The majority of participants (65%) were receiving oral medication (either monotherapy or combinations of two or three oral anti-diabetic 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 suffered T2DM, so we did not capture this

information. Socio-demographic 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 these 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

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	0.58	0.51	1.00

Factor 1: interpersonal distress; factor 2: emotional burden; factor 3: physician distress; factor 4: regimen distress.

depicts the factor loading 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 the 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's alpha 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 shown 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 versus 0.6).

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 validity of the DDS17 in this context. To the best of 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

Table 4. Measurement of floor and ceiling effects and Cronbach's Alpha for the four domains of the DDS17 Bahasa Indonesia.

Domain (item number)	Mean	SD	Floor	Ceiling	Cronbach's Alpha
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 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 to 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. However, differences exist in the sequence of the DDS domains. In DDS17 Bahasa Indonesia, factor 1, which had the highest loading factor, 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, physician and nurse-related distress and diabetes-related interpersonal distress. In the Thai version of DDS [23], the emotional burden and regimen distress domains were combined and renamed “emotional and regimen-related burden”. The physician distress domain was also modified and renamed “physician and nurse-related distress”. Furthermore, the three factors formed in a DDS validation study of the Chinese population [24] were emotional burden, regimen and social support-related distress and physician-related distress. The Chinese study [24] eliminated two 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 based on 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 [17] stated that the sample size in a study with a statistical test applying four factors of analysis should not be less than 100 participants [17,25], while Comrey [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 five to ten times the number of instrument variables or items to be validated [16]. As our DDS has a total of 17 items, the minimum number based on 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 collecting 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 co-morbidities began to appear. This situation is also reported by McCall [6], which explains that people in Indonesia who suffer from T2DM usually found out about their illness when it was too late and that most T2DM patients in hospital suffer from at least one complication to the disease. The most common complications are kidney failure and visual problems [6]. An additional concern that stems from our observations during the data collecting process is the need for improvement in primary care and secondary care data integration process to enable the reporting system to support comprehensive and sustained monitoring of individual T2DM outpatients.

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). For these elderly people, lack 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 seven hours in hospital during their visits (registration, physician consultation, laboratory, and medicines pick-up) 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 1-to-6 Likert scale for ease and convenience rather than after careful consideration. Finally, many participants may have felt sympathetic towards the investigators, which might have led them to intentionally avoid reporting any problems that they may have actually had.

DDS17 Bahasa Indonesia can be used as a reference for measuring DD in Indonesian T2DM outpatients. During our study procedure, some of the participants remarked that an instrument like this should regularly be employed to improve awareness among Indonesians about T2DM and related types of DD. 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 T2DM outpatients, 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. Where 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 T2DM outpatients to take their medication regularly. We recruited participants from various sources (PHCs, family doctor and hospitals) to enhance the representativeness of our study. However, it was not possible to assess the extent to which our study would be representative of Indonesian T2DM outpatients in general.

The present study has strengths and limitations. The strengths lie in the representativeness and generalizability of this study. These are deemed to be good because the study was conducted in several locations (primary and secondary health facilities) on Java Island, 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 to other diabetes-related health indicators. During the data collection process, patients were not only offered the DDS, but also the EQ-5D instrument [29]. However, many participants 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] reported comparable and consistent results between the DDS and SF36 (short form health survey) [9] and between the DDS and GDS (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. However, these assistants were all very helpful in helping 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 with the local language.

CONCLUSION

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 trials involving Indonesian T2DM outpatients.

CONFLICT OF INTEREST

None declared.

FUNDING SOURCES

The research was supported by a grant from Beasiswa Pendidikan Indonesia (BPI)/LPDP (the Indonesian Endowment Fund for Education, Ministry of Finance of Republic of Indonesia) and the University of Groningen in the Netherlands.

