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Development and validation of the Short Version of Diabetes Obstacles Questionnaire (DOQ) to assess obstacles in managing Type 2 diabetes among patients of Estonia

Master's Thesis

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ABSTRACT

Development and validation of the Short Version of Diabetes Obstacles Questionnaire (DOQ) to assess obstacles in managing Type 2 diabetes among patients of Estonia

The aim of this study was to develop the Short Version of Diabetes Obstacles Questionnaire (SDOQ), a less time consuming measure, to assess the obstacles in managing type 2 diabetes among patients in Estonia. The SDOQ is based on the 78-item Diabetes Obstacles Questionnaire previously validated in Estonia (DOQ; Kongi, 2001; Hearnshaw, Dale, Sturt, Vermeire, and Van Royen, 2007). 267 respondents participated in the study (137 in Estonia, 130 in Slovenia). General practitioners invited 5 consecutive diabetic patients to participate in the study, who completed the DOQ and the Problem Areas in Diabetes Score (PAID; Welch, Jacobson, and Polonsky, 1997). Demographic and medical data was collected in addition. Statistical analyses for estimating dimensionality and homogeneity of the measure, and correlations with the PAID and glycemic control were performed in SPSS version 15.0. Further analysis of dimensionality of the SDOQ subscales, and measurement invariance cross culturally was estimated on data of Estonian and Slovenian respondents with single- and multi-group Confirmatory Factor Analysis (CFA) with program Lisrel 8.80 (Jöerskog & Sörbrom, 2006). CFA resulted in the 40-item measure with 6 subscales. The subscales demonstrated acceptable internal consistency (Cronbach's alpha .67-.86 in Estonia, and .66-.85 in Slovenia) and CFA models showed acceptable fit levels. Most subscales were significantly correlated with the PAID (Pearson r from 0.15 to 0.46 in Estonia, and .07-.45). Acceptable measurement invariance was only partly confirmed. Therefore, future research is needed to confirm the cross-cultural validity of the SDOQ. In conclusion, the SDOQ is a valid instrument to measure obstacles to treatment adherence and diabetes self-management living in Estonia.

Keywords: type 2 diabetes, management, confirmatory factor analysis, measurement invariance

Running head: Development of the SDOQ in Estonia

KOKKUVÕTE

Diabeediga Kohanemise Takistuste Küsimustiku Lühiversiooni väljatöötamine ja valideerimine teist tüüpi diabeediga patsientidel Eestis.

Antud uurimuse eesmärk oli töötada välja ja valideerida kasutaja-sõbralik Diabeediga Kohanemise Takistuste Küsimustiku Lühiversioon Eesti andmetel, et hinnata diabeediga toimetulemisel sagely esinevaid takistusi. Küsimustik on väljatöötatud baseerudes eelnevalt Eestis valideeritud 78-väitelise Diabeediga Kohanemise Takistuste Küsimustikul (DOQ; Kongi, 2001; Hearnshaw, Dale, Sturt, Vermeire, and Van Royen, 2007). Uuringus osales kokku 267 vastajat (137 Eestis, 130 Sloveenias). Perearstid kutsusid 5 järjestikust diabeediga patsienti uuringusse, kes täitsid Diabeediga Kohanemise Küsimustiku ja küsimustiku diabeediga seotud probleemide kohta. Samuti koguti demograafilisi ja meditsiinilisi andmeid. Hindamaks küsimustiku dimensionaalsust, sisemist reliaablust ja seoseid veresuhkru taseme ning diabeediga seotud probleemide küsimustikuga (the Problem Areas in Diabetes Score; Welch, Jacobson, and Polonsky, 1997) viidi läbi statistiline analüüs programmis SPSS 15.0. Kinnitava faktoranalüüsiga leiti andmetele kinnituvad faktormudelid, mille sobituvust mõõdeti ka Sloveenia andmetel. Analüüsiks kasutati programmi Lisrel 8.80 (Jöerskog & Sörbrom, 2006). Kinnitava faktoranalüüsi tulemusel loodi mõõdik 40 väitega, mis jaotusid 6 alaskaala vahel. Alaskaalade sisemine reliaablus oli aktsepteeritav (Cronbach's alpha .67-.86 Eestis, ja .66-.85 Sloveenias) ja mudelite sobitusandmetele oli väga hea. Enamik alaskaaladest olid statistiliselt oluliselt korreleeritud PAID-ga (Pearson r vahemikus 0.15-0.46 Eestis ja .07-.45 Sloveenias). Küsimustiku mõõtmise invariantsus leidis vaid osaliselt kinnitust. Seega, vajab küsimustiku kultuuride-vahelise kasutuse hindamine edasist uurimist. Kokkuvõttes on Diabeediga Kohanemise Takistuste Küsimustiku Lühiversioon valiidne mõõtmisvahend, et hinnata diabeediga patsientide toimetulekut ja takistusi Eestis.

Keywords: II tüüpi diabeet, küsimustik, kinnitav faktoranalüüs, mõõtmise invariantsus **Running head:** *Development of the SDOQ in Estonia*

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INTRODUCTION

Type 2 diabetes mellitus has become one of the most common chronic diseases worldwide (Shaw, Sicree & Zimmet, 2010) and is considered to account for 90-95% of all diabetes cases. According to the International Diabetes Federation Annual Report 2011, it is estimated that about 366 million people above 20 years of age are diagnosed with diabetes and the rise in the numbers of people with diabetes was estimated to reach 554 million by 2030. Increasingly higher rates of people who suffer from diabetes are a consequence of the population aging and urbanization, even if the prevalence of obesity remains the same (Wild, Roglic, Green, Sicree & King, 2004).