ACKNOWLEDGEMENT

The authors wish to 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, Prof. Dr. dr. Muhamad Bambang Purwanto SpPD KGH, FINASIM, dr. Supriyanto Kartodarso, SpPD KEMD FINASIM, Endang Prihatin, B.A., S.Pd., M.Si., M.A, Nick Brown and our research assistants (Nurmutmainnah Saidah, SKM, MPH and Selly Ristya Ningsih SKM, MPH) for their participation in this research.

REFERENCES

1. Wild S, Roglic G, Anders G, Sicree R, King H. Estimates for the year 2000 and projections for 2030. *Diabetes Care*. 2004;27:1047-53.
2. IDF. IDF diabetes atlas Seventh edition [Internet]. Brussels Belgium: International Diabetes Federation; 2015. p. 1-144. Available from: <http://www.diabetesatlas.org/resources/2015-atlas.html>
3. IDF. IDF diabetes atlas sixth edition 2014 update [Internet]. Int. Diabetes Fed. 2014 [cited 2016 Feb 2]. Available from: www.idf.org/diabetesatlas
4. WHO. Diabetes [Internet]. World Heal. Organ. 2014 [cited 2016 Jan 22]. Available from: <http://www.who.int/mediacentre/factsheets/fs312/en/>
5. PUSDATIN. Situasi dan analisis diabetes [Internet]. Jakarta; 2014. Available from: <http://www.depkes.go.id/resources/download/pusdatin/infodatin/infodatin-diabetes.pdf>

6. McCall C. Country in Focus : Indonesia struggles to pay for the Indonesia is facing an upsurge in new cases of diabetes , and is finally taking real action to. *LANCET Diabetes Endocrinol.* Elsevier Ltd; 2016;4:653-4.
7. Fisher L, Mullan JT, Skaff MM, Glasgow RE, Areal P, Hessler D. Predicting diabetes distress in patients with Type 2 diabetes: A longitudinal study. *Diabet. Med.* 2009;26:622-7.
8. IDF. *IDF diabetes atlas* [Internet]. 6th ed. Brussels, Belgium: International Diabetes Federation; 2013. Available from: www.idf.org/diabetesatlas
9. Graue M, Haugstvedt A, Wentzel-Larsen T, Iversen MM, Karlsen B, Rokne B. 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.* [Internet]. Elsevier Ltd; 2012;49:174-82. Available from: <http://dx.doi.org/10.1016/j.ijnurstu.2011.08.007>
10. Polonsky, W.H., Fisher, L., Earles, J. E Al. Assessing Psychosocial Distress in Diabetes. *Diabetes Care.* 2005;28:626-31.
11. Polonsky WH, Anderson BJ, Lohrer PA, Welch G, Jacobson AM, Aponte JE, et al. Assessment of Diabetes-Related Distress. *Diabetes Care.* 1995;18:754-60.
12. Schmitt A, Reimer A, Kulzer B, Haak T, Ehrmann D, Hermanns N. Research : Educational and Psychological Aspects How to assess diabetes distress : comparison of the Problem Areas in Diabetes Scale (PAID) and the Diabetes Distress Scale (DDS). *Diabet. Med.* 2015;33:835-43.
13. Fisher L, Glasgow RE, Mullan JT, Skaff MM, Polonsky WH. Development of a brief diabetes distress screening instrument. *Ann. Fam. Med.* 2008;6:246-52.
14. Koller M, Aaronson NK, Blazeby J, Bottomley A, Dewolf L, Fayers P, 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 cross-cultural research. *Gastroenterology.* 2004;126:S124-8.
16. Krabbe PFM. *The measurement of health and health status: concepts, methods, and applications from a multidisciplinary perspective.* San Diego: Elsevier/Academic Press; 2016.
17. Gorsuch RL. *Factor Analysis.* 2nd ed. Hillsdale, New Jersey: Lawrence Erlbaum Associates 365 Broadway; 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, Roy S, Chen N, Safikhani S, et al. Reliability and Validity of the Work Instability Scale for Rheumatoid Arthritis. *Value Heal.* [Internet]. 2015;18:1008-15. Available from: <http://linkinghub.elsevier.com/retrieve/pii/S1098301515050743>
20. Streiner DL, Norman GR. *Health measurement scales: a practical guide to their development and use.* 5th ed. Printed in Great Britain and Published in New York United States of America: Oxford University Press; 2015.
21. Scientific Advisory Committee of the Medical Outcome Trust. *Assessing health status and quality of life instruments: attributes and review criteria.* *Qual. life Res. Life Res.* 2002;11:193-205.
22. Joensen LE, Tapager I, Willaing I. Research: Educational and psychological issues diabetes distress in type 1 diabetes-a new measurement fit for purpose. *Diabet. Med.* 2013;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* [Internet]. 2014;9:1353-61. Available from: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=4140395&tool=pmcentrez&rendertype=abstract>
24. Ting RZW, Nan H, Yu MWM, Kong a. PS, Ma RCW, Wong RYM, et al. Diabetes-Related Distress and Physical and Psychological Health in Chinese Type 2 Diabetic Patients. *Diabetes Care* [Internet]. 2011;34:1094-6. Available from: <http://care.diabetesjournals.org/cgi/doi/10.2337/dc10-1612>
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 R a, 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. *Eur. Qual. Life.* 2016.