Type 2 diabetes mellitus

Type 2 diabetes mellitus develops gradually and is diagnosed mostly in later adulthood. Diabetes mellitus leads to persistently elevated blood glucose levels due to increasing deficiency of insulin production or insulin resistance of body cells (Kuzuya, Nakagawa, Satoh et al., 2002). Normal glucose levels in the blood range from 3.6 to 5.8 mmol/L. Prolonged elevated blood glycose levels, referred to as hyperglycemia, damage various organs and tissues that may lead to death (Kuzuya et al., 2002). Glycated (HbAc1) haemoglobin has been a widely accepted indicator of glycemic control while promising data from the series of United Kingdom Prospective Diabetes Studies have shown reduction of the risk of some diabetes related complications and mortality with intensive treatment of hyperglycaemia (Stratton et al., 2000; Turtner et al., 1998, UK Prospective Diabetes Study Group, 1998). Based on the International Diabetes Federation webpage, cardiovascular diseases account for 50% of causes of death in people with diabetes. Damaging effects of diabetes on blood vessels can also cause kidney failure, neuropathy as retinal failure or blindness due to nerve damage, and loss of sensitivity in limbs that may lead to ulceration and amputation of the toes, feet and lower limbs (International Diabetes Federation Annual Report 2011).

Diabetes has a negative impact not only on the physical health, but also sets a heavy psychological burden on the person due to the continuously present risk of serious health complications, and demands significant changes in the habits and every day life routine of a person. This can be a source of emotional stress (Rubin & Peyrot, 2001). Fischer and colleagues (2007) used the CESD (Center for Epidemiological Studies Depression Scale) and

CIDI (Composite International Diagnostic Interview) to evaluate the relationship between diabetes and depression and they reported that 22% of diabetic patients had scores above a cut-off point on the CESD of which 9.9% had clinical depression. Diabetic patients experiencing emotional stress (CESD >15) had higher HbA1c, consumed kilocalories, consumed calories from saturated fat, and lower physical activity. Anderson and colleagues (2001) have also reported that diabetes raises the risk of burnout and consequently may lead to depression. Depression itself and its pharmacotherapy may decrease (tricyclic antidepressants, Aronne & Segal, 2003; Lustman, Griffith, Clouse, et al., 1997) or increase insulin sensitivity (selective serotonin reuptake inhibitors, Rubin, Ma, Marrero et al., 2008; Maheux, Ducros, Borque, Garon, Chiasson, 1997). Thus, diabetes management is a complex process, which needs interventions planned by considering various aspects (Cox, Stephenson, Britten, Dundar, 2004; Gentili, Maldonato, Grieco, Santini, 2001).

Adherence to treatment of type 2 diabetes

Diabetes management involves administrating medication or insulin, monitoring and maintaining normal blood glucose levels by proper diet, physical exercise and other behaviors, e.g. avoiding smoking (Saudek, & Margolis, 2009). Therefore, management of diabetes does not demand from health-care professionals merely prescribing medicine or conducting other medical treatment procedures, but rather expects active partnership between health-care personnel and diabetic patient (Vermeire & Hearnshaw, Van Royen, Denekens 2001; Hearnshaw & Lindenmeyer, 2005).

Diabetes treatment often requires regular pharmacotherapy and adherence to prescribed medication regime can be undermined by unreported side effects and low confidence in treatment (Grant, Devita, Singer & Meigs, 2003). Moreover, constant need to adapt one's daily life to diabetes treatment may be considerable obstacles to the successful adherence to treatment and management of the disease (Hearnshaw & Lindenmeyer, 2005; Vermeire et al., 2006). Patients need to be provided with information and involved actively in discussion about the disease, treatment and it's alternatives, and also advice and mentoring to achieve effective self-management skills, e.g. continuous self-monitoring of blood sugar levels (up to 4 times per day), strict diet, additionally physical activity (Vermeire et al., 2001; Hearnshaw & Lindenmeyer, 2005). A systematic review of various diabetes interventions' effectiveness by Renders and colleagues (2001) suggested a positive effect on treatment outcome and process when multiple professional interventions were incorporated into diabetes care, e.g. patient education, feedback, and nurse consultations.

In addition, monitoring patient's social support levels and involving family members in diabetes interventions are recommended, since research has demonstrated that patients selfcare behaviors are either discouraged or supported by family or friends (Mayberry & Osborn, 2012; Al-Qazaz, Hassali, Shafie, Sulaiman & Sundram, 2010).

Besides direct communication in the primary care or hospital settings, providing patients with reliable printed materials or online sources, web-based diabetes management programs or communication platforms has demonstrated to improve glycemic control, improve various parts of care processes and reduce financial cost of diabetes treatment (Bu, Walker, Adler-Milstein et al., 2007; Ralston, Hirsch, Hoath, Mullen, Cheadle, Goldberg, 2009).

Development and validation of Diabetes Obstacles Questionnaire

Valid measures are essential for not only estimating the outcome (lower glycemic levels), but also the process of diabetes, e.g. communication with health-care, diabetes related emotional stress (Welch, Jacobson & Polonsky, 1997), and persons' own reports of difficulties with managing diabetes (Hearnshaw & Lindenmeyer, 2005) in order to improve diabetes interventions.

Based on literature (Rubin & Peyrot, 2001; Piett, Schillinger, Potter, Heisler, 2003; Vermeire et al., 2001), qualitative studies of focus group discussions with diabetic patients in UK and Flandria (Vermeire, Van Royen, Coenen, Wens, Denekens, 2003), and consecutively in 6 European countries (Vermeire, Hearnshaw, Rätsep et al., 2007) Hearnshaw and colleagues (2007) developed a 78-item Diabetes Obstacles Questionnaire (DOQ) measuring patients' beliefs and opinions on the following areas: medication adherence, information and knowledge of diabetes, relationship with medical personnel, lifestyle changes and daily selfmonitoring, burden of diabetes, and social support. This was developed on 176 diabetic patients in United Kingdom along with The Problem Areas in Diabetes Scale (PAID; Welch et al., 1997), and Diabetes-Dependent Quality of Life (ADDQoL; Bradley, Tood, Gorton, Symonds, Martin, Plowright, 1999) to test construct validity. PAID and ADDQoL are both widely used measures to estimate diabetes related emotional stress and quality of life. The DOQ 78-items were divided into 8 subscales and all subscales demonstrated significant correlations with the PAID scale, while only some subscales were significantly correlated with the ADDQoL. Moreover, the DOQ subscales related to HbA1c levels, were significantly related to patients' objective glucose levels. It also demonstrated good internal consistency on all 8 subscales (Cronbach's alpha >.75; Hearnshaw et al., 2007).

Validation of the Diabetes Obstacles Questionnaire is currently in process in six other countries of Europe (France, Belgium, Slovenia, Serbia, Turkey, and Estonia). The DOQ has demonstrated sufficient reliability (Cronbach's alpha > .76) on Belgium data (Vanderkerckhove, Vermeire, Weeren & Van Royen, 2009), however correlations between the PAID and the 8 subscales of the DOQ were only partly statistically significant and weaker (between .03 and .48) compared to UK (Hearnshaw et al., 2007). Kongi (2011) has reported the reliability (Cronbach alpha's from .67 to .90) and validity (correlations with PAID between .21 and .55) of the DOQ for Estonian data. In addition, dimensionality of the DOQ subscales in Estonia was analyzed by use of Exploratory and Confirmatory Factor Analysis, and elimination of 16 items was recommended (Kongi, 2011).

Present study

The Diabetes Obstacles Questionnaire development was based on intensive analysis of literature and qualitative studies. It covers numerous important aspects in diabetes care and management (Vandekerckhove et al., 2009). Kongi (2011) has suggested that the DOQ has acceptable reliability and validity, but changes made in the original the DOQ measure by eliminating items could result in a more cohesive measure. Therefore, the goal of the present study was to develop a shorter version of the Diabetes Obstacles Questionnaire. A measure with fewer items would be less time consuming and easier to administer for practitioners for identifying and adapting to patients' needs, and also for research purposes to estimate the process and outcome of interventions designed to enhance self-management in diabetes in Estonia.

The item content, discriminability, and inter-correlations were more rigorously analyzed to achieve the DOQ measure specifically tailored for Estonian data. Moreover, previous research has suggested that concerns and management of diabetes may be influenced by ethnical and cultural differences (Caballero, 2007), the final goal of the present study was to examine the DOQ cross-cultural applicability by analyzing measurement invariance of the Estonian Version of the DOQ on data collected in Slovenia. Multi-group Confirmatory Factor Analysis with LISREL 8.80 (Jöerskog, and Söbrom, 2006) was applied to analyze measurement invariance (Milfont & Fischer, 2010)

METHOD

Instrument Development

The Diabetes Obstacles Questionnaire

The Diabetes Obstacles Questionnaire (DOQ) was developed in UK by Hearnshaw et al. (2007). The questionnaire initially comprised 78 items assigned to 8 different subscales: Medication (10 items), Self-Monitoring (5 items), Knowledge and Beliefs (10 items), Diagnosis (6 items), Relationships with Health-Care Professionals (18 items), Lifestyle Changes (13 items), Coping (8 items) and Advice and Support (8 items). The items were rated on a 5-point scale from 1 to 5 (strongly disagree, disagree, neutral, agree, strongly agree).

The Problem Areas in Diabetes Scale

Also included in the current survey was the Problem Areas in Diabetes Scale (PAID; Polonsky et al., 1995), a 20-item questionnaire that is widely used as a measure of diabetes-related psychosocial distress. Each item is rated on a 6-point Likert scale, reflecting the degree to which the item is perceived as currently problematic: 0 - "not a problem" and 4 - "a serious problem". A total scale score ranging from 0 to 100, which is hypothesized to reflect the level of diabetes-related emotional distress, is then computed by summing the total item responses, with a higher total scale score indicating greater emotional distress.

Translation procedure

The questionnaires were conducted simultaneously in 6 different countries - Estonia, Slovenia, Serbia, Turkey, France and Belgium. However, in this thesis only the data of Estonia and Slovenia is included. The studies were approved by the Ethics Committees and the questionnaires were coded for anonymity. In Estonia the study coordinator was Anneli Rätsep, in Slovenia Davorina Petek.

The translations into native languages and the back translation into English were performed in all 6 countries. The Estonian questionnaire was also piloted in a sample of five people with type 2 diabetes in order to identify any potential problems of comprehension. However, no changes were required.

Participants and procedures

In this study participated 267 individuals with diagnosed type 2 diabetes mellitus (61

males of 137 participants in Estonia and 74 males of 130 participants in Slovenia). General practitioners were randomly selected from the list of the National Associations of GPs and invited by e-mail to participate in the study. They invited five consecutive diabetes patients to participate in the study. The inclusion criteria for the patients were: outpatient status, diagnosis of type 2 diabetes mellitus, any age and gender. Participants were given a study pack, which included an information leaflet, a questionnaire pack and pre-paid, self-addressed envelopes. Participants were provided the opportunity to complete the packet in the clinic or take it home for completion. Altogether in two countries 267 participants returned the study packs.

The means or frequencies of gender, age, body mass index (BMI), diabetes duration, and most recent levels of glycated hemoglobin are reported in Table 1. T-test indicated the statistically significant differences between countries in age, BMI, and HbA1c. Cohen's d's and effect-size correlations were following: age, (d=.37; r=.18), BMI (d=.28; r=.14), HbA1c (d=-.31; r=-.15). However, it is currently not known if these differences between countries exist in general or only in the sample of the current study.

The age of participants ranged from 34 to 89 years, with the mean age being 66.8 years for Estonian participants and 63 years for Slovenian participants. Participants' body mass index varied between 18.7 and 50.2 and diabetes duration ranged from 0 to 26 years. HbA1c levels ranged from 5.20 to 14, when an HbA1c level above 8.00 is considered hazardous.

Table 1		Gender	Age	BMI	DD	HbA1c
Estonia	Mean	61 Male	66.8 (9.8)	32.5 (6.0)	8.61 (5.1)	7.1 (1.2)
	(SD)	76 Female				
	Ν	137	137	130	132	131
Slovenia	Mean	76 Male	63.0 (10.9)	30.9 (5.0)	9.7 (6.6)	7.5 (1.4)
	(SD)	54 Female				
	Ν	130	130	127	126	125
Total	Mean	135 Male	65 (10.17)	32 (5.56)	9.13 (5.85)	7.00
	(SD)	132 Female				(1.34)
	Ν	267	267	257	258	256

Table 1. Demographic information of Estonia and Slovenia.