APPENDIX

Table A. The complete instrument processes

Items	Original DDS	Final Result of translation phase Forward : Version 1 Backward: Version 2 This version was applied to (10volunteers of healthy people & 10 T2DM outpatients)	Result of revision phase Version 3 This version was 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. 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. 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. I felt that my friends or family didn't give enough support to my self-treatment (for example: taking me to eat unhealthy food).
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.	15. I felt that I didn't have a special doctor whom I can meet regularly to consult about diabetes.
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.	16. I myself didn't feel motivated to continue my diabetes treatment.
6.	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.	4. I felt angry, scared and/or stressful when I think about life with diabetes.
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.	2. I felt that diabetes has taken up too many energy and physics everyday.

Final Result of translation phase		DDS17 Bahasa Indonesia
Forward : Version 1		
Backward: Version 2		
This version was applied to (10volunteers of healthy people & 10T2DM outpatients)		
Result of revision phase Version 3		
Items	Original DDS	This version was applied to 314 participants
8.	Feeling that I am often failing with my diabetes routine.	I felt that I have often failed with my routine 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 to my self-treatment (for example: taking me to eat unhealthy food).
10.	Feeling that diabetes controls my life.	I felt that diabetes controlled my life.
11.	Feeling that my doctor doesn't take my concerns seriously enough.	I felt that the doctor wasn't serious enough in taking care my concerns.
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.
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.
14.	Feeling overwhelmed by the demands of living with diabetes.	I felt overwhelmed by the pressure of living with diabetes.
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 special doctor whom I can meet regularly to consult about diabetes.
16	Not feeling motivated to keep up my diabetes self-management.	I didn't feel motivate to continue the diabetes treatment.
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 I wanted. For example, constantly reminding me to eat healthy food, to exercise regularly, to take my medication and to be clean.
		14. I felt overwhelmed with life pressure from diabetes. 7. I felt that I would end up with serious long-term complication, no matter what I do. 3. I didn't feel confident with my daily ability in handling diabetes problem. For example: taking my eating habit and cleanliness, taking regular medicine and regular exercise. 1. I felt that my doctor didn't have enough knowledge on diabetes treatment. 5. I felt that doctor didn't give enough explanation on how to handle diabetes. 11. I felt that the doctor wasn't serious in taking care of concerns with diabetes 6. I felt that I didn't have enough test on blood sugar. 8. I felt that I have often failed with my routine diabetes. 12. I felt that wasn't strict in preparing healthy food. 10. I felt that diabetes has controlled my life.