Note. DD - duration of diabetes; N - sample size; SD - standard deviation (in the brackets)

Statistical Analysis

All data from questionnaires completed by patients and collected by the practice staff was placed in a Microsoft Excel spreadsheet, coded and then transferred to SPSS format. Statistical analyses were conducted using SPSS version 15.0. Internal consistency was calculated for all scales separately for both Estonian and Slovenian data. Next, a Confirmatory Factor Analysis with program LISREL 8.80 (Jöerskog, and Söbrom, 2006) was performed on each scale separately with a slightly different number of participants (due to exclusion of all individuals with missing data while performing the CFA). Alternative hypothetical models based on the unpublished thesis of Kongi (2011) and on the results of the Exploratory Factor Analysis (principal axis method, varimax) were performed first on Estonian data. The estimation method used was unweighted least squares (ULS), as there was non-normality in the data.

One of the goals of this research was to decrease the number of items in order to make the questionnaire more easy to use for practitioner. Therefore, based on goodness-of-fit indices, models with the highest fit indices and with least number of items were included in the final measure. A chi-square goodness-of-fit test and information about modification indices were evaluated to make the changes in the model to find a better fit of the data to the model. Also, additional goodness-of-fit indices used to evaluate the structural models included: root mean square error of approximation (RMSEA), standardized root mean square residual (SRMR), comparative fit index (CFI, values between .00 to 1.00), and goodness of fit index (GFI, values range from .00 - 1.00). The values of the RMSEA of .05 or less indicate a close fit, and values between .05 and .08 the modest fit. SRMR ranges from .00 to 1.00, and a value of less than .08 indicates a good fit. GFI values above .95 indicate a good fit. A value of >.95 is considered as a criterion for adequate fit in CFI, a measure of complete covariation in the data (Hu, and Bentler, 1999).

After conducting the CFA on the Estonian data, the measurement invariance across two countries was tested by performing the multi-group CFA on Estonian and Slovenian data. Measurement invariance (or equivalence) can be evaluated by increasing restrictions set for models (decreasing numbers of parameters). Four of the models are in hierarchical order. Configural invariance (form invariance) model constrains the factorial structure to be the same across groups, indicating that participants from different groups conceptualize the constructs in the same way. Metric invariance model constrains all factor loadings to be the same across groups, testing if different groups respond to the items in the same way (needed to estimate weak measurement invariance). Scalar, or intercept, invariance model constrains

the intercepts of items to be the same across group to test if participants who have the same score on latent construct obtain the same score on the observed variable regardless of their group belonging. Error variance model is applied to test if the error variances are the same across groups (Milfont & Fischer, 2010). These increasingly constrained models are applied to evaluate the fit of the data to the model in multi-group CFA (Cheung & Rensvold, 2002). Weak measurement invariance is demonstrated by metric invariance. Strong measurement invariance requires fit on metric and scalar models. Strict measurement invariance is achieved, when all 3 levels demonstrate good fit (Dimitrov, 2012).

RESULTS

The reliability and the validity of the new shorter scale were estimated by measuring internal consistency, latent factor structure, and correlations with the PAID and the HbAc1. In addition, the measurement invariance model fit indices are reported to estimate potential applicability of Short Version of DOQ across cultures.

Homogeneity and dimensionality of the Short Version of DOQ

The results of internal consistency of the new shorter scale are reported in comparison with the original scale in Table 2. The reliability of the new scales is mostly acceptable: all scales have Cronbach's alphas above .70, except Medication scale with 7 items (Cronbach's Alpha of .66) on the data of Slovenia and Self-Monitoring scale with 4 items (Cronbach's Alpha of .68) on the data of Estonia. In the Short Version of DOQ, two new subscales were developed through merging the subscales 3 and 4, also 6 and 7.

DOQ Subscales	N1	EST	SLO	N2	EST	SLO
1. Medication	10	.76	.73	7	.70	.66
2. Self-Monitoring	5	.74	.79	4	.68	.71
3. Knowledge and Information	10	.79	.88	0	70	05
4. Diagnosis	6	.67	.79	8	.79	.85
5. Relationships with Health-Care	18	.90	.92	7	.84	.83
6. Lifestyle	13	.79	.83	0	97	05
7. Coping	8	.81	.76	9	.86	.85
8. Support	8	.79	.82	5	.70	.75

Table 2. Internal Consistency of all scales for Estonia and Slovenia (Cronbach's alpha).

Note. N1 - number of items in original the DOQ, N2 - number of items in the Short Version of DOQ

A Confirmatory Factor Analysis was carried out on Estonian data separately on each subscale. The number of individuals varied from 101 to 128 due to exclusion of all individuals with missing values. At first, single factor models including all items were carried out in order to test the approach applied in the studies of Hearnshaw et al. (2007) and Vandekerckhove et al. (2009), however this approach resulted in poor fit on all subscales of Estonian data.

The aim of the subsequent CFA was to reach the model with the best goodness-of-fit indices for the data. A CFA with alternative models was carried out based on reducing the

item content similarity and preserving items with high percentage of participants reporting to have had "obstacles" with the theme of an item were excluded. The CFA resulted in a 40item measure with 10 latent factors and 6 subscales (see Table 3). Goodness-of-fit indices indicate a good or acceptable fit for all models. However, 90% confidence intervals of the RMSEA are above .08 for models of scales 1, 2 and 8 indicating a chance of a poor fit.

DOQ Subcales	Ν	Observed	χ²	df	р	RMSEA	SRMS	CFI	GFI
		indicators							
1. Subscale	7	Eliminated: 4 5 6							
Doubts with Treatment		123	11.77	12	.46	.00	.059	1.00	.98
Tablet Intake Obstacles		378910				(.00089)			
2. Subscale	4	Eliminated: 5							
Self-Monitoring Difficulties		1234	.79	2	.67	.00 (.0015)	.026	1.00	1.00
3-4. Subscale	8	Eliminated: 3 scale	e: 5789	010 4	scale:	346			
Diabetes Knowledge		3: 1 2 67 4: 1 5	10.78	18	.90	.00 (.00034)	.038	1.00	.99
Lack of Information		3: 2 3 4				(
5. Subscale	7	Eliminated: 1 2 3 4	457111	3 14	17 18				
Treatment advice		68910	7.17	12	.85	.00	.029	1.00	1.00
Relationships with Health-Care		9 12 15 16				(.00052)			
6-7. Subscale	9	Eliminated: 6 scale	e: 2391	2 13	7 sca	le: 4 5 6 7 8			
Managing Diabetes		6: 1 4 5 6 7 8 7: 1 2 3	36.70	41	.59	.00 (.00052)	.052	1.00	.99
Exercising Obstacles		6:481011				· · · · ·			
8. Subscale	5	Eliminated: 1 5 7							
Support		23468	4.77	5	.44	.00 (.0012)	.048	1.00	.99
Total	40					```			

Table 3. Goodness-of-fit indices for 10 latent indicators of the SDOQ (with 40 items in total, and 38 items of the original DOQ excluded) in Estonia.

Note. χ^2 - chi-square index; df- degrees of freedom; p- statistical significance for chi-square; N - Number of items after the CFA

Excluded items included the following: 3 items of the Medication subscale (4, 5, 6), one item of the Self-Monitoring subscale (5), 5 items of the Knowledge and Beliefs subscale (5, 7, 8, 9, 10), 4 items of the Diagnosis subscale (2, 3, 4, 6), 11 items of the Relationships with Health-Care Professionals subscale (1, 2, 3, 4, 5, 7, 11, 13, 14, 17, 18), 5 items of the Lifestyle Changes subscale (2, 3, 9, 12, 13), 5 items of the Coping subscale (4, 5, 6, 7, 8) and 3 items of the Advice and Support subscale (1, 5, 7).

Multi-group CFA on the data of Estonia and Slovenia

The measurement invariance of the models developed on the data of Estonia was

tested with a multi-group CFA on the data of Slovenian participants (see Table 4.)

SDOQ Subscales	Inv*	χ²	df	p-	RMSEA	CFI	GFI	SRMR
				value				
1. Medication	1.	31.88	31	.42	.016 (.00072)	1.00	.98	.068
N1=129 N2=106	2.	41.65	39	.36	.024 (.0007)	1.00	.97	.076
	3.	49.09	44	.27	.032 (.00072)	.99	.97	.075
	4.	49.09	44	.27	.032 (.00072)	.99	.97	.075
2. Self-Monitoring	1.	2,80	4	.59	.00 (.0013)	1.00	1.00	.032
N1=101 N2=95	2.	4.92	8	.77	.00 (.00082)	1.00	.99	.048
	3.	16.60	11	.12	.072 (.0014)	.98	.99	.061
	4.	16.03	15	.38	.027 (.0010)	1.00	.99	.061
3-4. Knowledge and	1.	23.22	28	.72	.00 (.00053)	1.00	1.00	.041
Information	2.	29.27	37	.81	.00 (.00041)	1.00	.99	.053
N1=125 N2=123	3.	38.62	43	.66	.00 (.00051)	1.00	.99	.053
	4.	50.55	59	.77	.00 (.00039)	1.00	.99	.066
5. Relationships with	1.	33.12	25	.13	.052 (.00096)	.99	.97	.11
Health-Care	2.	41.14	33	.16	.046 (.00085)	.99	.96	.11
N1=122 N2=118	3.	44.58	38	.21	.038 (.00078)	1.00	.96	.11
	4.	52.03	44	.19	.039 (.00076)	.99	.95	.12
6-7. Lifestyle Changes	1.	127.66	84	.00	.066 (.041088)	.98	.95	.12
N1=128 N2=125	2.	150.21	97	.00	.068 (.045088)	.98	.91	.13
8. Support	1.	6.88	9	.65	.00 (.00031)	1.00	1.00	.030
N1=125 N2=124	2.	10.19	14	.75	.00 (.00063)	1.00	.99	.043
	3.	18.00	18	.46	.001 (.0008)	1.00	.99	.049
	4.	26.73	24	.32	.030 (.00081)	.99	.98	.077

Table 4. Goodness-of-fit indices of measurement invariance on the data of Estonia and Slovenia.

Note. χ^2 - chi-square index; df- degrees of freedom; p- p-value for chi-test; 1-Configural invariance; 2-Metric invariance; 3-Scalar invariance; 4-Error invariance; N1 - sample size of Estonia; N2 - sample size of Slovenia

The majority of models demonstrated good or acceptable measurement invariance fit with an exception of a factor model based on the items of subscales 6 and 7 (p-value is <0.05, SRMR>.08; 90% confidence interval for RMSEA exceeds .08). Factor models of the subscales 1, 2, 5, and 8 had RMSEA values exceeding .08 in their 90% confidence intervals, and a factor model of the subscale 5 demonstrated poor SRMR fit index (SRMR>0.10). These factor models (Lifestyle Changes, Relationships with Health-Care, Self-Monitoring) indicated

poor fit according to some or all fit indices also on the data of Slovenia).

Validity of the Short Version of DOQ

In order to estimate the criterion validity of the DOQ scales, the correlations between the DOQ scales, the PAID and the glycated hemoglobin (HbA1c) are reported in Table 4. The correlation between the PAID and the HbA1c is reported for comparison purposes, since the PAID is considered to be a valid measure for estimating diabetes stress and beliefs.

Table 5. Correlations between the SDOQ Scales and the PAID (Pearson's bivariate correlation coefficient) for data of Estonia and Slovenia.

SDOQ Subscales	Items	Estonia		Slo	venia
		PAID	HbA1c	PAID	HbA1c
Doubts with Treatment	3	.15	.01	.07	.13
Difficulties with Tablet Intake	5	.20**	06	.34**	.15
Self-Monitoring Difficulties	4	.37**	06	.37**	.20*
Knowledge about Diabetes	6	.37**	04	.30**	.16
Lack of Information	3	.24**	03	.21**	.09
Treatment advice	4	.31**	06	.30**	.16
Communication with Health-Care	4	.30**	14	.28**	.06
Managing Diabetes	9	.43**	.11	.45**	.22*
Exercising Obstacles	4	.20**	03	.16	.09
Support	5	.46**	.10	.43**	.20*
PAID	20	1	.05	1	.23**

Note. * - Correlation is significant at the .01 level (2-tailed).

** - Correlation is significant at the .05 level (2-tailed).

Correlations with the PAID remained between .15-.46 for the data of Estonian participants and .07-.45 for the data of Slovenian participants. The majority of correlations were statistically significant at the .05 level. However, the correlations with PAID remained statistically insignificant and weak with Doubts with Treatment in both countries, and Exercising Obstacles in Slovenia. Correlations between the glycated hemoglobin (HbA1c) and DOQ scales were weak and statistically insignificant in Estonia, but two statistically significant, though rather weak, correlations were seen between HbA1c and Managing Diabetes (Pearson's r= .22), and HbA1c and Support (Pearson's r= .23).

DISCUSSION

Development of the Short Diabetes Obstacles Questionnaire

The main goal of the study was to develop a new shorter version of the Diabetes Obstacles Questionnaire (SDOQ), since the original DOQ comprises 78 items and therefore is rather time consuming to administer in every day practice of health-care providers. A Confirmatory Factor Analysis (CFA) resulted in a 40-item measure with 10 latent indicators compounded of items from all 8 subscales of the original 78-item DOQ.

The CFA was only partly guided by the division of 8 subscales suggested by previous research (Hearnshaw et al., 2007; Vandekerckhove et al., 2009). Due to content similarity of items in subscales 3 and 4 (Knowledge and Beliefs; and Diagnosis) and subscales 6 and 7 (Lifestyle changes; and Coping), these subscales were submersed and items from both subscales were combined in the CFA. The aim was also to reduce the number of items similar in content. For example, in the original DOQ the values of Cronbach's alpha were .90 for Estonia and .92 for Slovenia, indicating the high likeness of items in the subscale 5 (Relationships with Health-Care Professionals). This was recognizable also from the content analysis of the measure in Estonian. All new subscales demonstrated acceptable or good internal consistency: Cronbach's alphas between .68 and .86 for Estonia and from .66 to .85 for Slovenia. Also, both in Estonia and Slovenia, less than 10% of respondents reported having obstacles related to the quality of basic communication (e.g. I am not being heard at all, my questions are not being answered). Therefore, the present study supports the notion reported previously (Anderson & Funnell, 2005), that problems expressed more widely in today's health-care are related to discussion of treatment alternatives, advice from health-care providers related to self-management of diabetes, also a perceived feeling of partnership where both medical professionals and a patient participate in the treatment design. Aforementioned aspects of communication in medical care could be met by applying the new patient empowerment paradigm suggested by Anderson & Funnel (2010). However, it requires from Health-Care providers the ability to acknowledge more patients being in control of their daily diabetes care and medical personnel taking more action in listening and guidance than telling and controlling the treatment course.

Various goodness-of-fit indices suggested the dimensionality of most subscales that resulted from the CFA has an acceptable fit to the data. Only one fit index (90% confidence interval for RMSEA) exceeded acceptable criterion for the Medication, Self-Monitoring and Support subscales and refers the possible risk of accepting a model not fitting the data (Type I

Error). However, RMSEA tends to have a positive bias (artificially high values) in case of small degrees of freedom and low sample size (Kenny, Kaniskan & McCoach, 2011). Thus, future research with a larger sample size would allow clarification of the latent factor structures of the SDOQ.

The SDOQ measurement invariance across cultures

The cross-cultural use of a measure is a general aim in many areas of clinical research and practice. However, data collected by self-reports, including beliefs and other psychological constructs, may yield to unreliable results due to measurement biases. Four levels of equivalence (functional, structural, metric and scalar) have been distinguished in cross-cultural literature (Fountaine, 2005). Functional invariance means that the construct exists in all groups studied and cannot be directly measured or declared by statistical tools. In case of the Diabetes Obstacles Questionnaire, the functional equivalence cross-culturally could be claimed to exist at least in main aspects of a construct drawing on the qualitative studies with focus groups in several European countries (Vermeire et al., 2007). It has been reported previously that differences and accentuations do exist in the quality and approach of health-care services for diabetic patients (Rothe, 2008; Ralston et al., 2009), availability of valid information about the disease and treatment (Hearnshaw et al., 2007), preferences and traditional customs in food consumption, access to suitable and affordable forms of physical activities, and in the level and type of social support (Caballero, 2007). These differences are also reflected in the results of the multi-group the CFA performed with the data of Estonian and Slovenian participants.

The measurement equivalence varied across subscales. The goodness-of-fit indices suggested that factor structures, scores and levels of errors are equivalent (strict invariance) in both countries for the Medication subscale, and for the Knowledge and Information subscale (based on the original subscales 3 and 4). All goodness-of-fit indices suggested the general factor structure equivalence (also known as form invariance) in Slovenia and Estonia. However, the invariance of factor loadings, scores and error variance of Support subscale and for all the invariance tests of the subscale Self-Monitoring demonstrated good fit in general, with an exception of an RMSEA 90% confidence intervals >.08. Since the rest of the goodness-of-fit indices are acceptable for the subscale, then, as noted earlier, high values for the RMSEA could be due to positive bias of the RMSEA index with small samples. The Support subscale measures the perceived lack of support and discouragement of family and friends. So, it could be inferred that the level of social connectivity might differ in Estonia

and Slovenia, despite both being European countries. Similarly, the measurement invariance of the Relationships with the Health-Care subscale demonstrated unacceptable values of fit indices (RMSEA and SRMS), which could again be due to the positive bias small samples and low degrees of freedom. Thus, this study does not offer a clear answer if the differences would be present with a larger sample, although the cross-cultural differences in the objective quality and subjective patient's satisfaction levels with health-care services in Europe have been previously reported (Hearnshaw & Lindenmeyer, 2005).

The Lifestyle Changes subscale (combined with items from subscales 6 and 7) was the only subscale where measurement equivalence was not confirmed at any level (most fit indices indicated poor fit). The Lifestyle Changes subscale comprises items that express burden and difficulties experienced when making adjustments to daily routine (proper diet, physical activity, overall coping with diabetes in everyday life) perceived by diabetic patients. This confirms the results found in other studies (Garfield et al., 2003) that there exist actual differences in the level of burden caused by the daily struggle with diabetes. Nevertheless, it could be partly due to the differences in the way the problems are expressed traditionally in a culture. However, this seems unlikely since, if this bias existed, it would have an impact on all subscales of the SDOQ. The statements of this subscale could reflect the differences of other subscales, because the patient's ability to cope with changing diet, fitting physical exercise and self-monitoring activities in their daily routine, depends both on his or her personal effort, social support (or discouragement), relationship with the health-care provider and general attitude toward diabetes, healthy diet and physical activity. Thus, this scale could be more sensitive to cultural differences than other subscales.

The criterion validity of the SDOQ

Criterion validity of this questionnaire was evaluated by correlations between the SDOQ scales and the PAID, a measure widely used by researchers and pediatricians to estimate emotional stress of diabetes. Hearnshaw and colleagues (2007) have previously reported relatively strong and significant correlations between the PAID and the original DOQ subscales (Pearson r between .38 and .71.) However, correlations of the current study for both in Estonia and in Slovenia demonstrated values at a more modest level, similarly seen in the Belgium study (Vandekerckhove et al., 2009). The correlations between the SDOQ Scales and blood sugar levels remained mostly insignificant in both Slovenia and Estonia, showing again more similarity with the result of Vanderkerckhove and colleagues (2009) study. The only significant correlations with the HbA1c were seen between two of the

subscales (Self-monitoring Difficulties and Managing Diabetes) in Slovenia. These two correlations were also the strongest in the study of Hearnshaw and colleagues (2007). These two subscales would be the most likely candidates for searching the direct correlations with physiological parameters. Self-monitoring informs the diabetic person about the current levels of blood sugar, and the daily burden of diabetes indicates the level of success in controlling the HbA1c. Although the correlations were not as strong as in the study of Hearnshaw and colleagues (2007), similar tendencies were seen between the subscales of the SDOQ, the PAID and blood sugar levels as previously reported.

In the general conclusion

The latent factor structure proposed as a result of the CFA suggests the SDOQ as a reliable measure for use in Estonia. This measure, which comprises both behavioral and attitudinal statements, possesses great potential as a tool for identifying specific obstacles of diabetes treatment, and after corrective changes in the treatment, the effect can be evaluated by this questionnaire. The factor structures of the SDOQ subscales compared on the data of Estonian and of Slovenian participants are mostly equivalent and the results of both countries are comparable with an exception of a subscale Lifestyle Changes. The future research with larger sample could allow exploring further the reasons causing this measurement bias. The SDOQ correlations with the PAID were mostly statistically significant, but remained between weak to moderate values.

Limitations and suggestions for future research

This study was part of a larger study conducted in 6 countries. Therefore, the future studies should explore the measurement invariance of both, the original 78-item DOQ and 40-item SDOQ, in all 6 countries.

One of the limitations of this study is the sample size below 200, which has been set as the minimum requirement for conducting CFA by some researchers (Barret, 2007). To reduce the risk of accepting false factor models due to small sample size, various goodness-of-fit indices were reported. Thus, future studies with a larger sample would allow further exploration of the factor structures of the SDOQ show adequate fit on the sample at least with 200 respondents. Moreover, the reliability of this measure and value in predicting the course of the disease and treatment should be explored with a longitudinal study.

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Appendix A

1. Medication Scale

Please place one tick against each comment to indicate how much you agree or disagree with the statement in relation to your diabetes medicine (tablets or insulin) **<u>not</u>** other medication that you may be taking.

StronglyStronglyAgreeAgreeNeutralDisagreeDisagree

1 I do not feel I am being prescribed the medication that is right for me

2 I do not feel I am being prescribed the medication dose that is right for me

3 I don't know what to do about taking my medication

when I am feeling unwell

Even if you do not have insulin, please answer what do you think about:

- 4 Using insulin makes life too complicated
- 5 Using insulin means my diabetes is getting worse
- 6 People treat insulin users differently
- 7 I am not in a convenient place when it is time to

take my medication

- 8 I often forget to take my medication
- 9 My medication causes unwanted side effects
- 10 I feel resentful that I have to take my medication

Scale 2 - Self-Monitoring Scale

If you do not monitore, skip the block of questions

Please place one tick against each comment to indicate how much you agree or disagree with the statement in relation to self-monitoring your blood glucose levels.

Strongly Strongly Agree Neutral Disagree Disagree

- 1 I find it especially hard to test when I'm busy
- 2 Self-monitoring makes me feel frustrated
- **3** Self-monitoring makes me fearful of a high reading
- 4 I don't feel that self-monitoring is helping me to control my diabetes
- **5** I find it too uncomfortable to self-monitor

Scale 3 Knowledge and Beliefs Scale

Please place one tick against each comment to indicate how much you agree or disagree with the statement in relation to your experiences of accessing knowledge about diabetes.

Strongly			Strongly
Agree	Agree	Neutral Disagree	e Disagree

- 1 I do not know as much as I need to know to manage my diabetes
- **2** I have difficulty accessing information that is relevant to me personally
- **3** I have difficulty understanding the information from literature
- **4** I have difficulty understanding the information from health care professionals
- **5** I think that the information on diabetes is not consistent
- 6 I do not know as much as I need to know about the consequences of having diabetes
- 7 I do not know enough about the treatment for diabetes
- **8** I believe type 2 diabetes is mild compared with type 1
- **9** I do not know enough about the benefits of diabetes treatment for me personally
- **10** I don't believe the consequences of type 2 diabetes are serious

Scale 4 – Diagnosis Scale

Please place one tick against each comment to indicate how much you agree or disagree with the statement in relation to when you were first diagnosed with diabetes.

Strongly Strongly Agree Agree Neutral Disagree Disagree

- 1 The way that I was told that I had diabetes made me feel confused
- **2** The way that I was told that I had diabetes made me feel afraid
- **3** The way that I was told that I had diabetes made me feel that it was not a serious condition
- 4 The way that I was told that I had diabetes did not motivate me to manage my diabetes well
- **5** I was not given as much information as I needed about the consequences of having diabetes
- 6 The way that I was told that I had diabetes made me feel guilty

Scale 5 - Relationships with Health Care Professionals Scale

Please place one tick against each comment to indicate how much you agree or disagree with the statement about your relationship with healt care professionals.

Strongly Strongly Agree Agree Neutral Disagree Disagree

- 1 I feel my questions about diabetes are not answered
- 2 I feel I am not listened to
- **3** I feel my judgment is not trusted in managing my diabetes
- **4** I am not advised at all on what to do about my diabetes
- **5** I am not assisted in setting realistic targets for changing my lifestyle
- 6 Treatment alternatives are not explained to me
- 7 I have not been told what to expect from my diabetes
- 8 I have not been told what to expect from my treatment
- **9** I do not feel I am part of the group who caring my diabetes
- 10 The good and bad aspects of each choice have not been discussed with me
- **11** I am not asked at all which choice consearning my diabetes I would prefer
- **12** Talking about my diabetes with group who caring my diabetes does not make me feel better
- 13 Adjustments to my diabetes plan cannot be discussed
- 14 I feel threatened when I go for a checkup
- **15** I feel a sense of helpless when consulting with nurses
- **16** I feel a sense of helpless when consulting with doctors
- 17 Times for check visits are inconvenient for me

18 I have to spend too much time waiting in clinics

Scale 6 - Lifestyle Changes Scale

Please place one tick against each comment to indicate how much you agree or disagree with the statement in relation to changes in your lifestyle.

Strongly Strongly Agree Neutral Disagree Disagree

- 1 My diabetic diet spoils my social life
- 2 I generally still feel hungry after finishing a meal
- **3** My diabetes has placed a strain on my personal relationships
- **4** There is little hope of leading a normal life when you have diabetes
- 5 Changes in my diet have put a strain on my family
- **6** I have difficulty sticking to my diet when I am away from home
- 7 I feel resentful that I am obliged to change my eating habits
- 8 I am unable to fit exercise into my lifestyle
- **9** I am unable to afford the cost of exercising on a regular basis
- **10** I haven't found an exercise I enjoy
- **11** I lack the motivation to exercise
- 12 Weight control is real problem for me
- **13** I am able to change my lifestyle in accordance with advice from health care professional(s)

Scale 7 - Coping with Diabetes Scale

Please place one tick against each comment to indicate how much you agree or disagree with the statement in relation to problems with sticking to your diabetes treatment plan.

StronglyStronglyAgreeAgree Neutral DisagreeDisagree

- 1 Self management of diabetes is difficult to maintain because diabetes complications are not immediate
- 2 Good control of diabetes involves a lot of sacrifice
- **3** I find it difficult to get into a suitable routine to cope with my treatment plan
- **4** I am not convinced that the treatment I receive for my diabetes is effective
- **5** I feel overwhelmed by the responsibility of having to take my medication
- 6 I feel that I would like to take a holiday from my diabetes
- 7 I feel that my family would like to take a holiday from my diabetes
- 8 I eat something I should not rather than say I have diabetes

Scale 8 - Advice and Support Scale

Please place one tick against each comment to indicate how much you agree or disagree with the statement in relation to receiving advice and support about your diabetes.

StronglyStronglyAgreeNeutral DisagreeDisagree

- 1 I am not convinced health care professionals believe the treatment I receive will work for my diabetes
- **2** I am told too often what I should and should not be doing to manage my diabetes
- **3** Constantly repeating what I should be doing to manage my diabetes makes me do it less
- **4** I am criticized too often about the way I manage my diabetes
- **5** I would manage my diabetes much better if I had more encouragement socially
- 6 I feel very alone with my diabetes
- 7 I feel I get little support from my family
- 8 I feel I get little support from my friends

Appendix B

Problem Areas In Diabetes (PAID) Questionnaire

INSTRUCTIONS: Which of the following diabetes issues are currently a problem for you? Circle the number that gives the best answer for you. Please provide an answer for each question.

	Not a			Somewhat		
	proble m	Minor problem	Moderate problem	serious problem	Serious problem	
1. Not having clear and concrete goals for your diabetes care?	t 0		t 2	t 3	t 4	
2. Feeling discouraged with your diabetes treatment plan?	0	1	2	3	4	
3. Feeling scared when you think about living with diabetes?	0	1	2	3	4	
4. Uncomfortable social situations related to your diabetes care (e.g., people telling you what to eat)?	0	1	2	3	4	
5. Feelings of deprivation regarding food and meals?	0	1	2	3	4	
6. Feeling depressed when you think about living with diabetes?	0	1	2	3	4	
7. Not knowing if your mood or feelings are related to your diabetes?	0	1	2	3	4	
8. Feeling overwhelmed by your diabetes?	0	1	2	3	4	
9. Worrying about low blood sugar reactions?	0	1	2	3	4	
10. Feeling angry when you think about living with diabetes?	0	1	2	3	4	
11. Feeling constantly concerned about food and eating?	0	1	2	3	4	
12. Worrying about the future and the possibility of serious complications?	0	1	2	3	4	
13. Feelings of guilt or anxiety when you get off track with your diabetes management?	0	1	2	3	4	
14. Not "accepting" your diabetes?	0	1	2	3	4	
15. Feeling unsatisfied with your diabetes physician?	0	1	2	3	4	
16. Feeling that diabetes is taking up too much of your mental and physical energy every day?	0	1	2	3	4	
17. Feeling alone with your diabetes?	0	1	2	3	4	
18. Feeling that your friends and family are not supportive of your diabetes management efforts?	0	1	2	3	4	
19. Coping with complications of diabetes?	0	1	2	3	4	
20. Feeling "burned out" by the constant effort needed to manage diabetes?	0	1	2	3	4	

Käesolevaga kinnitan, et olen korrektselt viidanud kõigile oma töös kasutatud teiste autorite poolt loodud kirjalikele töödele, lausetele, mõtetele, ideedele või andmetele.

Olen nõus oma töö avaldamisega Tartu Ülikooli digittaalarhiivis DSpace.

/Anni Kuusik/